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Disclosure Status of the Zambian Pharmaceutical Sector



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LIST OF ABBREVIATIONS

LDC Least Developed Countries
MCTI Ministry of Commerce and Industry
MeTA Medicines Transparency Alliance
MOH Ministry of Health
NGO Non-Governmental Organization
PRA Pharmaceutical Regulatory Authority
WHO World Health Organization
ZPPA Zambia Public Procurement Authority
ZPBF Zambia Pharmaceutical Business Forum



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1.



Background

Zambia

Zambia, which gained its independence from Britain in 1964, is a land-locked country bordered by Angola, Botswana, the Democratic Republic of the Congo, Malawi, Mozambique, Namibia, Tanzania and Zimbabwe. With an area of 752 614 square kilometres, the population was estimated at 11.2 million in 2005. In the 1980s and 1990s, declining copper prices (the main engine of what had been a robust economy prior to the price decline) and prolonged drought damaged the economy severely. The real growth rate of GDP was estimated at 4.6 percent in 2004, and public debt was 127.5 percent of annual GDP. The infant mortality rate was estimated at 88 per 1,000 live births. Life expectancy was estimated to have plummeted from 50 years at independence to a controversial 37 years by 2000, among the lowest in the world, primarily the result of underlying poverty combined with HIV/AIDS, which had an estimated prevalence rate of 16.5 percent (Central Statistics Office 2002; CIA 2005; Gaynor 2005; UNDP 2004).

Zambian Pharmaceutical Sector

The pharmaceutical business in Zambia is regulated by the Pharmaceutical Act No. 14 of 2004. The Act establishes the Pharmaceutical Regulatory Authority (PRA) which is responsible for registration and regulation of pharmacies; registration and regulation of medicines, herbal medicines and allied substances intended for human use and for animal use; regulation and control of the manufacture, importation, exportation, possession, storage, distribution, supply, promotion, sale and use of medicines, herbal medicines and allied substances. The key functions to achieve this include the registration of medicinal products, inspections of facilities and products, licensing of pharmaceutical premises (retail, wholesalers, and manufacturing sites) and issuing of import and export licenses and permits. However, the Act does not regulate the practice of pharmacy professionals. Pharmaceutical staffs are registered under another piece of legislation (GRZ, 2009).

Registration of pharmaceutical products for use on the Zambian market is done by the PRA through the directorate of Product Registration. The directorate further submits evaluation reports to the Medicines Committee for consideration before inclusion of products on the register. The formation of medicines committee is provided for under section 9 in the Pharmaceutical Act No. 14 of 2004.



Forecasting and quantification is done by the Ministry of Health's Directorate of Clinical Care and Diagnostics Pharmacy Unit in liaison with cooperating partners. The unit is also responsible for capacity building in pharmaceutical management in public sector health institutions.

The procurement of medicines for government health institutions is done by the Procurement and Supplies Unit of the Ministry of Health. Currently the Ministry of Health has undergone restructuring which has also included the procurement supplies unit. The Head of Procurement reports directly to the Permanent Secretary. Under him are now three chief procurement officers of whom one is a pharmacist specifically for procurement of medicines and other pharmaceuticals. Under the chief procurement officer are two senior purchasing and supplies officers, again one of the two is a pharmacist.

The sources of funding for procurement of medicines are the government and cooperating partners. For 2007-2008, the Ministry of Health embarked on Framework Contracts with pharmaceutical suppliers to improve (without interruptions) supply of medicines and other pharmaceuticals.

The Ministry of Health in its procurement operations is guided by the Zambia Public Procurement Authority (ZPPA 2009) laid down procedures for public procurement. All procurements above the authorized thresholds (US\$1,000,000 for MOH) are channeled through procurement methods as per ZPPA guidelines. The procurement methods recommended by ZPPA includes: the International Competitive Bidding (ICB); Limited International Bidding (LIB) and; National Competitive Bidding (NCB).

Procurement of pharmaceuticals and related supplies is one of the key roles of the MOH Procurement and Supplies Unit. The storage and distribution of pharmaceuticals and medical supplies is done by the national medical stores (Medical Stores Ltd), a parastatal company owned by the Ministry of Finance and the Ministry of Health. The management of Medical Stores Ltd has been contracted to Crown Agents. Medical Stores Ltd's mandate is storage and distribution of medicines and allied products to district health offices and hospitals. District management teams in turn distribute to health centers and clinics within their districts.

