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ADVOCACY FOR AFFORDABLE MALARIA DIAGNOSIS IN UGANDA

Gaps in the implementation of tax exemption on rapid diagnostic kits

The National Malaria Control Policy recommends that parasite-based diagnosis before treatment is performed for any suspected malaria cases. However, access to testing is still far from universal due to high prices, among other factors. Malaria diagnosis in the public sector is in principle accessed free of charge, but in the private sector it accessed at a cost. Basing on results from an assessment of the value chain of malaria rapid diagnostic test (mRDT) kits, this brief highlights existing gaps in the implementation of the tax exemption policy and their implications for affordability of mRDTs in the private sector in Uganda.

CONTEXT

Malaria is the biggest single cause of illness and death in Uganda. The country has the third highest number of malaria deaths and one of the highest reported malaria transmission rates in the world.[1] Malaria accounts for 30%-50% of outpatient visits, 15%-20% of hospital admissions, and up to 20% of all hospital deaths.[2] Overall about 16 million cases and about 10,500 deaths are reported per year.[3]

Early diagnosis and treatment of malaria reduces disease and prevents deaths. Accurate diagnosis is vital to good malaria case management. Testing makes treatment more effective; allows a health work to carry out further investigations on a patient who tests negative; and plays a central role in combatting rising levels of resistance to anti-malarial medicines. It also contributes to reducing malaria transmission.

The National Malaria Control Policy recommends that parasite-based diagnosis with microscopy or malaria rapid diagnostic test (mRDT) before treatment is performed for any suspected malaria cases. However, access to testing is still far from universal. An end-use verification (EUV) survey conducted in April 2016 by the US President's Malaria Initiative (PMI) found that only 69% of the treated malaria cases received a diagnostic test – still lower than the 90% national target, but an improvement from the 2015 survey (61%).

Malaria diagnosis in the public sector is in principle accessed free of charge, but in the private sector it accessed at a cost. A poll conducted by HEPS Uganda and Trac Fm among 3,200 listeners of eight FM radio stations spread in different parts of Uganda – conducted in January and February 2017 – showed that up to 24% of them do not test for malaria before treatment because of high prices of the test.

In addition, the number of mRDT manufacturers and mRDT brands have increased rapidly over the past few years. These have led to different prices, which has created confusion among policy makers, service providers and service consumers alike and undermined access and confidence in making choices. High prices also result from the fact that some importers are – against policy – taxed. Others are not taxed, but make provision for taxes – which they the pass on to consumers in form of high prices – for fear that future tax audits may require them to pay tax arrears.

1 World Health Organization (2013): World Malaria Report
2 Ministry of Health (2012). Health Management Information System
3 Ministry of Health. http://health.go.ug/programs/national-malaria-control-program

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IMPORT PROCEDURES AND GAPS IN THE IMPLEMENTATION OF TAX EXEMPTION OF mRDTs

Most importers of pharmaceutical products and medical devices – first line buyers (FLBs) – are pharmacies which are wholesalers. Ideally, the importer is required to present to URA customs an import license, a pro forma invoice, and a valid NDA verification certificate. NDA charges the importer a verification fee of 2% of the cost, insurance and freight (CIF) value of the consignment and issues them a verification certificate. The importer presents the verification certificate to URA for customs clearance. By policy, no import taxes are supposed to be levied on pharmaceutical products and medical devices.

However, mRDTs are a relatively new product, having been introduced on the Ugandan market in 2012. As such, they have – until recently – not been explicitly recognized by, let alone being classified in tax policy implementation guidelines for tax purposes. Although they are medical devices and are tax-exempt, they have been subject of inadvertent taxation, tax-audit safety provision, tax evasion – and a fertile ground for bribery and extortion.

Some FLBs have been charged VAT and withholding tax. In cases, it is not clear where and how that revenue is posted, given that mRDTs did not have a tax code.

