# Combating Medical Drug Counterfeit in Tanzania: The Role of Technology

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## Abstract

*The infiltration of Counterfeit Drugs (CDs) in the Pharmaceutical Supply Chain (PSC) is adversely affecting health sectors in their efforts to provide quality health services to the public. According to the World Health Organisation (WHO), over 30 percent of anti-malaria drugs sold in the developing countries are substandard. Furthermore, the Confederation of Tanzania Industries (CTI) estimated that 60 percent of the medicines imported into Tanzania are counterfeits. Several initiatives have been taken in an attempt to curb the selling of CDs. However, the effectiveness of these initiatives remains questionable. There is an urgent need to formulate more effective strategies to secure the PSC by involving all stakeholders. In this regard, technology-based solution could be an effective uptake in mitigating CDs. This study assesses how the technology-based system can secure PSC and enable medical drugs verification in Tanzania. The proven adoption of Information and Communication Technologies (ICTs), especially mobile technology, could be leveraged to enable the enforcement of laws and regulations and advocate community awareness on medical safety.*

**Keyword** – Counterfeit drugs, Healthcare, Pharmaceutical supply chain.

## 1. Background

The growth of the market for Counterfeit Drugs (CDs) continues unabated despite the regulatory efforts to curb it by governments and international organisations such as World Health Organization (WHO) and Interpol. CDs can be defined as drugs that are deliberately and fraudulently mislabelled with respect to identity and/or source (WHO, 1999;TFDA, 2003). WHO has discovered an alarming growth rate in CDs market especially in developing nations which has caused alarming rate of ill-health and eventually deaths amongst all level of human development (Agbaraji, 2012). And yet, the problem of CDs remains largely underreported and there has been little information on its prevalence. The few published estimates indicate that CDs prevalence globally ranges from one percent to 50 percent of the global medicine market (WHO, 2005). The developing countries are reported to be mostly

victimised by the effects of CDs (WHO, 2012). According to a survey by WHO conducted in 2010, almost a third of anti-malaria drugs sold in the developing countries were substandard (WHO, 2010).

The circulation of CDs in a pharmaceutical supply chain (PSC) is a problem that contributes to morbidity, mortality, and drug resistance, and leads to spurious reporting of resistance and toxicity and loss of confidence in health-care systems (Newton, Green, Fernández, Day, & White, 2006).The estimate of 192,000 patients killed by fake drugs in China in 2001 indicates the scale of human suffering (Agbaraji, 2012). Therefore, it is important to crack down on this illicit trade, which has been a threat to health services in the developing countries.

Poverty, high cost of medicines, lack of an official supply chain, easy accessibility to computerised printing technology, ineffective law enforcement machinery, and light penalties provide the counterfeiters with an enormous economic incentive without much risk (Utreja & Singal, 2009). Therefore, the war against CDs remains ominous.

Tanzania is also facing the problem of CDs. In 2008, the Confederation of Tanzania Industries (CTI) estimated that 60 percent of the medicines imported into Tanzania were counterfeit. Furthermore, in 2009 CTI claimed that Tanzania was a 'dumping ground' for fake drugs from China, India, Europe and the US, which used the country as a gateway into Africa (Emily, Eva & Maura, 2011). Reports suggest that counterfeit drugs have not only infiltrated the informal health sector but also the official health sector (Emily *et al.*, 2011).

Although several measures have been taken to restrain the selling of counterfeit medicines in developing countries, the problem is far from over. Recently, the Short Messaging Service (SMS) verification method has been adopted in some developing countries such as Nigeria and Kenya. Initiatives such as Hakikisha Dawa campaign in Tanzania (24Tanzania.com, 2013), mpedigree in Ghana (Mpedigree.net, 2014) and Pharmasecure in India (pharmasecure.com, 2014) are among the proposed measures for verifying the drugs' authenticity. However, their effectiveness in addressing CDs in these countries is questionable as their emergence came in enterprise terms; therefore, they have less impact in securing public health system (Dipika & Swathi, 2013).

Generally, there is a need to formulate strategies to secure the PSC from the manufacturer to the end user. Involvement of key stakeholders is vital for understanding the magnitude of the CD problem and how to curb it.

The strategy which will include inputs from various stakeholders can result into an effective way of detecting counterfeit products, increasing audit compliance, enhancing PSC management capabilities, preventing brand erosion, and eliminating the supply chain routing leakage such as misplaced inventory and drug expirations (Sanjay & Sanjeev, 2009).

