

Medicines Transparency Alliance: Implementing our pilot phase

Summary:

Despite increased government and donor financing for health, one third of the world's population still lacks access to essential medicines.¹ This situation persists, in part, because of fundamental inefficiencies in both the pharmaceutical market and across the health and commodity supply systems of many countries.

Weak governance and a lack of transparency in medicines selection, regulation, procurement, distribution and sales contribute to this inefficiency and can make the medicine supply chain more vulnerable to corruption and fraud. In response to these challenges, many countries have pioneered work to increase transparency and accountability in medicines supply chains. Building on this, the UK Department for International Development (DFID) has been working with a range of partners to develop a new global Medicines Transparency Alliance (MeTA), which is officially launched in May 2008. Those involved in the process include developing country governments, global and national civil society organisations, pharmaceutical and other companies, the World Health Organization (WHO) and the World Bank.

MeTA draws on lessons from a number of multi-stakeholder² initiatives, from ongoing efforts by developing country governments to improve governance and strengthen national procurement and pharmaceutical supply systems, and on work done to promote transparency in the health sector by WHO,³ Health Action International (HAI),⁴ the World Bank and Transparency International.⁵ This document (which sets out plans for the pilot phase of MeTA) reflects these lessons and builds on existing efforts. It is the result of extensive research and consultation during 2006 and 2007.

The pilot phase of MeTA will encourage a new multi-stakeholder approach designed to increase transparency around the selection, regulation, procurement, sale and distribution of medicines in developing countries. It aims to strengthen governance, improve efficiency, and encourage innovative and responsible business practices. The goal of MeTA is to increase access to affordable essential medicines in developing countries, in co-operation with pharmaceutical companies (in line with Millennium Development Goal 8, Target 17) with the ultimate goal of improving the health of poor people in developing countries.

MeTA will focus on strengthening the capacity of seven pilot countries⁶ to collect, analyse, disseminate and use data on the quality, availability, pricing and use of medicines. This will help improve transparency and accountability with regard to the selection, regulation, procurement, distribution and supply of medicines – including the ways in which they are prescribed to and used by patients.

MeTA is an alliance in which country members can participate to support their own work to reform health systems, improve stakeholder engagement, strengthen governance in the health sector and broaden transparency efforts. It will support and complement other activities designed to increase access to medicines in developing countries, particularly for poor and vulnerable people.

¹ WHO Medicines Strategy 2004-2007

² Multi-stakeholder initiatives involve processes which aim to bring together all major stakeholders in a new form of communication, decision-making (and possibly decision-making) on a particular issue. They recognise the importance of achieving equity and accountability in communication among stakeholders, involving equitable representation of three or more stakeholder groups and their views. <http://www.earthsummit2002.org/msp/index.html#Introduction>

³ see <http://www.who.int/medicines/areas/policy/goodgovernance/home/en/>

⁴ see <http://www.haiweb.org/medicineprices/>

⁵ see *The Global Corruption Report 2006* at http://www.transparency.org/publications/gcr/download_gcr

⁶ Seven pilot countries have been chosen to date: Ghana, Uganda, Zambia, the Philippines, Peru, Kyrgyzstan and Jordan.

The disclosure of data on the quality, availability, pricing and use of medicines – and the proactive collection of such data if this is not already done routinely – is a core component of the initiative. All relevant stakeholders in countries implementing MeTA will commit to disclose four types of data, supplemented by contextual information.

The four data types are:

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

For each of these areas, disclosure should cover:

- (1) Policy – what relevant laws and policies are in place?
- (2) Practice – for instance, what is the procedure for the registration of medicines?
- (3) Outcomes – such as the pricing outcomes achieved through public procurement.

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

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

MeTA will provide financial and technical support to the pilot countries to help them progressively disclose, analyse and use data and information. It will also help countries to bring different stakeholders (including those from government, civil society, and the private sector) together to scrutinise available data and information, discuss the issues highlighted through this process, and consider how best to respond. MeTA will provide support to strengthen the capacity of stakeholder groups that would otherwise find it difficult to engage effectively in such dialogues. 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;
- Sign up to an agreed set of principles that govern MeTA;
- Form a national multi-stakeholder group, which will develop a two-year work plan, and meet regularly to arrange data collection, disclosure and dissemination, and to discuss implications for policy and practice; and
- Participate in the MeTA International Advisory Group (IAG). This will review findings, assess global trends and provide MeTA's Management Board with advice and recommendations for the future direction of MeTA.

An International Secretariat will support MeTA pilot countries by helping them to access technical assistance and support for capacity strengthening available from both MeTA international partners and elsewhere. It will also provide support and guidance to:

- (1) Help with the establishment and operation of national multi-stakeholder groups and secretariats, and
- (2) Manage the flow of finances to pilot countries and others as appropriate.

The Secretariat will also organise MeTA meetings and conferences, manage MeTA communication and sharing of knowledge, and support the IAG.

Several of MeTA's international partners will also work 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 will help pilot countries to make use of this global ATM research network. The ATM research network will also help to collate medicines data generated by others outside MeTA (such as global health partnerships), which will then be accessible through the MeTA website.

At the end of the 24-month-long pilot phase, we will use an agreed set of indicators to evaluate MeTA. These indicators, which are currently being developed, will focus on the process of facilitating greater transparency and accountability. However, MeTA will also use these evaluation efforts to begin mapping the contribution that greater transparency and accountability can make:

- (1) To improving the efficiency of markets and health systems, and
- (2) To the ultimate goal of increasing 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.

DFID is extremely grateful to all those that have contributed to the proposals outlined in this document, including those who took part in pilot country scoping exercises, expert discussion meetings, stakeholder workshops and one-on-one dialogue. It is not possible to represent fully such a diverse range of views, but it is hoped that this proposal achieves a good compromise and demonstrates common agreement on MeTA's core agenda.