The Churches Health Association of Zambia (CHAZ) is also involved in medicines supply management as a complementary service (about 20 – 30%) to the government supply system. CHAZ through a revolving drug fund sales essential medicines to member institutions and others not for profit organizations including government health institutions. In addition CHAZ with support from cooperating partners run antiretroviral therapy and malaria treatment programs which includes procurement, storage and distribution.

According to Aart van Os, the Zambian private health sector is one of the smallest in the world with no more than 10 - 15% of total health care services (Os, 2009). In



2009 there 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 were operational with a very limited product portfolio.

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 pharmaceutical production. Although manufacturing companies have their own in-house Quality Control Labs, there is no national Quality Control Lab in the country. Occasionally PRA outsourcers its QC functions to laboratories abroad.

The private sector has joined forces and formed “Zambia Pharmaceutical Business Forum” with the objective of creating a stronger representative body in discussions with other stakeholders, mainly the Government.

A. Disclosure Survey

Zambia like other MeTA pilot countries is developing strategies to promote greater transparency and accountability regarding policies, practices, and outcomes in the pharmaceutical sector. A survey looking at four areas; Medicines registration and quality assurance; Availability of medicines; Price of medicines, Policies and practices concerning the promotion of medicines, was conducted. Data was collected using a disclosure tool.

For each core area, disclosed information should cover **policies** – the laws and regulations that are in place; **practices** – suggested procedures to follow and actual practices; and **results** –achievements in the core area.¹ The objectives of describing the current disclosure status of information in the core areas are to: (1) enable the Zambia MeTA Council to prioritize potential activities to facilitate progressive disclosure over time; and (2) create a baseline against which changes in transparency and disclosure during pilot implementation can be measured.

Administration of the Tool and Respondents

The questionnaire divided into the four areas Medicines Registration and Quality Assurance, Medicine Availability, Medicine Prices and Medicine Promotion was administered by interviewing key informants and in some cases the questionnaire was self administered. The total number of KIs interviewed and their institutions is shown in the table below.



Area / Function	Total number Respondents	Government Official (MOH)	Private Sector (Pharmacy/Clinic/Hospital)	Media	Other (NGO/Insurance Company)
Registration and Quality assurance	12	1	10	0	1
Medicine Availability	6	3	3	0	0
Medicine Prices	7	2	4	0	1
Medicine Promotion	15	3	4	4	5
Total	40	9	21	4	7
%	100	23	50	10	18

To validate information by key informants some institutions such as Pharmaceutical Regulatory Authority (PRA) and the Ministry of Commerce and Industry were asked to confirm some findings and give documentary evidence. Fifty percent of respondents were from the private sector while 23% were from the Government officials

1. Medicines Registration and Quality Assurance

Maintaining a transparent and organized process for registering medicines allowed to be used in a country is essential for ensuring that only high quality medicines are available on the local market. Through the registration process, manufacturers and importers demonstrate their compliance with pharmaceutical sector regulations on registered products. Drug supply managers and clinicians need to know which medicines are registered for use so that they can make appropriate therapeutic choices. The registration of pharmaceutical and allied products in Zambia is the responsibility of the Pharmaceutical Regulatory Authority (PRA).

1.1 Market Registration Procedures and Registration Status of All Medicines

To assess the existence, availability and disclosure of information concerning market registration procedures and registration status of all medicines, a structured questionnaire was administered to key informant. A questionnaire on medicines registration and quality assurance covered five issues. These are Good manufacturing practice (GMP) for domestic and foreign manufacturers, Market Registration Procedures and Registration Status of All Medicines, Quality assurance processes in public and non-profit tenders, Quality assurance data during registration or procurement, Routine quality testing and adverse event monitoring. 12 key informants were interviewed and distributed as follows: Two (2) government officials, Ten (10) private sector pharmacist/chemists and one (1) Private hospital. Other secondary sources of information such as pharmaceutical acts were also reviewed

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Survey results indicated strongly that in Zambia laws regulating market registration procedures and registration status of all medicines exist and are published. The associated regulations also do exist. From the ministry of health point of view, these laws and associated procedures are published and are available at government printers where anybody wishing to have the data can purchase the documents.

- i. The Pharmaceutical Act of 2004 has provisions for register products by the Pharmaceutical Regulatory Authority (PRA). The act is widely published
- ii. There is a list of registered products which is accessible though it would be more accessible if placed on the website
- iii. There are -4011 number of registered products

Practices: Are procedures published? How enforced? Which data exist? Who has access?