## 2. Research objectives

This study takes the first step in understanding the magnitude and the challenges of addressing the CD problem in Tanzania. Furthermore, the study assesses how the technology can be applied to mitigate CDs.

## 3. Research methods

In this study, three research instruments were used to gather information. These include the questionnaire, focus group discussions and documentary review.

A 25-question structured questionnaire was designed and administered with citizens in three different regions of Tanzania. The regions were Mtwara, Mwanza and Dar es Salaam. The selection of data collection areas was made based on the prevalence of Malaria. The prior assumption was that the prevalence of malaria is directly proportional to the demand of anti-malaria drugs and naturally the high demand for anti-malaria drugs attracted counterfeiters to produce fake drugs to meet the high demand. The following formula was used to determine the sample size of the study (Yamena, 1967):

$$n = \frac{N}{(1 + N(e)^2)}.$$

Here, $n$-Sample Size, $N$-Total Population, $e$-Detection error expressed into percentage (5%-10%). For $N$=8,407,904 (total population of Mwanza, Dar es Salaam and Mtwara) and $e$=5%, the sample size $n$ becomes 400. A total of 665 participants filled in the questionnaire, 51.8% was from Dar es Salaam, 24.8% from Mwanza and 23.3% from Mtwara.

A plenary and focus group discussion was carried with key stakeholders of the Tanzanian PSC. Six focus groups were randomly created out of 23 participants. The groups included manufacturers, distributors, regulators, consumers, and others such as researchers and health

professionals. Each group was given a checklist to guide their discussion and came up with answers for each question.

Literature review of conference proceedings, technical reports and journal articles was carried. out The process of reviewing selected articles followed the 'literature review steps' defined by Oates (2006). The articles that fall on the context of our objectives were chosen and reviewed accordingly.

Data analysis was performed through the use of the Statistical Package for Social Sciences (SPSS) version 16 and MS-Excel software.

## 4. Results

### 4.1 Respondents Demographic Information

Results based on the demographic information of the general public respondents of gender and educational levels are presented in figures 1 and 2.

**(i)** **Gender:** Results in Figure 1 show that the majority of the respondents in Dar es Salaam (51.9%) and Mtwara (51.6%) were females whereas in Mwanza the males accounted for 56.4 percent of all the respondents. On average, however, there was almost equal representation of females (49.8%) and males (50.2%) in the filling out of the questionnaire. The significant proportion of females' representation in the field data collection and subsequent stages of the research is vital. This is so since females are generally highly affected by the consumption of counterfeit medical drugs, especially during pregnancy (antenatal) and postnatal. This point is further amplified by the fact that two out of three health related MDGs directly target mothers [(i) Reduce Child Mortality (MDG 4) (ii) Improve Maternal Health (MDG 5)]. Moreover, the proportion of females in the population in Tanzania is relatively larger than that of males (URT, 2012; Population and Housing Census, 2013).

**(ii)** **Education level:** Results on the education levels of the respondents indicate a wide variation among the three regions as presented in Figure 2. Whereas 37.7 percent of respondents in Dar es Salaam were degree holders and 19.5 percent were secondary school leavers, the situation was different in Mtwara where 60.9 percent were primary school leavers and 25.2 percent were secondary school leavers. The situation in Mwanza indicates that 42.4 percent of the respondents were secondary school leavers

followed by primary school leavers (33.3%). The difference in levels of education reflects the gap that exists in accessing education among the three regions. Furthermore, the results could be a reflection of the general trend among learned persons to migrate to big cities to pursue employment opportunities. The results suggest a need to take into account these variations in education levels in the intended technology for easy adaptability.

