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Ministry of Health and Social Welfare

Mid Term Review of the Health Sector Strategic Plan III 2009-2015

Pharmaceutical Services

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Mid Term Review of the Health Sector Strategic Plan 2009-2015

Pharmaceutical Services

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Contents

List of Tables

List of Figures

Acronyms

ADDO	Accredited Drug Dispensing Outlet
AIDS	Acquired Immune Deficiency Syndrome
CHF	Community Health Fund
CPD	Continuing Professional Development
DfID	Department for International Development
DHIS2	District Health Information System 2
eLMIS	electronic Logistics Management Information System
ERP	Enterprise Resource Planning
GMP	Good Manufacturing Practices
GOT	Government of Tanzania
HBF	Health Basket Fund
HMIS	Health Management Information System
HSSP	Health Sector Strategic Plan
ILS	Integrated Logistics System
LMU	Logistics Management Unit
MEMS	Mission for Essential Medicines Supplies
MOHSW	Ministry of Health and Social Welfare
MSD	Medicals Stores Department
MTC	Medicines Therapeutics Committee
MTR	Mid Term Review
PIFS TWG	Pharmaceutical Infrastructure & Food Safety Technical Working Group
PMO-RALG	Prime Minister's Office – Regional Administration and Local Government
PPRA	Public Procurement Regulatory Authority
PSM	Procurement & Supply Management
PSS	Pharmaceutical Services Section
SARA	Service Availability and Readiness Assessment
SMS	Short Message System
SOP	Standard Operating Procedure
SPD	Service Panel Districts
SWAp	Sector Wide Approach

TFDA	Tanzania Food and Drugs Authority
TSH	Tanzania Shilling
URT	United Republic of Tanzania
USAID	United States Agency for International Development
USD	United States Dollar
WHO	World Health Organisation

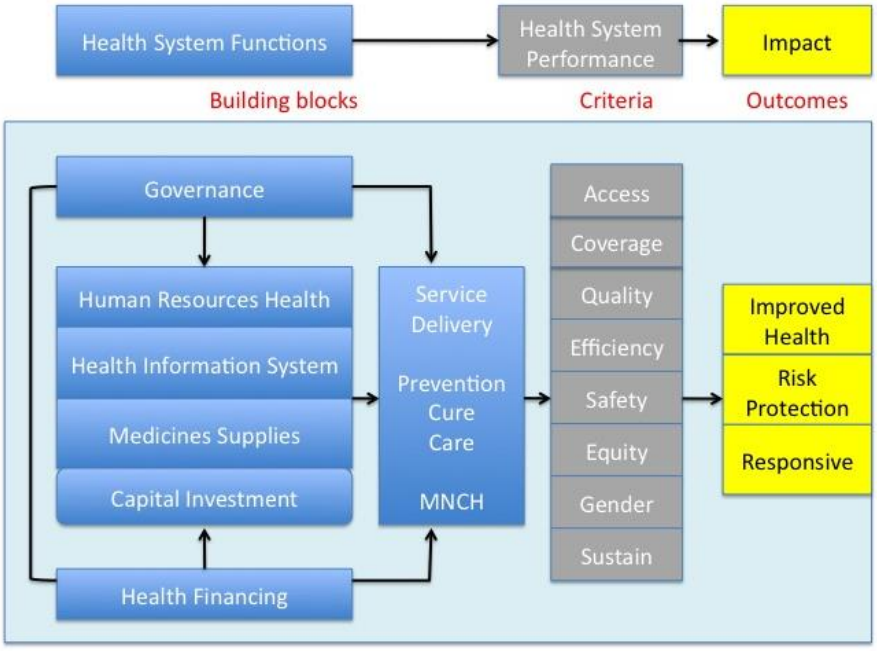
1. Introduction

The Tanzania Health Sector Strategic Plan III (HSSP III) 2009 – 2015 is the overall guiding document providing strategic direction for the health sector for the period. The HSSP III provides for monitoring of implementation progress and in this context a mid-term review is foreseen. The mid-term review has been conducted by a team of internal and external consultants during the period July to September 2013. The outputs are one general report and nine technical reports addressing priority areas in more detail. This report deals with medicines and supplies (pharmaceutical supplies) – one of the three "other important issues" included in the HSSP III.

As per Terms of Reference the overall objective of the mid-term review was to assess HSSP III implementation progress, challenges and lessons learnt and to propose options for improvement for the remaining period. The specific scope of work for the pharmaceutical supplies review included documentation of quantitative and qualitative achievements against the specific strategic objectives and results; analysis of enabling and impeding factors; and an assessment whether expected results can be achieved, are still relevant or need to be revised. Crosscutting areas to be addressed were quality improvement, equity for underserved populations and vulnerable groups, and gender (see Annex 1 for specific Terms of Reference).

The overall analytical framework for the mid-term review was adapted from the WHO Health Systems Framework.[1] Pharmaceutical supplies are part of the support system that provides crucial inputs for service delivery (see Figure 1).

Figure 1: HSSP III mid-term review analytical framework



[1] World Health Organization. 2006. *Everybody's business*; WHO, Geneva

The assessment is based on a comprehensive document review, and observations and stakeholder interviews in Tanzania, including in three regions (see list of persons met and field visit reports annexed to the main review report). The approach was participatory and holistic working closely with the stakeholders in MOHSW and the other specialists of the mid-term review team. Preliminary findings were presented to the Technical Working Group Pharmaceuticals, Infrastructure and Food Safety (PIFS TWG) and the mid-term review Steering Committee. The draft report was circulated amongst stakeholders and discussed at a consultative meeting in September 2013. All feedback received has been considered in the final draft version of this report.

2. HSSP III: Pharmaceuticals Strategic Objectives and Expected Results

The HSSP III strategic objectives, results and indicators for the area of pharmaceuticals are listed in Table 1 below. They were derived from a situational analysis that noted challenges such as persisting shortages of medicines at health facilities; late disbursement of funds for procurement; inadequate number and/or qualified human resources; lack of transport and adequate storage facilities; weak logistics management information system; availability of sub-standard products on the market; and low capacity of the local pharmaceutical industry.

Table 1: HSSP III Strategic Objectives and Expected Results for Pharmaceuticals

Strategic Objective	Expected Results	Indicator
1. To ensure accessibility at all levels of safe, efficacious pharmaceuticals, medical supplies and equipment	A. National medicines policy developed, implemented & monitored	Availability of policy
	B. Necessary (human, financial, material) resources for procurement & distribution of medicines & supplies available	Disbursement of funds for medicines & medical supplies
	C. Domestic production of quality and affordable pharmaceuticals in place	Certificates of Registration of pharmaceutical producers
	D. Number of Accredited Dispensing Outlets (ADDO) increased	Number of ADDOs
2. Strengthen control of quality, safety and efficacy of pharmaceuticals, medical supplies, medical equipment	A. Perform systematic pre-procurement & post-marketing sampling and testing as well as pharmaco-vigilance in public and private sectors	Number of quality tests performed
3. Ensure gender sensitive, equitable availability and rational use of quality pharmaceuticals, medical supplies and equipment in health facilities	A. Health facility & district level competent in forecasting, procurement, stocking & rational prescription of medicines	Availability of tracer medicines in health facilities
	B. Adequate MSD warehousing, communication & distribution capacities at zonal level in place	Lead time between district order & delivery to district
4. Enhance harmonisation and coordination and information management of procurement, stocking and distribution of medicines and supplies for specific health programmes	A. Standard Operating Procedures in place for development partners & other stakeholders for procurement of medicines & supplies to be utilised in the Tanzanian health system	Percentage of partners following SOP for procurement

Strategic Objective	Expected Results	Indicator
	B. Standard Operating Procedures (SOP) in place for stocking & distribution of donated medicines & medical supplies	Percentage of partners following SOP for stocking & distribution
	C. Logistics management information system introduced & used in all facilities	MSD awareness of actual stock-outs in sentinel health facilities

3. Findings and Issues by Strategic Objective and Crosscutting Issues

The assessment of progress to date is based on the HSSP III expected results and indicators, and considers their contribution to achieving the strategic objective. A progress summary is provided in Table 2 below followed by detailed findings and issues.

Table 2: Summary of Progress against Expected Results to date (August 2013)

Achievements	Yet to be addressed
Strategy 1: Accessibility at all levels	
National Medicines Policy & Implementation plan developed	Official approval, implementation, Monitoring & Evaluation
National quantification exercise initiated Increase in Health Basket funding for health facility accounts at MSD	Timely budget disbursement; low budget Recovery of vertical programmes' distribution cost by MSD
New postgraduate course in industrial pharmacy established	Development of quality assured local production
Number of ADDOs increased	Refocus on & sustain quality assurance; improve geographical equity
Strategy 2: Quality, safety, efficacy	
Pharmaco-vigilance guidelines available; Reporting Forms distributed; 96% of 675 medicines samples analysed	Increased inspection, sampling & testing
Strategy 3: Availability & rational use	
	Low availability at service delivery level
ILS training at district level	Sustain & support
Guidelines & training for Medicines Therapeutics Committees	Sustain & broaden scope in practice; RUM strategies for health centres & dispensaries
New MSD zonal warehouses & expansion of direct delivery system	Monitoring of impact (e.g. lead times) Sustainability
Strategy 4: Harmonisation & coordination	
e-LMIS being developed; LMIS unit being established	SOPs for harmonised procurement, storage & distribution (partners) Mainstreaming vertical programme products Exist strategies for projects supporting PSM

3.1 Ensure accessibility at all levels of safe, efficacious pharmaceutical commodities

Strategic Objective 1 and the expected results focus on the enabling environment, pre-conditions and critical inputs required to ensure that pharmaceutical supplies are available in public and private sectors in all parts of the country.

