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**EXPERT CONSULTATION MEETING: TRANSPARENCY AND
ACCOUNTABILITY IN THE SUPPLY OF MEDICINES
28 Feb – 1 March, 2007**

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1. BACKGROUND TO THE CONSULTATION

‘The UK will: Build on the experience of EITI to help developing countries improve transparency and value for money in public procurement, and develop international proposals to increase scrutiny of public spending in the defence, construction and health sectors to help fight corruption.’

UK White Paper 2006 ‘Eliminating world poverty: making governance work for the poor’

Following on from the UK Government’s 2006 international development White Paper, and drawing on lessons from the successful Extractive Industries Transparency Initiative (EITI), the UK is exploring the potential for an international Medicines Transparency Alliance (MeTA).

One third of the world’s population lacks access to essential medicines¹. Pharmaceuticals are the largest health sector expenditure after personnel costs in most low-income countries, and can constitute 50–90% of out-of-pocket spending on health for poor households. Improving the availability and affordability of essential medicines of assured quality is therefore key to increasing access to healthcare².

However, in many countries, weak governance and a lack of transparency in medicines regulation, procurement, distribution and sales contribute to high levels of inefficiency, and increase vulnerability to corruption and fraud. Issues include bribery, theft and diversion, supply of counterfeit and substandard medicines, and ‘rent-seeking’ behaviour – where the mark-ups at different points along the supply chain are unnecessarily high. This increases the cost of quality assured medicines and reduces their availability, undermining health services and outcomes. It also harms those that supply medicines and other health-related goods and services – increasing their operational costs, reducing their competitiveness and damaging their reputation.

Increased transparency in procurement can help cut corruption, improve efficiency and increase value-for-money. The significant increases in aid to developing countries, within which health spending is rising most rapidly, and new commitments around access to medicines – particularly for HIV/AIDS, TB and malaria – mean greater resources will flow through health procurement and supply systems in developing countries. Differential pricing, generic substitution, subsidies and other initiatives are also reducing the supply cost of many medicines. It is vital that these advances benefit patients and service users and are not lost to inefficiency or corruption in the supply chain. Increasing consumer and civil society awareness is therefore particularly important.

In response to these challenges, the UK Government, the World Health Organisation (WHO), Health Action International (HAI) and others – including developing country governments, the pharmaceutical industry and civil society groups– are working to facilitate international support for, and commitments to, transparent working practices on the part of governments, donors, the private sector, civil society organisations and other stakeholders. The principal objective is to support national efforts to enhance transparency and build capacity in medicines policy, procurement and supply chain management. The added value of this initiative would entail explicit commitments from international actors in support of national efforts, coupled with focused technical and financial support to strengthen transparency and accountability. Such national efforts would seek to improve

¹ WHO Medicines Strategy 2004-2007

² see *Increasing access to essential medicines in the developing world: UK Government policy and plans* June 2004, for more information on the UK’s strategy and efforts in this area

access to information about medicine quality, availability and pricing, with strong civil society and consumer involvement in scrutiny and debate.

What Might MeTA Look Like?

MeTA is likely to be launched as a global alliance including all key stakeholders, with pilots in at least four countries, from mid-2007 onwards. The aim is to secure as pilots countries that have already started to address transparency in medicines regulation, procurement, distribution and sales, and whose experience may provide lessons in how best to reduce vulnerability to corruption and increase access to affordable, quality assured medicines. A first step would be a commitment – at a high political level – to prioritise the issue. Based on consultation to date, it is envisaged that in participating countries MeTA might include:

- Supporting countries to **extract and collate data** on medicine quality, availability and pricing along the supply chain;
- Facilitating agreement by pharmaceutical companies (global and domestic) to disclose their own data on quality, availability and price. Triangulating those with tender data;
- Supporting countries to undertake studies assessing the level of transparency and good governance in medicines regulation and procurement;
- Helping countries establish and maintain **a multi-stakeholder working group or forum**, made up of stakeholders from the public, private and non-profit sectors, which would be active in developing MeTA at the country level and would scrutinise and discuss data generated, and use this dialogue to inform development of policy and regulation;
- Working with countries to produce country-specific MeTA **reports**, which would bring data together and further analyse and contextualise issues related to quality, availability and price, and to disseminate these reports through the media and public interest groups;
- With support from a dedicated research ‘observatory’, developing and building awareness of guidelines and case studies on good practice, as appropriate; pooling information from different countries to build a global resource.