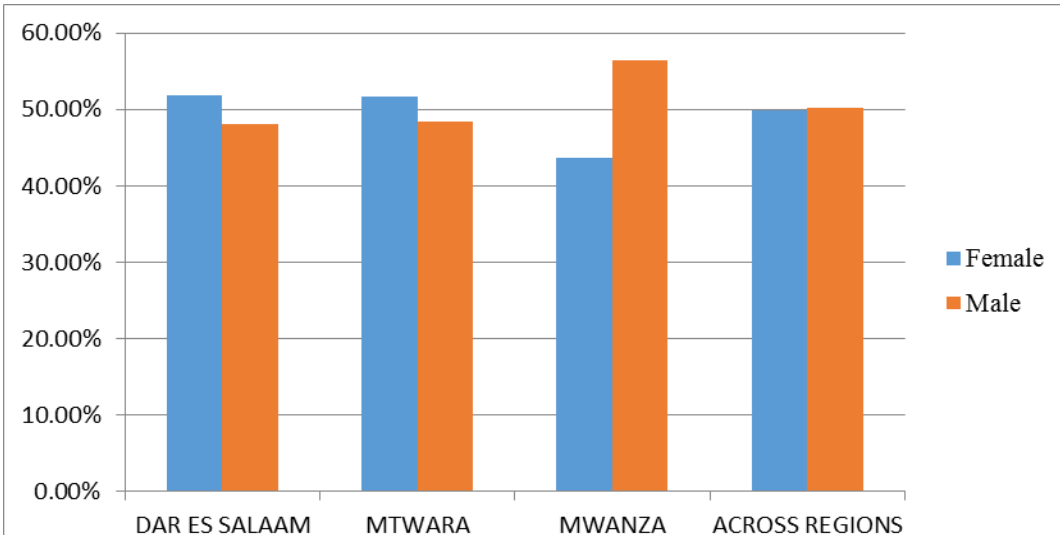



Figure 3: Gender Distribution of Respondents

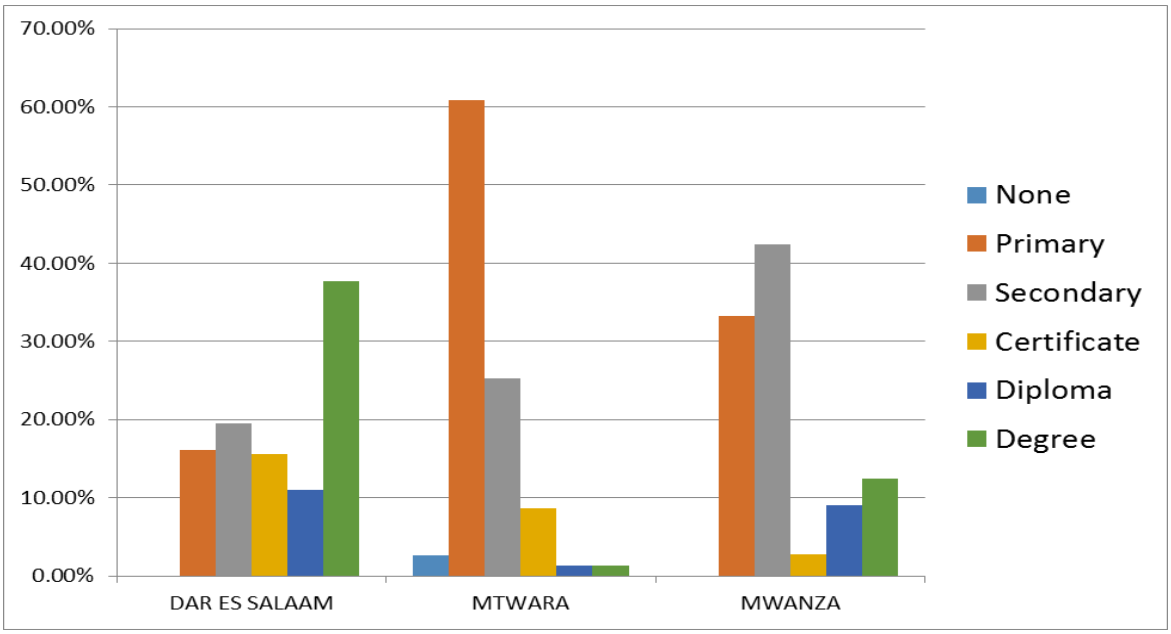



Figure 4: Education Levels of the Respondents by Region

### 4.2 Medical Drugs that Respondents Mostly Deal With

General public respondents indicate that the medical drugs they mostly deal with were anti-malarial drugs (38.7%), painkillers (35.9%) and antibiotics (23.4%). The findings can imply that more often than not anti-malarial drugs and painkillers are taken complementarily. Results presented in Figure 3 show that anti-malarial drugs are mostly dispensed in Mtwara (43.3%) and Mwanza (47.0%) followed by painkillers (33.5%) and (33.6%), respectively.

However, a slightly different trend was observed for respondents in Dar es Salaam where painkillers were identified as the mostly used (38.4%) compared to anti-malarial drugs (34.9%). The findings, among other things, support our initial assumption on the scope of the research that identified anti-malarial drugs as a pilot.

