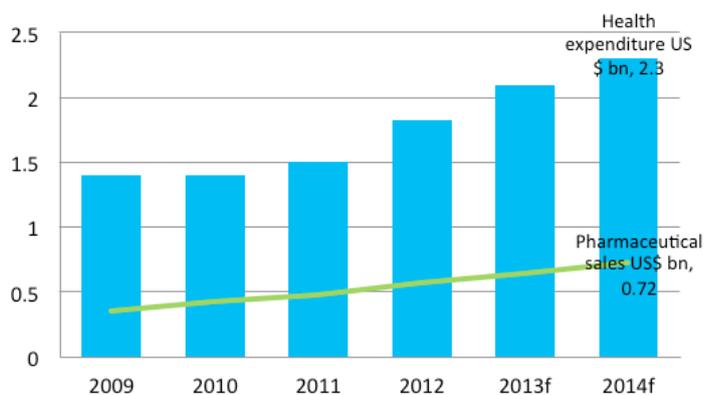


## Spotlight on pharmaceutical pricing regulation in Kenya: how much does it really contribute to access?

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### Introduction

Ensuring access to essential medicines by low income consumers is a challenge to many countries. Pharmaceutical expenditure is rising in Kenya, as is the health expenditure. However, our research found that on average, public sector facilities interviewed had only 50% availability of essential medicines (up to 60% in hospitals and as low as 46% at the dispensary level).



The Government does not impose any tariffs (duty and VAT) on finished pharmaceutical products, whether locally manufactured or imported. Public sector procurement of pharmaceutical products, which is governed by the Public Procurement and Disposal Act (2005), is based on the principle of lowest bidding price. Arguably, this targets value for money aimed at ensuring accessibility of pharmaceuticals in public health facilities for low income earners. Nevertheless, challenges in availability of pharmaceuticals in public health facilities mean that the common *mwananchi* is highly dependent on pharmaceuticals from the private sector.

This brief considers the main regulatory frameworks and the scope for achieving better access to medicines. The regulatory frameworks addressed here are: the Public Procurement and Disposal Act (2005) and the Competition Act No. 12 (2010). A number of key issues are identified.

### Key issues:

- Large “out of pocket” payments for pharmaceutical products

About 80% of total pharmaceuticals expenditure is funded privately, with “out of pocket” payments at the point of service being predominant.

- Medicine prices in the private sector matter to the common *mwananchi*

Private sector health facilities, wholesale and retail outlets set their pharmaceutical prices independently on a full cost recovery basis. The common *mwananchi* is highly dependent on the private health sector for essential medicines.

- A “no pricing regulation” not equivalent to best possible consumer prices

There are various reasons why the current policy on pharmaceutical pricing regulation is not tantamount to better consumer prices.

- Is it time to rethink Kenya’s procurement policy?

Policy coherence is crucial. Would a shift from negotiating procurement of pharmaceuticals on price be a more viable pathway for achieving and sustaining better health for the common *mwananchi* in line with Vision 2030?

- Macro-economic policy including industrial policy critical

Industrial policy has a huge influence on the behaviour of firms, particularly in extending and deepening technological capabilities. A long term perspective is key to better access to medicines.

## Pricing regulation in Kenya

Medicine prices and mark-ups in Kenya are not regulated. Price controls were abolished in October 1994. Indeed, this resulted in lowering of entry barriers into pharmaceutical distribution and in particular retailing, which requires a relatively low capital outlay for market entry. The basic underlying expectation is that this liberal pharmaceutical pricing regulation encourages stiff competition amongst suppliers resulting in highly competitive consumer prices. Does it really?

**Pricing of essential medicines is not regulated** There are various and substantial mark-ups applied along the distribution chain, which contribute to the final price. The common *mwananchi* is highly dependent on pharmaceuticals from the private sector.

## Kenya's Competition Policy and the protection of consumer welfare in access to medicines

Regulation of prices and competition practices dates back to the Price Control Ordinance of 1956, which was revised in 1972 then replaced by the Restrictive Trade Practices, Monopolies and Price Control Act (Cap. 504) in 1989. Various challenges identified in Cap 504 led to the tabling of the Competition Bill in 2009. These challenges included lack of coherence with other policy instruments, lack of attention to consumer welfare issues such as pricing, and the need to integrate emerging interests relating to regional harmonisation.