The need for medicines

One third of the world's population lacks access to essential medicines.⁷ Pharmaceuticals are the largest health sector expenditure after personnel costs in most low-income countries and they can account for 50 to 90 percent of out-of-pocket spending on health for poor households. These costs can restrict access to medicines, and increase poverty and debt. Improving the availability and affordability of essential medicines of an assured quality is therefore key to increasing access to healthcare and improving the health of poor people.⁸

However, in many countries pharmaceutical supply chains are highly inefficient. This is partly because governance is weak and transparency is lacking in medicine selection, regulation, procurement, distribution and sales. These failings also increase the supply chain's vulnerability to corruption and fraud – through, for example, bribery, theft, diversion and the supply of counterfeit medicines. Mark-ups at different points along the supply chain can be unnecessarily high and taxes and tariffs may add to the cost of medicines.

All these factors reduce the affordability and availability of quality-assured medicines, undermining health services and health outcomes. Those supplying medicines and other health-related goods and services may also see their operational costs increased, their competitiveness reduced and their reputation damaged.

Significant increases in the amount of aid provided to developing countries, which include major commitments on health and access to medicines (particularly for HIV and AIDS, TB and malaria), mean more resources are flowing through health procurement and supply systems in these countries. Differential pricing, generic substitution, subsidies and other initiatives are reducing

the supply cost of many medicines. It is vital that these advances benefit patients and are not lost to weaknesses in the supply chain. Making patients more aware of issues of medicine quality, availability and pricing is a critical step in ensuring these gains benefit patients.

A number of countries – including Ghana, Jordan, Kyrgyzstan, Peru, the Philippines, Uganda and Zambia – have pioneered work to increase transparency and accountability in the medicines chain. Building on this, DFID has been working with others to develop a new global alliance – MeTA. These partners include developing country governments, global and national civil society organisations, pharmaceutical companies, WHO and the World Bank.

This work builds on lessons from the Extractive Industries Transparency Initiative⁹ (EITI) and other multi-stakeholder initiatives. It also draws on significant work to promote transparency in the health sector, specifically by WHO,¹⁰ HAI,¹¹ the World Bank and Transparency International.¹² This document, which sets out plans for the pilot phase of MeTA, also reflects extensive consultation and research conducted during 2006 and 2007.

⁷ WHO Medicines Strategy 2004-2007

⁸ see *Increasing access to essential medicines in the developing world: UK Government policy and plans (June 2004)* for more information on UK strategy and efforts in this area

⁹ www.eitransparency.org

¹⁰ see <http://www.who.int/medicines/areas/policy/goodgovernance/home/en/>

¹¹ see <http://www.haiweb.org/medicineprices/>

¹² see *The Global Corruption Report 2006* at http://www.transparency.org/publications/gcr/download_gcr

How can MeTA help?

Medicines	Essential health commodities, such as drugs, vaccines, contraceptives, diagnostics and laboratory supplies
Transparency	Improving information access, scrutiny and use, to support the development of viable, efficient medicines markets and supply systems that benefit all developing country consumers
Alliance	Stakeholders from public, private and non-profit sectors working together to effect significant positive change

Access to medicines is determined by complex interactions among stakeholders on the supply side of the pharmaceutical market and demand side needs, preferences, financial capabilities and funding mechanisms (see Figure 1). These interactions combine to determine the range, quality and price of medicines available in pharmacies and other outlets; the treatment recommendations made by providers; and the choices that individuals make about medicines when they purchase them.

The private market for medicines does not function as a perfectly competitive market, because it features information imbalances that favour suppliers over consumers. Suppliers also have the advantage of patents and other mechanisms that limit competition. These market failures and other system inefficiencies often lead to high prices, inconsistent levels of product quality, and the consumption of medicines that are neither cost-effective nor as clinically effective as possible.

