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Chapter 7

Prices and availability of locally produced and imported medicines in Ethiopia and Tanzania

ABSTRACT

Background: We sought to generate evidence about the effect of policies supporting local production of medicines as a means to improve access to medicines in low- and middle -income countries (LMIC).

Methods: We adapted the World Health Organization/Health Action International (WHO/ HAI) instruments measuring medicines availability and prices to differentiate local from imported products. We piloted the revised tools in Ethiopia and Tanzania in August 2013. In each outlet, selected according to the WHO/HAI methodology, data collectors recorded the price of all products in stock for each medicine listed on a country-specific list of commonly used medicines. We also collected government procurement (tender) prices. Prices were compared to an international reference and expressed as a median price ratio (MPR).

Results: Overall, the Ethiopian government paid more for locally produced products (21 medicines, median MPR=1.20) than for imports (12 medicines, median MPR=0.84). Eight of the nine medicines procured as both local and imported products had a cheaper procurement price when imported. Availability was better for local products compared to imports, both in the public (48% versus 19%, respectively) and private (54% versus 35%, respectively) sectors. Paired analyses of patient prices showed lower prices of imports in the public sector (10 medicines, median MPR=1.18 [imported] versus 1.44 [local]) and

higher prices of imports in the private sector (15 medicines, median MPR=5.42 [imported] versus 1.85 [local]). In the public sector, patients paid 17% and 53% more than the government procurement price for local and imported products, respectively.

The situation was very different in Tanzania where the government paid less for local products (9 medicines, median MPR=0.69) than for imports (7 medicines, median MPR=1.34). In the public sector, availability of local and imported products was 21% and 32% respectively, with patients paying slightly more for local products (9 medicines, median MPR=1.35 [imported] versus 1.44 [local]). In the private sector, local products were less available (21%) than imports (70%) but prices were similar (12 medicines, median MPR=2.29 [imported] versus 2.27 [local]). In the public sector, patients paid 135% and 65% more than the government procurement price for local and imported products, respectively.

Conclusions: Our results provide valuable insight as to how local medicines production can affect availability and patient prices, and how it can be influenced by preferential purchasing and mark-ups in the public sector. Governments need to evaluate the impact of local production policies on availability and prices, and adjust policies to protect patients, particularly in the public sector, from paying more for locally produced medicines. The method and tools used for this study can provide such information.

INTRODUCTION

Ensuring access to medicines requires policies to improve the availability and affordability of quality-assured medicines that meet local health needs (1). Surveys using the World Health Organization (WHO)/Health Action International (HAI) medicine price and availability tool have shown poor medicine availability (particularly in the public sector), high patient prices in both public and private sectors, and unaffordable treatments for those on low wages (2-6).

Increasingly, governments in low- and middle-income countries (LMIC) are supporting local production of medicines, expecting that it will result in increased availability and lower prices, as well as industrial and economic benefits (7). To assist countries the WHO, in partnership with the United Nations Conference on Trade and Development (UNCTAD) and the International Centre for Trade and Sustainable Development (ICTSD), commenced a project in 2012 on local production of medical products for improved access in LMICs. In

Phase I, a literature review showed inconclusive evidence as to whether local production improved access (8). A study in Tanzania showed an urban bias in the availability of imports, but not locally produced medicines (9). Some governments have a local preference policy when procuring medicines i.e. they will pay more, up to a fixed percentage, for locally produced medicines than for imports. The World Bank supports this policy, while the Global Fund to Fight AIDS, Tuberculosis and Malaria rejects it (10,11).

In Phase II, we developed a methodology to measure the availability and prices of locally produced and imported medicines. It was adapted from the WHO/HAI survey tool (12). Key features are listed in Table 1. In August 2013 the methodology was piloted in Tanzania and Ethiopia, with the support of the government in both countries. This article summarizes the key findings. Detailed reports on the individual country surveys are available on request.

