

HERA

HEALTH RESEARCH FOR ACTION



PRIVATE SECTOR MAPPING REPORT

ZAMBIA

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LIST OF ABBREVIATIONS

API	Active Pharmaceutical Ingredient
ATM	Access to Medicines
CHAZ	Churches Health Association of Zambia
DfID	Department for International Development (UK)
IMS	IMS health
IV	Intravenous
LIC	Low Income Countries
LMIC	Low-Middle Income Countries
MeTA	Medicines Transparency Alliance
MNE	Multi National Enterprise
MOH	Ministry of Health
NGO	Non-Governmental Organization
NMSG	National Multi-Stakeholder Group
OTC	Over the Counter (non-prescription)
PRA	Pharmaceutical Regulatory Authority
QC	Quality Control
Rx	Prescription Medicines
RRP	Recommended Retail Price
SA	South African
WHO	World Health Organization
ZPBF	Zambia Pharmaceutical Business Forum

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1. INTRODUCTION

The Medicines Transparency Alliance (MeTA) is an alliance of partners working to improve access to medicines by increasing transparency and accountability in the health care marketplace. The UK Department for International Development (DFID) is providing initial funding. Other partners include governments, global and national civil society organizations, pharmaceutical and other business interests, the World Health Organization (WHO) and the World Bank.

MeTA Zambia is intended to be a multi stakeholder forum created to improve access to all essential medicines for all people living in Zambia. The primary goal is to support national efforts to enhance transparency in the selection, regulation, registration, procurement, distribution, sales and rational use of medicines in Zambia. The MeTA Zambia initiative was formally launched in March 2009.

The Private sector are enthusiastic about being engaged in the MeTA process and see a lot of potential benefit. However they are concerned that if their issues are not dealt with adequately in MeTA very quickly their members will lose interest in the process. They have been unable to achieve any meaningful responses to their issues from government for the past 2 years and whilst they are willing to fully engage with MeTA they are mildly sceptical about getting action and consideration from government as a result of MeTA. They were very interested in the papers presented by MeTA on “ The Cash Cycle” and “The Margin Makers “ and consider that these identify relevant factors which may provide incentive for their members to become more interested in MeTA.

The most important issue for them is the disclosure of data on the Medicines market They are prepared to disclose margins and other relevant data but expect quid pro quo from the MOH, PRA and National Medical Stores. They are sceptical that this will happen.

2. BACKGROUND AND RATIONALE

The private sector in Zambia is made up of a diverse range of entities, with significantly different perspectives and interactions with issues of ATM. Contrary to quite a number of other countries in Africa and the world, the private sector (medicines volume and private doctors’ consultations) is minimal and constitutes around 10%-15% of the total health care sector. NGOs and the Government are omnipresent.

With the current size and structure of the Private Sector in Medicines supply, its role in helping towards MeTAs objective can only be limited. This sector is dominated by trading medicines and not by manufacturing and distribution mainly to the “high/middle” income urban regions.

The achievement of a sustained and meaningful improvement in access to medicines would imply a significant increase in the size of the medical market in Zambia. Currently the private sector supplies only 10% to 15% of the total healthcare products and services, and this



increase in market could lead to an important increase in the private sector market share. The Private Sector needs to become not only a player in the “upper” (private) segment of the market, but also in the “middle” segment. The Public and Private sectors can then collaborate and compete with the aim of improved access at affordable price.

Such an evolution of the private sector and its role in the total National Medicines Supply framework can only take place as part of a (Strategic) Government Industrial or Medicines Policy.

As such there is no doubt that an early and enthusiastic cross-sectoral representation in the MeTA initiative is of paramount importance. With the fragmented nature of the health care structure in Zambia, not different from other countries, easy engagement of all players in the process is a significant challenge and as such it was agreed between DFID and MeTA to develop the “Private Sector Mapping” tool, and hence this mapping of the Zambian private pharmaceutical sector.

The tool and process were established through similar exercises in 2008 in other MeTA countries.

This report outlines who the key private sector stakeholders groups are, assesses their current engagement and representation in the MeTA Zambia process, and presents a summary analysis of some key issues relating to MeTA and its aims in the Zambian context as recorded during interviews with the various private sector stakeholder group representatives. Interviews also took place with Government and NGO stakeholders.

