

Draft Social Appraisal Annex

1. The challenge: increasing equitable access to good quality medicines

Improving access to existing medicines and vaccines could save approximately 10 million lives per year, 4 million in Africa and South-East Asia.¹ For many conditions (especially communicable diseases?), the burden of disease falls most heavily on poor people. Biological vulnerabilities (such as the greater vulnerability of young children and older people to many diseases) intersect with the powerlessness and poverty of many social groups. Depending on the cultural context, for example, poor households may deprioritise treating illnesses of women and girls, or of older people, in favour of male breadwinners. In a context of generally more limited access to information among poor groups, these same social inequalities also structure access to information about medicines.

In most poor countries, access to essential medicines depends fully or in part on an ability to pay. Evidence from countries as varied as Vietnam, Thailand, China, and Uganda indicate the substantially greater burden of out-of-pocket payments for medicines on poor people.² There is strong and growing evidence that out-of-pocket payments for ‘catastrophic’ health care costs (acute and sudden conditions, conditions that require expensive treatment) is a major cause of impoverishment. Medicines can make up a substantial proportion of both out-patient and hospitalisation costs in both health emergencies and more routine care. Data from India, for example, suggests that 40-50 per cent of the cost of hospitalisation, and nearly 80 per cent of the cost of out-patient treatment consists of medicine costs.³

Inequalities in access to medicines are intimately connected to wider inequalities within health systems, that in general, favour urban and better-off rural areas, and leave remote areas undersupplied. Underinvestment in certain regions may reflect conflict, and/or concentrations of specific, marginalised ethnic groups. Maternal and child health remains seriously under-resourced in most countries, reflecting a deprioritisation of the investment in care, medicines and other commodities needed to reduce mortality rates, in the context of generalised underinvestment in health care systems. One consequence of the under-resourcing of health systems is the prevalence of official and unofficial fees or mark-ups on health care, including medicines, that allow facilities to continue functioning, but decrease the accessibility of medicines to poor and socially excluded people.

A combination of this underinvestment and supply chain factors that will be investigated more fully by MeTA contribute to the poor availability of many essential medicines in the public sector. Though there are significant variations between countries, depending on health policy and the functioning of insurance systems, in most low income countries, the poorest people depend primarily on small, informal, private sector medicine vendors to meet their medicine needs. This raises particular challenges for a programme focusing on increased accountability (since potentially relationships of accountability between individuals purchasing medicines in the informal private sector are substantially different to those between citizens and public sector bodies, or between citizens and the formal private sector which are governed by greater regulation).

¹ DFID (2004) *Increasing access to essential medicines in the developing world: UK government policy and plans*, DFID, London

² Palikavadath, S. et al (2007) *International scoping study on household out-of-pocket expenditure on pharmaceutical drugs (draft)*, University of Southampton, for MeTA, DFID, London

³ Palikavadath, S. et al (2007) *International scoping study on household out-of-pocket expenditure on pharmaceutical drugs (draft)*, University of Southampton, for MeTA, DFID, London

Equitable access to good quality medicines involves not only addressing barriers of cost and availability, but also issues related to the quality of medicines. Two issues are of particular concern within MeTA: the prevalence of counterfeit and expired medicines (in some countries), and the perception, accurate or otherwise, that generic or locally-produced medicines are less effective or reliable than branded and/or imported medicines. Counterfeit and expired medicines both waste poor people's money, and put lives at risk. Where generics and locally-produced medicines are wrongly perceived as less good quality than branded or imported drugs, as MeTA consultations in Uganda, for example, suggest, lack of accurate information increases the financial burden on poor people.

From the perspective of MeTA's supergoal of improving health outcomes for poor people in low income countries, an additional issue is the ways in which poverty and lack of information contribute to low rates of adherence to treatment regimes.⁴ An important body of work by grassroots organisations, particularly, in relation to HIV/AIDS, works with patients to enhance their knowledge of how medication should be taken, the consequences of not doing, and what their entitlements are in various public and private programmes. Though supporting initiatives such as these may be beyond the scope of MeTA, MeTA could profitably link in with, and draw on lessons from them, since they relate to broader issues of communication, and empowerment through provision of information in access to medicines.

Discussing the implications of current international trade rules on intellectual property, such as TRIPS, and bilateral trading agreements, for poor people's access to medicines goes beyond the scope of a social appraisal for MeTA. However, evidence from a recent Oxfam analysis of the effects of the US-Jordan bilateral trade agreement finds that the restrictions on production and supply of generics that this imposes, is increasing the cost of medicines within the public sector, and the cost on the private market to uninsured poor people.⁵ The UN Special Rapporteur on the Right to the Highest Attainable Standard of Health had made similar observations in relation to the US-Peru trade agreement.⁶ These agreements are a crucial part of the context affecting overall access to medicines, and in which MeTA will operate.