Pharmaceutical sectors

In Ethiopia, there were nine local pharmaceutical manufacturers, while in Tanzania there were seven. All made finished dosage forms, but not active pharmaceutical ingredients. Prices were not regulated in either country, nor were mark-ups regulated in the pharmaceutical supply chain. The Ethiopian and Tanzanian governments have a local preference when procuring medicines of up to 25% and 15%, respectively. In both countries, patients pay for most medicines out-of-pocket in the public sector (some medicines in the Tanzanian public and mission sectors are provided as part of the consultation fee). Neither country taxes medicines, but Ethiopia applies a 5% import tariff.

METHOD

Study design

(1) Sampling

In each country, patient price and availability data were collected in the capital and five other regions, as per the WHO/HAI methodology (12). In Ethiopia, the survey areas were Addis Ababa, Oromia, Amhara, Southern Nations, Nationalities, and Peoples' Region (SNNPR), Harari and Afar. In Tanzania, data were collected in Dar es Salaam, Manyara, Mbeya, Mtwara, Shinyanga and Tabora.

Table 1: Key features of the WHO/HAI tool for measuring prices and availability of locally produced and imported medicines

Answers these key questions	• What prices does the government pay, and quantities procured, for selected medicines that are locally produced and imported, and how do these prices compared with public sector patient prices? • What is the availability and patient price for medicines that are locally produced and imported, in different sectors and regions of the country? • Do prices and availability vary by product type (originator brand, branded generic and INN generic)? • How do prices compare with international reference prices? • How do prices vary by country of manufacture?
Data collected and sampling	*Availability and patient prices*: • Survey areas: capital city and 5 other regions of the country • Sectors: public, private and one other sector • Sample: 5 medicine outlets per survey region per sector *Government procurement prices and quantities*: collected from procurement department or Central Medical Store *Price components*: • Any additional costs when the government imports products • Wholesale procurement and selling prices: collected from the main wholesaler in the capital
Medicines	Minimum 25 medicines surveyed, each strength- and dosage form-specific. Selected nationally, known to be locally produced, with an international reference price For each medicine, data collected on all products in stock in each outlet. Country of manufacture from product label or national Medicines Regulatory Authority.
Data entry and analysis	Data double-entered into an Excel Workbook that accompanies the manual. Automated analysis of prices and availability across all and individual medicines, by sector, region and product type, for locally produced and imported medicines (paired and unpaired), and country of manufacture and manufacturer.

This article reports on the findings from the public and private sectors. In Ethiopia, 34 public sector outlets were sampled (hospital pharmacies and health facilities) and 30 private pharmacies. In Tanzania, data were collected from 33 public sector outlets (hospital pharmacies and health facilities) and 30 private sector outlets (private pharmacies and Accredited Drug Dispensing Outlets). Data were also collected from a third sector (mission facilities in Tanzania, and NGO and municipal pharmacies in Ethiopia) but are not included here.

Current government procurement prices and quantities were also collected. In Ethiopia, these were 2013 tender prices collected from the Pharmaceutical Fund and Supply Agency. In Tanzania, 2012 tender prices were collected from the Medical Stores Department.

(2) Medicines

Data were collected and analysed for 25 medicines in Ethiopia, and 24 in Tanzania (Table 2). The medicines were selected nationally, were strength- and dosage form-specific, and were made by at least one local manufacturer. In each outlet, for each medicine data were collected on all products in stock with the same active ingredient(s), strength and dosage form. The country of manufacture was identified from product labels.