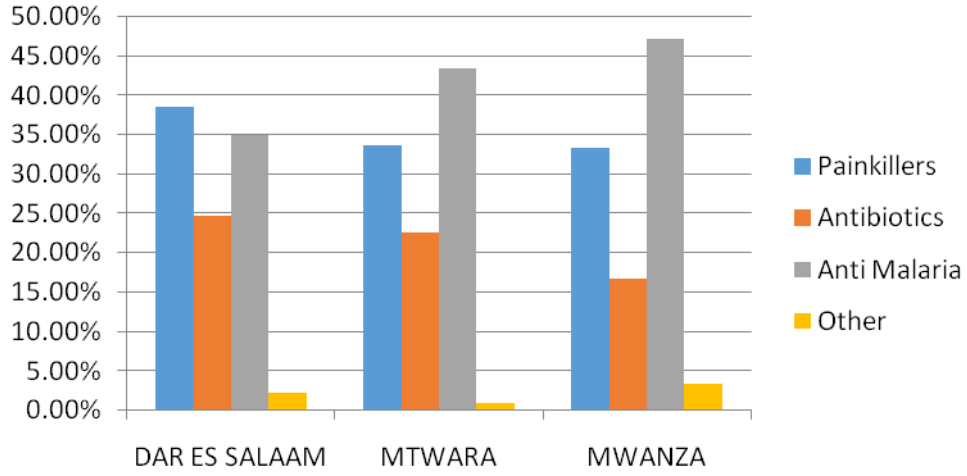



Figure 5: Types of Medical Drugs Respondents deal with by Region

### 4.3 Magnitude of Counterfeit Drugs in Tanzania

The magnitude of the drug-counterfeiting problem is difficult to gauge. Since the crimes of producing and selling counterfeit drugs generally become known only when the perpetrators are caught, any true estimate of prevalence is difficult. Participants in three aforementioned regions were asked to rate the magnitude of the CDs in their areas. As Figure 4 illustrates, 49.8 percent of the respondents in Dar es Salaam, 51.6 percent in Mtwara and 51.9 percent in Mwanza considered the problem to be serious. Moreover, 33.5 percent of the respondents in Dar es Salaam, 25.8 percent in Mtwara and 31.7 percent in Mwanza considered the severity of the problem to be moderate. In addition, 46.5 percent, 32.9 percent and 57.3 percent of the respondents in Dar es Salaam, Mtwara and Mwanza, respectively, reported to have experienced the effects associated with the consumption of counterfeit medical drugs. The

magnitude of the problem as perceived by the respondents calls for prompt action to contain the prevailing situation.

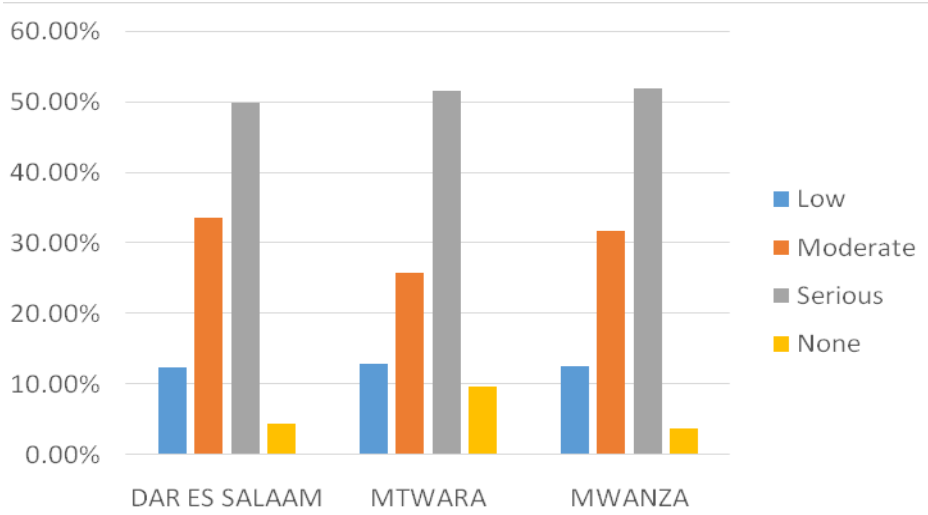



Figure 6 : Magnitude of Counterfeit Drugs in three regions (Mtwara, Dar es Salaam and Mwanza)