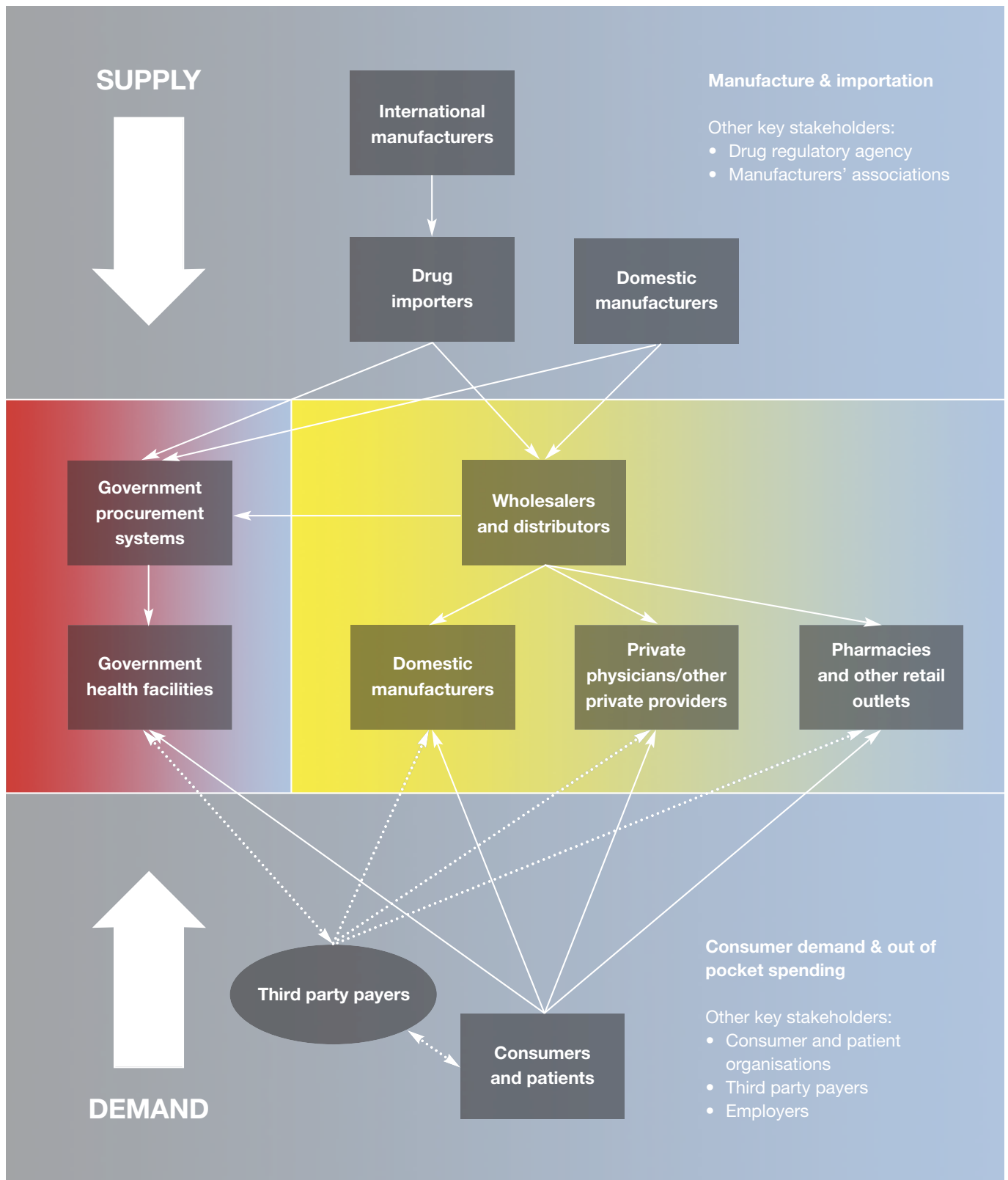
MeTA seeks to address these challenges by encouraging the disclosure of information about the quality, availability, pricing and use of essential medicines on the open market and those procured by public purchasers. It will also facilitate discussion, analysis and the use of this information by a broad range of stakeholders – including government agencies, civil society organisations, the media, the private sector, international agencies and donors, and the general public. This approach will shift some decision-making power to consumers, put greater competitive pressure on suppliers,

promote better governance and more appropriate resource allocation by public purchasers and improve the functioning of the pharmaceutical market.

MeTA will serve as a mechanism to monitor pharmaceutical market imperfections, increase market and health system efficiency, strengthen procurement operations, and encourage innovative and responsible business practices and good governance. It will also assess the effectiveness of relevant market and health system interventions, especially those focused on increasing access to medicines for poor and vulnerable people.

Some activities initiated by MeTA will be ‘upstream’, focusing on increasing transparency around issues of the quality, availability and pricing of medicines in the supply chain. Another important area of MeTA activity will be its work to disseminate independent and impartial information to healthcare professionals, patients and consumers. Special efforts will ensure that this information reaches all citizens and that they are able to use it. Key to achieving this will be work with national media and local civil society to ensure that information is disseminated in a useable form. Civil society organisations which work directly with poor and socially excluded people will have a key role to play in helping them make use of this information.

Figure 1: Key pharmaceutical system stakeholders and relationships with respect to transparency, accountability and efficiency



MeTA pilot

The purpose of the MeTA pilot phase is to explore a new multi-stakeholder approach designed to increase transparency around the selection, regulation, procurement, sale and distribution of medicines in developing countries. The aim of MeTA is to strengthen governance, improve efficiency, and encourage innovative and responsible business practices. Its goal is to increase access to affordable essential medicines in developing countries, in co-operation with pharmaceutical companies (in line with Millennium Development Goal 8, Target 17) in order to improve the health of the poor in developing countries.

MeTA will focus on strengthening the capacity of developing countries to collect, analyse, disseminate and use data on the quality, availability, pricing and use of medicines. This will help to improve transparency and accountability about the selection, regulation, procurement, distribution, supply and use of medicines.

Value of a global alliance

A global alliance is more effective in pursuing these activities than one-off country-specific efforts for several reasons.

- The pharmaceutical market is globalised and requires some degree of global response to facilitate access to it.
- Trade in pharmaceutical products is often weakly regulated and opaque. This results in poor quality control and illegal activities which affect many countries, such as the theft and diversion of products across borders, and the production of counterfeit items.
- Many different stakeholders are involved in the pharmaceutical sector around the world, some from within the development community and others from outside it, though there is some alignment of interests with regard to addressing the problems faced.
- Multilateral agencies have only minimal institutional capacity, particularly in key areas such as economics, business and public sector financial management.
- Global and regional public goods – such as the availability of comparable cross-country price data, cross-country co-operation and information exchange on product testing and notification, and the use of more efficient mechanisms for sharing validated data on patent status, regulatory status, inspection reports, standards and guidelines - have a key role to play.
- To address different aspects of the challenge we face, approaches need to be much better co-ordinated at all levels – country, regional and global. At the country level, for example, efficiency would be greatly increased by better co-ordination among donors and government programme managers on inventory management and on civil society participation and oversight. And at the regional and global levels, harmonisation and co-operation on regulation and procurement offer substantial gains.

MeTA core principles

We have developed a set of core principles governing the implementation of MeTA. These are set out in the box below. Signing up to these principles will be an important first step for developing countries and global stakeholders when committing themselves to be a part of MeTA.