Respondents further indicated that, even in cases where importers have not been charged, they have gone ahead to provide for taxes in their pricing, fearing that future tax audits may see them charged tax arrears. Either way, the overall effect of this has been higher consumer prices.

For unclear reasons, there are also importers who do not use the NDA channel, opting to import mRDTs through channels of general consumer goods that are inspected by Uganda National Bureau of Standards (UNBS). Through this channel, the importer submits a request for inspection UNBS before the consignment is shipped into the country. The items are inspected for quality upon arrival at the entry points and this entails both document checks and physical inspection of goods. In this channel, mRDTs are charged taxes just like any other general consumer good, which taxes are again passed on to consumers in form of higher prices.

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UNBS inspection is not appropriate for ascertaining the quality such sensitive medical devices as mRDTs, where inspection and verification of manufacturers are also needed, and advocacy from the civil society and engagements through NDA and Ministry of Health has seen this channel closed. mRDTs have accordingly been allocated Tariff Code 3002, which designates if as a medical device. In addition, URA customs now requires all importers of consignments including mRDTs to go through NDA, and not UNBS.

Ministry of Health has recommended that NDA under-takes lot testing. However, respondents reported that NDA does not have internal capacity to do lot testing the quality of mRDTs. It relies on the WHO quality assurance system, including pre-qualification. Respondents at Ministry of Health indicated that the Ministry is pursuing a memorandum of understanding with Central Public Health Laboratory (CPHL) to have samples of mRDTs tested routinely.

NDA reports that the number of FLBs seeking verification certificates for mRDTs from the authority has increased "drastically", but data on import volumes before and after the URA directive was not readily. It is not clear whether all mRDT importers currently go through NDA. One respondent indicated that URA's transition to a fully electronic system, expected in October 2018, will among other things, help ensure that all mRDT importers go through NDA.

According to respondents, previously, some importers who went through UNBS simply evaded import taxes by hiding mRDTs in other commodities. But whether this continues is not known; it is also not yet validated as to whether this kind of tax evasion leads to lower consumer prices – and it is difficult to ascertain.

The other challenge is that some unscrupulous tax officials have taken advantage of the vague status of mRDTs to extort bribes importers. According to respondents, they do this by threatening them with a high tax bill – well-knowing that a proportion of the tax assessment is illegal. They then offer to reduce the tax bill in exchange for a bribe – or "if they talk nicely", as stated by one respondent; mRDTs come in handy as an item the official will pretend to remove from the items being taxed. When importers pay bribes to a customs clearance of items which ideally should not be taxed, it is obvious that consumer prices will artificially be higher.

IMPLICATION OF mRDT TAXATION

Higher prices of malaria diagnosis increase the likelihood of health consumers choosing to use their scarce resources for purchase of anti-malarial medicines directly, leading to higher cases of irrational use of medicines and poor malaria case management.

Private importers which import mRDTs through UNBS, pay import taxes of VAT at 18% of CIF value and withholding tax of 6%. This is much higher than the 2% they would pay NDA for verification. Asked why FLBs would prefer to pay the higher taxes, respondents indicated that it could be due to lack of awareness of the tax exemption of mRDTs among importers, or a preference for convenience. Even though the difference in charges favors importers who use the NDA routine, some importers reportedly choose to avoid it because of its stringent quality assurance procedures.

NDA requires the prospective importer of medicines or medical devices to have an import permit, a technical representative of the manufacturer, and to undertake quality verification. The process of obtaining the status a technical representative of the product manufacture in-country is tedious, lengthy and costly. It is possible that all this is considered an avoidable or unnecessary inconvenience or cost.

In the end, the higher taxes are definitely transferred to health consumers in form of higher prices, which increases the cost of diagnosis. Higher prices of malaria diagnosis increase the likelihood of health consumers choosing to use their scarce resources for purchase of anti-malarial medicines directly, leading to higher cases of irrational use of medicines and poor malaria case management. This greatly undermines the Ministry of Health efforts to implement the test and treat policy for malaria in Uganda.