Table 2: Survey medicines

Ethiopia	Tanzania
Acetyl salicyclic acid 300mg tab/cap	Acetyl salicyclic acid 300mg tab/cap
Albendazole 100mg/5ml suspension	Albendazole 100mg/5ml suspension
Amoxicillin 250mg tab/cap	Amoxicillin 250mg tab/cap
Amoxicillin 500mg tab/cap	Amoxicillin 500mg tab/cap
Chloramphenicol 250mg tab/cap	Chloramphenicol 250mg tab/cap
Ciprofloxacin 500mg tab/cap	Ciprofloxacin 500mg tab/cap
Diclofenac 50mg tab/cap	Diclofenac 50mg tab/cap
Doxycyline 100mg tab/cap	Doxycyline 100mg tab/cap
Erythromycin 250mg tab/cap	Erythromycin 250mg tab/cap
Paracetamol 120mg/5ml suspension	Paracetamol 120mg/5ml suspension
Paracetamol 500mg tab/cap	Paracetamol 500mg tab/cap
Sulphamethoxazole+Trimethoprim 400mg+80mg tab/cap	Sulphamethoxazole+Trimethoprim 400mg+80mg tab/cap
Tetracycline 250mg tab/cap	Tetracycline 250mg tab/cap
Amitriptyline 25mg tab/cap	Artemeter+Lumefantrine 20mg+120mg tab/cap
Benzathine penicillin 2.4MIU injection	Azithromycin 250mg tab/cap
Chloroquine 50mg/5ml syrup	Cloxacillin 250mg tab/cap
Enalapril 10mg tab/cap	Erythromycin 125mg/5ml suspension
Fluoxetine 20mg tab/cap	Fluconazole 150mg tab/cap
Furosemide 40mg tab/cap	Ibuprofen 200mg tab/cap
Glibenclamide 5mg tab/cap	Quinine sulphate 300mg tab/cap
Ibuprofen 400mg tab/cap	Salbutamol 4mg tab/cap
Metoclopramide 5mg/5ml syrup	Sulfadoxine+Pyrimethamine 500mg+25mg tab/cap
Metronidazole 250mg tab/cap	Sulphamethoxazole+Trimethoprim 200+40mg/5ml suspension
Phenobarbitone 100mg tab/cap	Zinc sulphate 20mg dispersible tab
Sodium Chloride 0.9% 1L IV solution	

Data quality assurance

National investigators were trained in a two-day workshop which included piloting data collection. They then trained their survey personnel. Data were checked at the end of each day for completeness and possible errors, and validated by re-surveying in three outlets per country. Data were double-entered into the automated Excel Workbook. The country of manufacture and marketing authorization was validated with the Tanzanian Food and Drug Administration (TFDA), and checked on the website of the Ethiopian Food, Medicine and Health Care Administration and Control Authority (FMHACA).

Data analysis

In this study, local production was defined as products that were manufactured and packaged/labelled in the study country. Availability was based on whether the medicine was in stock on the day of data collection at the surveyed facility. For each medicine, where more than one locally produced or imported product was found, the median unit price for all local or imported products was used in the analysis.

International Commercial (INCO) terms were identified for each product procured by the government. To be more comparable with prices of locally produced products, adjustments were made to prices of imports which did not cover all costs to the national government store.

Prices were expressed as median price ratios (MPR). An MPR is the ratio of the price in local currency (Tanzanian Shilling/Ethiopian Birr) divided by an international reference price (IRP) converted to local currency using the exchange rate on the first day of data collection. The use of IRPs serves as a benchmark for price comparisons. The IRPs were taken from the 2012 Management Sciences for Health International Drug Price Indicator Guide for international procurements. They reflect prices that governments could be expected to pay for medicines. For patient prices, an MPR was only calculated for a medicine when at least four price points were recorded per sector. For public procurement prices, an MPR was calculated when one or more prices were recorded. Most analyses in this article are paired i.e. the analysis includes only medicines (same strength and dosage forms) where MPRs were calculated for both local and imported products.

Prices were also analysed by product type i.e. originator brands, branded generics and International Non-proprietary Name (INN) generics. An originator brand is the product that was first authorized world-wide for marketing (usually as a patented product) and always has a brand name. A branded generic is a generic equivalent product marketed

under a brand name. An INN generic is a generic equivalent product marketed under its INN name.