BOX 1: The core principles of MeTA

1. We believe that good health is crucial to human dignity and to social and economic development.
2. We underline that efforts to improve health depend on effective health systems, which have sustainable financing, the presence of quality-assured essential medicines and other health commodities, and sufficient doctors, nurses and other healthworkers.
3. We recognise that inefficient procurement, distribution, and supply of medicines, coupled with weak regulation and poor supply chain management, can result in quality-assured medicines being unaffordable and/or unavailable, especially for poor and disadvantaged people.
4. We believe that urgent action is required to address these challenges, as part of a comprehensive approach to the strengthening of health systems.
5. We recognise that a lack of information on the quality, availability and price of medicines in many countries can exacerbate these problems by obscuring inefficient or inappropriate practices.
6. We recognise that public understanding of information on the quality, availability and pricing of medicines could help inform public debate, enhance public policy and drive improvements in the procurement, distribution, sale and prescription of medicines.
7. We further recognise that high standards of transparency in all sectors of society can build trust in public institutions and can help to build accountability among those who make decisions affecting the health and well-being of citizens.
8. We come together to understand how greater transparency and accountability can be developed with regard to key information on the quality, availability and pricing of medicines in the public, private and non-profit sectors, and in their journey from port to patient.
9. We are strongly committed to taking a multi-stakeholder approach and seeking solutions that involve all stakeholders – including governments, the public, private, and not-for-profit sectors, and broader civil society.
10. We recognise that the achievement of greater transparency must be set in the context of respect for the rule of law.
11. We believe that actions to increase transparency and accountability should do no harm, and should support national development plans and any efforts to harmonise external support, including the support provided by donors.
12. We believe that actions to increase transparency and accountability should be guided by concerns for social justice, with a focus on the needs of poor and socially excluded people.
13. We recognise that we need to pilot and evaluate these actions to increase transparency and to ensure we meet these principles.
14. Our ultimate objective is to increase equitable access to medicines over the long term and we will measure our actions against this goal.

MeTA core approach - Promoting transparency and accountability

The MeTA approach is a way of working to increase transparency and accountability in the selection, regulation, procurement, distribution, sale and use of medicines in developing countries that choose to take part.

It is a multi-stakeholder initiative that countries can use to support their own objectives related to health systems reform, improved stakeholder engagement, strengthened governance in the health sector, and broader transparency efforts. It will also support and complement other activities designed to increase access to medicines, particularly for poor and vulnerable people.

There is widespread agreement that for MeTA to be successful – and to warrant an international partnership approach – it needs to have a common set of elements that MeTA countries must commit to. These common elements fall under two broad headings: transparency and accountability.

Transparency - Data collection and dissemination

MeTA countries will analyse and disclose data related to four core areas (see Box 2). This will then be supplemented by key contextual information relating to:

- **Supply chain operations** – for example supply chain mapping data;
- **Medicine affordability** – for example, generic utilisation data and data on the cost of treatment;
- **Equitable access** – such as data on health and medicines expenditure by income group, and information concerning the treatment of key illnesses by income group, and
- The **rational use** of medicines – such as household survey and prescribing data.

All MeTA pilot countries should commit themselves to disclosing these core data – though it is recognised that full disclosure cannot be realised overnight. At this stage, countries and relevant international stakeholders are therefore committing themselves to work towards achieving meaningful disclosure. Lessons learned from this process across MeTA pilot countries will be an important outcome from the MeTA pilot phase.

Countries may, however, wish to go beyond the areas listed here. This is, of course, compatible with MeTA objectives – and is to be encouraged. However, MeTA will prioritise the provision of financial, technical and political support to transparency activities that relate to the core data disclosure areas and the actions to support accountability outlined below. Progress in these areas will feature in the assessment of MeTA's implementation and its impact.

Common data disclosure

For each of the core areas listed above, the information disclosed should cover:

- (1) **Policies:** what relevant laws and policies are in place?
- (2) **Practices:** for instance, what is the procedure for the registration of medicines?
- (3) **Outcomes:** for instance, what are the pricing outcomes of public procurement?

Box 2: The core areas of information

The four core areas of data to be disclosed cover:

- the **quality** and registration status of medicines;
- the **availability** of medicines;
- the **price** of medicines; and
- policies related to the ethical **promotion** of medicines.

Countries already collecting these data, can disclose them straightaway. Otherwise, a means of collecting them will have to be developed first.

All MeTA countries (and other stakeholders as appropriate) should disclose or report on the following:

Quality

- Quality assurance processes applied in public, private and non-profit tenders – for example, the use of a pre-qualified list of quality assured suppliers;
- Good manufacturing practice (GMP) certificates for all manufacturing facilities (domestic and foreign);
- Quality monitoring data – including the quality assurance status of all medicines in the country (both domestically produced and imported);
- Routine testing processes and outcomes – including post-marketing surveillance data and information about the presence of substandard medicines in the local market;
- A list of all medicines registered for use in the country, and
- The processes used for medicine registration and selection.

Availability

- Standard treatment guidelines;
- Essential medicines (or drugs) list;
- A list of all pharmaceutical patents held in the country;
- Volume and value of medicines procured for the public and the non-profit sectors;
- Volume of medicines procured in the private sector;
- Availability of medicines to the consumer (for instance, stock levels in health facilities and pharmacy outlets), and
- Routine inventory and audit procedures for public sector medicines stores.

Price

- Public, private and non-profit sector consumer prices;
- Public procurement prices;
- Mark-ups and other charges in the public and non-profit sectors;
- Presence of taxes and tariffs on medicines, and
- Aggregated or 'confidential' reports¹³ on procurement prices and mark-ups in the private sector.

Promotion

- Promotion policies and practices in the public, private and non-profit sectors. This includes pharmaceutical manufacturers' codes and standard operating procedures for public procurement agents, as well as any other relevant data concerning promotion.

