EXECUTIVE SUMMARY

This report details the evaluation of the WHO Prequalification of Diagnostics (PQDx) programme financed by UNITAID. Euro Health Group was selected to conduct this evaluation; the work was undertaken by Jennifer Lissfelt and Julie Pasquier and consisted of 2 days of on-site visits to UNITAID and the programme implementer WHO DLT in Geneva, followed by 30 days of desk review. The desk review entailed analysis of a number of documents and telephone interviews with various stakeholders (authorities of beneficiary countries, international donors and procurement agencies and partner organizations, manufacturers and developers of in-vitro diagnostic technologies, as well as various staff members from UNITAID and the WHO LTD team). The report covers the project period from March 2009 to July 2012. The evaluation team has sought to answer the research questions covering four of the OECD/DAC evaluation areas of relevance, effectiveness, efficiency, and impact in addition to examining: 1) achievements and results, 2) project management and implementation, and 3) the project's integration and collaboration with UNITAID and other related global efforts.

The activities of the PQDx programme are consistent with its plans and objectives. The programme is highly relevant, in that there is widespread belief in the importance of better quality assurance for diagnostics, and a general sense that with the many new technologies and new developers coming along, that importance grows. The need for global prequalification effort is undisputed, and WHO's technical strength and mandate in the field are generally agreed to. However, the results of the PQDx programme to date (16 diagnostic devices prequalified) are generally not meeting expectations as of yet. The programme has however increased the speed at which devices are prequalified.

A main objective of the programme is strengthening of regulatory authorities in five pilot countries and support to these countries to institute post marketing surveillance of diagnostics. This objective has largely been met for Burkina Faso, Tanzania and South Africa and there are indications that this will also be the case for China within the next six months. The activities for Ivory Coast have been put on hold because of unrest in the country.

Although this is not fully justified, the PQDx programme is widely seen as too slow and ineffective (so far), with a relatively negative reputation among partners and suppliers, mainly due to the lengthy process of prequalification, lack of transparency and clarity, lack of leadership and lack of collaboration with other prequalification agencies. The WHO PQDx programme seems to have been too reactive and not able to anticipate or mitigate the risks it faces. WHO has mostly reacted to pressure from the outside to speed up the prequalification process. WHO has not communicated effectively about the value of its rigorous approach to quality, and does not appear to play enough of a role to lead the international discussion on how to effectively ensure quality of diagnostic devices.

Due to the low number of prequalified in-vitro diagnostic tests, the programme has not yet led to significant improvement in the diagnostic landscape. In fact the existing prequalified diagnostics had actually been on the market prior to their prequalification by WHO. International procurement agencies and beneficiary countries cannot rely only on prequalified products for their procurement due to the low numbers available on the market. This is however likely to change in the coming years as the programme is able to increase the overall number of prequalified diagnostics. As soon as procurement agencies are able to fully rely on the WHO prequalified list of diagnostic devices for procurement, the incentive for manufacturers to be on this list will be higher.

The following recommendations are based on the estimations and assessments of the evaluators from their document review and interviews with stakeholders, but are limited by

the fact that less than one day was spent with the PQDx team and UNITAID team in Geneva, and for some of these points much more in-depth analysis may be required. A more comprehensive list of all recommendations including a timeline plan of action can be found in section 7of this report.

Priority no 1: Expedite the Prequalification Process:

Resolve HR challenges:

- Conduct an external analysis to identify HR gaps
- Follow up on recruitment for open positions
- Focus efforts and funding on the PQ process, consider delaying further country activities
- Have discussion with WHO high-level management on how to improve the leadership of the programme
- Become more proactive in quality of diagnostics area, begin regular consultations with stakeholders

Streamline the PQ process without Compromising on Quality:

- Conduct a process analysis to examine the reasons/obstacles that have led to delays for each dossier
- Communicate the results of the analysis widely to stakeholders
- Adopt a strategy to remove non-performing manufacturers from the PQ process
- Through clearer web site instructions, guidance, outreach, enhance incentives/understanding among developers to submit for PQ

