



THE MEDICINES TRANSPARENCY ALLIANCE (MeTA)

SUMMARY DOCUMENT

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Summary

One third of the world's population lacks access to essential medicines¹. This situation persists despite increased government and donor financing for health, in part due to fundamental inefficiencies in the pharmaceutical market and across many countries' health and commodity supply systems.

Weak governance and a lack of transparency in medicines selection, regulation, procurement, distribution and sales contribute to this inefficiency and can also increase the vulnerability of the medicines supply chain to corruption and fraud.

In response to these challenges, the UK Department for International Development (DFID) has been working with others – such as developing country governments, global and national civil society organizations and pharmaceutical companies, the World Health Organization (WHO) and the World Bank – to develop a new global Medicines Transparency Alliance (MeTA).

Work to develop MeTA is drawing on lessons from the Extractive Industries Transparency Initiative (EITI) and other multi-stakeholder initiatives, as well as those from ongoing efforts by developing country governments to strengthen national procurement and pharmaceutical supply systems and to improve governance, and work to promote transparency in the health sector specifically by WHO², Health Action International (HAI)³, the World Bank and Transparency International⁴. This document, which summarises MeTA Phase One, reflects these lessons and builds on existing efforts, and is the product of extensive research and consultation conducted over the past year.

The **purpose** of MeTA Phase One is to pilot a new multi-stakeholder approach towards increasing transparency around the selection, regulation, procurement, sale and distribution of medicines in developing countries, thereby strengthening governance and encouraging innovative and responsible business practices. The **goal** of MeTA is, in co-operation with pharmaceutical companies, to provide access to affordable essential medicines in developing countries (reflecting Millennium Development Goal 8, Target 17) with the ultimate aim of improving health outcomes for poor people in developing countries.

MeTA's **focus** will be on strengthening developing country capacity to collect, analyse, disseminate and use data on medicine quality, availability, pricing and use. This will help improve transparency and accountability around the way medicines are selected, regulated, procured, distributed, supplied and then prescribed to and used by patients.

¹ WHO Medicines Strategy 2004-2007

² see <http://www.who.int/medicines/areas/policy/goodgovernance/home/en/>

³ see <http://www.haiweb.org/medicineprices/>

⁴ see The Global Corruption Report 2006 at http://www.transparency.org/publications/gcr/download_gcr

MeTA has been designed as a multi-stakeholder initiative in which developing countries can participate to support their own objectives around health systems reform, improved stakeholder engagement, strengthened governance in the health sector and broader transparency efforts. It will support and complement other activities designed to increase access to medicines in developing countries, particularly for poor and vulnerable people.

A core component of the initiative is the **disclosure** of data on medicine quality, availability, pricing and use – and the proactive collection of such data if this is not already done routinely. It is proposed that four types of data be commonly disclosed by all relevant stakeholders in MeTA countries, and that these data should be supplemented by additional contextual information.

For each of the areas outlined below, disclosure should cover:

- (i) The policy framework: what relevant laws and policies are in place?
- (ii) Procedures: for instance, what is the procedure for the registration of drugs?
- (iii) Outcomes: for instance, pricing outcomes achieved through public procurement.

The four data types are⁵:

- Data on the quality and registration status of medicines;
- Data about the availability of medicines;
- Medicine price data; and
- Policies concerning the ethical promotion of medicines.

The contextual information that should also be analysed and put into the public domain falls into the following areas:

- Supply chain operations;
- Medicine affordability;
- Equitable access; and
- The rational use of medicines.

MeTA will provide financial and technical support to MeTA pilot countries to help them disclose, analyse and use the data and information outlined above. It will also provide support to countries to enable them to bring different stakeholders together – from government, civil society, the private sector and elsewhere – to scrutinize the available data and other information, discuss the issues highlighted through this process and then consider how best to respond. MeTA will provide support to build the capacity of stakeholder groups who would otherwise find it difficult to engage effectively in such a forum.

Therefore, while the precise institutional arrangements will differ from country to country, we expect that each country will:

- Make a **formal government commitment** to pilot MeTA.
- Form a **national multi-stakeholder group**, which will develop a work plan for the next 2 years. This national multi-stakeholder group will

⁵ See annex for the full list

include representatives of relevant government departments and bodies, civil society, international development partners and relevant private sector organisations, such as medicines manufacturers and associations, importers, distributors and retailers. The national group will meet regularly to arrange data collection, disclosure and dissemination, and to discuss implications for policy and practice.