The procedures for registration of all medicines are published from the MoH point of view. However, other stakeholders contend that they are not readily available as whenever they need to look through them they have to go to PRA. However PRA does circulate from time to time publications which have all the details

These policies and procedures are basically enforced by the three functions of the Pharmaceutical Regulatory Authority (PRA). These procedures are basically self enforcing in that key players in the pharmaceutical sector cross check each other as they do business and as such there are no incentives by one player to flout the procedures. In addition various institutions such as local governments, customs officers who require adherence to the NDP and pharmacy Act when issuing trading licences and importing drugs, respectively.

- i. Procedures for registration and registration status of all medicines are published
- ii. PRA enforces regulations through inspections
- iii. Registration takes at least 11/2-2 years for initial registration
- iv. Registration includes herbal, generic and patented medicines
- v. Registration information can be accessed by the public upon request from PRA

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

In the process of executing their function PRA produces data in a register which gives details of the registration status of all medicines in Zambia. Register is published but stakeholders complained this is published with a lag.

For instance they say the current publication include the registration status of all medicines up to 31st October 2008. It is possible that this is updated but the fact is that it's not readily available.

- i. List of registered products is supposed to be updated annually (RA)

- ii. List of applications
- iii. Regulations for drug registrations
- iv. Fees and retention fees schedule
- v. Main users retailers, importers, distributors, manufacturers and health professional
- vi. Wider use can be promoted through sensitization and posting of information on the Website. PRA website has already been designed and information is posted. It only n to be activated and this will be done very soon.

1.2 Good Manufacturing Practice (GMP) for domestic and foreign manufacturers

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- Laws/policies concerning Good manufacturing practice (GMP) for domestic and foreign manufacturers exist (provision within the Pharmaceutical Act 2004)
- Associated regulations exist

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- i. Procedures are published by the PRA
PRA conducts (enforces) inspections for GMP certification following WHO guidelines and through post marketing surveillance.
- iii. List of all licensed manufacturers is published by the PRA

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

- i. List of licensed pharmaceutical manufacturers, importers, wholesalers and retail pharmacies
- ii. WHO Technical Series (GPM), Pharmaceutical Act 2004
- iii. Main users: Government, manufacturers, pharmaceutical companies
- iv. Lack of dissemination is main barrier

1.3 Quality assurance processes in public and non-profit tenders

Making efficient, cost-effective, and safe procurement decisions requires information on the quality and reliability of medicines suppliers. Public disclosure of tender results can lead to more assured medicines quality and more cost-effective procurement.

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- i. Laws/policies governing quality assurance processes in public and non-profit tenders exist
Zambia Public Procurement Authority ACT 2009 (ZPPA Act 2009) and PRA guidelines which are published
- ii. Associated regulations exist and stipulates procurement procedures that generally require competition and transparency

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- i. The procedures are published though respondents from the private thought they are not.
- ii. The ZPPA Act 2009 is still new
- iii. Respondents mentioned the following as being responsible for enforcement (Ministry of Health, tender evaluation teams, PRA, buyers, self)
- iv. However, most respondents did not know data that existed
- v. Data are accessed by PRA, manufacturers, suppliers, distributors and interested public

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

- i. List of licensed pharmaceutical manufacturers, importers, wholesalers and retail pharmacies
- ii. WHO Technical Series (GPM), Pharmaceutical Act 2004
- iii. Main users: Government, manufacturers, pharmaceutical companies
- iv. Lack of dissemination is main barrier



1.4 Quality Assurance data during registration or procurement

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- i. The PRA Product Registration directorate evaluates drug registration application based on dossiers submitted
- ii. Inspection of manufacturing site not usually a pre-requisite for medicine to be registered
- iii. Specialized tests such as bioequivalent not done; Zambia has no National Drug Quality Control Laboratory.
- iv. PRA also relies on Certificate of Product
- v. Standard operating procedures for manufactures, whole sellers and retailers are published

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- i. Quality Assurance is available at PRA but no independent – no drug quality control laboratory
- ii. PRA publishes alerts in print and electronic media in case of poor quality medicine issues
- iii. Procedures are enforced by PRA, MOH and Public Health Act – Health Inspectorate
- iv. PRA and ZPPA were mentioned as main users
- vi. PRA mentioned that data are accessed by PRA, manufacturers, suppliers, distributors and interested public
- v. But most respondents had no idea of the data on QA during registration or procurement

