

Inadequacies in the regulation of Health Products and Technologies: A time for County Governments to Act

INTRODUCTION

Regulation of Health Products and Technologies (HPT) play a key role in safeguarding the public from harm associated with the use of health products. Quality assurance for both pharmaceuticals and the entire spectrum of public health consumables, including food and food products-remains a major concern in the sector. The Kenya Health Policy 2014-2030 and the Health Act 2017 seek to forestall this challenge by comprehensively addressing regulation through an autonomous, harmonised, national regulatory framework that brings on board human drugs, vaccines, blood and its products, diagnostics, medical devices and technologies, animal and veterinary drugs, food products, tobacco products, cosmetics, and emerging health technologies. A draft Bill¹ currently in parliament seeks to establish a single regulatory body for HPT.

Key policy and regulatory concerns for County Governments

Currently, the regulation of HPT is governed under several legislations and policies. The overarching policy is the Kenya National Pharmaceutical Policy while the overarching legislation is the Pharmacy and Poisons Act, Cap 244. These are complemented by legislations and policies of standards, industrialisation, industrial property, public procurement and prevention and treatment of various diseases. These legislations have provided direction to county governments in various aspects of the HPT supply chain.

Despite efforts to strengthen the HPT regulatory environment, there are gaps in the implementation and/or enforcement of existing policies. Amendments to existing health policies have not considered effecting the principles and objects of devolved government in respect to assigned functions according to the Fourth schedule of the Constitution² with no requisite enforcement responsibilities extended to the county government to implement sector policies. There is need to enforce clear policies to safeguard consumer interests and enhance the involvement of county governments providing guidance for instance on the level of government that is suited to control different aspects of HPT regulation in respect to quality.

HPT regulatory environment

The Ministry of Health has put in place several HPT specific guidelines to support implementation of the Kenya National pharmaceutical Policy 2012. These include strategy³, essential lists, forecasting and quantification handbook, and guidelines for the establishment of medicines and therapeutic committees

¹ Kenya Food and Drugs Authority Bill, 2019

² The constitution of Kenya 2010

³ The Kenya Health Supply Chain strategy 2020-2025

(MTCs). They complement the efforts of the Pharmacy and Poisons Board (PPB) and other regulatory agencies.

The Board⁴, regulates the manufacture and trade in drugs and poisons to ensure quality of health products and technologies (HPT) in the country. However, there are gaps in HPT regulation which are yet to be addressed such as intensifying internal and cross-border quality control of HPT, enforcement of pharmaceutical procurement, and pharmaceutical care services such as polypharmacy, inappropriate use of antibiotics resulting in ineffective treatment and increased risk of drug resistance and cost of health care; lack of enforcement on the use of the standard treatments and clinical guidelines towards rational drug use, curbing antimicrobial resistance, or managing promotional activities by drug companies- areas that county governments are best effectively placed for enforcement.

Constitutional oversight role of County Governments on pharmacies

The fourth schedule of the constitution of Kenya 2010, Part 2. 2(a), assigns 'county health facilities and pharmacies' to counties. This role may be interpreted to include oversight of all health facilities including retail pharmacies. However, this is yet to be operationalized and has not been considered under the Kenya Food and Drugs Authority Bill, 2019.

Additionally, the Bill does not provide for the representation of counties in the governance of the proposed authority, despite provisions under schedule 1V of the Constitution of Kenya being specific on some regulatory roles for food establishments, veterinary outlets, and pharmacies in the counties. While county governments in the quest to strengthen governance structures have established HPT Units for comprehensive HPT management at County level, few have made requisite legislations to effectively give mandate to the Units.

Legislations at the County level on HPT

County governments legislations such as County Health Acts, do not specifically address functions such as the regulation of county health facilities and pharmacies. Where supervisory roles or quality audit structures have been identified, this has been on county health facilities, necessitating an understanding on whether county facilities encompass retail pharmacies.

Effective regulation should reflect on both quality and cost of health products

Quality of HPT: The quality of HPT in Kenya is important for the achievement of highest attainable quality healthcare for all. The PPB regulates the trade in pharmaceuticals and related products through registration of medicines, medical devices, licensing for import/export and pharmaceutical facilities and regulation of trade in medical products and health technologies.

Quality monitoring interventions by the Board in collaboration with other quality oversight bodies point to a reliably good quality HPT with products that meet quality specifications, an indication that the existing regulatory and quality assurance systems are effective. However, there are exceptions with incidences of sub-standard and counterfeit medicines, weak investments in HPT storage infrastructure,

⁴ Pharmacy and Poisons Board established by the Pharmacy and Poisons Act (PPA) CAP 244

gaps in the regulation and post market surveillance for nutrition products, medical devices, and non-pharmaceuticals and lack of clear feedback mechanism to support information sharing.

Cost of HPT: Prices of health commodities remain a key driver of the cost of healthcare. However, there is a gap in the implementation and enforcement of past policies that have always encouraged cost awareness⁵ for HPT in the sector and proposed interventions for controlling drug prices in Kenya⁶.

County governments are best positioned to invest in data systems and operational research towards health technology to inform the costing of health products, medical devices, diagnostics, and medical equipment. Such investments are critical in informing decisions such as reimbursement of essential medicines under the UHC benefit package.

RECOMMENDATIONS

The following actions are necessary to strengthen the regulatory environment of HPT:

- Comprehensive legislative review of national and of County Health Services Acts to affect the principles and objects of devolved government in relation to county government oversight role on pharmacies that puts in place a national legislation (including within Draft KFDA Bill where possible) that clarifies the oversight role of county governments.
- Immediate actions by county governments to address illegal outlets and quality concerns. The PPB (and other regulators) inspectorate should ensure compliance with laws and regulations on HPT through mechanisms that ensure joint inspections of pharmacies with county representation.
- Establishment of mechanisms and forums to facilitate timely information sharing between the regulator and county governments on HPT quality monitoring data generated by the testing laboratories for use in decision making especially in the supplier pre-qualification and monitoring systems.
- County governments to strengthen HPT institutional mechanisms at County Health Departments for effective regulation, implementation, and enforcement of HPT policies at the county level through county specific legislations on HPT Units/Directorates with clear mandates.
- Establish clear collaboration mechanism for national and county governments to manage and regulate the cost of HPT including ensuring that the UHC insurance benefit package reimburses the cost of HPT for sustainability.
- County governments to promote the essential medicines concept as a cost-effective intervention for maintaining HPT costs and enforce compliance in both public and private facilities.

⁵ The Kenya Drug Policy 1994

⁶ The Kenya National Pharmaceutical Policy 2012