This report builds on other reports, such as the country visit report of Marianne Schurmann March 2009 and the 2008 Supply Chain report by Prashant Yadav and Bonface Fundafunda “ Matching Demand and Supply for Pharmaceuticals in a Multi-Donor Environment: The Drug Supply Budget Line in Zambia”.

Based on analyses of the private sector stakeholders’ interests and concerns, this study suggests a number of private sector priorities which may inform an overall strategic direction for MeTA Zambia, and through their adoption, encourage a more active multi stakeholder engagement and ownership.

The initial findings and recommendations were presented during a debriefing at the last day of the visit. The presentation and list of participants are attached.

3. TERMS OF REFERENCE (summary)¹

1. Perform a pharmaceutical private sector mapping exercise in Zambia.

Completed: This was conducted between 8th to 14th July in Lusaka and surroundings.

17 interviews in total, mostly with the private sector.

Please see list of participants attached as Annex 2.

2. Inform private stakeholders about MeTA concepts

¹ A detailed terms of reference is attached as Annex 1

Completed: All interviewees were asked whether they knew and understood MeTAs principles. Those, minority, that needed refreshing their memories, were informed...

- Interview key private sector stakeholders; obtain their ideas and suggestions as to what their role could be, and what they expect from it.

Completed: All stakeholders were asked and responses are provided in section 5.

- To debrief with MeTA Zambia before leaving Zambia

Completed: A 1.5 hour meeting was organized with representatives from the private sector such as importers, distributors, representatives of multinational companies, civil society, NGOs, and MOH.

4. METHODOLOGY²

The methodology used in the pharmaceutical private market mapping for Zambia consisted of, literature review, private market stakeholder interviews and site visits, reference interviews with NGOs and Government (MOH and PRA) and Nurses associations as well as a multi-stakeholder debriefing with presentation and discussion.

Interview participants were selected depending on their location, role in the supply chain, their position as stakeholder representatives and/or based upon their knowledge of ATM Initiatives and MeTA in particular. The list of participants is given in Annex 2.

Within the private sector, key issues explored were:

- Knowledge or awareness of, and interest in MeTA
- Key issues/constraints relating to ATM in the Zambian context
- Proposed strategies to address constraints and improve access to medicines in Zambia

5. ZAMBIA GENERAL AND HEALTHCARE

Zambia is populated with around 11 m inhabitants, in three relatively more prosperous regions, Lusaka, Copper Belt and the Southern Province and the poorer rural areas. The country is neighbouring 8 countries. The Zambian Kwacha significantly fluctuates to the USD/Euro. More than 300 international NGOs (all sectors) are operational. In 2007, the public and international cooperating partners healthcare spending was USD 270m (of which USD 180m was on HIV/AIDS).

20 years ago Zambia had 6m inhabitants of which 500.000 belonged to the so called formal economy (tax payers). In 2009 the number of tax payers is estimated to be around the same figure of half a million, including many Zambians now working for international NGOs.

The Health Care Structure is mainly driven by the MOH/Government in collaboration with NGOs like the Churches Health Association of Zambia (CHAZ), and commercial enterprises

² for this Zambia private sector study

such as Crown Agents, contracted for the storage and distribution of medicines to the districts at Medical Stores Ltd.

The private sector is one of the smallest in the world with no more than 10 - 15% of total health care services. The private sector cannot function effectively with no more than 70 registered pharmacy retail outlets, 80 pharmaceutical importers/wholesalers, 300 private (dispensing) clinics (1 to 2 doctors), private health insurers with no more than 30.000-50.000 people privately insured, six officially registered manufacturers of which only 3 are operational with a very limited product portfolio.

Statistics on medicines importation and use in the private market were unavailable at the time of this mission. The most obvious source would be the importation data, available at the PRA, though these would need to be reworked into useable data references. Peter Stephens (IMS Health) is in discussion with the PRA and other stakeholders to facilitate this process.

Currently more than 95% of medicines volume (public/NGO/private) is imported, of which more than 80% is coming from India (rough estimations through interviews). Medicines' sourcing comes from Governmental procurement, NGOs' direct importation and importation by the private sector. Illegal imports enter via Tanzania and other neighbouring countries or briefcase business. Regularly, government procured drugs find their way into the private market.