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

All respondents did not know the data on QA during registration or procurement

- i. Standard operating procedures for manufactures, whole sellers and buyers (PRA)
- ii. WHO guidelines and Pharmaceutical Act were mentioned as data that existed
- iii. No evidence was provided of data that exist

1.5 Routine quality testing and adverse event monitoring

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- I. Respondents did not know laws/policies for routine quality testing and adverse event monitoring
- II. Pharmacovigilant Unit at PRA responsible for adverse event monitoring
- III. The PRA Product Registration directorate evaluates drug registration applications based on dossiers submitted
- IV. Inspection of manufacturing site not usually a pre-requisite for medicine to be registered
- V. Specialized tests such as bioequivalent not done; Zambia has no National Drug
- VI. Quality Control Laboratory. A Regulator is not supposed to conduct bioequivalence studies but can inspect CROs involved in this type of tests)
- VII. PRA also relies on WHO-type Certificate of a Pharmaceutical Product
- VIII. Standard operating procedures for manufactures, whole sellers and retailers are published

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- I. No independent National Drug Quality Control Laboratory. Meanwhile PRA is using Mini lab kits for post marketing surveillance; PRA publishes alerts in print and electronic media in case of poor quality medicine issues
- II. Procedures are enforced by PRA, MOH and Public Health Act – Health Inspectors
- III. PRA and ZPPA were mentioned as main users
- IV. PRA responded that Adverse reporting forms as well as IEC material are available and being distributed with assistance from cooperating partners like ZPCT. They are also posted on the website (to be launched soon).
- V. But most respondents had no idea of the data on QA during registration or procurement

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

All respondents did not know the data on QA during registration or procurement. PRA responded that the reports are available at PRA.

2. Medicine Availability

In this data disclosure survey the availability of medicines was analyzed from different perspectives. These are availability of Standard treatment guidelines, Essential medicines list, Pharmaceutical patents held in the country, Volume and value of medicines procured in the public and non-profit sectors, Volume and value of medicines supplied in the private sector, Availability of medicines to consumers, Routine audits for public, private, and non-profit medicines outlets.

6 key informants were interviewed and distributed as follows: Two (3) government officials, Ten (3) private sector pharmacist/chemists I. Other secondary sources of information such as pharmaceutical acts, and other publications were also reviewed

2.1 Standard Treatment Guidelines

Standard treatment guidelines are one strategy for ensuring the availability of appropriate medicines to treat common health problems. Evidence-based and up-to-date standard treatment guidelines (STG) for key illnesses can guide the therapeutic decisions of health providers and the formulary decisions of health institutions and systems. STGs can be tailored for different levels of care and used as the basis for monitoring prescribing according to STGs. The survey looked at three key areas: existence of policies, procedures and results

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

In Zambia, policies and related STGs regulation exist and are published for targeted institutions and individuals (MoH, 2004)². These polices are formulated and updated by the National Formulary committee which meets every after five years. These laws and policies are contained in the Pharmacy Act of No 4 of 2004 and the National Drug policy document. The guidelines are implemented at the local level by the Drug Therapeutic Committees (DTC) who are tasked to ensure guidelines are adhered

- i. Policies and related Standard Treatment Guidelines (STGs) exist and are published and disseminated
- ii. Policies are formulated by the National Formulary Committee and are reviewed every five years

² CBoH Zambia National Formulary Committee (2004): Standred Treatment Guidelines, Essential Medicines List, and Essential Laboratory Supplies List For Zambia (First Edition 2004)

iii. Policies are contained in the National Drug Policy

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Procedures concerning the STGs are also published and enforced through the DTC who come up with local policies which guide adherence. To ensure adherence all medical personnel in each section in a facility should have STGs and every section head is supposed to ensure that the guidelines are followed. To a large extent adherence are self regulatory whilst institutions like Medical Council of Zambia and PRA usually do perform regular checks on the institutions' files just to ensure that the guidelines are followed.

- i. The STGs and National Formulary are published
- ii. STGs are enforced through the Drug and Therapeutics Committees at institutional level
- iii. Zambia National Formulary, STGs, Essential Medicines List, disease specific (Malaria, TB, HIV and AIDS) are available but supply is limited
- iv. Mostly private sector

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

The STGs are distributed to institutions which are tasked with prescribing and dispensing medicines. In areas which are hard to reach the guidelines are distributed as the medicines are being delivered.