3.1.1 National Medicines Policy

Tanzania's first National Medicines Policy was approved in 1991 and was accompanied by an implementation plan for the period 1992-2000. In 2009 a revised National Medicines Policy and implementation plan were drafted and stakeholders were consulted in writing and during a national workshop. The revised draft was submitted to the Ministry of Health and Social Welfare (MOHSW) / Directorate of Policy & Planning in April 2013, and is currently awaiting internal approval and submission to Cabinet. The overall objective of the draft National Medicines Policy is to "ensure provision of quality and equitably accessible pharmaceutical services at all levels"[2].

The related implementation plan provides more detail on the 17 priority strategies of the policy, which are coherent with those of the HSSP III. MOHSW through the Pharmaceutical Services Section[3] is charged with overseeing implementation of the policy, and will also be directly involved in implementation of certain aspects. Other implementing partners include the Tanzania Food & Drugs Authority (TFDA), Pharmacy Council, Medical Stores Department (MSD), Prime Minister's Office – Regional Administration and Local Government (PMO-RALG), training institutions and the private sector[4]. Implementation budgets are provided but funding sources have not yet been identified.

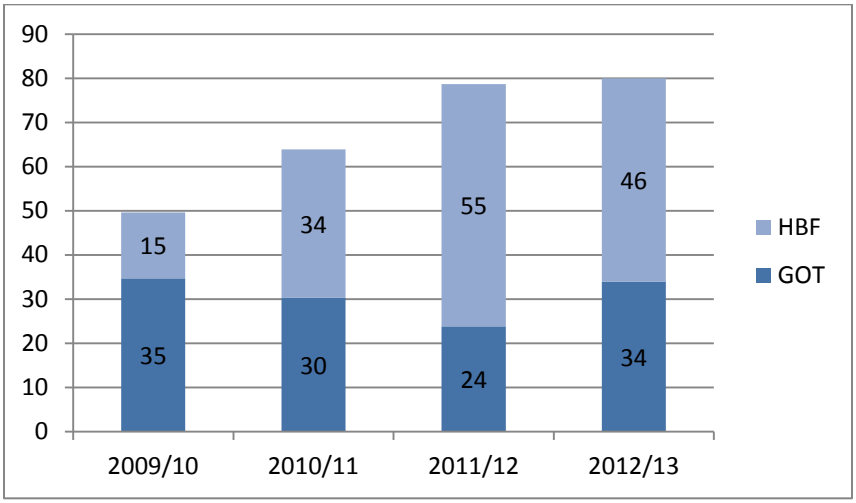
3.1.2 Financial resources

The pooled budget (Government of Tanzania & Health Basket Fund) for essential medicines and medical supplies to be held at health facility accounts at MSD increased in monetary terms by 62% during the period under review (from TSH 49.6 billion in 2009/10 to TSH 80.6 billion in 2012/13).[5] However, an analysis performed for the Medicines Performance Profile Report 2012 showed that in real terms the budget only increased marginally from USD $0.80/capita in 2009/10 to USD $0.84 /capita in 2011/12 (adjustments were made for inflation, exchange rate and population growth).[6] During the Medium Term Expenditure Framework process in 2009 the required allocation for essential medicines and supplies had been established as USD $2.50/capita/year.[7] In fact, the very low budget for essential medicines procurement was always mentioned as a major challenge for service delivery during stakeholder interviews in the MTR at national, regional and district level.

The share of Government contribution to the pooled fund decreased during the period under review until 2011/12, with a slight nominal increase in 2012/13 (Figure 2).

[2] MOHSW. 2013. *The National Medicines Policy – Tanzania Mainland* / draft; URT
[3] Previously Pharmaceutical Services Unit (PSU); with the move to Health Quality Assurance Division PSU became the Pharmaceutical Services Section.
[4] MOHSW. 2013. *National Medicines Policy Implementation Strategy – 2013-2018 – Tanzania Mainland* / draft; URT
[5] N.B.: Not all of this budget is transferred to health facility accounts. As per overall allocation formula 10% are supposed to be held in MOHSW accounts at MSD for national emergencies, special medicines/ medical supplies distributed free of charge (e.g. family planning commodities), and special services such renal dialysis.
[6] Pharmaceutical Infrastructure & Food Safety Technical Working Group 2012: *PIFS Input (pharmaceuticals) Health Sector Performance Profile*; unpublished
[7] MOHSW, Policy and Planning Department. 2011: *Health Sector Performance Profile Report 2011*. MOHSW Tanzania Mainland

Figure 2: Composition of pooled fund for essential medicines (in TSH billion)



Updated from PIFS TWG 2012 Health Sector Performance Profile

In addition to the pooled budget, around USD $5.00/capita/year are made available by mainly global health initiatives for procurement of HIV/AIDS, malaria, and tuberculosis supplies and new vaccines; while USAID, DfID and AusAid support procurement of family planning commodities. For HIV/AIDS and malaria treatments and tests alone a value of USD $2.00/capita/year was established for 2011/12.[8]

In response to uncertainties about the actual needs for essential medicines and medical supplies a quantification exercise is currently being implemented by the National Institute for Medical Research. This includes data collection (e.g. consumption, patient attendance, morbidity) from a representative sample of health facilities and development of a quantification model. PSS plans to use the quantification model to update information every other year. Information from this exercise will be used to assess adequacy of available budgets, advocate for needed budget increases, and assist MSD in procurement planning.

Efficient use of the limited budget is undermined by several factors as noted in the Medicines Performance Profile Report and other recent assessments:[9,10]

- Disbursement of the pooled budget to the MOHSW tended to be less than the approved amount (75% on average). This is mainly due to under disbursement of the Government of Tanzania (GOT) share of the pooled fund. On a positive note a 94% disbursement of the GOT share was reported to the PIFS TWG for 2012/13 fiscal year.
- Disbursements from MOHSW to MSD are sometimes less than the amounts released by Treasury for this purpose because some funds may be reprioritised by the MOHSW.
- Disbursements are not predictable in terms of amount and timing. Allocations are usually low during the beginning of the fiscal year. Ordering by primary health care facility is less affected by late disbursements, because MSD grants them credit against approved budgets awaiting payment by

[8] MOHSW. 2013. *Annual Health Sector Performance Profile 2011/12 – Final Draft*. MOHSW Mainland Tanzania
[9] Printz N et al. 2013. *Strategic Review of the National Supply Cain for Health Commodities in Tanzania*; URT, Ministry of Health and Social Welfare; Tanzania
[10] Innovex ©. 2011. Report of the Controller and Auditor General on Special Audit on Drugs Availability at Medical Stores Department (MSD) for the Period from 30th June 2009 to 30th June 2011; URT, National Audit Office; Dar es Salaam; June 2012

government. Both (late/incomplete disbursements and providing credit to health facilities) negatively affect MSD cash flow and working capital that depend on regular payments by health facilities for orders received. As a consequence implementation of MSD procurement can be delayed.

- The lead time until funds are credited to the health facility accounts at MSD remains long. For 2006/07, the average was 55 days for MOHSW procedures and 6 days for MSD procedures.[11] More updated quantitative information could not be traced but related complaints persist.

Erratic and delayed disbursement of funds to health facility accounts at MSD continues to be mentioned in Joint Annual Health Sector Technical Review (JAHSR) Meeting reports since 2010. A mechanism for timely and predictable disbursement of funds to MSD facility accounts was supposed to be established during 2011(SWAp milestone for PIFS TWG 11). This has not yet been implemented successfully. The PIFS TWG minutes from April 2013 state that PSS and MSD will begin implementation during fiscal year 2013/14.

Inefficiencies also occurred through the allocation formula applied by the MOHSW PSS to apportion the essential medicines budget to health facilities. Until 2010/11 flat amounts were used for either health centres or dispensaries. This did not account for the differences in workload between individual health facilities. Consequently some facilities exhausted their budgets fast while others were left with considerable balances at the end of the fiscal year. The revised formula now being applied takes into account the service population (catchment area) of health facilities[12]. Anecdotal evidence suggests that this has led to a decrease of the range of either over- or under-spent health facility budgets.[13] A systematic assessment in terms of efficiency and equity gains has not yet been performed. Full functionality of the MSD Enterprise Resource Planning system will allow up to date information on health facility transactions and budget status that will assist such an analysis.