These early ideas will be refined further through detailed consultation with a range of Low Income Countries (LICs) and Lower Middle Income Countries (LMICs), and other stakeholders, during the first half of 2007.

2. PURPOSE OF THE CONSULTATION

The objectives of this consultation were introduced by the two DFID team leaders responsible for leading the MeTA initiative. The initial response to the MeTA concept has been very positive. Questions for this and other consultations include:

- Which issues should be prioritised? Price and/or availability and/or quality?
- How to promote transparency in an essential medicines framework, whilst keeping data collection and dissemination manageable?
- How might MeTA link most effectively to other initiatives, such as the Global Fund and UNITAID (new international drug purchase facility)?
- How best to engage all relevant stakeholders? How to involve consumers?

This consultation was organised to focus on issues of procurement and supply management of medicines. It is one of three consultations to be held in order to further define the content and direction of MeTA. The other two consultations will take place in March/April with the involvement of stakeholders from Civil Society groups and the Pharmaceutical Industry.

The primary concerns of this consultation were to;

- Identify areas of the supply chain that could benefit from increased political support and financial resources for transparency and accountability;
- Create an inventory of tools that are available to assess or diagnose problems in the supply chain and improve access to medicines; and
- Identify interventions that would lead to improved governance and gains in transparency and accountability within the medicines supply chain; looking at possible interventions in both government and in the market.

3. PROCEEDINGS OF THE CONSULTATION

Four key areas were outlined for the panel discussion session;

- What needs to be monitored?
- What do we know about effectiveness?
- How is information disseminated?
- What are the critical barriers to improving effectiveness?

Presentations of the experiences and findings arising from involvement in programmes, training, surveys, assessment tools and research, were presented by representatives of HAI, WHO/PSM, World Bank, GFATM, Boston University, Management Sciences for Health (MSH), and IMS International.

3.1 Overview of Panel Discussion Presentations

(full copies of the individual presentations can be viewed/downloaded from www.dfidhealthrc.org)

HAI reported that, comparing similar countries, there is a large variation in the prices of medicines with some extremely high prices in particular situations (examples were cited for Catopril). Mark-ups, taxes and duties added to the procurement price vary widely. Tools have been developed and used to conduct price surveys and these tools are currently being refined.

WHO (Department of Medicines Policy and Standards) developed and tested in 4 countries, in 2006, an assessment tool for measuring the level of transparency (and vulnerability to corruption) in key areas of registration, selection and procurement in a standardized way that allows cross-country comparisons.

World Bank found that it is a problem to obtain robust and reliable data in the health sector and there is corruption and lack of transparency and accountability. Tools used by the World Bank include public expenditure reviews, public expenditure tracking surveys, procurement assessment, governance and corruption surveys, consumer satisfaction surveys, household surveys.

The Global Fund requires grant (principal) recipients to draw up a procurement and supply management (PSM) plan before procurement disbursements start and monitors progress in implementing the PSM plan. The GF requires also PR to report procurement information including prices of selected medicine categories and health products (ARVs, ACTs, TB medicines, condoms and bednets) on the Price Reporting Mechanism (PRM) on the GFATM website. These procurement information are publicly available on the website. They have begun to enforce quality assurance procedures for reported procurement data.

Research (at Boston University School of Public Health) into utilising available ARV prices available on websites in the public domain compared prices across countries, found significant price increases in generics (between 2003 and 2006); for 2nd line ARVs generic prices were found to be higher than originator brand prices; did not find much apparent linkage between purchase volume and price. Follow-up of outliers identified by this type of analysis would provide a good entry point for making rapid improvement in affordable access to these medicines.

MSH has developed many different tools and training approaches to assess situations and to try to improve the management of medicines at all levels.

In looking at the data from one country (Peru) IMS International noted that whilst there is a constant mark-up on branded products there is a variation of mark ups on generic products, that there is no correlation between availability, price and market share because retailers will always make more money on brand product sales (therefore they will always keep stock even if low demand), collection of data in some countries is difficult especially if the “players” wish to distort the information to protect their interests.

Follow-Up Discussion

Several participants contributed in response to the presentations and the panel members also had an opportunity for further response.