### 4.4 Awareness of Counterfeit Drugs

Raising community awareness on CDs is one of the strategies in combating the menace poised by the CDs. The community should be empowered with knowledge that will enable them to be vigilant in detecting any abnormally low-priced medicine as decoy for fake drugs (Davison, 2011). In this regard, the level of awareness among Tanzanians was surveyed. Figure 5 depicts the levels of awareness of CD problems in three study regions. Only 28.5 percent of the respondents said that they were aware of the CD problem, and among these respondents 34 percent were from Dar es Salaam, 23.5 percent were from Mwanza and 16.5 percent were from Mtwara. The discrepancy in levels of awareness among the regions surveyed could reflect the limitation to media access. Thus, the battle of combating the CD problem could be geared towards increasing access to information on the existence of CDs (Newton *et al.*, 2006).

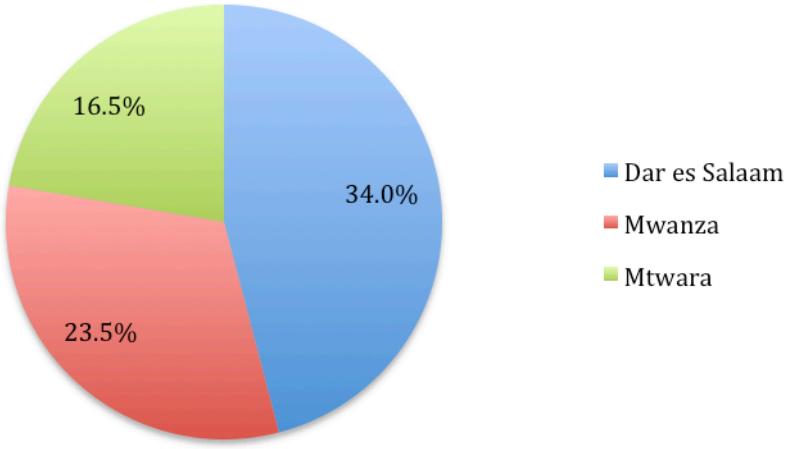



Figure 7 : Level of awareness on Counterfeit Drugs in three regions

### 4.5 Current practices of verifying medical drugs

Currently, there are some methods that are applied by the community to verify the authenticity of medical drugs. During field data collection it was established that only 41.1 percent of the respondents knew at least one method of verifying drugs authenticity. Amongst these respondents, 68.8 percent were from Dar es Salaam, 9.5 percent were from Mtwara and 21.7 percent were from Mwanza. Regarding the methods, which are used n verifying medical drugs, 50.1 percent said they checked the expiration dates, 13.9 percent indicated that they did nothing, 14.8 percent checked the manufacturer's brand (logo), 17.2 percent checked the quality of the packaging, 2.9 percent examined the visible labels and 1.1 percent used other methods such as colours and smell test as depicted in Figure 6. The survey did not find any technology-based tool for verifying medical drugs in public PSC.