In summary, the challenges of enhancing poor and socially excluded people's access to good quality medicines in low income countries involve a combination of factors including: poverty and socio-economic inequalities; underinvestment in health systems, limited access to information about quality and use of medicines; and the wider trade and intellectual property environment.

2. Potential Impact of MeTA on Poor and Socially Excluded People: Assumptions behind MeTA Approach and Planned Approaches

The core conceptual framework for MeTA suggests that:

At national level

Catalyzing a multi-stakeholder approach aimed at increasing transparency and accountability around the selection, procurement, sale, distribution, and use of medicines will lead to (a) greater local disclosure of information (transparency), (b) greater stakeholder engagement, commitment, and action (accountability), and (c) more cost-effective supply and use of medicines (efficiency), which will in turn lead to expanded access to essential medicines, especially by the poor (equity).

⁴ For example, an estimated 1 in 7 people on ARVs in Uganda do not comply with the treatment regimen.

⁵ Oxfam International (2007), *All costs and no benefits: how TRIPS-Plus intellectual property rules in the US-Jordan FTA affects access to medicines*, Oxfam Briefing paper 102, Oxfam, Oxford

⁶ <http://www.ictsd.org/weekly/04-07-14/story3.htm>, accessed 2 August 2007.

At global level

International multi-stakeholder engagement aimed at increasing transparency and accountability around the selection, procurement, sale, distribution, and use of medicines will result in (a) greater global disclosure of information (transparency), (b) greater involvement and investment in pharmaceutical sector governance (accountability), and (c) broader availability and greater use of publicly available tools and metrics for pharmaceutical sector decision making, assessment, and monitoring (efficiency).

Table 1 below breaks down these assumptions in more detail and examines how increased access of poor people to good quality medicines is expected to occur, whether or not these assumptions are justified, and how proposed MeTA activities or plans may address them. It also signals areas where further work is needed to do so.

Assumption	Comment	How MeTA plans to address issue
Transparency		
1. Increased transparency will lead to reductions in mark-ups along the medicines chain.	Some areas of medicine chain may be more amenable to mark-up reductions. Price reductions may be more likely for some medicines than others.	Not yet clear – depends on outcomes of supply chain mapping studies and price components analysis.
1.1 this will, in turn, lead to reduced prices for consumers purchasing medicines directly	Only if wholesalers and retailers do not compensate for lost revenues in other ways. Particularly in remote rural areas, where transport costs are high, reductions may be limited.	
1.2 reductions in mark-ups will reduce public sector costs, potentially freeing up resources that can be redeployed to enhance provision of essential medicines/ other areas of health policy.	Depends on both policy commitments by Ministries of Health, and by individual facilities. Assumes that purchasers are not tied into agreements and don't have specific reasons for preferring particular products/ suppliers (including unethical promotion).	
1.3 reduction in mark-ups will reduce costs of medicines in insurance-based systems, thus potentially enabling them to be run more efficiently and/ or to extend coverage.	As for public sector (1.2).	
2. Improved transparency will reduce possibilities of practices that undermine availability eg leakage/ diversion of medicines	Assuming that sufficient political will and incentives can be built to rein in such practices.	Through analysis of data on availability and through multi-stakeholder working groups.
3. Increased availability of price information will empower consumers who can then purchase medicines at cheaper outlets, or challenge sellers whose prices appear unjustifiably high.	May be more applicable in urban areas where density of medicine outlets greater; in remote rural areas with only one outlet, price information may be unusable. Price of medicine only one factor influencing purchase; other transaction costs and perceived quality of advice given also important. Social barriers to access to information (based on levels	Civil society, including media, identified as key actor in communicating price (and other information) in country reports (eg Philippines, Uganda). Also the need to support capacity development in communications in this area identified in some reports (eg Jordan, Ghana). Dual foci: to raise media coverage of access to medicines issues generally