The following points were made during the plenary discussion;

- The presentations demonstrated the increase and globalisation of information about availability and affordability leading to opportunities for regional and country comparisons. What is still lacking is a global reporting mechanism for product quality and consumers need reassurance about product quality particularly with respect to generic products. There is an information asymmetry that needs to be addressed.

- The failure of governments is not the only reason for failures in transparency and accountability, it can be donor failure and donors and agencies need to be accountable and to improve efficiency. A discipline/value based approach to behaviour change, code, values etc are important but there are countries that have best policies and best practice on paper, but also the highest levels of corruption. What may be needed are global standards and accreditation for access to global money and procurement.
- Procurement lead times are too long and it is no longer acceptable to take 18 months to get bednets. There is a need to put limits on order placement and process procurement activities much more quickly. The electronic procurement database is good but why not go on to e-procurement and use technology and move forward – “countries wanted drugs not money”
- There may be a need for global standard and accreditation for access to global money and procurement. Although written codes for transparency and accountability have value in defining best practice there are countries with written codes that demonstrate the highest levels of corruption.
- Where generics were higher for 2nd line ARV regimens, was this because of regulation or to do with the timing of the patent? The innovator products might have been offered at artificially low prices.
- Consumers do exhibit brand-seeking behaviour but often there is a lack of information on prices. Jamaica now publishes information on prices for consumers to force change and response and demand rights. Also the free-market concept needs to be addressed because although a government may reduce taxes, the benefits are frequently retained in the system and not passed on to the consumer. How do we ensure that the advantages of competitive tendering are processed through to the consumer?
- There is value in the MeTA approach – lots of data are available but how to convert this into actionable information? The findings that might come out of META will only result in change if there is multi-stakeholder buy in, up front to avoid obstruction – multi-stakeholder approach is essential in terms of setting up the concept of MeTA. Important to ensure that MeTA does not get too ambitious too quickly – there is a need to identify diseases or therapy areas for focus – now less sensitivity around pricing information and may get increasing cooperation. Major donors are using public money and big databases – about regulation and other directions therefore focused approach would help. Avoid any unintended consequences e.g. squeezing the distribution prices may discourage wholesalers from doing their job of distribution.
- Prices are only one aspect – what factor drives consumers to buy brand drugs – quality is an issue – need to educate professionals to use private sector marketing strategies to encourage greater use of generics and therefore efficiency in resource usage.

Concluding Comments from DFID Team Leaders

Important aspects of MeTA work going forward are to use the pilot phase to test ideas and to identify how MeTA can have an impact in a way that builds confidence. Agree that MeTA is to get information out there but recognition that that alone is not enough; the intention is to generate recommendations for action

It is apparent that in lower middle income countries the policies that grow out of information that is not always the most useful. We need a collaborative research network to provide evidence to identify policies. A more competitive market is the preferred way to drive down prices rather than artificial controls, but we need an increased evidence base of what

policies actually work and we need data to provide the baseline to link policy interventions with it. Receptivity to information accountability arrangements need to be generated more effectively. We would like to see accountability for donors but also within country. We need recommendations as to how to create accountability arrangements.

3.2 Further Observations from Organisations Present

(in addition to panel presentations above)

Crown Agents observed that one tool that contributes towards transparency in procurement is prequalification of suppliers according to commercial criteria. Another tool is to set up framework contracts with suppliers (for medicines and other supplies e.g. test kits) on the basis of provisional guarantees of orders to be placed.

PFSCM encourages transparency with publication of information and providing public dashboards of public spend and also the prices being obtained. Being a US gov't organisation it is controlled by gov't. regulations and decision for supply overseas are on basis of US practices and not therefore subject to "dark influences". One objective is to work with countries to improve security of in-country distribution channels in public sectors. There is no data on the actual figures for substitution and leakage in public and mission sectors. Supply chain management is done in collaboration with other systems going on globally. In terms of laboratory standards and supplies, PFSCM is working with WHO and CDC to standardise lab supplies and equipment. The aim is to try and persuade manufacturers to reduce the length of the supply chain.

Gates Foundation is using WHO/HAI methodology to monitor prices. There is a focus on ACT, tracking price quality and availability and price along the supply chain to see how price changes. Also monitoring global policies around ACT and identifying concrete and practical policy directions.