In all these areas, the quality and accuracy of the data disclosed may be questionable in some way. In addition, the processes operating in practice may differ considerably from policy guidelines. Each country should make clear any such issues at the time of disclosure.

Contextual information

Much of the contextual information that MeTA requires will be collected from surveys. This information will complement disclosed data and help with its interpretation. It will also play a role in the evaluation of MeTA's long-term impact.

Accountability - A multi-stakeholder approach

Experience tells us that initiatives that bring a mix of key stakeholders to the table (private enterprise, civil society, government and others) can tackle effectively complex system-wide challenges which could not be addressed easily by one sector acting alone.

¹³ At least initially, MeTA will collect data from private sector outlets in a confidential or aggregated fashion, in order not to distort the competitive forces that exist in the market currently. The desirability of this approach will be assessed over the course of Phase One.

Examples of such initiatives include the Extractive Industries Transparency Initiative (dealing with oil, gas and minerals), the Ethical Trading Initiative (which addresses labour standards in supply chains), the Forest Stewardship Council (sustainable forestry), the Marine Stewardship Council (sustainable fishing), and the Multifibre Arrangement (MFA) Forum (which tackles responsible competitiveness in apparel supply chains).

Success depends on sincere multi-stakeholder approaches that create a neutral ‘space’ in which to work, shared understanding of the problems, common ways of working, and an agreed agenda to which each actor feels able to contribute and which meets their differing needs and incentives. In addition, where government has an important role to play in supporting change, high-level political commitment is critical for success.

The multi-stakeholder approach often acts as a global ‘club’. Publicly joining the club, peer pressure within the club, and access to political, financial and technical support from the club, combine to create a set of incentives that help participants to sustain their efforts and deliver results, across public, private and non-profit sectors. This way of working often starts with a relatively limited agenda, which expands as trust and understanding grow among participants.

MeTA relies on the premise that all key actors must work together in order to make the supply chain more transparent and accountable and so change the nature of the selection, regulation, procurement, distribution, sale and use of medicines. This means government and the public sector working with the private sector, professional groups and civil society.

We believe that this type of multi-stakeholder approach – underpinned by international action and high-level political commitment – results in the following:

- The creation of incentives to support and encourage new ways of doing business (in public, private and non-governmental sectors);
- An increase in the likelihood that governments and the broader public sector will support a programme of reform;
- Incentives for agents within the private sector supply chain to change how they do business;
- Opportunities for international companies to (1) demonstrate innovative and responsible business practices and show their support for development efforts, (2) encourage the uptake of these approaches by other companies, and (3) ensure that their national operations are aligned with their global commitments;
- A significant and meaningful role for civil society to play, which reinforces and helps to sustain reform, and strengthens existing national accountability mechanisms, and
- The chance for donors to deliver on their broader governance and public expenditure goals alongside (in the case of MeTA) health goals.

Building accountability in MeTA countries

At the country level, MeTA will employ a multi-stakeholder approach, underpinned by high-level political commitment and supported by co-ordinated international political, financial and technical assistance.

MeTA countries will each take the following steps to help build accountability across the medicines procurement and supply chain:

- Each government will make a high level political commitment (at the level of Secretary of State or above) and sign up to the core MeTA principles.
- Each government will commit itself to working with civil society and the private sector in order to take MeTA forward.
- Each government will appoint a named individual to lead the implementation of MeTA on behalf of the government.
- Each government will support the formation of a national multi-stakeholder group¹⁴ made up of the principal public, private and civil society actors.
- The multi-stakeholder group will advise on the development of a national workplan for MeTA implementation. It will regularly convene to assess progress and plan future responses in relation to, for example, new work on transparency, work to promote results widely, and work to respond to weaknesses in procurement and supply systems, as identified in MeTA reports or related publications.
- Each government will support the formation of a small secretariat to provide services to the country's multi-stakeholder group and to implement its workplan. Ideally this secretariat will be housed within an existing agency to avoid creating new bureaucratic structures.
- Each government will make information publicly available on the quality, availability, pricing and use of medicines through websites, publications, and strategic communication channels including radio, town hall and/or community meetings, workshops and other approaches.

¹⁴This group will include government (various ministries and agencies) and the broader public sector (health service managers and facilities), the private sector (pharmaceutical companies, suppliers, wholesalers, distributors, retailers), professional groups (doctors, pharmacists and others), and civil society (representing communities, patients, consumers, good governance, transparency groups, media and other parts of civil society such as faith-based organisations), and donors and international agencies as appropriate (such as The Global Fund to Fight AIDS, Tuberculosis and Malaria [GFATM]).



Making the multi-stakeholder approach work

There are four critical factors that have to be addressed to ensure that a multi-stakeholder approach will work:

- The approach must be developed to fit the local context;
- The right people must be brought together around the table (see box 3);
- Time must be devoted to building trust, and
- The ability of groups to play an active role and to engage with their wider constituencies must be strengthened.

MeTA will develop guidance during the pilot phase to help countries get the right people around the table.

To strengthen capacity, MeTA must direct support to civil society and other groups (as appropriate) in order to build their understanding of the following:

- The strengthening of health systems;
- The transparent selection, regulation, procurement, distribution, sale and use of medicines;

- Public financial management;
- Good governance;
- Public-private dialogue, and
- Communication.

In addition, it will be important for members of national multi-stakeholder groups to work with their wider constituencies and endeavour to represent their perspectives.

MeTA reports

Each MeTA country report will contain disclosed data, additional contextual information, and any supporting analyses. It will also outline progress made relative to the country's MeTA workplan and will provide an assessment of impact to date. How often such reports will be produced will be determined during the course of the pilot phase. A synthesis of these country reports will be used to produce a global MeTA report on a regular basis.