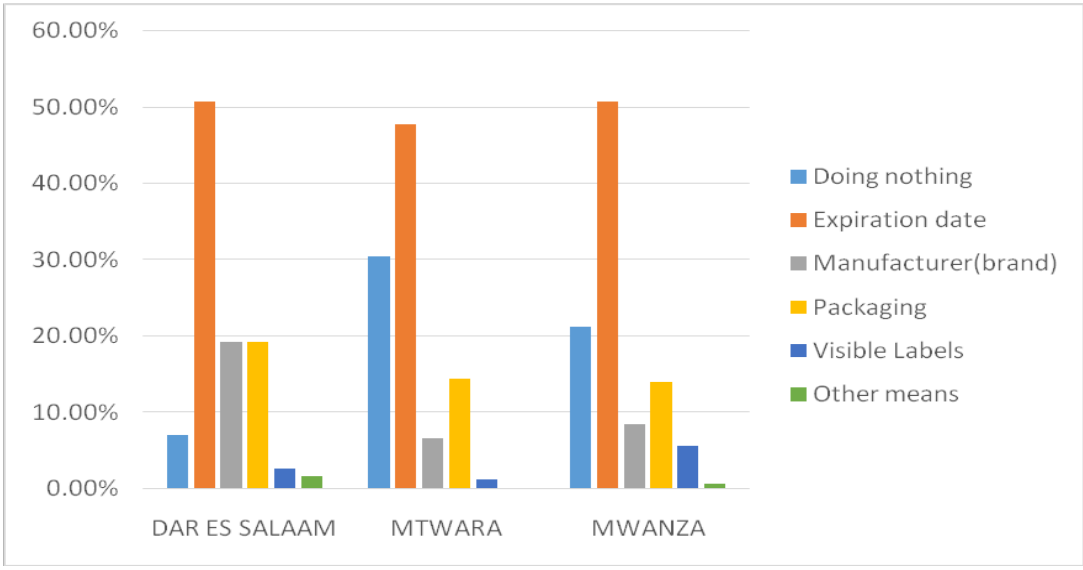



Figure 8 : Methods used to verify drugs authenticity in three regions

The current methods of verifying medical drugs are weak and some are hard to operationalise in the Tanzanian settings. For example, the pilot uptake by TFDA, which used minilabs to improve the testing capacity of regulatory authorities (Peter et al., 2008), has not proved to be cost-effective and did not succeed to reduce the CD problem. Table 2 describes drawbacks of the current practises used by the community and regulatory authorities to verify medical drugs authenticity. Moreover, current efforts to combat CDs encounter gaps which need to be bridged to ensure a secure medical drugs service.

Table 3 presents the gaps of the current efforts for combating CDs.

Table 2: Current Practices on Verifying Medical Drugs

| SN | Current Practice | Weakness /Drawback |
|---|---|---|
| 1 | There are machines for validating the quality of medical drugs at the regional pharmacist offices. | - The machines are few and only few samples are tested.<br>- Lack of experts for operating these machines. |
| 2 | The use of expiration dates to validate medical drugs before consumptions. | - The large community is illiterate.<br>- Expiration dates can be easily forged. |
| 3 | The use of difference in price and sources of medical drugs. | - Sources can be forged easily. |

| | | |
|---|---|---|
| 4 | The use of packaging style and labels. | - These metrics are weak and are easily forgeable. |

**Table 3 : Gaps in the current approaches of combating counterfeit drugs**

| Gaps | Implications | Strategies |
|---|---|---|
| Lack of co-ordination among stakeholders | No comprehensive programme on combating counterfeit drugs.<br>Difficulty to trace the suspect, as there are no terms of reference on cases that may cut across authorities. | Develop national taskforce on stakeholder coordination. (Terms of reference for key play players in the supply chain).<br>Develop a national health interoperability framework to streamline the inter-sectoral co-ordination in combating CDs.<br>Develop database of counterfeit drugs and alert system upon detection. |
| Lack of community awareness on the severity of the CDs problem. | There are no serious community campaigns on the severity of CDs | Develop awareness campaigns on the impact of CDs through media (e.g. TV and Radio).<br>Increase regular workshops for the specific PSC stakeholders. |
| There is weak law on counterfeit Drugs. | No deterrent sanctions | Strengthen legislation by enacting and enforcing laws against drugs counterfeiting. |

### 4.6 Opportunities for Combating CDs using technology

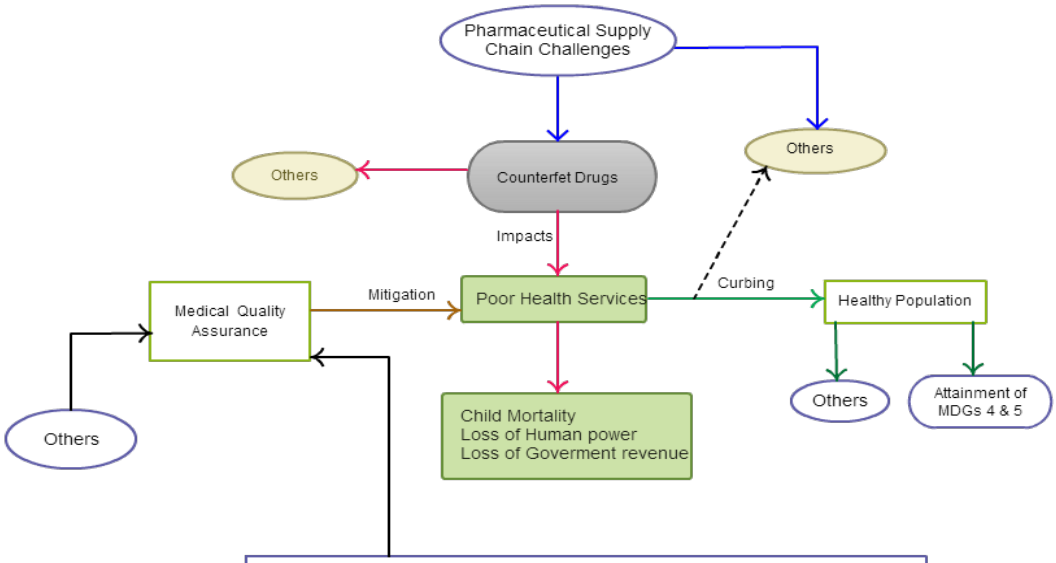
The tremendous adoption of mobile technology in communities could be a stepping-stone in devising methods of reducing the magnitude of CDs. The statistics from International Telecommunications Union (ITU) report that mobile phones are now in the hands of more than 96 percent (6.8 billion) of the seven billion global population, 128 percent in developed countries and 89% in developing countries (ITU, 2013).