RESULTS

Ethiopia

Government procurement prices and quantities

Across the medicines, the government procured 48 locally produced products and 13 imported products. Based on the INCO terms, 22% was added to the procurement price of nine products found to be Free Carrier or Free on Board (15% freight, 0.5% insurance, 1.5% bank charges, 5% import duty) and 7% was added to four products found to be Cost and Freight (0.5% insurance, 1.5% bank charges, 5% import duty).

Overall, procurement prices for locally produced and imported medicines were 1.20 and 0.84 times international reference prices (IRP), respectively (Table 3). For local products, half ranged from 0.99-1.33 times IPRs, whereas for imported products half were 0.77–1.26 times IRPs.

7

Table 3: Summary of Ethiopian government procurement prices for locally produced and imported medicines (unpaired analysis)

	Locally produced	Imported
Number of medicines (products)	21 (48)	12 (13)
Median MPR	1.20	0.84
Interquartile range	0.99–1.33	0.77–1.26

For nine medicines the government procured both local and imported products, at variable prices and quantities (Table 4). For example, for ciprofloxacin five locally produced products (total of 49.295 million tablets at 0.6580–0.7300 Birr per tablet) and one imported product (13.6 million tablets at 0.5119 Birr per tablet) were purchased. The lower priced imported product accounted for only 21.6% of the total quantity of ciprofloxacin purchased. For eight of the nine medicines, median procurement prices of local products were higher (45% more) than those of imported products. They ranged from 1% more for doxycycline to 134% more for erythromycin. The sole exception was

Table 4: Government procurement prices in Ethiopia for medicines both locally produced and imported

	Locally produced products				Imported products			Ratio of median price of locally produced product to imported product	Savings if only imported product procured (USD)
	No. products procured	Unit price (Birr)	Quantity procured *in millions*	Median unit price (Birr)	No. products procured	Median unit price (Birr)	Quantity procured *in millions*		
Amoxicillin 500mg	2	0.665 0.6918	30 115	0.6784	1	0.4610	20	1.47	$1,744,765
Erythromycin	1	1.1353	15	1.1353	1	0.4853	9.5	2.34	$520,833
Ciprofloxacin	5	0.658 0.693 0.6997 0.71 0.73	0.795 10 20 16.5 2	0.6997	1	0.5119	13.6	1.37	$501,496
Paracetamol 500mg tab	3	0.1109 0.115 0.118	60 60 50	0.1150	1	0.0783	50.8	1.47	$328,152
Amoxicillin 250mg	2	0.32 0.34	61.179 27	0.33	1	0.2617	20	1.26	$303,463
Sulphamethoxazole + Trimethoprim	4	0.2498 0.25 0.2598 0.3154	40 13 26.858 26.171	0.2549	1	0.2217	58	1.15	$265,283

Table 4: Government procurement prices in Ethiopia for medicines both locally produced and imported *(Continued)*

	Locally produced products				Imported products				Ratio of median price of locally produced product to imported product	Savings if only imported product procured (USD)
	No. products procured	Unit price (Birr)	Quantity procured *in millions*	Median unit price (Birr)	No. products procured	Median unit price (Birr)	Quantity procured *in millions*			
Albendazole*	2	7.5	0.210	7.9	1	5.1362	0.220		1.54	$50,178
		8.3	0.140							
Doxycycline	4	0.285	6.5	0.3549	1	0.3504	12		1.01	$20,372
		0.3448	21.84							
		0.365	19.68							
		0.3884	16.88							
Phenobarbitone	3	0.115	27.571	0.1200	1	0.3692	17.127		0.32	no savings
		0.12	10							
		0.13	20							
									Mean: 1.45#	$3,734,542

*Price and quantity data for albendazole is for a 20ml bottle

Excludes phenobarbitone

7

locally produced phenobarbitone which was a third of the price of the imported product. For these eight medicines, the government would have saved about $3.7 million USD if only the imported products were procured.