Box 3: Getting the right people around the table – an example from the Extractive Industries Transparency Initiative (EITI)

Under the terms of the EITI, countries must form a multi-stakeholder group to oversee its implementation. This group consists of all appropriate stakeholders, including (but not limited to) the private sector, civil society (including independent civil society groups and the media), parliamentarians and relevant government ministries (including the lead agency). The group should agree clear, public terms of reference.

EITI implementation is assessed by independent validators who look for evidence of an effective multi-stakeholder approach. Such evidence includes:

- Whether stakeholder assessments have been carried out;
- Whether the invitation to participate in the multi-stakeholder group was open and transparent;
- Whether stakeholders are (and believe themselves to be) adequately represented;
- Whether stakeholders feel they can operate as part of the group free of undue influence or coercion – which includes liaising with their constituency groups and other stakeholders;
- Whether civil society members are independent of government and/or the private sector (both operationally, and in terms of their policy).

These core features of effective multi-stakeholder working can be broadly replicated beyond EITI.

MeTA will serve as a mechanism to monitor pharmaceutical market imperfections, increase market and health system efficiency, strengthen procurement operations, and encourage innovative and responsible business practices and good governance. It will also assess the effectiveness of relevant market and health system interventions, especially those focused on increasing access to medicines for poor and vulnerable people.

Who will manage and fund MeTA?

The MeTA international advisory group (IAG)

A MeTA international advisory group (IAG) will be formed in the second quarter of 2008. This 20-member group will be made up of public, private and civil society representatives. Its job will be to provide advice to the MeTA Management Board through:

- Reviewing findings emerging from MeTA pilot countries and considering their implication to help MeTA to achieve its goals;
- Providing comments on trends within the global pharmaceutical market relevant to MeTA's aims of achieving greater transparency and accountability;
- Making recommendations to the Access to Medicines Research Network on research streams which could improve understanding of how access to medicines can be enhanced;
- Making suggestions on the content of MeTA global meetings, and
- Analysing the developments and lessons emerging from MeTA and providing recommendations on the future direction of MeTA beyond the pilot phase.

The IAG will play a key role in MeTA, providing a critical intellectual steer and advisory function to the initiative. The IAG will benefit from the unique mix of perspectives represented on the group and from the unusual experience of bringing together civil society, financial analysts, senior pharmaceutical management and experts from other sectors in problem-solving mode. The IAG will meet at least twice a year.

The International MeTA Secretariat

An International Secretariat has been established. It coordinates, organises, promotes and supports implementation of MeTA at global and national levels, channels technical and financial support to MeTA pilot countries, maintains contact with all stakeholders and pilot countries, strengthens capacity, organises global and regional meetings of MeTA working groups, and services the global MeTA governance structures.

The Secretariat will enhance communication and knowledge sharing among stakeholders in the MeTA countries through various mechanisms including the establishment and maintenance of a MeTA website (www.MedicinesTransparency.org), supporting interactive dialogues, and the development of a number of tools and materials. A Management Board has been formed with representatives from DFID, WHO and the World Bank to oversee and inform the work of the Secretariat.

We anticipate the need for a global MeTA conference that will be managed by the Secretariat. This will be held towards the end of the two-year pilot phase. It will bring together a broad range of key stakeholders at both national and international levels, to share methods, knowledge, lessons learned and examples of good practice, and to discuss overarching strategic issues facing MeTA. Its primary functions would be the sharing of knowledge and building of networks both across MeTA countries and at the international level.

Support to participating countries

DFID has committed itself to providing initial financial support for the pilot phase of MeTA, although it is very much hoped that other funders will begin contributing over the course of the pilot phase. International partners can also contribute technical and human resources.

The MeTA resources will support a range of activities at both country and international levels. Examples include the following:

At the country level:

- The launch of events in participating countries;
- The development and operation of national multi-stakeholder groups;
- The collation, analysis, disclosure and dissemination of data on the quality, availability, price and promotion of medicines, and
- The provision of support to participating countries to help them use data for policy-making, regulation, advocacy and evaluation.

At the international level:

- The provision of support to the MeTA International Advisory Group;
- The programme of support managed by the International Secretariat;
- The development of tools and methodologies to promote the collection and exchange of information on the quality, availability, price and promotion of medicines;
- Research on the impact of specific policies and programmes on the quality, availability, price, affordability, access and rational use of medicines;
- Comparative analyses of data from across MeTA countries and of global level datasets (procurement prices of medicines under global access programmes);
- Knowledge sharing and communication activities, including the international MeTA conference, and
- Work to evaluate MeTA.

MeTA is therefore offering countries participating in the pilot phase the following:

- Financial support for local action;
- Technical support and support for capacity strengthening from the global alliance of MeTA partners;
- An opportunity to set the agenda for research to develop improved policy and operational responses, and an opportunity for pilot country academic institutions to

participate in the proposed Access to Medicines Research Network, and

- Participation in the MeTA International Advisory Group.

Financial support for local action

MeTA is able to provide around £100,000 (approximately US\$200,000) per year to each pilot country to support local actions in the MeTA focus areas. These actions should complement existing access to medicines programmes supported by the government and other partners. For larger countries, where sub-national governments are largely responsible for ensuring access to medicines, the level of financial support needed and offered may be higher.

Pilot countries will develop a workplan and activity budget for the first two years of MeTA support, identifying priority goals and actions.

As the principal initial funder, DFID would like to work to the fullest extent possible with existing mechanisms for co-ordinating development financing and providing technical assistance. MeTA will use various funding channels, depending on the best approach for each country.

Centrally funded technical support and support for capacity strengthening

In addition to this financial support, MeTA pilot countries will be able to call on the global partners engaged in MeTA for technical assistance and support for capacity strengthening.