Manufacturing facilities investments were done some years ago but business has not taken off due to unfavourable macroeconomic policies. This has failed to create a sustainable working environment for local production. Although manufacturing companies have their own in-house Quality Control Labs, there is no national Quality Control Lab in the country. Occasionally PRA outsources its QC functions to laboratories abroad.

Generally local importers may quote on drug tenders of the government, but aren't able to compete with international companies. However, government does invite the private sector for emergency supply tenders, but these are usually done at short notice and local suppliers can only bid for products that they have in stock at the time of the tender.

Recently, about a year ago, the private sector joined forces and formed the so called "Zambia Pharmaceutical Business Forum" with the objective of creating a stronger representative body in discussions with other stakeholders, mainly the Government.

Costs, mark ups and margins

Pricing of pharmaceuticals, both Rx and OTC, in the private market is free. There are no fixed or maximum margins on wholesaling, distribution, retailing or dispensing. Retail prices are lowest in the competitive areas in the big cities and are highest in the rural areas, in private dispensing clinics and in high socio-economic areas where rental space is expensive.

The following table illustrates the current mark-ups, levies and margins which are added to medicines which are imported into Zambia

	%	Value	Total
Ex Factory Price	100	Value	100.00
Shipping and transport	15	15.00	



Insurance	2	2.04	
Customs Clearance	2	2.04	
Import duties	0	0.00	
PRA Levy	2	2.04	
Landed Cost		21.12	121.12
Importers costs			
Internal transport	8	9.69	
Warehousing	2	2.42	
Finance and insurance	7	8.48	
selling and distribution	10	12.11	
Total Importers costs		32.70	153.82
Importers margin	15	23.07	
Price to distributor			176.90
Distributor costs			
Selling and distribution	10	17.69	
Total Distributor cost			194.59
Distributor margin	15	29.19	
Price to Retailer			223.77
Retail margin	40	89.51	
PRICE TO PATIENT			313.28

From a supply chain perspective importers/distributors represent some foreign firms and sell directly to all outlets (retail; private clinics, government) through their own distribution infrastructure. Importation of finished drugs is duty free, whilst local manufacturing companies pay significant duties on the importation of raw materials (with the only exception of the active ingredient (API)) and pay sales tax on locally procured packaging materials.

The duties on API can be claimed back from the Ministry of Finance, but need to be paid and thus pre-financed first.

With such a small private market and 4000 products formally registered (PRA databank) it can be concluded that a very high proportion of the medicines have minimal sales volumes.

Public Sector procurement

Regarding procurement in the Public Sector, this is done through the Ministry of Health, either through individual tenders, direct shopping or framework contracts. These framework contracts seem to result in shortlists of providers (going even up to 7) and occasionally in longer term price volume specific supplier agreements.



For more information on Government procurement and Supply Chain I refer to the report “Matching Demand and Supply for Pharmaceuticals in a Multi-Donor Environment” by Prashant Yadav and Bonface Fundafunda.

Storage and distribution to all districts in the public sector is performed by Medical Stores Ltd, whereby the management has been outsourced to “Crown Agents”.

CHAZ, the Churches Health Association of Zambia, plays a very significant role in providing health care services. With 136 members they are responsible for around 30% of health care services in the country (hospitals, clinics, training of personnel, like nurses and lab. Technicians etc.). Donor supplied drugs are budgeted for about USD 20 m per year with more than 95% directly imported (60% HIV/AIDS; 10% anti malaria; 20% reagents supplies and 10% others). CHAZ takes care of its own distribution to 62 hospital and health centre outlets.

5.1 MeTA Zambia Current status

MeTA Zambia was formally launched on 31st March 2009 in Lusaka. The Governing MeTA Zambia Council is chaired by Mr Chota (MP). All relevant stakeholders are represented, although it still is recommended adding a private health insurance representative.

An initial 6-months work plan was developed and approved by MeTA International Secretariat, and an MOU signed. The MeTA Council members have been appointed, and the chair, vice-chair and secretary elected. There was a delay in signing the MOU, and thus release of funds for implementation of the workplan. However, since the release of funds on July 1st, the Council through its subcommittees are actively meeting and implementing the 6 month workplan.

