

| SUMMARY SHEET        |                |                    |              |
|----------------------|----------------|--------------------|--------------|
| Agenda Nr. 2.06-11.0 | Subject        | DIAGNOSTICS FOR TB |              |
| For Information      | For Discussion |                    | For Decision |
| Pationalo            |                |                    |              |

#### Rationale

Most people in the world who have tuberculosis (TB), or live in TB risk areas, do not have good access to rapid and accurate testing. Improved tests and renewed efforts in laboratory strengthening could bolster international TB control efforts.

A significant and largely untapped global market exists for more effective and affordable tests to diagnose tuberculosis in low and middle income countries, where most TB cases occur today. One third of the world's population is infected with latent TB and at risk of developing the active disease. Of the estimated 9 million people who develop active TB every year, most still do not receive a laboratory-confirmed diagnosis. High-tech molecular and rapid culture diagnostics available in developed countries are too complex and costly for many settings where TB is most prevalent. Yet traditional sputum smear, x-ray and culture tests may not accurately identify active TB, particularly in HIV-positive patients. Such diagnostics also may fail to make critical distinctions between latent and active TB, and between drug sensitive and drug resistant forms of the disease.

The report calls for industry investment in new diagnostic tools targeted to low and middle income countries.

#### Summary

TDR and FIND have compiled existing epidemiological data and generated new data on the availability of laboratory services, variations in physician's diagnostic practices, workloads on national laboratories and manufacturers' sales to document the volume and market volume for TB diagnostic testing in nearly 200 countries.

Compared to vaccines and medicines, the cost of developing new diagnostics and adapting existing ones is relatively low – about US \$1-10 million per technology platform. The report projects demand for seven hypothetical products that could feasibly be developed within such an investment scale. A test that detects latent infection and predicts progression to active disease could see the greatest use, with a potential available market of some 204 million patient evaluations a year. Such a test, if widely implemented and accompanied by successful treatment, could revolutionize TB control.

## **Decisions requested (from the Stop TB Coordinating Board)**

TO NOTE

### **Implications**

**NONE** 

# **Next Steps Action Required:** None Focal Point: Dr Giorgio Roscigno Timeframe: Not Applicable