Availability and patient prices in the public sector

The mean availability of the medicines (whether imported or locally produced) in the public sector outlets was 64% (Table 5). Local products had greater mean availability (48%) than imported products (19%). The availability for individual medicines was highly variable. Branded generics (37%) were more commonly found than INN generics (14%) for local products, whereas for imported products the availability of branded generics (10%) was similar to INN generics (9%). No originator brands were found in the public sector.

Table 5: Availability and patient prices in Ethiopia, public sector, for locally produced and imported medicines

		Locally produced	Imported
Availability	Mean availability of all products (local and imported) and product types	64%	
	Mean availability of all product types	48%	19%
	• Originator brands	0%	0%
	• Branded generics	37%	10%
	• INN generics	14%	9%
Patient prices	Number of medicines (products)	10 (177)	10 (129)
	Median MPR	1.44	1.18
	Median interquartile range	1.08–1.56	1.02–1.42
	Median MPR (products)*		
	• Originator brands	-	-
	• Branded generics	1.41 (331)	1.14 (89)
	• INN generics	1.45 (125)	1.41 (79)

*Unpaired analysis of prices

Public sector patient prices for local products were higher priced (median MPR=1.44) than imported products (median MPR=1.18) across the 10 medicines in the paired analysis. Hence, patients were paying 22% more when being dispensed local products.

Across all medicines (unpaired), patients in the public sector were paying 23% more for locally produced branded generics (median MPR=1.41) than imports (median MPR=1.14). For INN generics, the difference was minimal.

Public sector patient prices compared to government procurement prices

Across the 20 locally produced medicines that the government procured and sold to patients in public sector outlets, patients were paying 1.17 times (17% more than) the government procurement price (Table 6). For imported products (9 medicines), patients were paying 1.53 times (53% more than) the procurement price.

Table 6: Median ratio between public sector patient prices and procurement prices in Ethiopia for locally produced and imported medicines

	Number of paired medicines	Median ratio between Public Sector Patient Price MPR and Public Sector Procurement Price MPR
Locally produced products	20	1.17
Imported products	9	1.53

Note: This analysis does not use International Reference Prices

7

Availability and patient prices in the private sector

Mean availability of the medicines (imported or locally produced) was 73% in the private sector (Table 7). Availability of local and imported products was 54% and 35%, respectively, with variability for individual medicines. Branded generics were more commonly found than INN generics for local products (42% versus 13%) and imported products (29% versus 3%). No locally produced originator brands were found. The mean availability of imported originator brands was 9%.

Overall, patient prices for local products (median MPR=1.85) were lower than imported products (median MPR=5.42) across the 15 medicines in the paired analysis (Table 7). Overall, patients were paying 193% more for imported products in the private sector.

Across all medicines (unpaired), imported branded generics (median MPR=4.33) were 153% higher priced than local branded generics (median MPR=1.71). Locally produced INN generics were slightly higher priced (median MPR=2.17) than imported INN generics (median MPR=2.08). The few imported originator brands were far high priced (median MPR=20.35) compared to the generics.

Table 7: Summary of availability and patient prices in Ethiopia, private sector, for locally produced and imported medicines

		Locally produced	Imported
Availability	Mean availability of all products (local and imported) and product types	73%	
	Mean availability of all product types	54%	35%
	• Originator brands	0%	9%
	• Branded generics	42%	29%
	• INN generics	13%	3%
Patient prices	Number of medicines (products)	15 (306)	15 (403)
	Median MPR	1.85	5.42
	Median interquartile range	1.71–1.96	2.65–9.34
	Median MPR (products)*		
	• Originator brands	–	20.35 (69)
	• Branded generics	1.71 (330)	4.33 (411)
	• INN generics	2.17 (98)	2.08 (25)

*Unpaired analysis of prices

Tanzania

Government procurement prices and quantities

For each medicine procured by the government, locally produced or imported products were purchased but not both. A total of nine local products and ten imported products were procured. Based on the INCO terms, no price adjustments were needed. Overall, government procurement prices for local and imported products were 0.69 and 1.34 times IRPs, respectively (Table 8). For local products, half ranged from 0.65–0.97 times IRPs, whereas for imported products half were 0.69–4.85 times IRPs.