	of education, gender, age etc) can be overcome. Risk that benefits will be captured by better-off.	increase relevant targeted communications to poor and socially excluded people. Impact monitoring analyses how far & where poor and excluded people access information on medicines issues. Country equity analyses examine barriers to access to information.
4. Increased availability of price information will empower public and private sector health care providers to purchase medicines more cost-effectively. These cost savings will be translated into improvements in other areas of care.	As above (1.2 and 1.3). Savings may be redirected to other current political priorities.	MeTA country plans also have strong emphasis on improved communication to national policy makers so relevant audiences should be informed. Some work on addressing political obstacles to identified cost savings may be needed.
5. Increased availability of information about medicine quality will contribute to improved health in the following ways:	Note that MeTA may not be able to attribute improved health outcomes to its activities so activities and monitoring may need to focus on intermediate outcomes instead.	
5.1 consumers will be able to make purchasing decisions based on knowledge about the quality of medicines. This will mean that they do not waste money and/ or endanger their health by buying low quality or expired medicines.	Sufficient levels of literacy/ awareness of issue can be built so that consumers can check expiry dates. Social barriers to information can be addressed. Unrealistic to expect that poor consumers will be able to check for low quality medicines.	Detailed info eg around importance of checking expiry dates need to be part of communications work outlined above.
5.2 consumers will not waste money buying more expensive branded or internationally-produced medicines, if they can be assured of the quality of generic or locally-produced medicines.	Effective communication to disadvantaged people – MeTA manages to engage media in creative ways, and this creates shifts in perceptions of quality, and purchasing patterns.	Communications programmes as outlined above (2). Impact monitoring examines shifts in medicines purchasing patterns, and impacts on overall household expenditures.
5.3 public (and private) sector health care providers will be able to make better-informed purchasing decisions, leading to offering better quality medicines more cost-effectively.	Effective communication to professionals; policy or incentives to address blockages to changing current patterns can be established.	As 4 above.

5.4 companies will not compensate for reduced mark-ups by other activities that work against consumer interests eg unethical promotion.	Importance of MeTA engaging civil society and media effectively to monitor emergent practices.	Not clear yet – needs to be factored into workplans.
Accountability		
6. Accountability structures can be developed that achieve changes in poor and socially excluded people’s interests.		
6.1 Civil society organisations: a) will be accepted as full partners in national accountability structures;	CSOs are equipped with sufficient technical knowledge to play accountability role. Government and private sector stakeholders treat CSOs equally – do not withhold information etc. Trust can be built between different stakeholders. Principles of democratic selection of representatives within constituencies apply; CSO reps are not hand-picked by government, or represent industry interests.	Part of national and international capacity building plans. Work needed to ensure CSOs treated as equal partners in national fora, and that they genuinely represent CSO constituency.
b) will be able to articulate the interests of poor and socially excluded people effectively.	National, advocacy-oriented CSOs (including some patient groups) may not be strongly connected to grassroots. May be weak fit between concerns of poor people and MeTA national agenda; CSOs may not have skills to translate one to the other.	Suggest that national multi-stakeholder groups include representatives of CSOs working at grassroots level. Or that CSOs represented on working group have these grassroots contacts.
c) agree on the importance of increased accountability and transparency in relation to access to medicines.	In some countries, CSO priorities may not be consistent with those of MeTA.	Active outreach work may be needed to engage CSOs (eg Peru, some constituencies in Philippines).
6.2 Improved accountability ‘upstream’ in the medicines chain (eg around mark-ups, regulatory environment, quality) will translate to tangible improvements for poor people lower down the	This may be the principal way in which increased private sector accountability affects poor people. Impacts may relate to price reductions, quality improvements and more	Promoting activities laid out here is planned as core activity of national multi-stakeholder fora.

medicines chain.	ethical promotion of medicines. In some countries CSOs may engage in specific advocacy around private sector behaviour, eg against dumping of expired stock. It is not yet clear whether there will be sufficient political space within MeTA multi-stakeholder groups to permit this, or whether this is something MeTA may support in other ways.	
6.3 Local structures to increase accountability around medicines issues can be fostered and are able to change practices.	May be easier in relation to public sector provision. Much CSO experience in health sector and beyond to draw on.	MeTA to commission overview of community level action to promote accountability.
6.4 International accountability MeTA Forum able to increase transparency and accountability in medicines policy and practice.	Power imbalances between constituencies do not mean international governance structures marginalise CSO concerns. Effective structures for linking with country MeTA teams and poor people's concerns can be developed.	TORs for international forum give parity to all constituencies. More work needed on building linkages between national and international fora, once these are in place.
Other		
7. MeTA's focus on essential medicines is consistent with the burden of disease faced by poor and socially excluded people in MeTA countries ie it will address some of their priority health needs.	MeTA team should ensure that this does not exclude key drugs and conditions in particular contexts. Any country focus on particular medicines reflects burden of disease and costs of treatment faced by poor and socially excluded people.	Some probable country foci strongly reflect burden of disease on poor and socially excluded people (eg Ghana – malaria, reproductive health). Not yet clear for other countries. This needs to be an important focus of country equity analyses.