The Competition Act No. 12 of 2010 became effective on 1 August 2011. Kenya's Competition policy is

focused on protecting the process of competition and in so doing seeks to protect consumers from unfair and misleading market conduct as outlined in Part VI Consumer Welfare (sections 55 to 70).

**Does this policy instrument really address the question of better health for the low income earner in Kenya?** There is no policy guidance on the pricing of medicines. It remains unclear to what extent the Competition Act is likely to serve as an adequate corrective intervention for pricing of pharmaceutical products if at all.

The Competition Act contains provisions on Consumer Welfare. However, this does not appear to alleviate the disproportionately high burden of the cost of pharmaceuticals on low income earners. The brunt of the various and substantial mark-ups on pharmaceutical products is also borne by the common *mwananchi* who relies on the private sector for essential medicines.

## Does a "no pricing regulation policy" really mean better access?

Arguably, the abolishment of price controls two decades ago has seen various shifts in the pharmaceutical industry and in particular higher competition in distribution. Whilst the "no pharmaceutical pricing regulation policy" may have resulted in increased competition, it is debatable whether the level of competition that has been achieved thus far offers the best possible consumer prices. There are various reasons why the current policy on pharmaceutical pricing regulation is not tantamount to better consumer prices. These include:

(i) *High mark-up by distributors along complex private sector supply chains*

The supply chain of pharmaceutical products in Kenya is long and complex. Exploitation of information asymmetries on prices is rife in the sector and exacerbated by the complex supply chain. Distributors are able to exploit market information to achieve substantial mark-ups. Whilst competition in distribution and particularly at the retail level may have increased substantially net gains in terms of better consumer prices remain minimal.

(ii) *Limited influence on public procurement prices on the private market*

The principle of the lowest bidding price may be thought of as offering the main basis for a pricing benchmark and in particular generics. However, challenges in the public sector supply chain of pharmaceuticals suggest that this has little influence on pricing in the private sector, and on which low income earners are highly dependent.

(iii) *Parallel importation of pharmaceuticals underexploited*

Parallel importation, a TRIPS (WHO) flexibility, aimed at mitigating exclusive rights and promoting competition and in so doing improving access to medicines is underexploited in Kenya. Section 58 (1) of Kenya's Industrial Property Act (2009) allows for international exhaustion of rights – once a patent product is in the market anywhere in the world, it can be freely imported into Kenya. Article 6 of the TRIPS agreement states that this practice cannot be challenged under the WTO dispute settlement system and so is effectively a matter of national discretion.

**Article 6 of the TRIPS agreement underexploited!** The complexity of the pharmaceutical supply chain in Kenya has made discussion on the exploitation of Article 6 of the TRIPS agreement messy and contrived. Deliberate government intervention critical for implementation.

Parallel importation occurs where international price differences exceed transaction cost. This has clear benefits in terms of competitive prices. Although parallel importation is legal in Kenya, more deliberate government intervention would be critical in realising substantial benefits for the common *mwanachi* who is highly dependent on the private sector.

*(iv) Prescribing habits of physicians*

The Kenya National Drug Policy (1994) and the more recent Kenya National Pharmaceutical Policy (2008) recommend prescription by international non-proprietary name. Prescription by generic name is recommended but not required.

Physicians influence patient choice with a bias towards branded products. This stems from at least two factors. Firstly, training of medical practitioners is traditionally based on brand names. The trickle-down effect has resulted in the creation of mindsets that associate high cost to quality at the patient level. Secondly, top physician tend to have specialised relationships with brand manufacturing firms; they also tend to set trends for prescription choices for the range of pathologies.

*(v) Dispensing of pharmaceutical products*

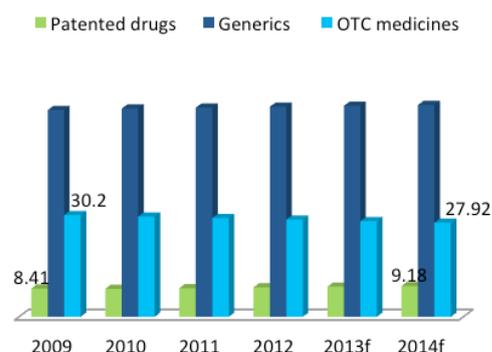
At the dispensing level, the Kenya National Pharmaceutical Policy (2008) requires generic substitution as a means of increasing accessibility

and affordability of essential medicines. However, enforcement of this requirement remains lax. To some extent, pharmacists may be viewed as neutral with regard to influencing patient choice. However, there is substantial leeway for influence that could go in opposite directions. A pharmacist (or pharmaceutical technologist) does have choice discretion based on affordability - suitable options based on the purchasing power of the buyer may be proposed. Conversely, the pharmacist may encourage choices that are driven by price margins. Price difference on available brands and generics presented to the buyer may be explained in a misleading manner; the branded product is commonly referred to as "the original" leading to speculation on the part of the buyer that the alternative (generic) is non-authentic and therefore counterfeit. Advocacy campaigns on pharmaceutical products are non-existent although the relatively newly created Competition Authority does have a competition advocacy role.