Priority no 2: Improve Relations with Stakeholders

Improve Communication about PQ Dx with Stakeholders

- Fill open position of Communications Officer
- Begin regular communications with global community
- Enhance reporting to UNITAID
- Explain and illustrate the rationale behind the PQ Dx methodology for PQ on the website
- Publish on the website more information on the progress of the PQ individual processes
- Clarify expectations and guidance for manufacturers for PQ including a mock dossier
- Specifically address the need for information of the different stakeholders on web site
- Build better relationships with experts in the diagnostics field, and with other PQ agencies

Priority no. 3: Adapt the PQDx programme to the needs of the market

- Adopt a specific strategy and procedure to ensure the quality of new technologies on the market until the developers have sufficient manufacturing data to PQ
- Integrate TB testing into the programme
- Address urgent needs expressed by physicians, countries (e.g. point of care)

ACTION PLAN
Summary recommendations for the WHO PQDx program financed by UNITAID

Below is a summary Action Plan based on recommendations made in the external evaluation report on the WHO PQDx support project. This evaluation was conducted by EHG, and was based mainly on stakeholder interviews and a desk study of available documents. The recommendations are based on the estimations and assessments of the evaluators, but are limited by the fact that less than one day was spent with the PQDx team and UNITAID team in Geneva, and for some of these points much more in-depth analysis may be required. Please refer to the evaluation report and full list of recommendations for more information and details.

Priority number 1: Expedite the Prequalification Process:

Identified Issues	Recommendations	Proposed Timeline
Resolving HR challenges		
1. Inadequate manpower to process suppliers through PQ, given demand and workload	1.1. **Conduct an external analysis to identify gaps in the human resources** *(quality and quantity) with the work to be completed for timely process of suppliers through PQ.*	Immediately (March-April 2013)
	1.2. **Follow up on recruitment.** *Some positions are still vacant. Taken into consideration the difficult and lengthy process of recruitment within WHO, UNITAID might want to follow up with a log frame indicator on the recruitment. Alternative methods for recruitment (e.g. medium term contractor) might alleviate the cost and difficult process of recruitment.*	After completion of the above (April 2013)
	1.3. **Focus efforts and funding on the PQ process,** *consider delaying more country activities until in-house PQ issues resolved (resume the country activities when the backlog in the PQ pipeline has been resolved).*	March 2013. Some on-going commitments might have to be fulfilled, e.g. China
2. Lack of leadership of the PQ programme	**2.1 Have discussion with WHO high-level management on how to improve the leadership of the programme.** *Heavy criticism from other stakeholders about leadership, bottleneck created by director, need to decentralize some functions. Consider Operations Manager position?*	Immediately (and in concert with 1.1)
	2.2 Become more proactive in quality of diagnostics area, begin regular consultations with other stakeholders in diagnostics field *(and UNITAID staff should take part) - The program should lead the debate on ensuring quality of diagnostics. Several initiatives are run in*	Before end of 2013

	parallel, and coordination and harmonisation are needed. (E.g. consider organizing a symposium, taking the lead on developing a standard protocol for testing of diagnostics, convening regular meetings with key experts, etc). Re-establish credibility in the field, which has suffered.	
Streamlining the PQ process without compromising on quality		
3. Long delays, confusion about reasons for this	**3.1 Conduct a <u>process analysis</u> to examine the reasons/obstacles that have led to delays for each dossier** *WHO is not responsible for all the delays, many can be attributed to the manufacturers.* **3.2. <u>Communicate the results of the analysis</u> widely to stakeholders.** *Explain the responsibility and reasons for the delays (e.g. PQDx finding critical non-conformities). In the absence of PQ this would help stakeholders to make procurement decisions. This may require amendment of confidentiality policy signed between PQDx and manufacturers.*	In parallel with 1.1 (by June 2013) As soon as process analysis is complete (June-July 2013)
4. Non-performing or sub-standard manufacturers	**4.1 Adopt a strategy to <u>remove non-performing manufacturers</u> from the PQ process,** *Non-performers drain the time/resources of the program and reflect badly on performance. (E.g. a deadline to comply or a fee if process is to be extended beyond a given deadline).*	Decide and adopt methodology by July 2013 Manufacturers to comply before end of 2013.
5. Confusion, lack of interest among developers	**5.1 Enhance incentives/ understanding among developers to submit for PQ** *Improve guidance, outreach through clearer web site instructions and templates*	June 2013