WHO Global Drug Facility has tools and best practices for performance. All suppliers and prices are in the public domain on the website with published prices from global tenders. They have joint activities with NGOs in pricing reports and publish global market projections. Challenges on transparency arise when, sometimes, beneficiaries want only to pay for some parts of the package, e.g. "we don't want to pay for quality assurance". On product quality a transparent assessment comes down to whose standards and who is regulating the regulatory authority. If there is no link of price to quality where governments are tendering, then lowest prices may not have quality assurance. A major issue for governments in procurement is how to guarantee quality of product.

UNFPA emphasise supplier prequalification and product quality when sourcing multisource products. Reproductive health product prices, including all aspects of costs, are in the public domain. UNFPA maintains a detailed price database with information on the website in general terms.

MOH Zambia is trying to introduce transparency and accountability to meet expectations of donors and government. However, systems are the least of the problems in a situation where demoralised colleagues and lack of commitment both work against capacity building (e.g. salaries and career path)

Commonwealth Pharmaceutical Association (CPA) is not involved as an organisation in procurement and supply but pharmacists have an important role in ensuring transparency and accountability. CPA has a distance learning package targeting all who handle medicines in supply. CPA holds CPD workshops to focus on critical issues of medicines supply management including regulation and transparency.

Jamaica practices transparency in procurement through international tenders that conform to government regulations as implemented by several different government sectors. The National Health Fund circulates a handbook on subsidies on medicines for patients suffering from 15 chronic diseases including diabetes. Have post marketing surveillance systems and client feedback and evaluation of tenders. Finally minister requires monthly reports on stock levels of critical items.

AstraZeneca supports and welcomes MeTA initiative and agrees with many of the principles outlined. Interested to note how much is already available but the next question is– how to collate to make use of tools etc. to influence action? One surprising element is that it is difficult to collate pricing and supply data and AstraZeneca rely on IMS and others to supply this data. A multistakeholder approach is important for progress.

USAID funds several health projects in the area of pharmaceuticals, e.g. RPMplus; RH programmes including procurement. There is a new project (SPS) looking at governance and financial issues. Agree that transparency is lacking in the area of quality. Suggest consideration of a National Health Accounting methodology with a framework that tracks funding through financial institutions down to the provider and shows where resources are going and how they are used. USAID also uses a health sector assessment tool – rapid assessment tool to dissect health sector into several areas including financing.

IDA Solutions, for whom supply is primary activity, is happy to supply procurement prices. They organise training in supply management (focus on ARV, ACT) and have a buffer stock project to provide fallback stock for ARVs. Still see difference in pricing based on different prequalification systems.

WHO (Department of Medicines Policy and Standards) is working on developing policy option papers – e.g. on generics, policy and practice in EMRO and relationship to prices; looking at specific disease treatments; looking also at total cost of treatment (diabetes); comparing guidelines for medicines promotion; working with IFPMA to look at drug pricing and the basis for pricing.

Missionpharma observed that donors are putting lots of money and drugs into Africa but nothing into national regulatory authorities so there is little or no chance of quality assurance at country level. We need to enable national authorities to know and find out about these issues. To lower prices there is a need to speed up registration in countries; it can take 1 to 5+ years. Products are expensive because registration of competitors is not fast enough. We ourselves need to be role models in transparent procedures and avoid charging high margins for simple tasks, e.g. charging a percentage mark-up simply for sending a fax to get procurement. On corruption, normally if we try to take out corruption we slow the programme so what should be our priority, do we countenance this or do we act?

USP is the only nongovernmental pharmacopoeia in the world, establishing public standards for pharmaceutical ingredients. USP distributes standards, monographs, reference standards and also does training for capacity building in analytical techniques. It is a not-for-profit independent organisation and can work with a variety of organisations conducting training of lab staff to establish post-marketing surveillance programme with specific products. Have draft operational guide for quality assurance of medicines in low income countries. The website lists drug quality monitoring indicators and various tools.