The STGs are available mainly to members of the DTC, prescribers (Clinical Officers, medical officers etc), and pharmacists. The general public are not availed this information nor are they encouraged by way of posters or deliberate dissemination to have this information. This is also reinforced by the lack of interest by the general public on issues to do with STGs

Though the general public have the right to know about the medicines being prescribed to them, there is however, a danger that when the public has a lot of information it may lead to self prescription and treatment which might be catastrophic

Interviews with Private clinics revealed that they are also supposed to adhere to these guidelines but usually refer to it only when there is need and sometimes to use their own guidelines. The use of different STGs in the private sector could be to

justify a different high fee structure for their procedures. Interviews also revealed that while all public health facilities are sent copies of any changes to STGs, private institutions are not given these guidelines.

A number of recommendations were made concerning the promotion of wider use of STGs. In addition the Ministry of Health should intensify the distribution of STGs especially to private clinics.

Standard treatment guidelines, disease (HIV/AIDS, Malaria, TB) specific guidelines and Zambia National Formulary are published but need to be circulated widely

Monitoring of adherence to treatment guidelines is challenge especially in the private sector

STGs should be widely circulated and should include training of private sector health, Providers

iv. Mostly private sector

2.2 Essential Medicines List

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

In Zambia laws on the EML, is published, is publicly available and can be accessed by anybody interested in it. The main users of the EML are basically health professionals, health institutions such as MoH, DHMTs, Hospitals and clinics. Others users include manufacturers and importers of medicines

- i. National Drug Policy 1998 which is currently being reviewed
- ii. Zambia National Essential List (according to level of care) is published, guide to medicines that can be procured in Government and not for profit facilities,
- iii. Zambia Essential List has less products than those registered by PRA and does not apply for the private sector

Practices: Are procedures published? How enforced? Which data exist? Who has access?

Zambia National Formulary Committee is responsible for the productions of Essential Medicines List, and Essential Laboratory Supplies List for Zambia. Policies concerning the inclusion of medicines in the essential medicines list and associated regulations do exist and are published. The formulary Committee meets every five years to update the list. Basically at the local level, the Drug Therapeutic Committee may see the need to update the list because of resistance or new illnesses observed and they advocate for changes in the list at national level.

- i. The Zambia National Formulary is published and is supposed to be reviewed every five years
- ii. The multidisciplinary Zambia National Formulary Committee appointed by the MOH (Includes private and public sector health professionals) formulates the formulary.
- iii. Inadequate distribution especially to the private sector limits use

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?



- i. Formulary is published and is used by health professional and procurement officers
- ii. However, the formulary is not widely distributed especially to the private sector
- iii. Increase copies and widen distribution, include private sector
- iv. Formulary is not reviewed according to stipulated time (every 5 years).
- iv.

2.3 Pharmaceutical patents held in Zambia

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- i. Laws/policies exist and are published - Zambia Patent Act Cap 400, Zambia is a member of ARIPO protocol on Patents and Industrial Designs and is also a member of Patent Cooperation Treaty
- ii. Law incorporates selected TRIPS Flexibilities including those in the Doha Declaration on TRIPS that do not prevent Members from measures to protect public health
- iii. As a Least Developing Country (LDC) and is in transition period to implement the TRIPS agreement until 2016
- iv. Associated regulations exist

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- i. Procedures are published, for example for issuing compulsory licensing
- ii. Looks like affected Ministry can enforce, compulsory license for manufacture of ARVs was issued by the Ministry of Commerce
- iii. All interested parties such as manufacturers, regulators , health and other Professionals

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Compulsory License issued by Phacro to manufacture first line ARVs, though the project failed due to commercial reasons.

2.4 Volume and value of medicines procured in the public and non-profit sectors

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- i. Policies/laws exist (ZPPA)
- ii. Respondents did not answer but can get some information from ZPPA and the Ministry of Health value of medicines procured in public sector

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- i. Ministerial Tender Committee ceilings
- ii. Bids must conform to ZPPA regulations
- iii. MOH Budget for Drugs 2010
- iv. In Zambia information concerning the volumes of medicines procured is published and publicly available. To ensure transparency the ZPPA issued a circular in which all ministries, including ministry of health, are supposed to publish in the newspapers and government gazette the winning bid, the value and volumes of procured goods and services (GRZ, Zambia Public Procurement Authority, 2009)

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Interviews with key stakeholders, however, expressed a view that most public institutions including MoH do not publicly declare the winning bid and its value in time. This can sometimes only be available to someone upon request and with written permission from relevant authorities with a time lag.