Resource allocation formulas between districts and between levels of care (primary health care, hospitals, other) are modelled on the overall health sector allocation formula. Formulas for allocation to district hospitals (service population) and higher level hospitals (number of beds) remained unchanged. The need for updating these has been identified.

3.1.3 Human resources

Different from other health worker cadres, the number of pharmacists and pharmacy technicians per 10,000 population has decreased from 0.15 in 2008 to 0.12 in 2012 with great variations between regions.[14] However, not all pharmacists working in private pharmacies are included in the statistics. There may be more pharmacists working in the country than officially recorded. According to the Pharmacy Council training capacity for the 4-years Masters in Pharmacy has increased but there are only 2 training schools for pharmacy technicians with low output. Training of pharmacy assistants is also inadequate in terms of capacity. This has resulted in an upside-down pyramid (many highly qualified staff and relatively few staff with basic training), disproportionately affecting pharmaceutical services provision of lower level health facilities where pharmacist assistants are most likely to be posted.

For further issues related to human resources reference is made to the respective technical report of the MTR.

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[11] Euro Health Group. 2009. *Essential Medicines Supply Monitor Tanzania: The Flow of Funds, Medicines, and Information*. Euro Health Group; Denmark

[12] PSS is still in the process of collecting the required information. Facilities for which information on service population is not yet available continue to receive budgets based on the old formula.

[13] Feedback from stakeholders at MOHSW PSS and during field visits.

[14] MOHSW. 2013. *Annual Health Sector Performance Profile 2011/12 – Final Draft*. MOHSW Mainland Tanzania

3.1.4 Domestic pharmaceutical production

The HSSP III states that domestic pharmaceutical production was only covering 30% of the national requirements. Supporting domestic production of quality assured medicines is expected to increase overall access to affordable medicines. A multi sector 'National Task Force for Promotion of Domestic Production of Pharmaceuticals' is in place chaired by the Chief Pharmacist MOHSW and with members from different ministries, agencies and private sector, but is not very active.

In 2009, there were 9 licensed pharmaceutical manufacturers in Tanzania according to TFDA, and the same number is licensed in 2013. During the same period one registered facility was suspended and one was closed. None of the licensed manufacturers is in procession of a Good Manufacturing Practices (GMP) Certificate issued by TFDA. TFDA applies current GMP standards as per WHO definitions and the local industry does not (yet) comply with these. However, the standards applied by TFDA to local manufacturers still ensure that adequate procedures are in places to protect public health.

The National Medicines Policy Implementation Plan notes existing challenges and includes related objectives and strategies. These mainly focus on creating a conducive business environment for the local industry. Activities are also expected to take place at regional (East African Community) level with the implementation of the recently published Regional Pharmaceutical Manufacturing Plan.[15]

3.1.5 Accredited Drug Dispensing Outlets

In 2002, the MOHSW launched a new strategy to address prevailing problems with existing Duka La Dawa Baridis (Part II drug shops), the Accredited Drug Dispensing Outlet (ADDO) Programme. The goal of the ADDO Programme was to improve access to affordable, quality medicines and pharmaceutical services in retail drug outlets in rural or peri-urban areas where there were few or no registered pharmacies. The main strategy of the programme consisted of the transformation of existing Part II drug shops into ADDOs where medicines can only be dispensed by trained and certified dispensers in premises that comply with defined standards. The programme was implemented by TFDA through support from several partners including Bill & Melinda Gates Foundation, the Global Fund, the President Malaria Initiative, USAID and DANIDA. By 2011 the programme had been extended to 15 regions and plans were to have all regions covered by end 2012 with a concurrent phasing out of Part II shops. With the gazetting of the Pharmacy Act 2011 responsibility for registration and inspection of pharmacies, including ADDOs, was transferred from TFDA to the newly established Pharmacy Council. Table 3 documents how the number of ADDOs evolved over the past 4 years.

[15] EAC Secretariat. *East African Community Regional Pharmaceutical Manufacturing Plan of Action 2012-2016*. EAC Arusha

Table 3: Increase in Number of Accredited Drug Dispensing Outlets

Year	Estimated number of ADDOs	Source of Information
2010	2,215	MOHSW (Tanzania Private Sector Assessment, p 80) 16
2011	3,484 (functioning) 5,853 (potential)	East African Drug Seller Initiative; ADDO results summary 17
2013	3,591 accredited 977 with renewed license in 2012/13	Pharmacy Council Records covering 20 regions

While this indicates good progress in terms of the HSSP III expected result (i.e. number of ADDOs increased) recent assessments and feedback from stakeholder interviews at national, regional and council level suggest that there are some challenges with sustaining quality of services and products provided by ADDOs, including:

- In the decentralised model it is the responsibility of Council Food & Drugs Committees to supervise ADDOs. While these committees were said to exist in the districts visited by the MTR teams there was less clarity on whether they effectively execute their roles. Some Comprehensive Council Health Plans include budgets for supervision and inspection of ADDOs but others do not.
- Council Health Management Teams reported that ADDOs frequently do not comply with the existing regulations (e.g. inadequate record keeping, sale of unauthorised medicines, sometimes MSD medicines are found), a concern shared by senior national level stakeholders. The main reason given was inadequate council capacity to conduct regular supervision and inspections. Sanctions mentioned included confiscation of medicines, issuing of warning letters and closure of shops.
- A 2012 assessment of community services for childhood illnesses established that ADDOs are mostly located in urban and peri-urban areas, and that prices at rural ADDOs tend to be high. The objective of providing an alternative for the rural poor in case the public sector health facility faces medicines stock-outs is thus not being achieved.[18]

On the other hand there were positive experiences with using ADDOs for increasing access to artemisin-based combination therapy for malaria. Such successes depended on adequate training of dispensers and supervision.[19]

The expected result in the HSSP III framework concentrates on numbers but not equitable geographical distribution and quality of services and products. While some ADDOs are accredited as provider under the National Health Insurance Fund, Community Health Fund (CHF) benefits are not extended to ADDOs, which is a disincentive for prospective owners to establishing ADDOs in more rural areas.

[16] White J et al. 2013. *Tanzania Private Sector Assessment*. Bethesda, MD: Strengthening Health Outcomes through the Private Sector Project, Abt Associates Inc.
[17] East African Drug Seller Initiative (EADSI). n/d. *Creating a Sustainable Private- sector Drug Seller Program in Tanzania*; MSH, Dar es Salaam
[18] USAID, MCHIP, SHOPs 2012: *Report of the Tanzania Assessment of Community Services for Childhood Illness*;
[19] Rutta et al. 2011. *Increasing Access to Subsidized Artemisinin based Combination Therapy through Accredited Drug Dispensing Outlets in Tanzania.* Health Research Policy and Systems 2011, 9:22

3.2 Strengthen control of quality, safety and efficacy of pharmaceuticals, medical supplies, medical equipment

The expected HSSP III results under this strategy focus on pre- and post-marketing quality control and pharmaco-vigilance in public and private sectors. TFDA is mandated to perform these activities to safeguard public health. The TFDA quality control laboratory has been on the WHO list of pre-qualified quality control laboratories since January 2011.[20]

3.2.1 Post-marketing surveillance

In terms of post-marketing surveillance, TFDA reported that during their strategic plan period 2008/09 to 2010/11 4,199 samples were collected, 73% were actually tested in the quality control laboratory, and 89% of those tested complied with specifications. While non-compliance with specification does not necessarily imply that the product is ineffective or harmful, a failure rate of 11% is a reason for concern. Weak product monitoring in the market was noted as one challenge, and post-marketing surveillance plans and related staff training are included as priorities in the current strategic plan.[21]

Half-year reports for the period 2010 to 2012 showed an increase of medicines samples available for analysis by nearly 100% (from 340 to 675), while the percentage of samples that actually were processed increased from 52 to 96. Information on the source of samples (e.g. routine surveillance, submitted by customers) and the pass rates is not provided. For the current fiscal year TFDA plans to collect and analyse 600 medicines samples and 60 samples of diagnostic test kits. Inspections aimed at identifying the presence of counterfeit medicines are also planned.[22]

TFDA also receives funds under the Global Fund Round 9 Health Systems Strengthening grant. This was to contribute to increased testing of antiretrovirals, anti-tuberculosis and anti-malaria products. Except for anti-malaria products, the percentage of batches tested fell short of the plan during Phase 1 of grant implementation. Continued support in Phase 2 of the grant was subject to submission of realistic targets for achieving higher testing coverage.[23] TFDA has established mobile testing kits at 15 regional hospital sites, which allows testing of medicines procured by the hospitals from MSD and other sources.