In Tanzania, the mobile penetration by the end of 2013 was 61 percent according to TCRA (TCRA, 2013). Similarly, field data in this study report shows that 83.2 percent of the respondents owned mobile phones, 29 percent smartphones and 71 percent basic phones.

Regarding the services that are commonly accessed by these mobile phones, 33 percent use SMS, 51.1 percent voice calls and 15.9 percent access Internet services with their mobile phones. This growth could be an important asset in the development of any solutions for combating CDs in Tanzania such as awareness creation campaigns and even mobile-based drugs verification systems.

Another stepping-stone in the war against CDs is the serious readiness of the key stakeholders. In the focus group discussions with key informants, the researchers recognised the serious desire of different stakeholders in addressing the CD problem. For example, the participants from the Tanzania Food and Drugs Authority (TFDA) and Medical Store Department (MSD) reported how the CD problem affected the quality of services and expressed their readiness to join efforts aimed at solving the problem. Besides, the study indicates that 97 percent of respondents expressed their readiness to explore the use of technology in verifying medical drugs. This study calls for the authorities such as the Ministry of Health and Social Welfare (MOH&SW) to recognise and organise the efforts from various stakeholders to forge a joint national taskforce to combat CDs.

Other strategies that could be implemented to curb the existence of CDs in PSC include the use of technology-based solution, which is touted to be an effective uptake in the process of mitigating CDs. The proven adoption of ICTs, especially mobile technology, could be leveraged to enable laws and regulation enforcement, raise community awareness on CDs, enable consumers to verify drugs, enable data-driven decision and policy-making process and eventually the realisation of a sustainable and secure public healthcare system. Figure 6 presents a proposed conceptual framework of building national medical quality assurance technology-based system:




| Mobile Technology Based Solution | |
|---|---|
| **Description** | **Supply Chain Actor** |
| Enable community awareness creation | Consumers |
| Enable enforcement of Laws and Regulations | Manufactures, Wholesalers, Distibutors,Pharmacies. |
| Enable medical drugs verification | Consumers |
| Enable data driven policy and decision making | Medical drugs regulators and distributors |
| Enable tracking and tracing in the pharmaceutical supply chain | Medical Drugs regulators |

**Figure 9 : Proposed conceptual framework of a national medical quality assurance-technology based system**

The study has identified potential actors in Tanzania's PSC and their roles. The actors include manufacturers, public and private wholesalers, the DMO, pharmacies, street markets, consumers, TFDA (enforcement agency) and Ministry of Health and Social Work (MoH&SW).

### 4.7 Impact on policy and practice

The use of ICTs in tracking and tracing the PSC can play great role in combating counterfeit and eventually improve the decision-making process. Combating counterfeit medical drugs can ultimately lead to improved health services that reduce child mortality rate, loss of manpower, loss of government revenue through illegal production of fake drugs and eventually improve national economic stability.

### 4.8 Conclusion

Combating CDs at the national level is a shared responsibility involving relevant government agencies, pharmaceutical manufacturers, distributors, health professionals, consumers and general public. Therefore, the Tanzania government needs to create an environment that will allow different stakeholders to co-ordinate efforts in the battle against CDs. After all, technology itself and on its own is not panacea in the battle against the menace poised by

CDs, a collection of efforts needs to be realised. In a more proactive manner, community Health Workers (CHWs) can play role of raising awareness on CDs among the patients. CHWs should report any suspected medicines and reach out to any other patients who might have taken the medicines too. Also, the media can help by reporting responsibly and accurately on the danger of purchasing medicines from unsafe sources and spreading the word to alert the patients whenever counterfeit medicines were found. Authorities, on their part, can fight counterfeit medicines by supporting CHWs, putting proper legislation in place, financing secure health systems, working with the police and customs to ensure the imports are well-inspected. Generally, the CD problem is beyond the national boundaries; it is a transnational problem. Thus, there is a need to foster inter-country, sub-regional and regional co-operation in the fight against the CD scourge. However, the battle should start with national strategies regarding CDs. In this regard, the Tanzania government and pharmaceutical industry must communicate the danger to ensure public health remains safe and secured.