2.5 Volume and value of medicines supplied in the private sector

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- i. Laws/policies do not exist
PRA has started collecting information on volume and value of medicines supplied in the private sector

Practices: Are procedures published? How enforced? Which data exist? Who has access?

In general data on the volumes and values supplied in private sector is difficult to find as these institutions are not obliged to publish this information to the public. The private sector chooses who to give this information and usually only disclose it in situations where they are compelled such as for taxation purposes.

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

Interviews with managers of private health facilities showed that managers are not allowed to disclose financial information of the company unless authorised by the hospital board.

In terms of values of medicines the private health facility can avail to the public how much they charge when they prescribe a certain drug but not the cost price of the drug. It's difficult to tell if at all the patients are being overcharged or not. In short there is lack of transparency in the private sector pricing of medicines. Policies to compel the private sector to disclose the value of their procured medicines should be put in place to ensure transparency and also to ensure that private facilities do not put high profit margins on the prices

2.6 Availability of medicines to consumers

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- i. Zambia national Drug Policy and Essential Medicines List intended to promote access to medicines
- ii. Quantification and tender process
- iii. Standard Operating Procedures

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- i. Procedures are published
- ii. Regular checks by PRA and Medical Council
- iii. Not available to all but clinic has not STGs, people who are supposed to have information include nurses, doctors, nurses, pharmacists and clinical officers
- iv. National Drug Policy is publicly available

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

2.7 Routine audits for public, private and non-profit outlets

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- i. There is a policy for PRA to inspect pharmaceutical outlets including public sector but regulations not yet in place
- ii. Inspections include new premises, routine and targeted (unregistered products and premises)
- iii. Associated regulations are published
- iv. Pharmaceutical Act 2004 has provisions for inspection of registered and unregistered premises

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- i. Procedures for inspections are published and available on request
- ii. Inadequate number of inspectors to conduct regular inspections
- iii. Data on inspection (reports) not made available to public

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

- i. Inspection reports are not generally available to the public
- ii. PRA is inadequately staffed to carry out audits on a regular basis
- iii. PRA perceived as not doing much by public and health professionals
- iv. Dissemination of activities being carried out by PRA is lacking.

Routine audits for private outlets are also done and reports available at PRA. Interviewees were however very sceptical on the ability of the PRA to conduct effective routine checks on all outlets. This is evidenced by the mushrooming of illegal or unregistered pharmacy outlets that are manned by unqualified individuals working as dispensers who don't even ask for prescription.

To this end the government should ensure that capacity at PRA be increased to conduct routine inspection to curb illegal vending of drugs as they encourage self prescription and abuse of drugs such as antibiotics.

3 MEDICINE PRICES

Prices charged in public, non-profit, and private sector medicines outlets determine the affordability of medicines for consumers. In Zambia medicines are provided free of charge in public and mission health facilities in rural areas but facilities in urban charge user fees. Zambia being a liberalized economy there are no controls on original price charged by manufacturers and various mark ups as the medicines proceeds through the private supply system.

3.1 Consumer and Ex-Manufacturer Prices of Medicines in the Public, Private and non-profit sectors

Sources:	
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	
<ul style="list-style-type: none"> - Zambia has liberalized economy, there are no laws/policies on consumer and ex manufacturer prices in the Public, Private and non-profit sectors - The ZPPA provides regulations on competitive bidding/tendering processes <p>Most stakeholders interviewed recognized this fact and indicated that that there was no enforcement of prices of medicines as Zambian economy was liberalized. The Pharmaceutical Act 2004 which establishes the Pharmaceutical Regulatory Authority (PRA) has no provisions for the regulation of consumer and ex-manufacturer prices of medicines in the public, private and non-profit sectors in Zambia. Pharmacies are also free to decide the price they want to charge for their products.</p> <p>i.</p>	
Practices: Are procedures published? How enforced? Which data exist? Who has access?	
<ul style="list-style-type: none"> - No procedures and no enforcement and no data exist as Zambian economy was liberalized, - Information on the medicines prices was not readily available even at PRA. This is because it's of no practical use to them because price regulation is not part of its mandate. 	
Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?	