INTERVENTIONS TO PROMOTE THE AFFORDABILITY OF mRDTs

Clinton Health Access Initiative (CHAI) has identified five mRDT manufacturers who are pre-qualified by World Health Organization (WHO) and negotiated price reductions in the range of 23-25 US cents for mRDTs sold to Uganda, Kenya and Tanzania

Over the past two years, stakeholders have implemented interventions and undertaken engagements with different actors to try to achieve affordable, quality-assured mRDTs on the Ugandan market. On the aspect of affordability, HEPS-Uganda engaged Ministry of Finance last year on the taxation of mRDTs. During one of the meeting between HEPS-Uganda and the Commissioner for Tax Policy at the Ministry of Finance, the latter sought clarification from URA by telephone and gave verbal instructions for taxation of mRDTs to be stopped.

Respondents in this survey indicated that they are no longer being taxed. However, FLBs continue to price mRDTs as if they were being taxed, for fear that in future URA might tax-audit them and force them to pay tax arrears. For them to be sure that they are not being taxed because of tax exemption of the item, they wanted a formal communication from URA. This communication has not been made yet. FLBs are reluctant to take assurances from third parties, including Ministry of Health and non-government actors. The study team was informed that a public statement and media briefing are being planned by Ministry of Health, in collaboration with URA and NDA to this effect.

Another campaign to promote the affordability of mRDTs has been spearheaded by Clinton Health Access Initiative (CHAI). CHAI identified five mRDT manufacturers who are pre-qualified by World Health Organization (WHO) and negotiated price reductions in the range of 23-25 US cents for mRDTs sold to Uganda, Kenya and Tanzania. CHAI promised to work with the malaria programs of the three countries to increase demand to help manufacturers gain economies of scale.

At the same time, CHAI engaged four FLBs in Uganda and linked them to the partner manufacturers, and convinced them to import from the manufacturers with whom lower prices were negotiated. CHAI also informed the FLBs of the expected wholesale prices of the different brands, after catering for the different costs as well as having incorporated/accounted for a modest mark-up therein. CHAI explained to the FLBs the different strategies to boost demand for mRDTs in order to increase their sales volumes. This includes Ministry of Health test and treat policy, the training of private health providers in malaria case management, etc. Two FLBs have since signed agreements with the manufacturers.

RECOMMENDATIONS

To ensure that tax exemption and other interventions to lower the price of mRDTs, the following recommendations are made to the different actors:

1) Ministry of Health should collaborate with URA to publish a public statement to officially state that mRDTs are exempt from import taxes, and that all importers, by policy, are required to obtain verification from NDA before importing mRDTs into Uganda.

2) Ministry of Health should engage FLBs to ensure that the implementation of tax exemption on mRDTs is reflected in their lower market prices.

3) CHAI should engage more FLBs and interest them in the negotiated price scheme with partner manufacturers.

4) Ministry of Health, CHAI and URA should sensitize FLBs and other importers on the country's tax policy generally, and on pharmaceutical products and medical devices in particularly to empower them against unscrupulous customs officials who are exploiting their lack of information to charge them irregular taxes and bribes.

5) URA should expedite the implementation of the electronic tax system to among others, facilitate the tracking of mRDTs through the import chain.

6) Non-government actors and NDA should respectively monitor the prices and quality of mRDTs on the market on a routine basis.

CONCLUSION

The use of mRDTs in malaria diagnosis has expanded in recent years, and this expansion has brought on board a growing number of manufacturers, importers and retailers. Ministry of Health is presently promoting the test and treat policy for malaria. This policy will not be effectively implemented if diagnostic kits are unaffordable. Irregular taxation remains a big barrier to achieving affordability.

HEPS-UGANDA

351A Balintuma Road, Namirembe
P.O. Box 2426, Kampala
Email: info@heps.or.ug
Website: www.heps.or.ug
Facebook: HEPS Uganda
Twitter: @hepsuganda
Blog: hepsuganda.wordpress.com