Availability and patient prices in the public sector

The mean availability of the medicines (imported or locally produced) in the public sector outlets was 52% (Table 8). Imported products had greater availability (32%) than local products (21%), with variability for individual medicines. Branded generics (15%) were more commonly found than INN generics (6%) for local products. The same was seen for imported medicines; availability of branded and INN generics was 27% and 5%, respectively. Originator brands were rarely available at 4% and 0% for imported and local products, respectively.

Public sector patient prices for local products were higher than imported products across the 9 medicines in the paired analysis (Table 8). Median MPRs of local and imported products were 1.44 and 1.35 respectively, hence patients were paying 7% more for local products.

In an unpaired analysis of all medicines sold to patients in the public sector, locally produced branded generics were 24% lower priced (median MPR=1.67) than imported branded generics (median MPR=2.20). For INN generics there was virtually no price difference between imports and products made in Tanzania (Table 8).

Table 8: Summary of procurement prices, availability and patient prices in Tanzania, public sector, for locally produced and imported medicines

		Locally produced	Imported
Government procurement prices*	Number of medicines (products)	9 (9)	7 (10)
	Median MPR	0.69	1.34
	Interquartile range	0.65–0.97	0.69–4.85
Availability	Mean availability of all products and product types	52%	
	Mean availability of all product types	21%	32%
	Originator brands	0%	4%
	• Branded generics	15%	27%
	• INN generics	6%	5%
Patient prices	Number of medicines (products)	9 (104)	9 (107)
	Median MPR	1.44	1.35
	Median interquartile range	1.00–1.85	1.29–1.75
	Median MPR (products)*		
	• Originator brands	–	3.48 (42)
	• Branded generics	1.67 (121)	2.20 (230)
	• INN generics	1.98 (49)	1.97 (36)

*Unpaired analysis of prices

Public sector patient prices compared to government procurement prices

Across the eight locally produced medicines that the government procured and sold to patients in public sector outlets, patients were paying 2.35 times (135% more than) the procurement price (Table 9). For imported products (7 medicines) patients were paying 1.65 times (65% more than) the procurement price.

7

Table 9: Median ratio between public sector patient prices and procurement prices in Tanzania for locally produced and imported medicines

	Number of paired medicines	Median ratio between Public Sector Patient Price MPR and Public Sector Procurement Price MPR
Locally produced products	8	2.35
Imported products	7	1.65

Note: This analysis does not use International Reference Prices

Availability and patient prices in the private sector

The mean availability of imported or locally produced medicines was 82% in the private sector (Table 10). Availability of local and imported products was 21% and 70%, respectively, with variability for individual medicines. As with the public sector, branded generics were more commonly found than INN generics for local products (19% versus 2%) and imported products (58% versus 12%). No locally produced originator brands were found. The availability of imported originator brands was 7%.

Table 10: Summary of availability and patient prices in Tanzania, private sector, for locally produced and imported medicines

		Locally produced	Imported
Availability	Mean availability of all products and product types	82%	
	Mean availability of all product types	21%	70%
	• Originator brands	0%	7%
	• Branded generics	19%	58%
	• INN generics	2%	12%
Patient prices	Number of medicines (products)	12 (131)	12 (331)
	Median MPR	2.27	2.29
	Median interquartile range	2.07–2.95	1.75–2.93
	Median MPR (products)*		
	• Originator brands	–	8.79 (50)
	• Branded generics	2.01 (149)	2.97 (567)
	• INN generics	2.07 (12)	2.38 (96)

*Unpaired analysis of prices

Across 12 paired medicines, patient prices for local and imported products were almost identical at 2.27 and 2.29 times IRP respectively (Table 10) although there was individual variability eg. imported sulfadoxine/pyrimethamine products (MPR=10.91) were higher priced than the local products (MPR=7.27).