While progress can be noted, some stakeholders interviewed in the context of a recent Tanzania Private Sector Assessment felt that not all medicines available for sale in the private sector are of guaranteed quality and often do not have TFDA approval. [24] This finding is supported by TFDA reports that only 46% of premises inspected complied with requirements during the implementation period of the 2010-2012 Strategic Plan. [25] The Pharmacy Council noted that pharmacies often need to be closed because of incompliance with regulations (e.g. not having a contracted pharmacist, selling unregistered or government owned medicines). Addressing these issues will be particularly challenging considering the shift in some inspection and licensing responsibilities from TFDA to the Pharmacy Council, where adequate capacity has yet to be built.

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[20] See: http://apps.who.int/prequal/lists/PQ_QCLabsList.pdf (accessed 14 August 2013)

[21] Tanzania Food & Drugs Authority. 2012. *Strategic Plan 2012/13 – 2016/17*. TFDA; Dar es Salaam; June 2012.

[22] Tanzania Food & Drugs Authority. 2013. *Business Plan 2013 – 2014*. TFDA; Dar es Salaam; July 2013

[23] The Global Fund. 2013. *Grant Funding Scorecard; The United Republic of Tanzania; Health System Strengthening (HSS)*. 17 May 2013

[24] White, James et al. 2013. *Tanzania Private Sector Assessment*. Bethesda, MD: Strengthening Health Outcomes through the Private Sector Project, Abt Associates Inc.

[25] Premises include those dealing with cosmetics and food products.

3.2.2 Pharmaco-vigilance

TFDA has published guidelines for pharmaco-vigilance, and forms for reporting adverse drug reactions are available for download at the TFDA website.[26] Forms for reporting of adverse drug reactions are also being distributed to health facilities and pharmacies in public and private sectors. Collection of reports is being coordinated through 7 regional centres (mostly situated in regional hospitals). Through this spontaneous reporting system TFDA was able to collect over 7,000 adverse event reports over the past 10 years. In addition, TFDA has a cohort event monitoring system for active surveillance of products with high public health relevance (e.g. anti-malarials, medicines to treat tuberculosis and HIV/AIDS). There is collaboration with PSS to support decentralised pharmaco-vigilance activities.

3.3 Ensure gender sensitive, equitable availability and rational use of quality pharmaceuticals, medical supplies and equipment in health facilities

Expected results under this strategic objective focus on the service delivery level. They address competencies and logistics systems required to ensure that medicines are available so that adequate treatment can be provided – an integral part of quality health care.

3.3.1 Medicines availability

Medicines availability is to be monitored to assess progress with the strategic objective and is also included as an input indicator for assessing overall health systems performance during HSSP III. The HSSP III does not provide a baseline for this indicator and the 2015 target was 'to be determined'.

Annual health sector performance profiles reported on the indicator for the first time for the period 2010/11. Due to on-going changes in the routine Health Management Information System (HMIS), including the definition of tracer medicines, data to assess availability was sourced from quarterly end user surveys supported by the President's Malaria Initiative. These surveys record availability at health facilities of a set of tracer medicines at the day of survey. The findings do not show major changes in availability over time, with tracer medicines being available in on average 75% of facilities in 2009/10 and in 71% of facilities in 2010/11.[27]

Additional sources documenting availability of medicines are the Service Availability and Readiness Assessments (SARA), the sentinel monitoring in Service Panel Districts (SPD), and the revised District Health Information System 2 (DHIS2). Table 4 provides a selection of related findings.

[26] TFDA. 2010. National Guidelines for Monitoring Medicines Safety. 2nd Edition. TFDA, Dar es Salaam
[27] MOHSW, Policy and Planning Department. 2011. Health Sector Performance Profile Report 2011. MOHSW 2011

Table 4: Medicines Availability – Various Sources

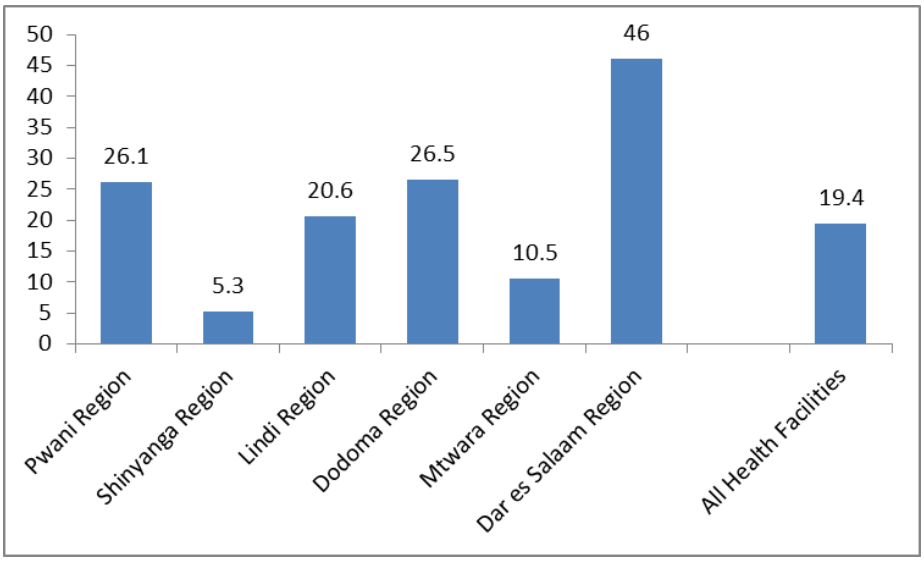
Indicator	Indicator Value	Data Source
Availability at day of visit all facilities (21 items, mean)	37%	SARA 2008/09
Availability at day of visit all health facilities (14 items, mean)	41%	SARA 2012
Availability at day of visit public sector facilities (14 items, mean)	37% (range 2-100%)	SARA 2012
Availability at day of visit private sector (14 items, mean)	55 % (range 7–100%)	SARA 2012
Availability throughout reporting month (10 items, mean)	<8: 9 districts >8: 8 districts	SPD 09-11/2011 (17 districts)
Facilities with no stock out of 10 tracer medicine in reporting month	28.6% (range between districts: 5.8 to 54.1%)	DHIS2 05/2012 (1 region)

While the data presented in table 4 are not necessarily comparable (different sample sizes, different number and type of tracer medicines, different methodologies) the overall picture shows that there is no clear trend with regard to improvement of medicines availability during the review period. The 2012 SARA survey established that availability is better in urban than in rural areas and in private than in public sector facilities. In addition, SARA results show that non-availability of generic medicines for the treatment of non-communicable diseases is particularly bad.[28] A previous study showed that availability seems to be more affected by individual district factors than by zonal factors, such as the availability at MSD zonal stores.[29]

The measurement approach applied in the DHIS2 is innovative as it intends to link availability of tracer medicines to service readiness.[30] For example, for some tracer items, alternative medicines are grouped together. Availability of just one of the alternatives would still allow adequate treatment (e.g. oxytocin OR ergometrine OR misoprostol for prevention of post-partum haemorrhage). In addition, in DHIS2, the availability of tracer items is measured as being in stock during the whole reporting period (1 month). For out of stock items, the DMIS2 form allows for capturing information on the period out of stock. For the MTR-Analytical Report a preliminary analysis for the 6 regions where DHIS2 is being implemented has been done. Figure 3 shows the great variability of medicines availability between regions. Amongst other reasons, this may be due to differences in scheduled receipts of MSD deliveries. Once information will be available for longer periods (e.g. 1 year) more valid conclusions can be drawn.

[28] *Tanzania Service Availability and Readiness Assessment (SARA) 2012* – final report submitted for review; 21 March 2013
[29] Chimnani, Jaya et al. 2010. *Tanzania: Review of the Health Facility Report and Request Forms at MSD Zonal Stores*. Arlington, Va.: USAID | DELIVER PROJECT, Task Orders 1 and 3.
[30] Tracer items for DHIS2 and SPD are: Vaccine DPT- HepB- HiB; Artemether- Lumefantrine oral; Amoxycillin or Cotrimoxazole oral; Albendazole or Mebendazole oral; Oral Rehydraton Solution; Ergometrine or Oxytocin inj. Or Misoprostol oral; Medroxyprogesterone injectable contraceptive; Dextrose 5% or Dextrose--- Saline IV sol.; Syringe and needle disposable; Malaria Rapid Diagnostic Test or supplies for malaria microscopy; 2 additional items can be added as per local government needs.