5.2 Findings of the mapping exercise by subgroup³

Research based multi-national enterprises (MNE)

No MNE is present in Zambia through its own affiliate. A number of MNEs are represented either directly or via their subsidiary in South Africa. MNEs also supply through tender processes directly to the MOH or through international procurement agencies.

Volumes in the private market are extremely small, reason why most MNEs deal through their SA affiliates. MNEs may have 1 or 2 medical reps in the country, which are housed with the local agent company.

Registration and file retention fees are being paid for by the MNE and not the agent. With the recent significant hike in fees, MNEs are rescreening profitability of medicines, and streamlining product portfolios accordingly.

No details on MNEs tender business to Government and NGOs could be obtained.

Local Manufacturers

There are currently 6 licensed manufacturers. However the investment climate is such that hardly any (continuous) production takes place. OTC medicines, some IV fluids, and only occasionally some essential drugs are the product portfolio of these companies.

³ (Private sector stakeholder analysis is included in Annex 4)

Local manufacturers are over-dependent on Government purchases, as the private market doesn't provide the required volume to produce efficiently. Government tenders are awarded based on price, quality and capacity to supply.

Indian pharmaceutical manufacturers seem to receive a significant export subsidy (up to 30%) and finished drugs are imported tax free. For local manufacturers import taxes exist for excipients, and sales tax on locally produced packaging materials. On API imports tax can be reclaimed though they need to be financed first.

Some local manufacturers were aware about MeTA, others not. All local manufacturers at the same time have import licenses for finished drugs, are wholesalers and distributors, and in a number of cases have retail pharmacies. Some have salesmen and/or medical reps. In other words, a fully integrated supply chain as a result of the small volumes in this market.

In order to develop a sustainable local manufacturing business, it should be considered to develop a framework to support local manufacturers in manufacturing a number of essential drugs for the government market. This framework would have to be designed taking into account financing, import duties, local sales tax, volumes to provide critical mass and continuity, credit terms, quality and reasonable profit margins. Such a framework would need to be described in a National Industrial or Medicines Policy.

The advantage of having local manufacturing versus finished product importation would be to decrease foreign dependency, to develop local technical capacities, create career opportunities for university graduates, lab technicians (the knowledge base) etc. All these are very critical to the support of building up a private healthcare sector.

Importers/Wholesalers/Distributors

There are no unique or specialized wholesalers/distributors in Zambia. A financially sound business model around this wouldn't be feasible due to the small private market volumes and the vertically integrated businesses that allow margin build up where opportune/feasible at any moment in time.

In the private market there are estimated 350-400 "consumer" outlets: 70 retail pharmacies and 300 dispensing doctors (clinics). Orders are supplied within 24 hours but in general within half a day.

Outlets official credit terms are 30 to 60 days though many pay only at 90 days putting a significant financing burden on the distributors. For higher volumes around 10% bonus in kind is usual.

The increase in registration and annual file retention fees by the PRA is regarded by the importers, wholesalers and distributors as having a negative impact on their business, however PRA respond that it doesn't agree with this view as the same companies that were paying retention fees before the increase were affected are still the same companies that are complying and, and ZPBF's claims are not evidence based. PRA would like to conduct a viability study on this matter and the same fees might even go higher or lower.

A detailed schedule of current Registration and Retention fees is included as Appendix 7

The fee structure makes no differences between essential drugs and other drugs or between locally manufactured drugs or imported drugs. It is suggested to review this policy such that the income flow for the PRA remains sufficient to run an effective organization (in addition to government funding), to create a barrier for medicines that are not marketed effectively but



also to assure that low volume essential medicines are not economically “blocked” from entering the country. A differential fee strategy could be a solution to the above problem.

Private sector stakeholders see the significant illegal imports and counterfeit drugs as directly affecting their business, not only in directly sold volumes but also inhibiting opportunities to further expand the retail pharmacy network to suburban areas. Quantification of volumes hasn't been possible and therefore substantiation of the argument.

The sector would be in favour of greater transparency with regard to government tenders. When discussing with individual stakeholders some argued that there was transparency (due to the Procurement Act) other argued that they still found it troublesome to get the right information at the right time. Whatever the situation might be, it is suggested that the ZPBF analyses and consolidates the opinions of all members and concludes, before discussing their conclusions with government bodies.

