

Enhancing Contribution of County Government in Promoting Local Production/ Manufacture of Health Commodities by the Private Sector

INTRODUCTION

Sessional Paper No. 4 of 2012 on Kenya National Pharmaceutical Policy underlined the pharmaceutical sector's unique characteristics and impact on health, national economy, international trade, and cooperation. It recognises the role of local manufacturing in providing essential HPT towards not only self-sufficiency in the domestic market but also enhanced exports. The importance of local production of HPT as a key contributor to availability, quality and affordability of HPTs is not in doubt. Indeed, the sector has already set clear policy objectives on reversing dependency on imports specifically expanding product portfolio to cover 90% of disease conditions, increasing value of purchases from local firms to 50%, and getting firms to venture in production of advanced formulations such as delayed release formulations, small injectables and double layered tablets.

Sizing the Market

The demand for HPT for use in the Kenya public health sector is over KES 110 billion¹ excluding medical devices, medical oxygen, and blood products. Counties needs account for almost 50% excluding the strategic program commodities. Budgetary allocations to HPT only meet about 32%² of the estimated counties' requirements. County governments acquire almost half of their HPT needs through KEMSA (43% in 19/20). In turn KEMSA has been procuring approximately 30% of from local manufacturers in line with the preferential and reservation schemes provided for in the Public Procurement and Disposal Act, 2015.

Considering that a significant proportion (circa 40%) of Out of Pocket (OOP) spending in health is on HPT, that imports of pharmaceuticals have experienced growth year on year³, utilisation of production capacity of local manufacturing firms ranges from 60-70%, the untapped potential in local production of HPT is immense.

Opportunities Transcend Pharmaceuticals

Opportunities for increasing production of HPT transcend pharmaceuticals. Only 16% (118 of the 764) products in the essential medicines list are locally produced. Most of these, fall into the following categories – dialysis solutions, pain medicines, disinfectants, and antiseptics, gastrointestinal, anticonvulsants, anti-allergy, diuretics, and cardiovascular medicines. Significant gaps exist in the following categories – muscle relaxants, immunological, immunomodulators, antineoplastics, blood

¹ MOH - Draft Annual HPT Quantification Report estimated requirement for counties KES 41B, national referral facilities KES 7.8B, Strategic Programs – HIV, TB, Malaria, FP, and TB- KES 41B, Immunization – KES 20B*

² Estimate based on County HPT Budgetary Allocation Analysis

³ Economic Survey Report, 2021 - Kenya imported pharmaceutical products worth an estimated US\$.690 million in 2020 and US\$.570 million in 2019. Medicinal and pharmaceutical exports were valued at US\$. 14.9 million in 2019 and US\$. 14.2 million in 2020

products and plasma substitutes, diagnostic agents, and vaccines. In terms of essential medical supplies, there is some local production of syringes, needles, catheters, hospital linen, surgical mask, Personal Protective Equipment (PPE) but little production of physiotherapy, occupational, orthopaedic, and dental consumables despite the immense demand from facilities. There is also wide scope for growth of production of medical devices such as drip stands, wheelchairs, examination couches, medicine trolleys, suction machines and pumps, beds, and examination lamps. Only two local manufacturers produce laboratory diagnostics -blood collection tubes, viral transportation media, bacteria culture media. Since most diagnostics are machine specific, the reliance on imports is quite high.

Laudable Ongoing Initiatives

Kenya has gained recognition as a regional leader in the medical and pharmaceutical research sector, has a well-established legal and regulatory system that supports product safety and quality assurance and operates in harmony with other regulators in the African Region. The national government through the Ministries of Industrialisation and Health has spearheaded several interventions to shore up HPT local production capacity. These include the development and support to implementation of the Kenya Pharmaceutical Sector Development Strategy (KPSDS) geared at helping the pharmaceutical industry to attain the WHO GMP Standards through a stepwise approach, and as such be able to compete for and improve market access. The regulator (PPB) has continued to support local manufacturers towards enhancing their compliance with the Good Manufacturing Practices (30 out of the 41 local manufacturers of pharmaceuticals are currently deemed to be compliant). Quality of other locally manufactured HPTs (e.g., masks, sanitisers, and disinfectants) is assured through KEBS inspection, testing and certification.

Additionally, the government has provided taxation incentives for importation active pharmaceutical ingredients (APIs), and capital support through provision of land under the special economic zones. The updated preferential procurement muster roll for public agencies that incorporates 128 HPT items⁴ provides a backbone for applying preferential rules in procurement of HPT from local firms. Most recently, the directive by the President to the Ministry of Health to work with Kenya Biovax Limited to initiate local production of COVID 19 vaccine in April 2021 has provided further momentum.

Industry players with the support of ministry of industrialization continue to explore potential bankable projects such as setting up multipurpose chemical plant for bulk production of intermediate inputs, manufacture of non-pharmaceuticals, commercial processing of traditional medicines, processing of locally available sugar, salt (sodium chloride) and ethanol to pharmaceutical grades for use as inputs by pharmaceutical industries, and investment in manufacture of medical equipment.

Need for acceleration

However, there has been little traction in making local production impactful despite the various policy actions initiated at regional and national level. Dependency on imported pharmaceutical products continues while local firms continue to produce below capacity. Key constraints in enhancing local production include inadequate raw materials and machinery; high cost of inputs including taxes and

clearance charges, high cost of bioequivalence studies owing to absence of clinical research organisations, inadequate incentives, misperceptions on local products especially medical devices as being of low quality, gaps in definition of local content and standards for medical devices.

To move the local manufacturing agenda, it is important that policies are linked to action and focus more decisively on quality improvement to adhere to international standards especially WHO-GMP, price preferences; allocating increased budgets for local firms embedding quality GMP linked incentives. As the largest users of health commodities in the country, county governments should prioritise the local production agenda and complement the current efforts by the national government for acceleration. Regional economic blocs should be optimised for economies of scale.

Considerations for county governments

County governments as key purchasers of health commodities have a significant role in enhancing local production. The following proposals should be considered in creating an enabling environment for production of various essential HPT – essential medicines, essential medical supplies, essential medical devices, and essential medical diagnostic supplies:

- Sensitisation of county executive committees, county health supply chain and procurement staff on opportunities in local production including but not limited to PPDA 2016 and PPDA Regulations 2020 incentives, preferential procurement muster roll: process of approval and certification
- Encourage local firms to update their manufacturing capabilities with the county government whilst ensuring that appropriate databases are maintained, and validation undertaken during the annual business license renewal process
- Apply preferential procurement provisions provided in the law for local producers within counties
- Apply restricted tendering for locally manufactured HPT and guaranteeing purchase of new products based on active demand estimation
- Advocate for taxation regime that supports local production through amongst others enabling recovery of input VAT
- Enhance collaboration with regulators (PPB and KEBS) in post market surveillance and support sharing of information to counter wrong quality perceptions
- County governments to facilitate collaborate with local research institutions, County Technical and Vocational Education and Training institutes and private firms in research and manufacture of select HPT especially diagnostics - One County One Product.