Priority number 2: Improve Relations with Stakeholders:

Identified Issues	Recommendations	Proposed Timeline
Improve Communication about PQ Dx with Stakeholders		
1. Lack of Communications Person on program team	**1.1. Fill the open position of Communication Officer** *Communicate (through communiqués, on web site, etc) with global stakeholders about program constraints and rationale behind the PQ methodology. Become proactive in leading the debate on how to best ensure the quality of in vitro diagnostic tests.* **1.2. Improve regular reporting to UNITAID** *consider revisions to indicators, enhanced reporting formats to more clearly report on*	Immediately By June 2013

	programme accomplishments vs. objectives	
2. Needed enhancements of PQ Dx website as main portal to the world	**2.1 Explain and illustrate the rationale behind the PQ Dx methodology for PQ on the website**. *Publish more information on the progress of the PQ individual processes.* *Fully clarify expectations and guidance for manufacturers for PQ (consider posting a mock PQ dossier)* *Specifically address the need for information of the different stakeholders on web site (NRAs, developers, procurement agencies etc.)*	Posting on website by August 2013. Full completion and improvement of site during the next phase of implementation
3. Inadequate relationships and cooperation with international stakeholders	3.1 **Begin high-level communications with top experts in diagnostics field.** *Leadership of the program to specifically concentrate on this task, with WHO top technical leads. (Related to HR2.2 above). A better understanding of the program is needed to obtain buy-in and support of international stakeholders.* 3.2 **Consider enhanced partnerships with FDA, EU, other agencies** *to coordinate, streamline PQ, share data, etc*	April 2013 By end 2013

Priority Number 3: Adapt the PQDx Programme to the Needs of the Market:

Identified Issues	Recommendations	Proposed Timeline
1. No procedure in place to ensure quality of new technologies on the market	**Adopt a specific strategy and procedure to ensure the quality of new technologies on the market until the developers have sufficient manufacturing data to PQ.** *Currently, developers cannot apply for PQ until they have undergone commercial manufacturing for some time. A process is required to ensure the quality of the devices upon entry to the market, and to facilitate PQ later when sufficient data have been generated.*	Immediately and in consultation with other key stakeholders
2. Urgent need for QA of TB testing devices	**Integrate TB testing into the program** *New technologies in that field have entered the market and in-country programmes are already reporting quality issues impacting their programmes. (supplier need to submit application and device added to the priority list)*	Immediately if possible
3. Increased focus required on priority technologies	**Address urgent needs expressed by physicians, countries** *e.g. for Point of Care technologies – prioritize these for PQ*	June 2013

WHO PQ DX ACTION PLAN		2013										2014	
		March	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb
HR	**Conduct an external analysis** to identify gaps in the human resources												
	Follow up on recruitment for positions on the PQ team that are still vacant												
	Focus staff efforts and funding on the PQ process, consider delaying more country activities until in-house PQ issues resolved												
	Have discussion with WHO high-level management on how to improve the leadership of the programme												
	Improve leadership, become more proactive in quality of diagnostics area, **begin regular consultations with other stakeholders in diagnostics field**												
Streamline PQ	Conduct a **process analysis to examine the reasons/obstacles that have led to delays** for each dossier												
	Communicate the results of the analysis widely to stakeholders												
	Adopt a strategy to **remove non-performing manufacturers from the PQ process**												
	Improve communcations and guidance to developers												
Improve Relations with Stakeholders	**Fill the open position of Communication Officer**												
	Begin c**ommunications with global stakeholders** to explain rationale and methodology												
	Improve **reporting to UNITAID** (format, contents)												
	Enhance **programme web site**, include instructions and templates												
	High-level **communications with top experts in diagnostics field**												
	Consider **enhanced partnerships with FDA, EU, other agencies**												
Adapt to Market Needs	Adopt **strategy and procedure to ensure quality of new technologies** not yet ready for full PQ												
	Integrate TB testing into the program												
	Address urgent needs expressed by physicians and countries (e.g. POC)												