### 4.9 Future work

The guidelines introduced by WHO (1999) suggest that to arrive at a concrete solution, the magnitude of CDs need to be understood, the PSC need to be deeply understood, legal procedures on CD crimes need to be understood and the need for technology-based solution must be assessed in the local context. Therefore, future work needs to work along these guidelines to realise the efforts on combating CDs in Tanzania.

## References

24Tanzania.com. (2013). *GSK launches SMS campaign to check fake drugs*. Retrieved April 21, 2014, from http://www.24tanzania.com/gsk-launches-sms-campaign-to-check-fake-drugs/

Agbaraji, E. C. (2012). Food And Drug Counterfeiting In The Developing Nations ; The Implications And Way-Out. *Academic Research International*, *3*(2), 24–31.

Davison, M. (2011). *Anti-Counterfeiting from Fake Drugs* (pp. 1–400). Cambridge, UK: Wiley.

Dipika, B., & Swathi, M. (2013). Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective. *Scientia Pharmaceutica*, *81*(1), 1–13. doi:10.3797/scipharm.1202-03

Emily, P., Eva, C., & Maura, R. (2011). *The Deadly World of Fake Drugs* (pp. 1–145). WHO.

ITU. (2013). *The World in 2013 ICT Facts and Figures* (pp. 1–8). Retrieved from http://www.itu.int/en/ITU-D/Statistics/Documents/facts/ICTFactsFigures2013-e.pdf

Mpedigree.net. (2014). *mPedigree to combat counterfeit drugs*. Retrieved April 21, 2014, fromhttp://mpedigree.net/mpedigree/index.php?option=com_content&view=article&id=55:mpedigreenews&limitstart=4

Newton, P. N., Green, M. D., Fernández, F. M., Day, N. P. J., & White, N. J. (2006). Counterfeit anti-infective drugs. *The Lancet Infectious Diseases*, *6*(9), 602–13. doi:10.1016/S1473-3099(06)70581-3

Oates, B. J. (2006). Researching Information Systems in Computing. In *Reviewing the Literature* (pp. 187–199). London: SAGE Publications.

Peter, G., Zera, M., Malcolm, C., Keith, J., Margareth, N., & Sigondab, T. (2008). No Title. *Health Policy*, *87*(2), 217–222.

pharmasecure.com. (2014). *Brand Protection psVerify™*. Retrieved April 21, 2014, from http://pharmasecure.com/integrated-pharmacy-solutions/psverify/

Sanjay, M., & Sanjeev, W. (2009). *Multiple Strategies And Technologies To Combat Counterfeit* (pp. 1–15).

TCRA. (2013). *Quartely Telecom Statistics Quarter 2 ( December 2013 ) Report 1 . Voice Prepaid Tariffs ( Without TAX )* (Vol. 2, pp. 1–5). Retrieved from http://www.tcra.go.tz/images/documents/telecommunication/telecomStatsDec13.pdf

TFDA. (2003). *The Tanzania food, drugs and cosmetics act, 2003* (pp. 1–89).

Utreja, A., & Singal, G. (2009). No Title. *Spurious and Counterfeit Drugs: A Growing Industry in the Developing World.*, *85*(1003), 251–256.

WHO. (1999). Guidelines for the development of measures to combat counterfeit drugs. Retrieved from http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf?ua=1

WHO. (2005). *Combating Counterfeit Drugs: A Concept Paper For Effective International Collaboration* (pp. 1–31).

WHO. (2010). *International Medical Products Anti-Counterfeiting Taskforce (IMPACT)* (pp. 1–164).

WHO. (2012). Accelerating progress towards the health-related Millennium Development Goals (pp. 1–25). Retrieved from http://www.who.int/topics/millennium_development_goals/MDG-NHPS_brochure_2010.pdf

Yamena, T. (1967). *Statistics, an Introductory Analysis*. (Harper & Ran, Eds.) (2nd Editio.). New York, USA.