Secondly, the regulations provide for importation of small volume life saving medicines even by individual patients or through the importers so to say in a report that slow, life saving drug

Regarding regulatory processes, most private market importers found that more clarity and transparency should be achieved. Setting clear process guidelines including timelines, “clock ticking” processes etc, would be critical to higher efficiencies and planning in the sector.

All interviewees were asked whether they would be able to agree on more transparency on pricing, mark ups and retail prices. While free retail prices allow adjustments to changed market circumstances anytime and anywhere, this at the same time confronts the market (the patients and insurance companies) with critical issues such as affordability, increased premiums etc. Higher volume products are sold by different importers under different brands. The combination of such price competition and the purchasing power of patients leads to a level of price hike containment in the competitive geographical areas.

It is more than obvious that the retail pricing needs to be “free” in countries with a very high import quota, significant currency exchange volatility and changing import and screening fees, the unpredictability of government tenders and other costs and that can hardly be influenced. However, more transparency and perhaps regulation of trade margins could create a more stable, uniform retail price level in the country, throughout the various outlets.

However at this moment patients and insurance companies have no visibility/transparency on drug prices. As such, a Recommended Retail Price (RRP) model was discussed with all interviewees.

The RRP is to be indicated on medicines by the importers. It would be calculated on an agreed trade margin (distribution/retail) by the ZPBF and the Government. This trade margin would then be added to the landed cost of the importer.

The concept would ask importers to sticker the RRP on the minimum pack size but at the same time to allow retailers to sell below-at or above the RRP based on specific market circumstances. This would allow patients to buy elsewhere (in urban areas), or pay partly out of pocket without reimbursement and insurance companies to reimburse at agreed price levels.

The RRP's per product could also be made available through the Internet and/or text/SMS⁴.

Importing companies weren't opposed to the concept provided that it would be worked out in full collaboration with the government, and that it would be voluntarily and with a small scale test period first.

Obviously this would be a major step forward in drug pricing transparency.

Importers' cash cycle

For an importer of medicines or raw materials to manufacture medicines in Zambia, one of the most important factors in his purchasing decision is the amount of time it takes from the point where he is required to make the investment of the value of the purchase until such time as he receives the final payment for this purchase from his customers in the market.

Action	Time to completion (Days)	
	Bill of Exchange	Letter of Credit
Purchase decision by importer	1	1
Creation of proforma invoice and submission to manufacturer for approval and return to importer by manufacturer	7	7
PRA submission and approval to import	7	7
Application to Bank for Letter of Credit		1
Approval and issuance of LC by Bank		10
Confirmation of purchase order by importer and transmission to manufacturer	1	1
Production of order by manufacturer	60	60
Shipping from manufacturer to importer	60	60
Customs clearance at port	3	3
Final liquidation of order by receipt of payment from customer	90	90
Total time from investment to recovery	229	240

As this model reveals, the Zambian importer will have to wait for 179 days or approximately 6 months before he fully recovers the initial investment he has made in the purchase together with his profit on the full transaction. With the very high bank interest rates at 25% in Zambia this delay can be extremely costly if he has borrowed to finance the purchase, which is the normal method of financing working capital,

Retail (Pharmacies, Drugstores and Private Clinics)

⁴ Google's mobile phone application that provides real time information "Google SMS Search Technology"; Joseph Mucheru, Google's lead for sub-Saharan Africa/ Elena Spitzer, Learning and Development, Google. Reference "Business Daily" (Kenyan) Tuesday July 7th, 2009.

As mentioned there are not more than 70 licensed retail pharmacies: the vast majority in Lusaka, Copper Belt and the Southern Province, and only in urban areas.

The law requires every pharmacy to have a licensed pharmacist to be present during opening hours. Pharmacies run a wide range of products next to prescription medicines. They provide over the counter advice as many patients bypass doctors for lack of funds.

Pharmacies seem to operate at a 30-50% mark-up. However as most stakeholders in the supply chain are vertically integrated it is difficult to judge total mark-ups on landed cost.

Drugstores are not allowed to dispense Rx drugs but only OTC. However it seems very likely that there is significant illegal distribution, especially in the rural areas.

Private Clinics (one or two doctors) provide medical treatment and dispense drugs, mostly at significantly higher prices than in the retail pharmacies. Poly-pharmacy is frequently mentioned by other stakeholders as a risk attributed to this model. The higher prices are amongst others the result of lower volumes in general and no bonus in kind received from importer/distributors.