Across all medicines, imported branded generics (median MPR=2.97) were 48% higher priced than those made locally (median MPR=2.01), as shown in Table 10. Imported INN generics (median MPR=2.38) were 20% lower priced than imported branded generics, but 15% higher priced than locally produced INN generics (median MPR=2.07), however, only 12 locally produced INN generics were found. Imported originator brands (median MPR=8.79) were far higher priced than imported branded generics (median MPR=2.97) and INN generics (median MPR=2.38).

Summary of results

The findings for Ethiopia and Tanzania show contrasting situations. In Ethiopia, the government paid more overall for locally produced products compared to imports, then applied a lower mark-up on these local products. However, patient prices remained higher for local products compared to imports in public sector outlets. The availability of local products was higher than for imports in both the public and private sectors. In the private sector, patients paid considerably more for imported medicines.

In Tanzania, the government paid less for local products then applied a higher mark-up which resulted in patients paying slightly more for local products compared to imported products in public sector outlets. The availability of local products was lower in public sector outlets compared to imports. In the private sector, imports were far more available than local products and prices were similar.

DISCUSSION

In Tanzania, the government was only buying one product per medicine so it was not possible to determine if their 15% local preference policy was being applied. About half the products purchased were made locally, and procurement prices for locally produced products were overall about 50% lower than for imports. Ethiopia presented a different picture. A higher proportion of products purchased by the government were locally made, but at prices 45% higher than imports. For nine of the 25 medicines surveyed, one or more locally made products and one import were purchased, at varying prices and quantities.

7

The reasons for this purchasing practice warrant further study. Perhaps the manufacturers were unable to supply greater quantities, or the government was buying from multiple local manufacturers to provide broader local support. The Ethiopian government's 25% local preference policy was being exceeded for some medicines, and significant savings would result if only lower-priced products (imports) were purchased.

Interestingly, the Ethiopian government applied a smaller mark-up on higher-priced local products (17%), than on lower-priced imported products (53%). This reduced the difference in patient prices between local and imported products to 22% in public sector outlets. This illustrates how the government supports local producers. The Tanzanian government was also applying variable public sector mark-ups i.e. 135% on lower-priced local products and 65% for higher-priced imports. This resulted in only a 7% difference in public sector patient prices between local and imported products. The revenue generated by these practices is returned to the government.

In the private sector in Tanzania, patient prices were similar for imports and local products. In Ethiopia, patients were paying 193% more for imports compared to locally produced products. This apparent consumer willingness to pay higher prices for imported products may reflect a perception that imported products may be of higher quality. To boost local industry the government may need to ensure and publicise the equivalent quality of locally produced products.

What is unknown, in the private sectors of both countries, are medicine price components i.e. manufacturer's selling prices, mark-ups and other add-ons in the supply chain that make up the final patient price. Local manufacturers may be selling at lower prices but add-ons may significantly increase patient prices making products less affordable for patients. Many WHO/HAI surveys have found it challenging to measure price components (2), so in this survey procurement and selling prices were measured for only one wholesaler per country. This has limited value so is not reported here. However, governments supporting local production should fully investigate price components, including mark-ups, local taxes, rebates and discounts, then regulate markets to ensure their support results in more affordable medicines for patients. South Africa has chosen to use a Single Exit Price (SEP) mechanism that bans discounts and rebates and provides transparent information about the prices of medicines sold in the private sector (14).

Limitations of the methodology include (1) the relatively low number of survey medicines (although over 2500 data points were generated per country) (2) measuring availability only on the survey day (3) not identifying clearance costs for imports purchased by the Ethiopian government (4) not measuring all price components in the pharmaceutical supply chain.