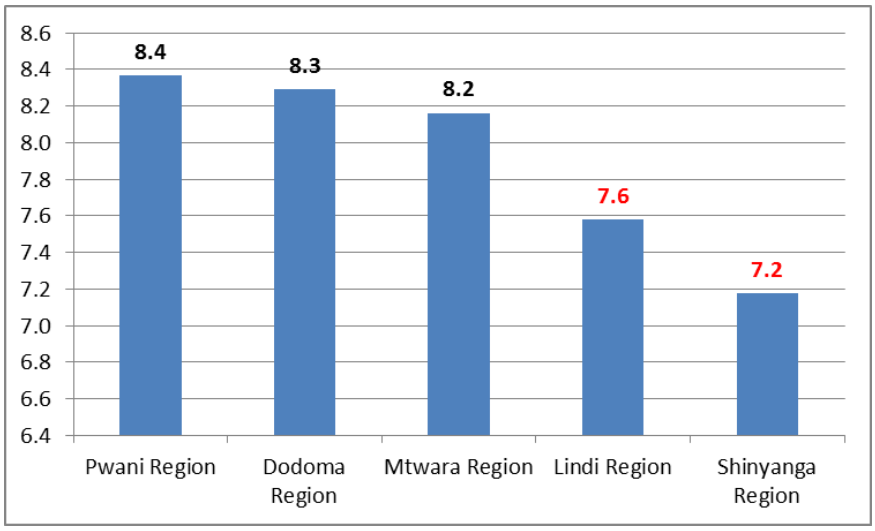
Figure 3: Percentage of health facilities with no stock-out of 10 tracer items during March 2013



Source: MTR-Analytical Report 2013 sourced from DHIS 2 (p 101)[31]

Based on the first findings using the new approach, PSS suggests availability of at least 8 of the 10 tracer items as a benchmark for quality. This reflects the target set in the Comprehensive Council Health Planning Guidelines (% of health facilities with at least 75% of tracer items in stock).[32] Figure 4 documents first results for this indicator for 5 regions for the period April to June 2013.

Figure 2: Average number of tracer medicines available (10 items; monthly average April-June 2013)[33]



[31] MOHSW, NIMR, IFI, WHO 2013. *Midterm Analytical Review of Performance of the Health Sector Strategic Plan III 2009-2015.* September 2013

[32] MOHSW, PMO-RALG. 2011: *Comprehensive Council Health Planning Guidelines 2011*; URT 2011

[33] Made available by the MOHSW Adviser - Health Quality Assurance and Pharmaceuticals

The source data reveals that variations between councils within regions can be high, e.g. the number of tracer items in Dodoma Region councils varies between 7.3 and 9.6., which indicates that council management capacity has an important impact on medicines availability. Further preliminary analysis of specific tracer items during the period April to June 2013 identifies the following items as being least available: malaria rapid diagnostic tests, medicines for treatment of post-partum haemorrhage, oral antibiotics and injectable contraceptives. Annex 2 provides more examples from the preliminary analysis.

The overall MTR finding is that availability of key medicines remains low and that no clear trend for improvement can be established yet. This negatively affects quality of care and performance of service provision in general.

3.3.2 Procurement and supply management system (logistics systems)

Effective logistics systems are a pre-condition for sustained availability of adequate quality assured medicines to the end user. Procurement and distribution of essential medicines by MSD and pharmaceutical logistics management practices at councils and health facilities have been extensively reviewed already – such as through the 2011 Controller and Auditor General Special Audit on Availability of Medicines and the Supply Chain Strategic Review in 2013. The first study was requested by Health Basket Partners to assess added value and risks related to the additional HBF allocated to health facility accounts at MSD, the second study was requested by the MOHSW responding to concerns raised in Parliament regarding low availability of medicines at the community level. Both assessments raised similar issues:

- **Central level procurement (MSD)**

  Inadequate quantification, prolonged tender processes, long supply lead times, and poor supplier performance all affect procurement effectiveness and efficiency. Cash flow is severely affected by the outstanding debt of MOHSW, mainly originating from unpaid clearing, storage and distribution fees for items procured by vertical programmes, and exacerbated by unpredictable disbursement of funds to MSD health facility accounts.

- **Order processing and delivery (MSD)**

  MSD order fulfilment remains low. Health facilities and councils report order fulfilment rates of 50% to 60% (in terms of value), while MSD current estimates stand at 65% to 70%. MSD does not always adhere to the established delivery schedules and health facilities report receiving non-ordered items. (The latter might be due to communication issues. For example, MSD does substitute for ordered items that are out of stock and also delivers items 'pushed' by vertical programmes. If no order is being received at all MSD sometimes decides to send supplies based on information available in the system.) Inventory and information management at MSD is still affected by delayed implementation of some features of the Enterprise Resource Planning (ERP) system.

- **Inventory management and order processing at health facility level**

  Capacity at health facilities to use the Integrated Logistics System (ILS) remains inadequate (knowledge, time, supervision). Overall record keeping (inventory control, prescribing, dispensing) is weak which facilitates leakages of supplies to the private sector (see Box below). Adherence to good storage practices varies. During field visits the MTR team noted very well kept storage areas for HIV/AIDS Care and Treatment Centre supplies, while in the same stores essential medicines storage was inadequate. Opportunities for extending the benefit of partners' technical support for vertical programmes to all essential medicines are not being realised. Accumulation of expired medicines at health facilities varies but there is lack of clarity at councils about the right procedures for their disposal.

- **Procurement at council level**

  When medicines are out of stock at MSD, health facilities and councils can use cost sharing and council health basket funds to procure from alternative suppliers. Councils are procurement entities as per the Public Procurement Act and do pre-qualification of pharmaceutical suppliers as required. The majority of health facilities find the procedures very complicated, but some funds are still being used for this procurement alternative. A study conducted in Dodoma region in 2012 showed that there were no common guidelines; that it was difficult to comprehensively trace these alternative procurements at the council level; that prices were higher than those of MSD and not-for profit suppliers; and that performance of pre-qualified suppliers varied in terms of quality assurance, availability and supply lead time.[34]

The problem of leakage

The 2007 drug tracking study found that record keeping at all levels is poor and that is was therefore difficult to establish whether all supplies that left MSD arrived at health facilities and were issued to patients. The same study cited TFDA reports stating that in 5% of Duka la Dawa outlets inspected MSD items were found.[35] At the Mbeya Regional Health Forum in July 2013 Mbarali district presented the results of an audit performed as a response to community complaints about unavailability of medicines. The audit established big discrepancies between recorded quantities received and issued. These were contributed to either negligence or lack of knowledge for record management. Warning letters were issued that requested explanations for apparent losses. At the Regional Health Forum it was resolved that councils form drug audit committees which will conduct quarterly audits in public and private sector health facilities.[36] A comprehensive study quantifying possible leakages from the public sector could not be identified.

During the period under review, work was initiated to address some of the issues causing underperformance of the system, including:

- MSD piloted and rolled out the direct delivery system to health centres and dispensaries to address transport constraints at council level and improve accountability and customer relations. By the end of 2012, ten regions were covered and plans were to cover all 25 regions by end 2013. Challenges mentioned by MSD were related to capital investment (vehicles), and how best to cover hard to reach areas. A comprehensive study assessing whether the direct delivery system has actually increased availability, and the status of contextual factors and challenges is about to start. Modalities for MSD to recover the high cost of direct delivery are still being considered. With support of USAID and the Global Fund, MSD also upgraded a number of zonal warehouses to improve storage conditions and space. MSD has pre-qualified 20 local pharmaceutical suppliers to be used in emergency stock out situations as an alternative to existing supply contracts (international tender) where lead times are long.[37] During June/July 2013, MOHSW debt to MSD was verified (96% verified - exit conference pending). However, the budget allocated by MOHSW in 2013/14 for repayment (TSH 2 billion) will only cover a small part of the outstanding debt (appr. TSH 40 billion)[38].

[34] Wiedenmayer K. 2012. *Report on private supplier assessment – Medicines management*. Swiss Tropical and Public Health Institute. Basel.
[35] Euro Health Group. 2007. *Drug Tracking Study – Final Report*. URT.
[36] Mbeya Regional Health Forum, 25-26 July 2013. Resolutions and Way Forward
[37] MSD would also consider having a formal relationship with Mission for Essential Medicines Supplies (MEMS) Ltd. once this new company has been successfully set up.
[38] Printz N et al. 2013. *Strategic Review of the National Supply Cain for Health Commodities in Tanzania;* URT, Ministry of Health and Social Welfare; Tanzania

- PSS has conducted training of health facility staff in ILS and ILS gateway during 2012 and 2013, and is currently finalising data analysis of the 'Medicine availability tracking and monitoring in public health facilities' study conducted in 21 regions. The study will provide up to date information on MSD performance (zonal stores) and pharmaceutical management practices at health facilities. PSS has also supported regions with the processes of disposing of expired medicines and is developing guidelines to that regard.

3.3.3 Rational use

Appropriate medicines use by health workers and the community is a precondition for quality health care provision, prevention of resistance, reducing the occurrence of adverse events, and efficient use of resources. A recent comprehensive study on medicines use in Tanzania could not be identified. Improved use of medicines is one of the expected outcomes of the revised National Medicines Policy. During the period under review the following was accomplished:

- Medicines and Therapeutics Committee (MTC) guidelines were developed, training conducted and MTCs re-established at public sector hospitals.[39]
- The National Medicines and Therapeutics Committee was re-established, and the Standard Treatment Guidelines and National Essential Medicines List from 2007 revised.[40]

An assessment of the effectiveness of the MTC training and a rational medicines use survey are planned by PSS.

During the MTR field visits, the existence of MTCs at hospitals was confirmed. Identified challenges indicated that meetings are not held regularly and that MTCs tend to focus on medicines procurement rather than on improving the use of medicines or monitoring of adverse drug reactions. The guidelines also foresee MTCs for primary health care facilities. Those have not yet been established.