Technical assistance is available to help partners standardise assessment tools for collecting data on medicine prices, availability, and affordability, poor people's access to medicines, and the key processes used to regulate and manage medicines supply chains. Developing countries will apply, review and consolidate assessment tools, with MeTA support, as noted below.

Training on price data collection and analysis is also available to help partners undertake cross-country analysis and comparison of the price of medicines. This will draw upon publicly available medicine databases such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) Global Price Reporting Mechanism database, WHO/HAI medicines survey data, Management Sciences for Health (MSH) International Drug Price Indicator Guide, and Intercontinental Marketing Services (IMS) databases of private sector market data.

Capacity strengthening

MeTA will support the participation of countries in global training and capacity strengthening events, with a particular emphasis on strengthening those with the least power to engage with the process. Examples of such would include:

- **Global and regional training courses** on issues such as how medicines benefit policies in health insurance schemes, medicine pricing and appropriate regulation.
- **A civil society support programme** which will assist civil society organisations (CSOs) to:
 - Build skills in engaging with national policy processes, including the multi-stakeholder working groups envisaged by MeTA;
 - Build knowledge on issues related to access to medicines, transparency and accountability;
 - Build skills in methods used to promote greater transparency and accountability at national, district and community levels, and
 - Build skills in the use of medicine price data and in policy advocacy.

Analytical and diagnostic instruments

Technical agencies have developed analytical tools and instruments to diagnose problems within both medicine markets and

the government institutions and processes responsible for regulating and financing medicine supply. Several MeTA international partners are able to provide technical support to pilot countries that wish to use these instruments. Feedback from MeTA pilot countries will aid the review, consolidation and standardisation of these instruments, which include:

- Inventories of publicly available medicines data;
- Country pharmaceutical sector surveys and profiles – for which a standardised template is being developed, with country examples, that draws upon methods developed by WHO, MSH, IMS and others;
- Household survey modules of questions focusing on medicines;
- Supply-chain mapping and economic analyses of medicine markets;
- Expenditure and financing studies, such as those based on the National Health Accounts, Public Expenditure Review and Public Expenditure Tracking Survey methodologies;
- Assessments (based on a manual developed by WHO) of transparency at different stages of the medicines supply chain, with a specific focus on how vulnerable they are to corruption;
- Assessments of medicine procurement and benchmarking, with support from the World Bank and drawing on the work of WHO, MSH and others;
- Communication and media mapping, and
- Political or stakeholder analyses.

Medium-term development of MeTA technical support

In the medium-term, the range of technical support, capacity strengthening and help with communication accessible through MeTA will be developed further (in consultation with MeTA pilot countries and with international stakeholders). This could include developing technical support and support for capacity strengthening in the area of medicines quality

and regulation, and to facilitate the increased transparency and effectiveness of National Drug Regulatory Agencies. This is judged to be important, given that a lack of credible quality and safety regulations is a major barrier to efforts to increase access to essential medicines (especially generics) in many low- and middle-income countries.

Policy research and evaluation

MeTA will support systematic reviews and policy and operational research. It will also support the evaluation of interventions and strategies adopted by pilot countries. The goal is to expand the evidence base available for policies and operational interventions that can effectively be used to address problems identified through data disclosure and the stakeholder dialogue supported by MeTA.

Very little health policy and systems research of a sufficient quality has been conducted in relation to access to medicines in developing countries, as much of it does not meet the quality criteria for systematic reviews set by, for example, the Cochrane Collaboration. As a result, there are some important gaps in our knowledge with regard to effective and scalable interventions that can influence the quality, pricing and rational use of medicines. This is a critical issue, especially in countries where most medicines involve out-of-pocket expenditure and where regulatory and legal institutions are weak.

Work with pilot countries to address these problems is likely to entail (1) developing a research agenda, (2) commissioning research, and (3) disseminating research and evaluation evidence to inform policy.

Developing the research agenda – Because MeTA pilot countries will be members of the MeTA International Advisory Group, a bottom-up process will be used to identify what research is needed to explore the issues identified in MeTA countries. This will be combined with a strategic, cross-country

perspective that will help to set priorities for research that will be of broad value.

Commissioning research – The MeTA Secretariat will link with a new global Access to Medicines Research Network (planned by DFID and several other international partners), which will be able to identify and support a research agenda informed by the needs of MeTA countries. Research will be commissioned in a way that:

- Facilitates participation and leadership in research contracts by institutions in developing countries;
- Strengthens capacity within research institutions in fields relevant to medicines policy;
- Fosters collaboration across research institutions and encourages interdisciplinary working, and
- Fosters open sharing and wide dissemination of data, research methodologies and findings, to the fullest extent possible.

Disseminating research and evaluation evidence to inform policy

– MeTA will support wider knowledge sharing and communication activities through regional meetings, the global MeTA conference, and its communication programme, including the MeTA website. It will also be possible for MeTA pilot countries to post information and reports of their own MeTA-related activities on the website, to facilitate sharing and learning among alliance members.

Measuring the impact of the pilot phase

Conceptual framework for assessing MeTA impacts

MeTA intends to support the expansion of policies and activities that encourage transparency and accountability in the pharmaceutical sector. Evidence suggests that this will improve the efficiency of market and health systems at both the national and global levels and so in turn increase access to medicines.

National level assumptions underlying MeTA strategy

It is expected that, at the national level, a multi-stakeholder approach aimed at increasing transparency and accountability around the selection, regulation, procurement, distribution and sale of medicines will lead to:

- (1) Greater local disclosure of information (transparency);
- (2) Greater stakeholder engagement, commitment, and action (accountability), and
- (3) More cost-effective supply and use of medicines (efficiency), which will in turn lead to expanded access to essential medicines, especially for the poor (equity).