CONCLUSIONS

The following are our key recommendations:
- Systems to regularly and reliably monitor the availability and prices of locally produced and imported medicines need to be established to assess the impact of local production policies on access to medicines.
- Governments supporting local production need to ensure that where the prices of locally produced medicines are found to be higher than imported ones, they adopt appropriate policies so that high prices are not passed on to patients, as this is contrary to the objective of improving access through local production.
- Where government procurement prices of locally produced products are higher than imports (as in the case of Ethiopia), the procurement prices of *all* medicines (imported and locally produced) should then be reviewed. Local preferences should also be reviewed to ensure medicines are affordable to the population. Lower procurement prices, whether for local or imported products, should be passed on to patients.
- Supporting local manufacturers through fiscal and/or non-fiscal incentives must be time-bound, developed and implemented in a transparent way, and not paid by patients through higher medicine prices. Balancing local production policies is critically important. Such policies should encourage foreign investments in pharmaceutical manufacturing in developing countries.

7

In July 2015, about two years after our study, Ethiopia launched a ten year strategy and plan of action for pharmaceutical manufacturing (13). The objectives include improving access to medicines through the local production of quality-assured pharmaceuticals, strengthening the FMHACA, promoting the production of APIs, and creating a research and development platform. Our survey establishes a baseline for measuring whether the plan of action results in improved access to medicines through greater availability and lower prices.

Following these pilot studies, the survey tools were refined and will be available on HAI's website (http://haiweb.org/what-we-do/price-availability-affordability) along with reports of all the findings from these pilots. We encourage governments and others who are interested in local production to undertake a survey and publish reports on the findings, on publicly-accessible websites, to increase our understanding of the impact of local production on prices and availability.

REFERENCES

1. WHO. World Medicines Strategy 2004-2007. Geneva: WHO, 2004.

2. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. The Lancet; 373 (9659): 240–249.

3. Van Mourik MSM, Cameron A, Ewen M, Laing RO. Availability, price and affordability of cardiovascular medicines: a comparison across 36 countries using WHO/HAI data. BMC Cardiovasc Disord 2010;10:25.

4. Volman B. Direct costs and availability of diabetes medicines in low- and middle-income countries. WHO/HAI 2008. http://haiweb.org/pricing-publications/

5. Cameron A, Bansal A, Dua T, Hill S, Moshe S, Mantel-Teeuwisse A, Saxena S. Mapping the availability, price and affordability of antiepileptic drugs in 46 countries. Epilepsia 2012 Jun;53(6):962-9. doi: 10.1111/j.1528-1167.2012.03446.x

6. Gelders S, Ewen M, Noguchi N, Laing R. Price, availability and affordability. An international comparison of chronic disease medicines. WHO EMRO/HAI 2006.

7. WHO. Local production for access to medical products. Developing a framework to improve public health. Geneva: WHO, Essential Medicines and Products: Policy brief, 2014.

8. Kaplan W. Local production and access to medicines in low- and middle-income countries. A literature review and critical analysis. Geneva: WHO, 2013

9. Mujinja P, Mackintosh M, Justin-Temu M, Wuyts M. Local production of pharmaceuticals in Africa and access to essential medicines: 'urban bias' in access to imported medicines in Tanzania and its policy implications. *Globalization and Health* 2014;10: 12.

10. The World Bank. Procurement of goods, works, and non-consulting services under IBRD loans and IDA credits and grants by World Bank Borrowers. Washington, 2011

11. Global Fund to Fight AIDS, Tuberculosis and Malaria. Guide to Global Fund policies on procurement and supply management of health products. Geneva, 2012.

12. World Health Organization/Health Action International. Measuring medicine prices, availability, affordability and price components. 2nd edition. Geneva, 2008. http://haiweb.org/what-we-do/price-availability-affordability/

13. Ministry of Health and Ministry of Industry, Federal Democratic Republic of Ethiopia. National strategy and plan of action for pharmaceutical manufacturing development in Ethiopia (2015-2025). Developing the pharmaceutical industry and improving access. July 2015. http://www.who.int/phi/publications/Ethiopia_strategy_local_poduction.pdf

14. Gray, AL. Medicine pricing interventions-the South African experience. *Southern Med Review* 2009;2(2): 15–19.