3. Addressing risks and concerns

MeTA has a broad agenda which includes transparency in prices paid by national governments to pharmaceutical companies, identifying locations where price mark-ups occur in supply chains, identifying leakage of drugs from public to private sector, transparency in medicines quality, communicating information to a variety of stakeholders, including national policy makers, civil society organisations and the general public, and developing accountability mechanisms to address problems identified.

Inevitably in an alliance with a number of stakeholders, priority emphases vary. In the initial set-up phase, there has been a strong emphasis on the upper end of the medicines chain, and on tools for analysing price mark-ups within the chain, based on an assumption that improved transparency will have a range of benefits, detailed in table 1. As MeTA moves into its pilot

phase, and the priorities of national stakeholders shape country activities, there should be a stronger emphasis on the end-users of information produced by MeTA, including poor and socially excluded people. While this is within the horizons of some of the country teams and proposed activities (most clearly in the Philippines), commitment to this group is likely to vary from country to country. The central DFID MeTA team and subsequently the Secretariat can continue to advocate for activities and foci that are intended to benefit poor and socially excluded people directly, and can facilitate this through the dissemination of tools and thinking around this issue. However, how far country activities are structured to benefit poor and socially excluded people will depend on the priorities of national multi-stakeholder groups and the strength of voice articulating an equity emphasis as a major priority. In this regard, ensuring an equal voice for civil society, and involvement of civil society organisations with strong linkages to poor and socially excluded people will be critical.

In addition to the specific actions outlined in table 1, the following actions are proposed to increase the impact of MeTA on poor and socially excluded people and ensure proper representation of civil society.

3.1 Diagnostic work

a) Assessments that will form the baseline for MeTA's ongoing process and impact evaluation will include consideration of equity issues. Depending on what these baseline assessments reveal about what is known about equity issues, country equity assessments may be undertaken.

b) Country equity assessments. These would examine the potential impact of proposed MeTA activities on poor and socially excluded people. The scope of these assessments will be clarified in the MeTA equity workshop on 4-5 October 2007. They would probably include an analysis of the relationship between the burden of disease experienced by poor and socially excluded people, and the medicines/ therapeutic areas that MeTA proposes to focus on in each country. It would also include analysis of how far, and how increased transparency and accountability might benefit these groups, and options for increasing positive impacts. This workshop will also clarify which countries plan to undertake such assessments.

c) Impact and process monitoring. Drawing on baseline and country equity assessments (where conducted), MeTA will monitor changes in access to and use of selected essential medicines. It will also monitor indicators which assess the effectiveness of the multi-stakeholder working approach that MeTA will be catalysing in each country and internationally. Importantly, this will include a focus on the quality of civil society engagement.

d) Further development of tools for examining equity in access to medicines. Work to refine measures of affordability used in WHO/ HAI medicines pricing surveys is planned. This will enable the MeTA Alliance and other stakeholders to more accurately assess poor people's access to essential medicines and design policy interventions to enhance it.

3.2 Strengthening of civil society capacity

Country reports have flagged the need to increase the ability of civil society to engage in various processes related to MeTA, including: undertaking communication activities central to MeTA workplans and participating as active and informed constituencies in multi-stakeholder groups, which can contribute to the group's function of increased accountability.

The processes by which this takes place need to be worked out, but are likely to include some combination of joint technical training for all interested stakeholders, and some specific support to civil society to increase their capacity to engage meaningfully with other stakeholders in MeTA multi-sectoral working groups; engage effectively in policy debates on access to medicines issues and enhance the accountability of medicines providers to users. In parallel with work to strengthen civil society, work with other stakeholders to recognise the legitimacy and value of civil society involvement may be needed.

Work with civil society (both on capacity strengthening and involvement in governance) needs to include a wide range of civil actors, including the media, academics and professional associations, as relevant in each country, and not be confined to NGOs. This is recognised in the MeTA team but it is not yet clear how it will be operationalised in practice.

4. Monitoring and Evaluation

Work currently under way is developing proposed indicators for monitoring:

- a) the impact of MeTA on poor and socially excluded people's access to medicines. Where possible, these will be monitored using data from existing surveys, though some additional qualitative data collection is likely to be needed.
- b) the adequacy of civil society inclusion in MeTA multi-stakeholder processes and its impact on decision-making. This is also likely to require periodic collection of data from stakeholders.

These will be an integral part of MeTA's monitoring and evaluation.