3.3 Reports of group meetings

“Supply Chain Management” Group Report

- Quality was seen as central issue and price cannot be viewed without quality.
- Function to ensure quality resides in the National Regulatory Authority (NRA) but Civil Society (CS) needs to demand quality and action. How to strengthen NRA capacity? Tools do exist to assess NRAs and identify weaknesses but the question– after assessment then what? CS is demanding quality and pushing politicians to action. One suggested option to strengthen regulatory capacity for action would be to copy “central bank setup” strategies that enable organisational independence and pay high salaries to eliminate one excuse for malpractice?
- Don’t neglect third sector – faith-based NGO sector – need to include in all discussions but tend to polarise into public and private.
- Supply chain management – lessons from accountability and tracking expenditure – need to involve CS and local community. Tools to assess and identify weaknesses are available but need force of advocacy to politicise the process for change and strengthening.
- No specific policy recommendations for intervention in the private sector – more about creating and encouraging competition.
- Information sharing about available tools.

“Procurement” Group Report

Q1. What are the challenges to increased transparency? Do the issues differ between public and private sectors?

Commercial Challenges – whether greater disclosure would undermine lower prices – differential pricing may be legitimate – differential pricing may be due to poor procurement – concern about policy options that might be advocated – perceived conflict between profit and public good.

Political Challenges

- Corruption infrastructure and lack of incentive for routine disclosure unless ...
- Government may have preferred suppliers or be prejudiced against other country sources.
- Costs v. time for pharmacists in advising generic substitution if QA/QC is weak
- Delivery of core procurement and regulation function different due to HR budget
- Legal liability if rely on other country regulatory inspections, QC testing etc. (noted Mekong delta collaboration where NRAs work closely together)

Technical Challenges

- Paper information difficult to access.
- Website information not widely known and used
- Methodological issues about presenting comprehensible, comparable information that won’t be distorted.

- Lots of quality reports from inspections etc. could be reported
- MeTA role on quality – support national capacity for rapid testing or assist in facilitating testing

Q2. Would an increase in information disclosure and other forms of transparency in the fields and countries you work in help to address problems of high prices, low availability and unreliable quality?

- Disclosure of price and quality data would make difference
- But availability problems will not be solved by disclosure
- Transparency in selection quantification and process of procurement is important
- Transparency in use of available budget to ensure you get value for money
- GF PSM plans contain data on quantification that may be useful

Q3. What types of data concerning medicine pricing/affordability, availability and quality are of greatest importance in (a) strengthening public sector institutions for accountability for medicines policy and supply management (b) informing the consumer (the non-expert) and (c) informing civil society engagement in policy making?

- CS engagement – consumers with specific disease problems would benefit from segregating data to specific areas.
- Could MeTA pilots focus on specific treatment groups with regard to publications and information?
- General points on how MeTA could clarify differences in methodologies being used
- Role of civil society to create demand – but how to build capacity amongst civil society and to enable structure to enable CS to function
- For public accountability (QA first) – need for information basics what, who from, who for, how much, price, quality
- Registration – publication of progress
- MeTA could focus on what people actually pay.
- Accessibility – presentation and packaging/quality trade off.
- Role of professional organisations.

How much information on pricing, procurement, and distribution is available, but not commonly in the public domain, and how could greater data release and information sharing best be facilitated?

3.4 Summary of Day One

Scope and Focus of MeTA at Country Level

- Segmentation – initial focus on particular therapeutic areas, and public/donor financed medicines for the “port to patient” disclosure in the pilots, in the comparative price analysis and quality data disclosure initiatives
- A broader focus may be appropriate for transparency initiatives at some stages of the supply chain: e.g. transparency in public procurement, licensing, public supply chain management

Plenary Comment

- MeTA should bring to bear in the health sector and medicines supply chain broader tools, such as the World Bank tools for public expenditure review and tracking, governance and corruption surveys, consumer satisfaction surveys, household surveys.– can MeTA produce “idiots guide” to the available tools for public sector analysis and audit of pharmaceutical financing and supply?
- Possible scope for WB to work closely with USAID/CA to produce something like PETS for medicines supply.

