

## SUMMARY SHEET

Agenda Nr. 2.05-14.3	Subject	GDF Diagnostics
For Information	For Discussion	<b><u>For Decision</u></b>

### Introduction

In the context of further contributing to DOTS expansion and more specifically to reaching the global target of 70% case detection, GDF developed kits for AFB microscopy. The *Diagnostic Kits* concept was presented to the Coordinating Board (CB) meeting of March 2004 in Delhi, India. The CB decided that before mandating GDF to procure and make these diagnostic kits available through its regular Grant and Direct Procurement Services the kits should be field tested, with a positive outcome in a limited number of countries.

### Summary

GDF reached an agreement with the National TB Programme (NTP) of Congo Brazzaville, Nigeria and Tajikistan, that the three different diagnostic kits could be assessed in their programmes. These were the Equipment Starter Kit, Consumables Kits and Microscope Kit.

#### The Pilot Process

- GDF, together with an external laboratory consultant from Management Sciences for Health (MSH), and in coordination with the Sub-group on Laboratory Capacity Strengthening of the DOTS Expansion Working Group, developed questionnaires for laboratory staff, heads of laboratory services and the heads of the NTPs concerned. These questionnaires were to be used for a base line assessment and once more six months after the kits had been in use.
- A simplified Quality Control system was also set up, which would show whether there had been any change in the number of false smear positive and false smear negative readings before and after the introduction of the kits.
- The laboratory services of the three countries were assessed by GDF and the MSH laboratory consultant prior to the receipt of the kits
- The quality of the reagents was controlled before shipment in two different ways: through chemical analysis by a laboratory of SGS Nederland B.V. and through actual smear preparation with the reagents and reading of the smears by the Institute for Tropical Medicine in Antwerp.
- Thereafter, the kits were shipped to the participating countries: Congo-Brazzaville in April 2005, Nigeria in June 2005 and Tajikistan in July 2005. Sufficient numbers of the kits (in line with the needs of the three participating NTPs) for the assessment were supplied.
- The final assessment visits are planned to take place in January/February 2006, with the final assessment report expected *by the end of March 2006*.

Informal communication from the participating countries so far indicates that:

Laboratory staff strongly favour the kits:

- Because they now have less work (no preparation of the reagents) and are assured of the quality of the products.
- The reading of the smears is easier, because of better quality smears.
- All equipment needed is now present including a good microscope, negating the need for improvisation and use of broken, non-functioning equipment
- The number of 'false' readings seems to have decreased (Note: this will have to be confirmed by the final assessment data).

## Summary continued...

In the mean time it has become clear that the need and demand for these kits is very high and GDF has received regular and numerous requests to supply the Diagnostic kits.

Countries that have already expressed *firm interest* to buy the kits are: Angola, DPR Korea, Mongolia and Philippines. Mongolia and DPR Korea have already placed direct orders with the GDF supplier that developed the prototypes of the kits. This is an unwanted situation, because it is important for GDF to be involved in the supply of these products, so as to ensure that they are used in the context of DOTS expansion/implementation and the bundled approach of GDF, which includes training and technical support. When Diagnostic kits are procured outside of the GDF remit, there is a risk that they will become a purely commercial commodity and improperly used, resulting in the goal for which they have been developed: improved case detection and thereby better TB control, to be compromised. Moreover, the crucial role GDF can play in ensuring that quality, low cost products are supplied via specification of standards, pooled procurement and prompt payment policies, is lost.

## Decisions requested from the Stop TB Coordinating Board

- To endorse inclusion of the three Diagnostic kits in their present form, in the GDF product catalogue, with pricing based on direct negotiation with the (currently sole) supplier of the kits. Following release of the final assessment report, GDF will issue an open tender for the kits to determine prices and suppliers competitively. The kits will only be supplied under the Direct Procurement Service.
- Based on the final assessment report, Spring 2006 Coordinating Board meeting to decide on whether the kits can be offered under the GDF Grant Service
- To already consider and identify potential funding sources for procurement of the kits, if offered under the GDF Grant Service.

## Next steps and time frame

WHAT	WHO	WHEN	FOCAL POINT
1. Include products in GDF catalogue 2. Open Tender	GDF Secretariat	By March 2006	GDF Manager