*(vi) Marketing campaigns related aspects*

As competition in the distribution of pharmaceuticals continues to grow, marketing campaigns in the form of visits to physicians and pharmacists, conference facilitation etc. have been ramped up for both brands and branded generics. From the distributor perspective, there is an advantage in supplying products that have strong marketing campaigns driven by the manufacturers. Firms producing branded products tend to have very strong local marketing teams pushing for the brands at the physician level, which then trickles down to patients through prescriptions. This heightened form of market competition rides high on the tide of strongly embedded cultural practices of association of quality to price by physicians

Distribution of drug sales % of total sales in Kenya



and pharmacists on the one hand, and patients on the other hand.

The percentage share of patented drugs has gone up by 8 per cent while that of generics has remained stable. The share of OTC medicines has fallen by 8 per cent.

**Thinking beyond explicit pharmaceutical price regulation to achieve better access to medicines and strategic positioning of the local industry in Kenya**

The various challenges surrounding a "no pharmaceutical pricing regulation policy", which suggest a critical need to identify measures that are more likely to achieve better access to medicines. Price fixing for pharmaceuticals may have to a large extent outlived its viability. However, other strategies could be put in place to improve access through improved affordability.

Public policy areas that are implicit have a greater impact than those that are explicit to an industry. Macro-economic policy, and in particular industrial policy (Kenya National Industrialisation Policy, 2010), is about structural change. Therefore, industrial policy is aimed at restructuring the production composition of the economy. Issues about creating a vibrant pharmaceutical industry are addressed in a specific manner by the pharmaceutical industry policy (Kenya National Pharmaceutical Policy, 2008) and implemented

through the industry development strategy (Kenya Pharmaceutical Sector Development Strategy, 2012). However, as is typical in any economy and industry, the national industrialisation policy has a huge influence (in comparison to a policy that is specific to a particular industry) on the behaviour of firms. This is specifically the case with respect to extending and deepening technological capabilities, which are central to driving the dynamics of an industry; technological capabilities induce the emergence of new and more technologically intensive activities that offer better prospects for industrialisation.

A number of forward looking issues would have to be addressed for Kenya to curve out a high growth technological trajectory for the pharmaceutical industry. Two of the critical ones include:

#### (i) Industrial Policy

Is the current industrial policy (Kenya National Industrialisation Policy, 2010) likely to steer and shape the economy into a direction that will encourage advanced pharmaceutical manufacturing as a pathway

for achieving and sustaining better health for the common *mwanaanchi* in line with Vision 2030?

A broad perspective is crucially important in driving better health through more competitive prices whilst at the same time triggering dynamic growth of the local pharmaceutical industry into a high growth technological trajectory.

#### (ii) Procurement Policy

Is it time to rethink Kenya's procurement policy as a way of achieving Vision 2030 aspirations?

In competitive procurement the *lowest bidding price* is not equivalent to the *best achievable price*. Government expenditure on pharmaceuticals mostly targets essential medicines and prioritises generics. Procurement is based on the principle of the lowest bidding price and indeed, sales to the public sector are driven by low prices (margins) and large volumes. This notwithstanding, there is scope to achieve much better prices for generics and branded products for which suitable generics are not available for essential treatment.

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**Policy coherence is critical!**  
Meeting Kenya's health system needs (health policy) in a sustainable way must be linked to the development of knowledge intensive capabilities in the economy (industrial development).

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A move away from price focused procurement should be evaluated in terms of achieving better value for money long term. The current procurement policy that allows 15% preference to the local manufacturer and 10% preference to local importers may reflect short-termism; it may be an insufficient incentive for deepening and extending technological capabilities aimed at global competitiveness. There may be scope for pegging pharmaceutical returns to increased rate of return on local investment (higher productivity or efficiency gains of firms) or level of local investment in both manufacturing and research.

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