It is suggested to analyze/review current practice with regard to drug dispensing by private clinics as part of the review of the National Medicines Policy. Pricing as well as nearby availability of retail pharmacy outlets could be elements for discussion.

Retail pharmacists would be in favour of opening more outlets. However, from their perspective, they face a number of obstacles:

- A lack of pharmacists to man these outlets. (Many pharmacists leave to work for NGOs/Government or abroad).
- Economically not justifiable in suburban areas at this moment
- Competition from illegal imports
- Competition from dispensing doctors
- Competition from the government and NGO sector.

Regarding the RRP concept, pharmacists interviewed said to be willing to participate in discussing the model. (This should be done outside pharmacy working hours as they cannot leave during opening hours).

Pharmacists believe they could play a role in further improving access and healthcare advice/information through expanding the number of outlets from the current 70 to at least 140 (consultants own estimation) gradual move from the key urban areas to sub urban. Public-Private Partnership could stimulate this move.

Young graduates could be motivated to operate suburban pharmacies under a regular supervision of experienced pharmacists. Also the role of experienced Pharmacy Technicians with additional education could be re assessed for this purpose.

Other Stakeholders

Private Health Insurers

The number of people with private health insurance in Zambia is not greater than 30,000-50,000. Mostly these are company and NGO employees and their families.



As such these insurers seem not to make profits but have been operational for some years now upon request (internationally) and to gain experience. Insurers do make deals with private clinics on the cost for consultation, but not on medicines, nor do they have visibility on drug prices. Reimbursement on drugs however is a very significant part of the total reimbursement (50-60%).

Premiums are age dependent and amount to an average of ZMK 2m/ p.a. (USD 400) per person insured (medical treatment and medicines).

Insurers obviously would be in favour of more transparency in the supply chain and would welcome the RRP system as this could give them a better reimbursement reference.

The MeTA project as such was not yet known to the interviewee. He was briefed accordingly.

Churches Health Association of Zambia (CHAZ)

CHAZ provides its own healthcare services, partly sponsored by the government and foreign aid with an estimated 30% stake in the healthcare services in volume. CHAZ is seen as well run, efficient and effective. It provides services through 36 hospitals and 100 health centres, has a nursing school as well as lab technician education. It provides drugs from the national essential drug list, with the majority from revolving drug funding and on top donor supported drug funds.

Civil Society

In the debriefing session the idea of the RRP concept was raised. The Civil Society representative was very much in favour of the initiative and agreed that this could help to create a higher level of transparency to consumers as part of the MeTA initiative in general.

Nurses associations

The representatives were briefed on MeTA, and welcomed the initiative.

Key issues concerning medicines for them are the distribution and use of medicines with unknown origin. The regular out of stocks in the public sector or the expired stocks in many health centres/hospitals around the country as well as the low to non availability of back up stocks in the private sector.

They would not be opposed to train Senior Nurses further to play a role in prescribing/dispensing.

6. SUMMARY FINDINGS and OBSERVATIONS

Amalgamated key findings from mapping exercise:



1. Retail price setting of medicines is free. This leads to important variations of prices in time as well as price variations per outlet, based upon geographical location or type of outlet.
2. Private sector stakeholders are extremely concerned about the elevation of regulatory fees.
3. Private sector stakeholders would be in favour of building an investment climate that could lead to a more extensive retail network.
4. Private manufacturers are eager to invest or re-invest if Government and NGOs would create a more sustainable business environment.
5. Private insurers would favour more pricing transparency on medicines to better plan and run their business, although they could take initiatives to set reimbursement levels for essential medicines already now, managed with a reasonable level of flexibility.
6. A number of private sector stakeholders would like to see enhanced transparency on Government tender processes, such as earlier announcements, more time to prepare quotes and clarity on tenders' allocation (companies, prices, volumes).
7. Importers advocate strict, transparent and adhered to registration processes (timelines).
8. Private manufacturers would like to see a level playing field as to import duties for API, excipient ingredients and local packaging materials, i.e. no import duties or equal import duties for all.
9. Private sector stakeholders would like to see improved controls on illegal imports.
10. There is a need to study possible legalisation of drug stores, e.g. "Addo" system in Tanzania.