3.4 Enhance harmonisation, coordination and information management

3.4.1 Standard Operating Procedures for procurement and distribution

Procurement of medicines through parallel systems using donor funds poses a management challenge to MSD, because information is not always provided on time (delays clearing, storage space might not be available) and items can overlap (e.g. some medicines for the treatment of opportunistic infections) leading to overstocks and expiry. In terms of distribution, some supplies are managed separately (e.g. using separate ILS forms).

Standard Operating Procedures that are agreed and adhered to by all partners have not yet been developed but the activity will be included in the Strategic Plan 2014-2016 for MSD (currently being drafted).

[39] MOHSW. 2012. *Medicines and Therapeutics Committee Guidelines – Tanzania Mainland*. URT.
[40] MOHSW. 2013. *Standard Treatment Guidelines and National Essential Medicines List – Tanzania Mainland*. URT. 4th Edition. July, 2013 (in print)

3.4.2 Logistics management information system (LMIS)

The main LMIS in use is the paper based ILS which does not provide easily accessible information at council, PSS or MSD level, and which health workers struggle to use properly, as reported during the MTR visits. A study done in 2010 noted submission of incomplete forms, submissions not in line with the scheduled ordering time or delivery group, and delays between completion of forms and arrival at MSD zonal stores.[41] According to the 2013 Strategic Supply Chain Assessment these problems seem to persist. Some evidence exists that mobile technology used for reporting of stock outs of 20 tracer medicines (ILS gateway) does improve reporting rates and timeliness. However, ILS gateway does not provide all logistics information and it will be difficult to extend that system to include all essential medicines (limited by number of lines accepted for Short Message Service/SMS). There are opportunities for lessons to be learned from initiatives in the region, e.g. the mobile ordering system at the Kenya Medical Supplies Agency.[42]

Availability of logistics information from zonal and national MSD stores has been affected by the delayed implementation of the new ERP system. MSD stated that by now the warehouse and sales modules are fully operational and reports on stock levels are available.

The MOHSW, with support from its partners, is currently developing the eLMIS including the establishment of a Logistics Management Unit (LMU). The number and scope of existing Supply Chain Management Advisors at zonal MSD stores will be increased. The eLMIS will computerise the ILS and vertical programme data at zonal levels and thereby increase data visibility and facilitate use of logistics information for decision making. The Central level launch of eLMIS is expected for September 2013. The MOHSW also plans to establish a LMU, requiring large investments, particularly related to human resources (with approximately 60 staff distributed at zonal and national level estimated). This is currently supported by partners (e.g. Global Fund and USAID), and concerns regarding sustainability arise.

The recent supply chain management assessments advocate for simplified logistics management information – including order preparation and processing - at the health facility level. There is overlap in reporting using the mobile systems (SMS for Life, ILS gateway) and the DHIS, which is seen as unnecessary burden by health workers.

3.5 Cross cutting issues

3.5.1 Quality improvement

Standard Treatment Guidelines and the National Essential Medicines List guiding appropriate selection and use of medicines are available and have just been updated. Recent surveys assessing the use of these documents or reviewing prescribing practices could not be identified. Unavailability of medicines is expected to negatively affect the provision of quality treatment as per guidelines.

Standard Operating Procedures and guidelines for supply management and pharmaceutical management are available, e.g. the ILS Manual and the MTC guidelines. The previous sections noted the existing challenges with implementation of these procedures, often related to insufficient follow-up and supervision.

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[41] Chimnani, Jaya et al. 2010. *Tanzania: Review of the Health Facility Report and Request Forms at MSD Zonal Stores*. Arlington, Va.: USAID | DELIVER PROJECT, Task Orders 1 and 3.

[42] See e.g. https://strikingpoverty.worldbank.org/#quicktabs-discussion_qt8=3 or http://www.cdcfoundation.org/blog-entry/kemsa-e-mobile-launch-kenya (accessed 22 August 2013)

Currently, Continuing Professional Development (CPD) is offered by the Pharmaceutical Council and others, but not yet mandatory. Pharmacy professionals are apparently reluctant to pay for related courses. The new Pharmacy Act 2011 mandates the Pharmacy Council to establish, develop and control standards for CPD. These are under preparation and in the future CPD will be mandatory to maintain registration with the Pharmacy Council.

3.5.2 Equity improved for underserved populations and vulnerable groups

Persisting problems with unavailability of medicines in public health facilities exacerbate existing inequities because the poor are much less likely to be able to buy prescribed medicines from alternative quality assured sources. In addition, alternative formal providers remain concentrated in urban and peri-urban areas. Medicines stock-outs are also the main reason for the rural poor and vulnerable not to enrol in the Community Health Fund and are also contributing to overall low outpatient attendance, as noted during the field visits. For equity gaps documented in the MTR-Analytical Report 2013 for some HSSPIII indicators (e.g. proportion of birth in health facilities) unavailability of medicines may be one of the contributing factors.

The new resource allocation formula for pharmaceutical supplies between districts now includes poverty index as one criterion, which should affect equity positively. The direct delivery system being rolled out by MSD is supposed to improve availability at more remote health facilities that were previously more likely to receive their supplies late due to transport constraints at council level. The planned study on the direct delivery system should provide some evidence on this assumption. In case MSD decides to apply higher transport charges for difficult to reach facilities there will be need for measures ensuring that these facilities will be compensated.

The revised National Medicines policy aims at ensuring availability and equitable access to essential medicines at all levels. The related draft implementation plan does, however, not include explicit strategic objectives and activities to address existing inequities. There is an opportunity to still address equity and other cross cutting issues in the final version, including in the monitoring and evaluation framework.

3.5.3 Gender

Gender is not specifically addressed in the National Medicines Policy, and specific gender sensitive strategies in terms of pharmaceutical supplies management could not be identified.

One relevant finding of the Draft Analytical Report is that contraceptive availability might have declined between 2008/09 and 2012. Similarly unmet demand for family planning did not decrease during the period. A 2011 study noted stock outs at primary health care facilities of specifically injectables (62%) and implants (26%), and client interviews revealed that 32% did not receive the family planning method of their choice.[43]

In terms of pharmaceutical services related to non-communicable diseases observed unavailability of adequate treatment options might disproportionately affect men who tend to have a higher prevalence of related risk factors (e.g. smoking, alcohol consumption).

[43] Kihombo A. et al. 2011. *A comprehensive reproductive health commodity security (RHCS) assessment in Tanzania Mainland – draft report*. Mzumbe University; Directorate of External Linkage and Community Engagement

4. Governance

There is continuing commitment of government and partners to strengthen the pharmaceutical procurement and supply system, but a champion within the MOHSW to lead reform processes and 'pull the strings together' is still missing. According to some respondents, the relatively low position of the PSS in the MOHSW hierarchy may contribute to this as it makes it difficult to effectively coordinate/communicate with other MOHSW departments, programmes and partners on an equal level.

Overall there is not sufficient clarity on the roles and responsibilities of the main players in the supply chain (MOHSW, PMO-RALG, MSD).

4.1 The Pharmaceutical, Infrastructure and Food Safety Technical Working Group

Under the Health Sector Wide Approach (SWAp) Committee, the PIFS TWG is a multi-stakeholder forum tasked to support government in implementation of its overall policies, the HSSP and the National Medicines Policy. It is chaired by the Assistant Director Pharmaceutical Services. Infrastructure and Food Safety have been included in the scope of work in 2009/10.

The PIFS TWG is supposed to meet monthly, although it only managed to meet 6 times during the previous 12 months (August 2012 to July 2013). Members include staff from MOHSW (PSS, Department Policy and Planning, Reproductive and Child Health Section, vertical programmes [TB, Malaria, HIV/AIDS]), MOHSW agencies (MSD, TFDA, Pharmacy Council), and donor and implementing partners (CDC, DANIDA, JSI, USAID, WHO). Individual members and the represented institutions vary and attendance is around 14 members for each meeting.[44] Representation of PMO-RALG in the PIFS TWG is not yet facilitated. Task teams are being set up to work on specific issues. From the minutes it is not clear whether these are working effectively.

In general, the PIFS TWG has clearly contributed to progress in crucial areas. Contributions to the annual Health Sector Profile Reports have improved considerably since 2011, and progress with implementation of process action plans in the context of Health SWAp Milestones has been made (e.g. resource allocation formula, on-going quantification study, definition and monitoring of availability of tracer medicines). In 2013, the PIFS TWG also began monitoring of stock status at MSD. The issue coming back over the recent years is timely and complete disbursement of funds to health facility accounts at MSD. In the PISF TWG, disbursements by Treasury to MOHSW are being reported regularly, those from MOHSW to MSD only from time to time; a system to speed up actual transfers to MSD is supposed to be set up for 2013/14.