3.5 Ideas for Global Activities of MeTA

- MeTA as a facilitator of international engagement among stakeholders around transparency and accountability, e.g. engaging on tax/tariff policy with IMF, ICU, etc
- “Low hanging fruit”: comparative country analysis and dissemination of available global databases of procurement prices, volume, methods (GFATM, GDF, global purchasing agents); active market search (IDA)
- “Putting our own houses in order” – increased disclosure, analysis, dissemination of procurement and distribution data of global development agencies; and ODA-financed national procurement (e.g. MDB finance)
- Integration/linkage/coordination over use of tools for assessment, monitoring, policy options etc for medicines supply management

3.6 Regulation & quality - what can MeTA do?

- Bring together/review/develop existing tools and policy options for regulatory assessment, governance and standards (including human resource issues, financing)
- Consult on scope of regulatory disclosure and release key performance indicators (and related ideas for sharing or disclosure of prequalification lists, inspection reports...)
- Link with initiatives to develop regional regulatory and drug lab. capacity and information sharing
- Plenary Comment - Regulation in private and public are different in terms of how they show accountability – theoretically can be good but implementation can be difficult and need to focus not just on inputs but also on how to make it happen.

3.7 Other issues and proposals for MeTA

- Civil society engagement – how to enlarge the number of those engaged, including professional associations of pharmacists, academe, broader health and governance CSOs; learning on effective models for engaging CS in accountability and governance

- Clarifying what kinds of disclosure/reporting are useful at different levels and for different uses/audiences
- Caution about potential unintended effects (e.g. issue of rural access to medicines if distribution mark-ups are regulated)

Plenary Comment - consideration of countries that are and are not willing – not all want CS groups and transparency and disclosure of data – if only work with cooperative countries then some will be ignored and missed out. Pilots will link with cooperative countries but thereafter consideration of “uncooperative” (hard to reach) will have to be addressed. One major direction of DFID is to work in “fragile states” and therefore it is on the agenda.

- there is a lot of basic conceptualisation around CS. CS work is encouraging in one way but work in this area is very slow and lot of effort required to maintain momentum and there are complicated dynamics involved – so a word of caution that working with CS will not be as simple quick and easy as might be suggested. If CS includes professional associations and academia there may already some structure in those areas. Working with CS is one of pillars of MeTA. There is a need to identify the winners and work with the winners in the voluntary organisations.

4 PRESENTATIONS AND DISCUSSION AROUND INCENTIVES AND BARRIERS TO PROGRESS

(Copies of any presentations can be viewed/downloaded from www.dfidhealthrc.org)

Chaired by Dr Hans Hogerzeil (WHO/PSM Director) presentations from PAHO, PFSCM MOH Zambia and Pharmaceutical Industry (comments from representatives present)

PAHO (verbal presentation) - Whole subject area is of high interest in the Americas because of issues of access. Focusing support on policy development, promotion of generic med policies, price references, supply management. PAHO supported negotiations for ARV block contracts and brought some transparency and accountability to the process.

Country Perspective - have to promote a culture of CS engagement. Many countries base health policy on principles of human rights and should take advantage of these principles to promote transparency and CS engagement.

Incentives for countries to buy-in;

- The political benefits accrued – efficiencies, resource utilisation, CS engagement etc.;
- Strong arguments for availability, affordability and quality;
- In Americas found improvement in information systems leads to consolidation of prices by comparison;
- Improved systems management process – whole transparency and accountability process requires these systems in order to generate information – a positive;
- Winning CS engagement – often quite difficult to ensure CS engagement but we have to reassure countries of wide benefits of CS involvement at all levels;

Barriers for Countries – there are high stake as well as wins!

- In Brazil the talk of social control – means participation and oversight – how can we ensure there is some CS oversight as a result of initiative?
- Slow to expose weaknesses in own systems and therefore loss of face - need to help countries to control the exposure of these weaknesses.
- Protectionism exists either deliberately or secondarily and this relates to both national and multinational companies
- Breaking and exposing corruption will be a barrier to transparency and accountability
- Fragmentation of regulatory processes – laws governing procurement, quality and IP but to promote transparency it has to be in all 3 areas and therefore need broad base and involvement to make it work
- Managerial and technical capacity to implement initiatives – is it there? New initiative in Brazil has 30-40 people working on it alone. HR intensive, so is there the capacity to generate own price information?

Industry Perspective

Incentives for industry to participate are;

- Greater transparency improves information and helps industry to identify opportunities to improve in the market;
- Increase in transparency and accountability will improve partnership in the public health sector – need for industry to improve role in public health and it will be a significant contribution for them;
- Key incentives are in identifying pricing structures – is free information available on drug patent process and what drugs are actually available?