MeTA is a welcomed initiative to enhance transparency and competitiveness for the private sector.

OBSERVATIONS

Based on the mapping of the private sector, certain key observations (of this consultant) are offered here for consideration by the MeTA executive and Governing Council in Zambia and the ZPBF.

- 1) For the Private Sector to fully comprehend and buy in on the MeTA initiative it will be critical that the ZPBF puts MeTA on every meeting agenda as a fixed item, following up on strategies and actions, assure full disclosure of discussions with other stakeholders etc.
- 2) Participation by the private sector in working groups is critical and as such leaders of the working groups need to ensure attendance by the sector.
- 3) In order to create a win-win culture between the private, public and NGO stakeholders, it is advised that all three sectors demonstrate flexibility in giving and taking. If hurdles seem very high for one or more stakeholders it is suggested to initiate a (small scale) test phase with clearly described key performance indicators.



- 4) The Council could review whether all relevant private stakeholder groups are correctly represented, including the insurance companies. The consultant composes private insurance companies to be represented in the council and in relevant sub committees.



7. RECOMMENDATIONS

Based on the above observations the following recommendations are offered for consideration:

STRATEGIC

The private sector in Zambia is small and significantly smaller than many other countries in Africa. As such, its role in helping to improve medicines supply to the lower socio economic classes must not be overestimated. “Illegal” drugstores operate in the country, filling a gap in supply that is not served by the Government, the private sector and NGO’s. MeTAs Council is suggested to discuss ideas and policies on how to develop and manage this apparent gap in the legal (controlled) supply with the aim of eradicating uncontrolled distribution, sales and usage.

TACTICAL

- a. For the private sector to play a role of more significance in medicines supply outside the key urban areas, a business climate should be created that would build incentives to the private retail sector to invest. The MeTA council is suggested to discuss and evaluate strategies to stimulate this process.
- b. Health insurance companies could play a role in designing a reimbursement model that would lead to more price transparency, price consistency and a more efficient supply chain process. The Council is suggested to invite representatives of this sector to participate in relevant working groups.
- c. The Council is suggested to develop recommendations on an industrial policy whereby the production of essential medicines is stimulated with the aim of more control over the supply chain, more control of prices and the stimulation of a skilled labour force in manufacturing, quality control etc.

A more significant part of government procurement going to the private sector could be one of the recommendations to support such a policy.

The Transparency Initiatives described below can be seen in the light of the Strategic and Tactical issues.

TRANSPARENCY

- A. The Recommended Retail Price model could be a tool to help creating a higher level of transparency in the market for medicines.
- B. Full disclosure of government tender processes and outcomes where not already applied could help the private sector to further enhance competitiveness.
- C. Design and Implementation of Regulatory Processes as to timelines and “clock ticking” processes to enhance transparency for private sector business planning.

Working groups (recommendation)



- Ad. A. “RECOMMENDED RETAIL PRICE” - “RRP” (chaired by representative ZPBF)
Stakeholders from the private and public sector would discuss and agree on a general mark up on landed cost as the basis for the establishment of the retail price. The project would start with a testing phase and expand by learning and agreement. A selection of essential drugs would be chosen for this test phase.
- Ad. B “PUBLIC PROCUREMENT DISCLOSURE IMPLEMENTATION” - “PPDI” (chaired by representative MOH)
- Ad. C. “REGULATORY PROCESS DESIGN AND IMPLEMENTATION” – “RPDI” (chaired by PRA representative)

Where the MeTA council would be “ACCOUNTABLE” for the scope and outcomes of the three transparency recommendations, it is suggested that the working groups are “RESPONSIBLE” for the project design (work plan) and implementation. The MeTA council would endorse the working groups’ design working plan, organization and possible resources, before start, such as to ensure buy in and full alignment.

The working groups would describe in the working plan which stakeholders would need to be “CONSULTED” at what time on which subjects and the working groups would describe who to “INFORM” at various intervals and milestones (ARCI working model).

Annex 1 - Detailed Terms of Reference

Background

MeTA is a new multi-stakeholder approach for increasing transparency around the selection, procurement, sale and distribution of medicines in Low Income Countries (LICs) and Lower-Middle Income Countries (LMICs), thereby strengthening governance and encouraging responsible business practices. The super goal of MeTA is to improve health outcomes for poor people in those countries. The MeTA goal is to ensure access to affordable essential drugs in developing countries (MDG 8, Target 17). The initiative is being supported financially by DFID⁵ during its present Phase One.