- i. Survey by MOH in collaboration with WHO-HAI on drug prices, availability, affordability (Part I) and price components (Part II) was carried out in August-September 2008 and January- March 2010 respectively but results are not yet out
- ii. MeTA Zambia has also commissioned study on medicine prices
- iii. Medicines are free in public and mission health facilities
- iv. Prices for some medicines were thought to be unaffordable

Most pharmacies surveyed provided price list of their medicines to the interviewers even though they considered them confidential. In most cases private clinics do not display the prices of medicines and as such patients only come to know the price after prescription has been given to them.

It should however, be noted that that the law does not allow private clinics to have dispensing pharmacies. This is to avoid the proliferation of dispensing doctors. It was also noted that in private clinics most patients are not given option of where to buy medicines and as such the price of medicines are considerably higher in the private clinics that in private pharmacies.

There is in general lack transparency and disclosure of information about the price of medicines in the private sector. The public should be availed this information in order for them to make choices whether to buy medicines with the within the private health facility or some other places. (MeTA-Zambia, 2010)

3.2 Public Sector Medicines Procurement Prices

Sources:	
Policies: Do laws/policies exist? Are they published? Do associated regulations exist?	



Laws/policies exist on procurement; Zambia Public Procurement Act 2009 and is published (GRZ, Zambia Public Procurement Authority 2009)

In Zambia Public procurement of medicines is done through the Ministry of Health Tender Committee (Centralized) up to a certain ceiling. Above the ceiling, procurement is done by the Zambia Public Procurement Authority with technical input from the Ministry of Health. Hospitals and District Management Teams also procure supplementary medicines through Hospital/District Tender Committees. Medicine procurement is mostly done through competitive tendering

The ZPPA act 2009 establishes the Zambia Public Procurement Authority whose responsibility is supervision of Public Procurement in Zambia. It gives guidance to Ministerial Tender Committees on (Tender Procedures and Guidelines). Although there is guidance as regards prices of all goods procured by the Zambian Government and public institutions, there are no specific provisions on public sector medicines procurement prices. The rule is to give the tender to the lowest bidder for a particular quality and type of medicine needed.

The regulation of prices at which medicines were procured in the public sector was reported to be done through the tendering system and procurement guidelines that allowed competition. However, there are no laws on recommended wholesale prices available to the public sector.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

The Tender Procedures (Procurement Guidelines), as regulations governing disclosure of procurement prices
MOH tender committee procures medicines up to a ceiling allowed by the ZPPA

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

- i. Tender documents, evaluation reports
- ii. Procurement prices of medicines available on request from the procurement unit in the Ministry of Health?
- iii. Medical Stores Ltd 2009 Catalogue indicates prices of medicines stored
- iv. Procurement data are not easily accessible from the MOH procurement unit as reported by the mid-term review team

Some respondents surveyed argued that the public procurement tendering procedures are supposed to be transparent. Certain information is not available to the public. This information includes the price components of the medicines bought by government. For instance FOB price of medicines, the freight and insurance, taxes to be paid and finally profits margins and distribution cost of these medicines. In addition this information is only available long after procurement has been done which renders the information obsolete

In order to ensure optimal use of public funds and resources government should be available to the public. Public disclosure of this information will also help in building confidence in the public procurement systems which is currently viewed by certain sections of the society as not being transparent and corrupt. This perception could be due to lack of information in the public domain

3.2 Medicine Price Components in the Non-Profit and Private Sectors

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

- Liberalized economy, no laws/policies on medicine components
- All imported essential medicines are tax free but some additives used by local manufacturers are taxable

Practices: Are procedures published? How enforced? Which data exist? Who has access?

- There are no procedures concerning Medicines Price Components in the Public, Non-Profit, and Private Sectors (all respondents)
- Government does not impose wholesale and retail prices

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

- I. There are no data on medicine price components in public, non-profit and private sectors and there are no laws or policies governing mark ups on medicines.
- II. Essential medicines are tax free though the industry has complained of high product registration fees.
- III. There is need to develop policies on medicines price components in Zambia. Especially mark-ups
- IV. Even if Zambia has liberalized economy such policies will help in ensuring affordability of medicines to consumers.