PIFS TWG so far has a limited role in coordinating / alignment of donor funded procurement and distribution, although this is part of the HSSP III Pharmaceuticals Strategic Objectives (enhanced harmonisation & coordination). The National Malaria Control and National Aids Control Programmes and the Reproductive and Child Health Division who could facilitate this coordination are rarely attending PIFS TWG meetings.

[44] Established from PIFS TWG minutes covering period August 2012 to May 2013

Members expressed their preference for having a TWG focussing on pharmaceuticals and not having to address infrastructure and food security as well.

4.1.1 Medical Stores Department

MSD is governed by a board and reports to the Permanent Secretary MOHSW. In practice, performance of MSD is to be monitored by the PSS. During the period of transition to the new ERP system relevant MSD key performance indicators could not be reported on.

In response to the findings of the 2011 Special Audit on Drugs Availability at MSD, MOSHW and MSD had set up an action plan. Progress status on implementation as per April 2013 is available and was discussed at the April 2013 PIFS TWG meeting.[45] Completion of some activities was pending. MSD reported to the MTR team that all issues were now addressed. Due to time constraints this could not be explored further.

The 2011/12 procurement audit performed by the Public Procurement Regulatory Authority (PPRA) still noted some of the issues found in the Special Audit.[46] With an overall score of 81% (PPRA threshold: 80%) MSD ranked number 9 out of the 20 audited entities (the MOHSW scored 66% and ranked number 19).[47] In terms of transparency, information available on the MSD website, such as the customer charter and standard tender and contract documents, is missing. Examples from the region are available on how information relevant to the public can be made available (e.g. by the Kenya Medical Supplies Authority KEMSA).[48]

4.1.2 Accountability and Responsibilities at Council Level

Council level actions to address accountability issues are not clearly specified in the MOSHW/MSD special audit action plan, probably because this would be the competency of PMO-RALG and Local Government.

MOHSW through PSS and partners has provided training to management teams and health workers on adequate record keeping in the context of the ILS. However, capacity constraints persist at health facility level but also a council level in terms of pharmaceutical human resources and vehicles for continuous mentoring and supervision. It is, however, crucial that councils and District Medical Officers take on their responsibility to ensure that medicines are available, handled properly and are not at risk for either expiry or pilferage. Lessons can be learned from other experiences, such as the approach used by the zonal Supply Chain Management Advisors for pharmaceutical supplies for HIV/AIDS Care and Treatment Centres and from the 'accountability' initiative in Mbeya Region mentioned earlier.

[45] *MoHSW & MSD Action Plan on Special Audit Report on MSD I Medicines (30/06/2009 – 30/06/2011)*. April 2013 update
[46] N.B. PPRA audits include assessment works and services procurement/contract management, while the Special Audit addressed procurement of pharmaceutical goods only.
[47] Public Procurement Regulatory Authority. 2012. A SUMMARY REPORT OF PROCUREMENT AUDITS IN ONE HUNDRED AND TWENTY ONE PROCURING ENTITIES – FY 2011/12
[48] See: www.kemsa.co.ke (accessed 02/10/13)

5. Crosscutting SWOC Analysis

The crosscutting SWOC analysis in Table 5 applies the health systems performance criteria from the analytical framework, i.e. access, coverage, efficiency, safety, quality, equity, and sustainability to the pharmaceutical sub system.

Table 5: Crosscutting SWOC Analysis

Strengths	Weaknesses
▲ **Efficiency, equity**: new resource allocation formula developed ▲ **Efficiency**: economies of scale through central level pooled procurement ▲ **Efficiency:** on-going organisational reform at MSD ▲ **Efficiency, quality**: innovative data management using mobile and web based technology ▲ **Coverage/Access**: distribution system up to health facility level ▲ **Quality:** availability of updated management & clinical guidelines ▲ **Quality**: WHO pre-qualified quality control laboratory at TFDA	▲ **Efficiency, Quality: little focus on appropriate use of and accountability for medicines** ▲ **Efficiency: procedures & practices using council and cost sharing funds for medicines procurement** ▲ **Sustainability: high dependence on donor funding for procurement & operational activities** ▲ **Access: inadequate pharmaceutical human resources especially at regional/district level** ▲ **Equity: stock-outs of essential medicines with no compensating measures to ensure access by the poor** ▲ **Quality: inadequate capacity for quality assurance of private sector pharmaceutical services & products (e.g. ADDOs)**
Opportunities	**Challenges**
▲ **Efficiency, equity**: learning from vertical programme successes and from pilot projects ▲ **Efficiency, quality**: EAC regional projects for medicines regulatory harmonisation & production ▲ **Sustainability**: on-going work on health financing strategy ▲ **Quality**: MOHSW focus on quality improvement ▲ **Coverage**: extending models of care & treatment centres to other chronic diseases	▲ **Sustainability: existing budgets unlikely to increase** ▲ **Coverage: increased prevalence of non-communicable diseases**

6. Conclusions and Recommendations

One of the main performance criteria for the medical supplies building block is availability of adequate quantities of quality assured and affordable essential medicines to the public. Medicines availability is included as health systems indicator in the HSSP III. For the first half of the HSSP III implementation period the MTR assessment found that despite completion of important interventions no real progress was made regarding medicines availability in the public sector; that while achievements in quality assurance can be noted, medicines quality in the private sector is still not always guaranteed; and that systems ensuring accessibility and affordability for the poor in the private sector are yet to be established.

Reasons given for existing problems with medicines availability tend to focus on inadequate budgets and MSD performance. However, downstream supply management issues such as inventory management capacity at health facilities and supportive supervision from council level do have a significant impact and need to be addressed as an additional priority. There is continuous commitment of partners to support pharmaceutical procurement and supply management but there is room for better coordination and lessons learning including from work done in the context of vertical programmes.

The revised policy milestones for pharmaceutical governance / management are an encouraging example for how the MOHSW and local government can work together to take up the challenges at council level, also taking into account the high performance variation between councils.[49]

Overall the HSSP III strategies for the area of pharmaceuticals remain relevant. For the remaining period the implementation framework for the National Medicines Policy, and increasing TFDA and Pharmacy Council capacity for market control (including ADDOs) will need to be addressed.

Many specific and valid recommendations were made in recent pharmaceutical sector reports. The focus of this MTR is on identifying broader approaches that will assist the MOHSW to achieve the objectives of the HSSP III.

6.1 Enable adequate performance of MSD

MOHSW should establish a task force to address as a priority all issues related to disbursement of funds to health facility accounts at MSD, to prepare a plan for settlement of MOHSW debts with MSD, and to establish modalities for payment of clearing, storage and distribution costs arising from vertical programme supplies.

6.2 Assess options for complementary supply through the private sector

Low budgets are not the only reasons for medicine stock outs. Even when funds are available in health facilities' accounts, MSD cannot currently supply what is being ordered. Two ideas have been mentioned by respondents in the MTR to address the situation, (i) MSD is assessing options for local contracting to address delays related to international procurement, and (ii) Dodoma region is considering a pooled

[49] '*Revised Milestones 16.09.2013 Pharmaceuticals*'. Made available by the Assistant Director Pharmaceutical Services

procurement system with a prime vendor for additional medicines procurement using health facility cost sharing and council funds.[50] A general challenge is the relatively small private sector which affects competition. The large market share currently held by MSD is one contributing factor. The Mission for Essential Medicines Supplies (MEMS) is in the process of setting up a not-for-profit wholesale business. The MEMS business plan envisages that the company will also serve public sector clients as an alternative to MSD, but also states the possibility of having a formal working relationship with MSD (not further defined).[51] Mixed models have also been discussed where an alternative private sector prime vendor could be contracted for procurement of items frequently out of stock at MSD but delivery would be through the MSD system.[52]

A comprehensive study should therefore be conducted to thoroughly identify and assess options and innovative solutions. Overall considerations need to include efficiencies through pooled procurement; capacity, performance and quality of private sector; which shares of health facility funds are best to be held where; and what the core business of MSD is / should be.

6.3 Capacitate regional and council level and focus on health facilities

Many of the identified challenges impacting access to medicines are related to skills and capabilities of front line health workers in charge of medicine management, prescribing and dispensing. Implementation of existing systems and procedures needs regular mentoring and supervision by Council Health Management Teams supported by their regional counterparts. There is need to continue and further strengthen capacity building of the decentralised levels. This is a mutual responsibility of MOHSW (providing technical support) and PMO-RALG. Local government is ultimately accountable for pharmaceutical management in their jurisdiction. The ILS system should be reassessed considering what realistically can be expected from health workers at health centres and dispensaries who will remain being in charge for pharmaceutical supply management for some time. The establishment of the Logistics Management Unit in the MOHSW foresees an increase in number and scope of the existing Supply Chain Management Advisors posted at MSD zonal stores. However, they will not be accountable to local government, and responsibilities need to be clearly demarcated. For the medium term the position of a district commodity manager (recommended in the Strategic Supply Chain Review) could be considered, who would support health facilities in pharmaceutical supply management and be answerable to the District Medical Officer. This would free up time for the district pharmacist to focus on quality of pharmaceutical care.