Barriers for Industry

- Struggle between corporate responsibility and social responsibility in public health area;
- Industry is fragmented and therefore countries are not simply dealing with one element (i.e. the industry) – different elements/levels have different needs and positions so how to take these on board;
- Industry is decentralised so regional price negotiations are difficult because it is only recognised with whom the arrangement was made – more of a network than a vertical structure;
- Challenge in terms of industry commitment to the whole concept – one may be willing, others might not be willing – there tends to be an all or nothing approach.
- Lack of country commitment for industry – no commitment to country will discourage commitment from industry.

PFSCM – the PEPFAR focuses on change mechanisms that are being introduced to improve ARV access mainly in 15 focus countries, emphasising generic product procurement (94% of total). Seeking to use existing supply chains (both government and

NGO) and to avoid creating new and vertical structures except where there are obvious gaps.

Major areas of weakness and challenge are quantification of need, late and infrequent orders, overstretched storage and delivery routes leading to theft, spoilage etc. Scale-up involves more consumers, increased volume of products and more pressure on overburdened systems. More efficient planned ordering, better security (lower stock levels, secure distribution systems, barcodes and product tracking, vehicle tracking), faster stock turnover and security and spot checks are the strategies in use.

Improved information sharing with both patients (“if you have bought this it was stolen”) and at the global level through web based visibility – forecasts, e-catalogue, product registration, dashboards of information. Also gathering information on usage of ARVS for OGAC (office of global aids coordinator) annual data.

MOH Zambia – MOH and partners created a structure to achieve transparent accountable and efficient procurement and supply platform and a “Drug Supply Budget Line” to provide financing - giving the responsibility back to the Ministry of Health.

INDUSTRY representatives

AstraZeneca welcome MeTA and can agree with the majority of aims objectives and they welcome initiatives for transparency and supply chain improvement. Also welcome all initiatives that will improve quality of products through the chain;

- Complex markets and situations – if quick action is desirable then better to focus on 2-3 disease or treatment areas and then find framework to progress;
- Publicly funded or donor funded programmes should collate and disclose data;
- Difficulty in getting buy-in from the commercial counterparts because of fragmentation of organisation and devolvement of responsibility and business models to country and regional level;
- Market is complex and transactions at country level are often based on tenders, often low volume, trying to extend length of contracts;
- Margins with agents are not always controlled by AstraZeneca and the supply chain is complex, so cost savings and credit agreements may not be easy to pass down the chain, it is not homogenous;
- Risks at periphery of supply chains
- Industry’s first reaction to CS involvement tends to be defensive but if there is a round table then this framework will be constructive way of working together.

Novartis

2nd largest producer of generic medicines in the world. Not all medicines are HIV and AIDS medicines and the focus of MeTA should be wider. Currently deal with transparency, price, quality etc.

Barriers for industry;

Perversity in tender awards which are not always just based on price and quality. Experience with a single worldwide price and no patent on Co-Artem has demonstrated this.

Perception that international policies are working against PI doing the right thing and working to get price down whilst maintaining quality –innovators could be squeezed out – generics may ‘bring lower costs but could lead to subsequent higher prices and some shortages because innovator has stopped production as no market!

IMS International – another barrier for industry is the lack of incentive, in a competitive market, to share information if they already have the largest market share.

4.1 Additional Comments from the Floor

Although financing is basic to procurement there is an absence of accurate information about real expenditure for each country and how expenditure reflects in availability. Can MeTA get real expenditure for each country and disaggregate into PHC v. 2ry/3ry care?

Important to focus on all essential medicines not just specialised items. Questions to be asked are “what has been allocated, where has it gone, where distributed and where used?” If we get drugs right and nothing else is right have we achieved very much? Other factors, e.g. capacity at district level, may need to be addressed.

In the interests of product quality transparency and information sharing is essential to the development of public monographs and standards.

MeTA should consider a bigger agenda than ARV and ART. Beginning to see changing disease burden and these common non-communicable diseases needs to be addressed. Industry participation and needs must be acknowledged. Jamaica has NHFund with subsidies on products and available to all – if consumer wants to pay for brand then he/she pays more. It is important to press for disclosure on margins and on professional fees so that all of the add-ons can be contained and capped to ensure affordability.

MeTA is certainly not just public sector – how to create political process to reduce excesses of winners and losers?

There appears to be a dilemma for domestic manufacturing with regard to international prequalification schemes – push of international is to international qualifications whereas countries want to emphasise local manufacturers.