- V. One way of ensuring affordability of medicines is through encouraging competition in the pharmaceutical industry.
- VI. Kick –backs should also be discouraged at the district level as it contributes to higher prices paid by most DHMTs. There is an allegation that that most public officials at DHMTs demand 10% of the value of medicines to be supplied to them before a tender is awarded. There need to come out in the open and speak against this vice if at all it exist. (MeTA-Zambia, 2010)

4 Medicine Promotion

While medicines are critical inputs in the health care delivery system, irrational prescribing and use of medicines often result in inappropriate treatment, and at times results in resistance to some medicines. “While the interests of medicines manufacturers and public health may coincide, they are often divergent and in the scramble for new and expanding markets for medicines, manufacturers vigorously promote their products. As a result, many countries have introduced a legislative framework to regulate the promotional activities of the pharmaceutical industry”³. These frameworks vary widely in content, implementation and enforcement. Indeed, some developing countries still lack any legislative structure to control promotion.

This section explores the existence of national policy regulatory frameworks on medicines promotion and assesses key stakeholders’ perceptions of the regulatory situation and outcomes of the process.

4.1 Medicines promotion regulations, policies and industry practices

Sources:

Policies: Do laws/policies exist? Are they published? Do associated regulations exist?

Generally laws and policies governing the promotion and medicines including associated regulation exist and are published. These are contained in section 43g of the Pharmaceutical Act of 2004. Section 43 subsections 1, 2 and 3 states that a person shall not advertise medicines unless the advert conforms to information submitted when obtaining the license. In addition only certain medicines registered under G8 can be advertised. Medicines sold by prescription only shall not be advertised to the general public without prior written permission from the PRA. Further, the laws provides for punishment for contravening which is in form of a fine or imprisonment (GRZ 2004)

Based on the above laws and policies pharmaceutical firms are not allowed to advertise their medicines, health facilities can not advertise themselves unless in medical journals. In short it’s unethical to advertise medicines

- The Pharmaceutical Act 2004 (*Section 43 Subsections 1,2,3 and 4*) provides for regulation of medicines promotion

Based on Pharmaceutical Act (No advert unless conforms to regulations General Sales, Prescription, work in conjunction with Public Health Act Cap 295 and within SADCC guidelines.

Practices: Are procedures published? How enforced? Which data exist? Who has access?

According to PRA, procedures for applying for the promotion of medicines are published and available to most interested users of the information. Most licensed practitioners are given this information and they are very much aware of the rules and regulations governing promotions of medicines in Zambia. Deliberate efforts are made in order to make available this information to licensed practitioners in the pharmaceutical industry.

However there has been no such effort targeted to the advertising firms. This, however, does not imply that they has no access to these sets of information. The general public inclusive of advertising companies have to go to government printers or PRA and request for the documents.

As already alluded, to promotion of medicines is generally prohibited. Enforcement of these laws and policies is done by PRA. However, regulatory authority faces a number of difficulties when it comes to enforcing these laws particularly the herbal medicines. Monitoring adherence is problematic due to capacity. Most advertising firms interviewed expressed ignorance on the need to ask for if at all permission from PRA was granted in order to advertise medicines. To this end PRA should sensitize the media firms on the need for PRA to approve promotion of medicines.

- i. Procedures are published (Pharmaceutical Act 2004 and Statutory Instrument Number 93 Of 2003)
- ii. However, not fully enforced by PRA especially in the advertisement of herbal medicines to the public
- iii. There is limited access to data on medicines promotion

Interviews with most pharmaceutical companies reported that they were very aware of the policies and practices regarding the promotion of medicines. Most firms indicated the knowledge of these laws and also know that contravening these laws attracted prosecution and even imprisonment. Most of them,

however, were skeptical about the capacity of the Pharmaceutical Regulatory Authority (PRA) capacity to enforce penalties for non-compliance regulations (Interview 2009)

Results: Which data are available? Who uses data? Barriers to use? How to promote wider use?

The government through PRA provides guidelines and compliance documents including fees for launching and advertising. Though these documents are not publicly publicized anybody can have access to these documents upon request.

During the execution of these functions PRA produces various information including products and companies that have been granted permission to engage promotional and advertising of medicines. This information is kept at PRA but not published either at their website or any publication. However, the information can be accessed upon request.

PRA collects data on information contained in the promotion application and relates this information with what it has already and decides whether to grant permission or not. Most of the information generated is publicly available though not published. Though publicly available this information is rarely used by the general public. There are many barriers to the use of this information. One being lack of knowledge by the general public on how useful the information can be to them.

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APPENDIX 1 List of Facilities and person interviewed

	PERSONS INTERVIEWED	ORGANISATION
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