BACKGROUND PAPER: COORDINATING BOARD MEETING 24-25 APRIL 2006

SUBJECT: BUSINESS ADVISORY COMMITTEE

Background

The Global Drug Facility (GDF) has established a unique model providing a package of services that include: Grant and Direct Procurement services to increase access to anti-TB drugs; technical assistance for in-country programmes and drug management; and support for quality assurance through the WHO TB Prequalification Project.

Recently, the GDF has taken on further challenges, with the supply of diagnostic kits, paediatric formulations, and, in coordination with the Green Light Committee, second line anti-TB drugs.

To execute such broad ranging operations, the GDF is required to have significant expertise and develop relationships in the fields of raw material manufacturing, pharmacy, product formulation for drugs and diagnostics, quality assurance, regulatory law, contract law, business development, competitive procurement processes, pricing and distribution.

Business Advisory Committee

For the GDF to effectively operate in this complex environment, the Coordinating Board (CB) may wish to consider setting up a Business Advisory Committee (BAC). The Committee’s role would be to consider the complex set of business issues specifically relevant to GDF procurement operations and strategy implementation and make recommendations to GDF and the CB.

The idea of a BAC for GDF was first raised at the Stakeholder Consultation on the GDF Strategic Plan: 2006-2010 on 28th February 2006 in Geneva. Stakeholders present, including Board members, supported the idea and asked that it be developed further and presented to the full CB in April 2006 for further consideration and possible endorsement.

Technical Review Committee

Currently, the GDF receives support from a Technical Review Committee comprising 12 - 15 members. The composition of the committee reflects the need for expertise in several areas, including TB control/programme management and drug management. The TRC supports GDF through:

- reviewing grant applications to the GDF, and making recommendations: (a) to the Stop TB Co-ordinating Board on necessary steps for programmes to meet conditions for GDF support; (b) on which grant applications to accept and the level and nature of the grant; (c) and to WHO on the non-drug aspects of the programme which require assistance.

- reviewing of periodic reports from technical agencies/consultants monitoring programmes receiving GDF grants and recommendations concerning continuation of GDF support to programmes.
providing technical advice on relevant GDF activities related to applications, review, monitoring and technical assistance, including drug management.

A BAC would strongly compliment the support of the TRC.

**Proposed structure, practice and composition of a GDF BAC**

- Committee composed of approximately 5 to 8 members with a strong background in pharmaceutical and diagnostic business operations, with no conflicts of interest. Due consideration given to appropriate geographic and Developed/Less Developed country representation.

- Committee meets once a year, with travel and accommodation expenses covered by GDF.

- Committee linked to GDF TRC and CB through overlapping membership.

- Areas of expertise sought:
  - Product formulation and manufacturing, quality assurance, regulatory expertise.
  - Raw material (API) manufacturing, quality assurance, regulatory expertise.
  - Diagnostics manufacturing, quality assurance, regulatory expertise.
  - Pharmaceutical commercial expertise in relevant countries.
  - Raw material (API) commercial expertise in relevant countries.
  - Legal and international contract expertise.
  - Business development expertise.

**Proposed timeline and process**

- Finalization of Specific Terms of Reference for BAC in May 2006.

- Call for nominations for BAC in June 2006.

- Active outreach to identify suitable candidates, June – July 2006.

- Deadline for nomination submission to secretariat by 1 August 2006.

- Selection committee (consisting of CB members and other GDF stakeholders) convened early September 2006.

- First BAC meeting before November 2006 CB meeting.