- Be represented on the planned **MeTA international stakeholder forum**. This forum will provide overall governance and direction for MeTA, identify issues emerging in the pilot countries that may require action by or support from international partners, including areas where further research would support MeTA goals at national level. It is expected that the international stakeholder forum will meet two to three times a year.

The international stakeholder forum will help to shape MeTA as it develops through the course of Phase One and will keep the MeTA model under review, drawing on lessons from MeTA pilot countries to make recommendations on whether and how MeTA should evolve beyond Phase One.

The international stakeholder forum will be supported by a **MeTA Secretariat**. This is expected to be fully established in early 2008, with interim secretariat arrangements in place until then. In addition to servicing the international stakeholder forum, the Secretariat will support MeTA pilot countries by facilitating their access to technical assistance and capacity building support from MeTA international partners and elsewhere, providing support and guidance on the establishment and operation of national multi-stakeholder groups and secretariats, and managing the flow of finances to pilot countries and others as appropriate. The Secretariat will also organize MeTA meetings and conferences, and will manage MeTA communications including the maintenance of the MeTA website.

Several of MeTA's international partners will also come together to facilitate the development of a global **research network** focused on improving access to medicines (ATM) in developing countries. This separate but linked initiative will include a core component on transparency and accountability issues in the medicines supply chain, to support MeTA pilot countries in learning from their ongoing efforts in this area and to build a robust evidence base. MeTA pilot countries will be guided in their use of this global ATM research network.

At the end of Phase One, which is intended to last for 24 months, MeTA will be fully evaluated against an agreed set of indicators. These indicators are currently under development. They will focus on the process of facilitating greater transparency and accountability – but through these evaluation efforts MeTA will also begin to map the contribution that greater transparency and accountability can make to improved market and health system efficiencies and to the ultimate goal of increased access to medicines in developing countries, particularly for poor and disadvantaged people. MeTA pilot countries will be fully and directly involved in all monitoring and evaluation activities.

This summary is available for comment until [Friday 12th] October 2007.⁶ Once finalised, it will set the frame for the launch and implementation of MeTA Phase One later this year. We are extremely grateful to all those that have contributed to the proposals summarized in this document, including through pilot country scoping exercises, expert discussion meetings, stakeholder workshops and one-on-one dialogue. Whilst it is not possible to fully represent such a diverse range of views, we believe this draft proposal achieves a good compromise and demonstrates that MeTA's core agenda is commonly shared.

⁶ Please direct any comments to Emma Back, MeTA consultant, at emma.back1@hotmail.com copied to Michael Borowitz m-borowitz@dfid.gov.uk and Danny Graymore d-graymore@dfid.gov.uk at DFID.

Annex

The table below lists the proposed data areas that should be commonly disclosed in countries taking part in MeTA. It is not expected that such disclosure can occur over-night, but rather that countries commit to work towards this disclosure.

All MeTA countries (and other stakeholders as appropriate) should make available information concerning:			
Quality	Registration and Availability	Price	Ethical promotion
Quality assurance processes for public, private and non-profit tenders (e.g. use of a pre-qualified list of quality assured suppliers)	Standard treatment guidelines	Public, private and non-profit sector consumer prices;	Ethical promotion policies and practices in the public, private and non-profit sectors (including pharmaceutical manufacturers' codes).
GMP certificates for all manufacturing facilities (domestic and foreign)	Essential medicines (or drugs) list	Public procurement prices	
Quality monitoring data, including: - Quality assurance status of all medicines in the country (domestically produced and imported)	A list of all medicines registered for use in the country	Policies and practices relating to mark-ups and other charges in the public and non-profit sectors;	
Routine testing processes and outcomes (including post-marketing surveillance data and related information on the presence of substandard and counterfeit medicines in the local market).	The processes for drug registration and drug selection	Presence of taxes and tariffs on medicines;	
	A list of all pharmaceutical patents held in the country	Aggregated or 'confidential' report on procurement prices and mark-ups in the private sector	
	Volume and value of medicines procured for the public sector, and the non-governmental sector, and volumes in the private sector.		
	Availability of medicines to the consumer (for instance stock levels of medicines in health facilities and pharmacy outlets).		