MeTA brings together, at both the international and national levels, a diverse group of people with an interest in the pharmaceutical sector (stakeholders) to find ways to improve information flows, and increase transparency and accountability about the selection, regulation, procurement, sale, distribution and use of medicines in developing countries. By doing so, MeTA will improve how decisions are made about medicines, improve the way they are purchased and supplied, encourage innovative and responsible business practices, and increase the voice of patients and consumers.

Rationale and specific objectives

The MeTA Secretariat is tasked to help to support the implementation of MeTA in pilot countries, including through facilitating support for the evolution and effective functioning of the National Secretariats, National Multi-Stakeholder Group (NMSGs) and other development partners, and implementation of work plans. Following the establishment of country MeTA structures, the International MeTA Secretariat may provide further support to the pilot countries that might include:

- Supporting countries to extract and collate data on medicine quality, availability and pricing along the supply chain;
- Supporting countries to undertake studies assessing the level of transparency and good governance in medicines regulation and procurement;
- 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;
- As well as exploring policy options and support needed for implementation e.g. of report recommendations.

⁵ It also responds to commitments made in the 2006 UK International Development White Paper to transfer lessons from EITI to other sectors, including specifically the health sector.



The **overall objective** of this contract is to:

Support the development of a national MeTA process, which needs to involve all three stakeholders: government, private sector and civil society.

The **specific objectives** are to:

- Undertake a mapping of the private stakeholders in Zambia
- Help mobilizing the private sector by generating interest for the MeTA principles and engagement in the MeTA Process Zambia

Tasks

The consultant will undertake the following activities:

1. Perform a pharmaceutical private sector mapping exercise in Zambia
2. Inform private sector stakeholders about MeTA concepts
3. Interview key private sector stakeholders, obtain their ideas and suggestions as to what their role in MeTA could be, and what they expect from MeTA
4. To debrief with MeTA Zambia before leaving Zambia

Note: the above terms of reference and outline methodology below are for discussion with MeTA Zambia at the start of the mission.

Methodology

A private sector mapping methodology was developed by a previous MeTA consultant.

1. Consult with MeTA Zambia and discuss Terms of Reference, methodology and expected outputs/outcome. Specific meetings with individual MeTA Zambia members for further information gathering.
2. Undertake a private sector mapping exercise.
 - a. Manufacturers
 - b. Distributors, wholesalers
 - c. Pharmacies and chemists.
 - d. Other private sector involved in medicines
 - e. Key public sector institutions
 - f. Faith based institutions
3. Based on analysis of above, schedule a meeting with representatives from key private/public sector stakeholders. (Including MeTA Council). During the meeting:
 - a. Discuss understanding of MeTA, what it aims to achieve;
 - b. Discuss private sector perceptions of constraints to improved access for drugs
 - c. Discuss potential opportunities and strategies/recommendations for facilitating improved access.



Deliverables

The Consultant will be accountable to the Technical Director of MeTA Secretariat (Wilbert Bannenberg) and will receive support from the local consultant (Violet Kabwe) and the members of the International MeTA Secretariat.

- Fill in (and submit together with your invoice) the MeTA reporting template for short-term assignments describing days worked and the activities performed according to the TOR.
- Short report, work plan (activities, responsible person/s, timeline, output and indicators) for improved access to medicines in Zambia, and participants' lists of all multi-stakeholder meetings attended. This can be included in the Country visits reports, if relevant.
- From the above interviews, report need to include at least the following:
 - a. Who are the key private sector (for-profit and not-for-profit, if any) stakeholders?
 - b. What do they know about MeTA?
 - c. What do they believe are key constraints to improved access, and who needs to undertake particular actions to improve access?
 - d. What do they propose as solutions/strategies?
 - e. What can they themselves offer?

Consultancy Schedule

Activities	Dates	Number of Days
Preparatory reading	Before 08/07/09	1 day
Zambian mission	07/07/09 – 14/07/09	Up to 8 days
Work resulting from the short-term assignment in Zambia	15/07/09 – 20/07/09	Up to 2 days
	Total:	11 days