Global level assumptions underlying MeTA strategy

It is expected that international multi-stakeholder engagement aimed at increasing transparency and accountability around the selection, regulation, procurement, distribution and sale of medicines will result in:

- (1) Greater global disclosure of information (transparency);
- (2) Greater involvement and investment in pharmaceutical sector governance (accountability), and
- (3) Broader availability and greater use of publicly available tools and metrics for pharmaceutical sector decision-making, assessment and monitoring (efficiency).

The activities promoted by MeTA will take place within the context of a broad range of existing pharmaceutical sector policies and programmes at both the national and international level, so determining MeTA's impact will be a challenge. In order to assess its impacts, MeTA will:

- (1) Assemble, organise and disseminate existing data describing key processes and outcomes in the pharmaceutical sector;
- (2) Collect additional quantitative and qualitative data where needed to fill important gaps prior to or during the early stages of implementation;
- (3) Monitor key metrics such as medicines quality, availability, pricing and use over time, and
- (4) Conduct multidimensional studies to evaluate how transparency, accountability, efficiency and access have changed at key points in time and to assess the contribution of MeTA activities to these changes.

It is unrealistic to expect that comprehensive evidence in these areas will be available by the end of the MeTA pilot phase, but sufficient evidence should have been gathered to inform decision-making around the potential for broader roll-out during any subsequent phases.

MeTA targets and evaluation domains

MeTA aims to increase transparency and accountability, promote efficiency and ultimately increase access to medicines, by focusing on both core and complementary targets.

Core targets:

- To facilitate a multi-stakeholder process globally and in each pilot country and assess what the process is achieving;

- To expand the availability of essential medicines in public sector, non-profit and private health facilities and medicine outlets;
- To lower the price of medicines offered to consumers and patients, by addressing every step in the value chain;
- To improve the affordability of care for major health problems, and
- To improve the quality of medicines by making more information publicly available and increasing public awareness about product testing.

Complementary targets:

- To improve the selection of essential medicines for standard treatment guidelines (STGs) and formularies in national and institutional healthcare systems;
- To rationalise public procurement processes and improve the cost-efficiency of medicine procurement;
- To encourage the appropriate use of medicines by expanding access to unbiased, independent information, and improving cost-effective prescribing by health providers and adherence to guideline-based treatment by patients;
- To decrease inequity in access by developing cost-reduction and quality improvement strategies focused on the needs of poor people.

We will assess progress towards each of these targets in participating countries with reference to the achievement of: greater transparency, improved accountability, increased supply system efficiency, and increased access to essential medicines.

Transparency

MeTA's process at both national and global levels will be centred on the public disclosure and dissemination of information in a variety of target areas summarised in this document. They can be easily monitored using process indicators.

Accountability

MeTA will develop systems to track stakeholder involvement, at both the national and global levels, and in the disclosure of information (which stakeholders disclose which types of information). MeTA will also develop systems to track stakeholders' access to and use of this information.

A key objective of MeTA is to facilitate stakeholder engagement, commitment and action. MeTA will develop approaches to assess the nature and degree of involvement by key stakeholder groups in national multi-stakeholder groups as well as at the MeTA IAG. To this end, MeTA will develop a range of tools that use both quantitative and qualitative approaches to assess the following key accountability domains:

- Government performance;
- Consumer empowerment;
- Involvement of healthcare professionals;
- Representation of needs of the poor;
- Responsible business practice.

Efficiency

Increased access to and use of information about medicines, coupled with greater stakeholder accountability, will lead to efficiency gains across the pharmaceutical system. Some areas in which MeTA activities might increase efficiency in pharmaceutical systems would include:

- Cost-effective medicines selection and procurement (value for money);
- Reliability of medicines supply and distribution (consistent availability);
- Guideline-based treatment (adherence to standard treatment guidelines), and
- Cost-effective consumer choice (overall and out-of-pocket cost per treatment).

Increased access

The ultimate goal of MeTA is to expand access to quality assured medicines, especially among the poor and other disadvantaged groups. Baseline assessment

will be carried out early in the MeTA process in each pilot country. Depending on the source of data used to assess each domain, we will assess some impacts periodically throughout MeTA implementation. For example, availability of key medicines, consumer prices of medicines in public and private facilities, and medicines quality, fall into this category. But other domains, such as consumer perceptions about medicines availability and affordability, unmet need for medicines, and equity of access across disadvantaged groups, may only be assessed after several years of MeTA implementation.

Potential tools and data sources for assessing progress

At the country level, MeTA intends to encourage multifaceted approaches to increase transparency, accountability and efficiency in pharmaceutical systems in order to expand access and improve equity. The approaches will be specific to each participating country and complementary to existing activities. The MeTA multi-stakeholder group in each pilot country will review existing activities, establish priorities and participate in the design of an assessment framework.

Many tools already exist for the assessments that MeTA needs to undertake in the domains it is addressing. We will develop new, targeted tools as necessary during the pilot phase.



Penny Tweedie/Panos Pictures

This plan for implementing the MeTA pilot phase is the product of a lengthy and comprehensive process of research and consultation. This process has included several expert discussion meetings (on research, procurement and supply, civil society engagement and consumer perspectives) followed by a global stakeholder workshop in April 2007. We have held a large number of focused discussions with stakeholders in Europe, North America and prospective participant countries in Asia, Africa, the Middle East and South America. We have undertaken scoping studies in Ghana, Uganda, Zambia, Peru, Jordan, the Kyrgyz Republic and the Philippines. Outreach to a broad range of stakeholders will continue throughout the pilot phase, to ensure that MeTA takes account of all available evidence, knowledge and lessons, and to facilitate commitment to MeTA's goals and principles by as broad a range of actors as possible.

How to contact us

If you would like to discuss the issues outlined in this document, or for more information on how your organisation can engage in MeTA, please contact the MeTA Secretariat:
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