Based on detailed analysis of medicines availability data from the DHIS2, weakest councils and health facilities should be identified and receive targeted support in management of pharmaceuticals.

In terms of accountability Health Facility Governing Committees should be capacitated to not only witness receipt of supplies but also to monitor availability. Where relevant Civil Society Organisations exist, these could be involved in monitoring and reporting of medicines stock outs. An example is the 'stop the stock-outs' initiative in Kenya, Uganda and Zambia.[53] Accountability measures included in the revised milestones mentioned above are fully supported by the MTR team.

[50] Mbwasi R. 2013. DODOMA STAKEHOLDERS' MEETING HELD AT NEW DODOMA HOTEL ON MARCH 22ND 2013 – Summary Report; Health Promotion and System Strengthening Project (HPSS); Dodoma
[51] MEMS. 2013. *Business Plan 2013-2015*. MEMS
[52] This would address restricted logistics capacity of the existing private sector.
[53] See: http://stopstockouts.org/ (accessed 03/10/13)

6.4 Create a common vision and plan of action for supply chain reform

There is the opportunity for the MOHSW for development of a prioritised Supply Chain Action Plan as a follow up to the Strategic Supply Chain Review. Led by the PIFS TWG the process should include all relevant stakeholders, most importantly PMO-RALG and councils. Options for action should consider the broad range of recommendations from recent assessments, the draft National Medicines Policy Implementation Plan, and lessons learned from pilot programmes. High impact work streams should be identified and prioritised, and partners be approached pro-actively for funding support. The resulting vision and plan of action would be owned jointly by the MOHSW and PMO-RALG and include clearly defined roles, responsibilities and lines of accountability for all levels.

6.5 Put the focus on efficiency and quality improvement

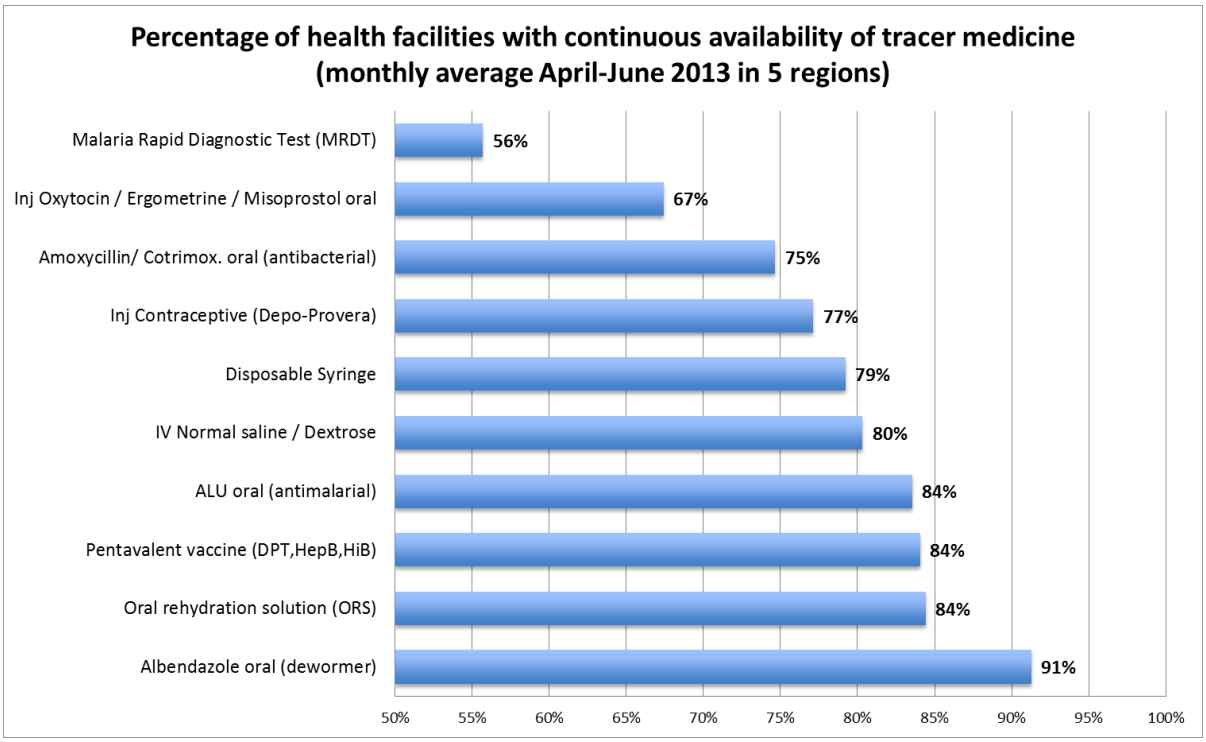
Medicines supply will continue to be constrained by low budgets. However, considerable savings can be achieved through efficiency gains. Efficiency is closely related to quality of pharmaceutical services (e.g. adherence to standard treatment guidelines, providing quality information to patients). Examples include appropriate prescribing and use of medicines, and improved inventory management at all levels (less out-of-stock, expiry, pilferage). This will lead to better availability of medicines to the community. What are the incentives that will support managers and front line staff to strive for quality improvements? What can be shown to the community? All options for priority actions to improve supply chain performance should be assessed against efficiency and quality criteria.

6.6 Consider pharmaceuticals as a proper strategy in HSSP IV

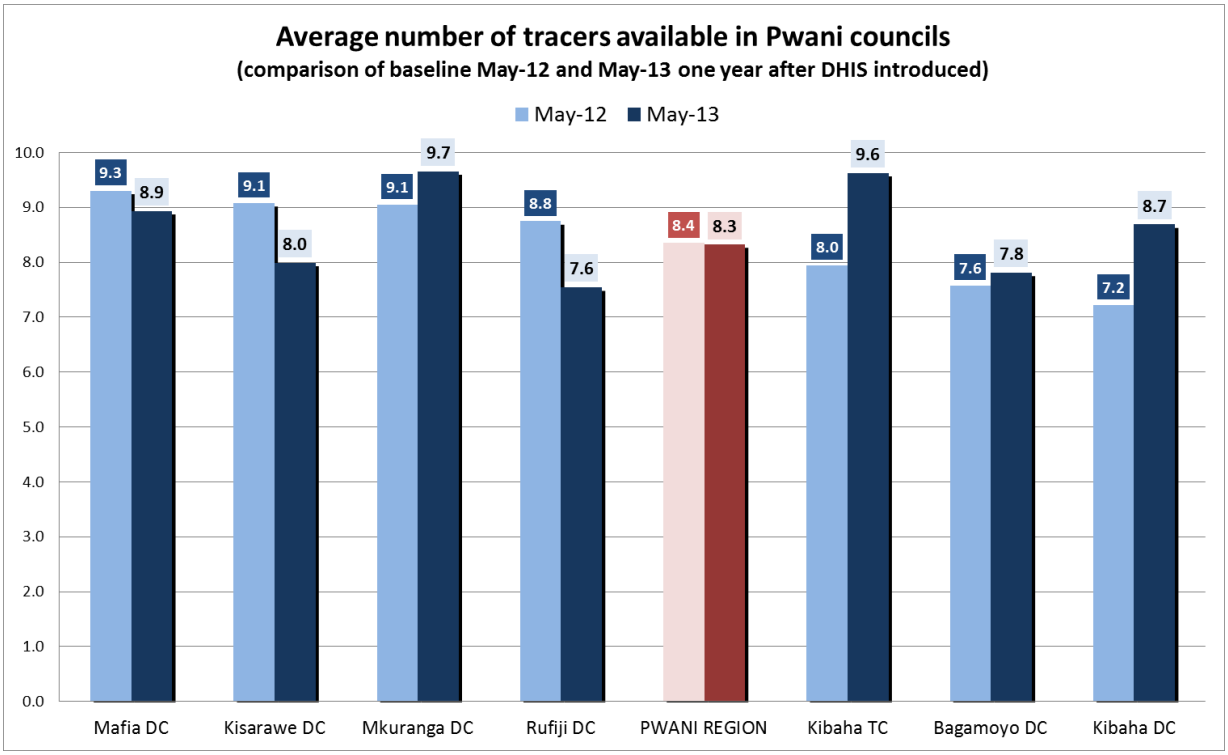
Under HSSP III medicines and supplies are addressed under 'other important issues'. Considering the importance of the pharmaceutical sub sector in terms of budget share and contribution to health outcomes HSSP IV it is recommended to address medicines and supplies in a more comprehensive way as one of the health system building blocks.

Annex A: Examples for results of preliminary analysis of DHIS 2 data on medicines availability

1. Availability of specific tracer medicines in health facilities in Lindi, Pwani, Mtwara, Dodoma, and Shinyanga Regions



2. Number of tracer medicines (out of 10) available in Pwani Region councils



This graph supports the findings of the MTR that there is no clear trend for improved medicines availability. It also shows the differences of performance between councils. Further analysis of the reasons behind these differences could provide valuable information for overall strategies to improve medicines availability.