

## Prequalification of Diagnostics

Update

Issue 5  
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*This issue of the Prequalification of Diagnostics Update provides information on applications, dossiers and inspections, including feedback based on lessons learned.*

### Progress of the prequalification process

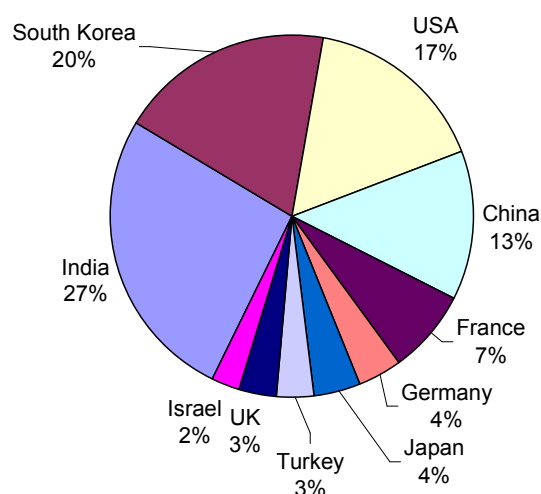
The Diagnostics and Laboratory Technology team is pleased to announce the prequalification of SD BIOLINE Malaria Ag P.f. This product was found to meet the criteria of the WHO Prequalification of Diagnostics programme, following review of the product dossier, inspection of the manufacturing site, and evaluation of the product's laboratory performance by the Global Malaria Programme. More detail may be found in the public summary report, available at [www.who.int/diagnostics\\_laboratory](http://www.who.int/diagnostics_laboratory).

Prequalification activities are ongoing to ensure a robust pipeline for 2011. Over 120 applications have been submitted from a wide geographical range of manufacturers (see Fig. 1). Of these, 51 were prioritized for review and are now in various phases of the prequalification process. In a first wave of review, 24 applications were accepted and manufacturers invited to submit a product dossier; products included HIV and malaria rapid tests and CD4. In a second wave, 27 additional applications were prioritized for review, including HIV viral load technologies and HCV tests as well as the product types above.

To date, the Diagnostics and Laboratory Technology team has completed initial dossier review for 18 products and manufacturing site inspections for 14 products. A decision on full prequalification status for these products is anticipated pending product testing results and resolution of all outstanding issues by the manufacturers. In addition, the team

is expecting receipt of additional dossiers in early 2011, and manufacturing site inspections and laboratory evaluations are being scheduled accordingly. Prequalification of products for diagnosis and clinical management of HIV and malaria address key country needs by facilitating access to safe and appropriate diagnostics of good quality.

**Fig. 1** Where are products manufactured?  
(applications by country and % of total, total n=128)



#### Reminder

All correspondence and enquiries regarding prequalification should be addressed to [diagnostics@who.int](mailto:diagnostics@who.int). In correspondence referring to specific applications, always include the prequalification tracking number to facilitate a response to any query.

## Meeting with regulatory authorities

In October 2010, the Diagnostics and Laboratory Technology team held a meeting with experts to review dossier assessment and inspection procedures. Invited participants represented both established stringent regulatory authorities and less established regulatory authorities. In the meeting, working documents were tested and refined where needed. In addition, participants discussed the potential to “fast track” prequalification procedures for products with existing stringent regulatory approval. Draft fast track procedures were developed to identify where evidence for a product may already exist, allowing expedited review for prequalification. The full report for the meeting will be posted on our website soon.

## Tips for success in submitting an application or product dossier

The points below are based on lessons learnt through initial programme activities. In this issue, our focus is on applications and product dossiers; future issues will address manufacturing site inspections. Please note that these highlights are not intended as an exhaustive guide to WHO Prequalification of Diagnostics. For detailed guidance, please refer to the instructions on our website at [http://www.who.int/diagnostics\\_laboratory/evaluations/Application/en/index.html](http://www.who.int/diagnostics_laboratory/evaluations/Application/en/index.html) and [http://www.who.int/diagnostics\\_laboratory/evaluations/PQDxInfo/en/index.html](http://www.who.int/diagnostics_laboratory/evaluations/PQDxInfo/en/index.html).

### ***Submitting the application***

- Submit a separate application form for each product to be considered for prequalification
- Ensure information in the application matches instructions for use, and that all required entries are complete
- Check instructions for use for clarity and accuracy

### ***Compiling the product dossier***

- Ensure that the dossier is clear, well-organized, and laid out per instructions. If any sections are considered not applicable, include justification
- Clearly identify the product in all documentation, and clearly define regulatory versions
- Provide a full Essential principles (EP) checklist

*Note that the EP checklist provided as an annex in the Instructions for Compilation of a Product Dossier is illustrative only. For further guidance, refer to GHTF/SG1/N41R9:2005 Essential Principles of Safety and Performance of Medical Devices*
- Explain risk analysis and control steps related to the manufacture and use of the product
- Clearly describe the manufacturing process, including critical sites for all stages of manufacture

*Note that if prequalified, only product manufactured at sites presented in the dossier will be considered to be prequalified*
- Provide detailed information on each performance claim— i.e., complete study protocols and final reports, including method of data analysis and study conclusion
- Support all claims for shelf-life, in-use and shipping stability with well-designed evaluations coordinated by the manufacturer; data should be clearly presented and linked to each claim

*For further guidance, refer to CLSI EP25-A Guideline (2009)*

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