There is no government asking for low quality standard in local manufacturers – trying to create fair regulation – encouraging local manufacturers to improve but disincentives because of high cost raw material and local taxes.

In some countries there is conflict of interest because government owns regulation and manufacturing! But this can be self defeating in terms of entering global market. In case of domestic private manufacture then it is up to the regulators to implement standards.

If industry is suggesting that small markets are a problem and the private sector is difficult to control. Is it correct to conclude that the private sector is not the best option for the patient and that therefore that we should focus on public sector?

5 CONCLUDING SESSION

Observations from DFID Team Leaders.

DFID tends to be country based rather than global but tries to work in all regions of the world

- Responding to demand from the countries — looked in a number of African countries; Bolivia and Peru; Kyrgyzstan; Philippines; Jordan and other possibilities include Pakistan; India; Bangladesh. Open to other countries whilst trying to strike the balance.
- Criteria of some activity already done on drug prices and government interest etc.
- There will be a country stakeholders meeting.
- A global stakeholder meeting is planned with CS on 18th April. There will also be discussion on demand side issues at household level and a consultation meeting with industry.
- Commissioning series of work – around HAI pricing survey – work on competition and freedom of information – some of financing issues to find any normative and overall expenditure on pharmaceuticals. Best practice. E-procurement. Explore options.
- DFID already has a network of research partners - LSHTM, Johns Hopkins, Boston, LSE. Need to create a network of research around access to medicines.
- Now need to include regulatory capacity to create infrastructure around quality. What can MeTA do on the quality side?
- Setup multi-stakeholder forum to continue dialogue.
- Need to create a multi-stakeholder forum – governments, international community, CS, pharmaceutical industry, pharmacists, suppliers in supply chain.
- Aiming to be in a position to launch pilot phase in May 2007.

6 LIST OF RECOMMENDATIONS FOR WHAT META NEEDS TO BE DOING AND HOW ORGANISATION'S REPRESENTED COULD WORK WITH META.

1. Identify and document work that has already been done in medicines procurement supply chain management, analyse initiatives and activities at country level
2. Note examples where there has been transparency without accountability and seek to understand the reasons behind such a situation.
3. Recognise that existing tools have some relevance and evidence already exists as to how efficiency might be improved. One objective should be to find ways for implementation of measures that will improve their effectiveness in-country.
4. Move towards some kind of global accreditation, this might be a long range goal and the standards might need to be developed. Further comment on this suggested that there are some debates about the pros and cons of international formal accreditation, but MeTA could look at informal standards and accreditation as an incentive to get involved. It was also observed that global accreditation might be more relevant to specific areas such as ACT activity.
5. Transparency and accountability are good specifics but good governance is such a wide area, it was therefore suggested that the focus of MeTA should be on transparency and accountability.

6. MeTA has an opportunity to identify areas where information is missing and to fill in the gaps. (info such as IMS data is not available for low income countries and therefore can MeTA help to rectify this through collaborative activities?)
7. MeTA should go beyond just assessment and not see scoping missions are not an end point.
8. Use META to consider applying the function of MeTA-analysis! – The opportunities to do so are limited for individual organisations but an “alliance” could do so.
9. The development of a price indicator reference for the resale level
10. CS organisations do have problems with maintaining their existence and therefore if MeTA is looking for active involvement with them MeTA has to be ready to support them in being an active player.
11. Areas of discount and rebate are ones that we all walk away from and do not address. MeTA should consider looking at these factors as part of work on the price issue.
12. Some responses from Organisations Represented;
 - a. WHO is already interested and ready to participate and particularly in assessment and accreditation of regulatory agencies. – WHO would be particularly interested in technical advice and support to regulatory agencies.
 - b. CPA involves 40 countries, the majority in the low, middle income category and CPA interested in collaboration for collection and dissemination of information and also research in the area of pharmaceuticals and service delivery.
 - c. Caribbean countries (CARICOM) are not yet included in the range of regions and countries for pilot activities and should be considered.
 - d. SCMS is happy to be involved and contribute data available. Increasingly working on the quality side, therefore will contribute efforts from that perspective.
 - e. MSH is willing to share tools and information and have them applied at a broader level, especially the Indicator Price Guide, for which support would be welcome