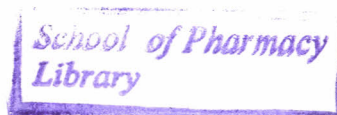


PHARMACY SERVICES IN POST DEVOLUTION KENYA

BY

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U29/2746/2009



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DECLARATION:

I solemnly declare that research dissertation submitted is my original work. Any use of work by other authors has been properly acknowledged. This original work has not been presented anywhere else for any degree programme or research paper.

NJOROGE NJUGUNA PATRICK

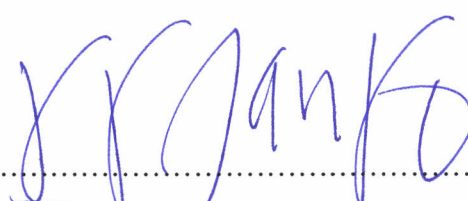
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ABBREVIATIONS

COMESA	Common Market of Eastern and Southern Africa
EPZ	Export Processing Zone
GDP	Gross Domestic Product
KEMSA	Kenya Medical Supplies Agency
MEDS	Mission for Essential Drugs and Supplies
PPB	Pharmacy and Poisons Board
WHO	World Health Organization

ABSTRACT

Background

The Constitution of Kenya 2010 requires county governments to establish and manage county pharmacies. Alongside other health services, pharmaceutical services are among the most devolved functions from national government to county governments. The pharmaceutical services sector is broad and encompasses distribution of medicines, hospital and community pharmacies, drug manufacturing, human resources, training facilities, public quality control laboratories and regulatory agencies.

Objectives

This study was aimed at assessing the impact devolved government framework on the structure and function of Kenya's pharmaceutical services sector.

Study design and analytical framework

The study used a modified decision space analytical framework to compare the degree of decentralization of various pharmaceutical functions. A variety of textual sources including the constitution, statutes, policy documents were reviewed to determine degree of administrative freedoms for the county governments in the management of pharmaceutical services.

Results

National Government is in charge of policy making, pharmaceutical services within National Referral Hospitals and training institutions. Functions assigned for County governments include: recruitment pharmacists and pharmaceutical technologists, procurement of drugs, county pharmacies and licensing of premises. Financing is a shared function between the National Government and County Governments.

Conclusion

Pharmaceutical sector is restructured in devolved government while functions are distributed to both National government and County Governments. Although County Governments are mandated by the Constitution 2010 to carry out certain functions, this has not yet been achieved.

CHAPTER ONE

1. INTRODUCTION

A pharmaceutical system describes various components that constitute the entire pharmaceutical sector in the country. Various components can be identified: manufacture, procurement, distribution, use, regulation and financing of pharmaceutical industry. Over years there has been significant changes in this sector with aim of improving quality of medicines, availing essential medicines to everyone and increase productivity of the sector. The structure of pharmaceutical sector in Kenya is will change after full implementation of Constitution, 2010. This because constitution, 2010 paved way for devolved system of government.

Under devolved system of government, National government and county governments were established. Both National Government and County Governments are allocated various functions according to Constitution 2010. Hence under devolution, more national resources that were centrally controlled under previous regime of governance are distributed equitably to the 47 counties. This is to ensure eradication of marginalization of some regions of the country. Also under devolution, service delivery is brought to grassroots hence public participation is fostered. Health services are among services that were distributed to County Governments. Since pharmaceutical sector is a component of health services, restructuring of this sector was not inevitable. Some components of pharmaceutical sector are under National Government while others under county governments.

Other than pharmaceutical sector being a component of health sector, it also a critical to the economic development of Kenya. Pharmaceutical companies in Kenya generate revenue from sale of drugs within Kenya and other countries and provide job opportunities for various groups

of people. Although in COMESA region, Kenya is the leading producer of pharmaceuticals, Kenya still imports large of its medicines.

Pharmaceutical sector will continue to grow as life expectance increases, rise in health spending by the government and increased awareness in preventive healthcare. There are also challenges to growth in this sector: poor funding, counterfeiting, poor implementation of policies.

2.1 LITERATURE REVIEW

2.1.2 DEVOLUTION

Devolution is the transfer of power from a central government to sub national government.^{1,2} Promulgation of the new constitution brought an end to the powerful centralized form government. Two systems of government, that is, national government and 47 devolved county governments were adopted after 2013 general election.¹ In this system, Kenya adopts cooperative system of devolved government³. The national government will oversee the implementation of national standards and policies and relinquish service delivery to the counties. Schedule 4 of the constitution gives the distribution of functions between the national government and county government.^{1,3,4} Among the functions to be distributed are health services. A four tiered health system is proposed:⁵

1. The community services
2. Primary care services
3. County referral services
4. National referral services

2.1.2 HUMAN RESOURCES

The availability of adequate number of health professional, competence and commitment of these personnel is a key factor in providing good health services. In pharmaceutical field, pharmacist and pharmaceutical technologist are key personnels.^{6,7} In Kenya, pharmacy schools include universities and colleges that provide degree and diploma training in pharmacy. Pharmacy education in most countries take an average of 4-6 years for B.pharm or a Pharm D. Students are expected to gain skills in pharmaceutical care, medication management, pharmaceutical analysis, pharmacology, pharmacy management and procurement. Pharmacy and poisons Board is responsible for regulation of pharmacy practice in Kenya.⁸

2.1.3 FINANCING

Pharmaceutical financing can be viewed in the overall context of health financing. Proper drug financing ensures access to essential drugs to all segments of the population.⁶ Kenya spends about 8% of its GDP on health. Kenya's budget for drugs 2010/2011 was 3.7 billion Kenya shilling.⁹ This is way below the required 15% by Abuja Declaration which Kenya is a signatory.

There have been several reforms on health financing since independence.

- 1 .Establishment of NHIF scheme in 1966
- 2 .Introduction of users' fee in 1989
3. The health policy framework of 1994
4. Health care financing strategy

Funding mechanisms for drug finance include:⁶ public sector financing (government budget), private sector financing, health insurance, donor funding, users charges and developmental loans

2.1.4 PROCUREMENT AND DISTRIBUTION

Procurement in public sector is done by procurement agency, Kenya Medical Supplies Agency (KEMSA).^{6,7,10} It is responsible for procurement of pharmaceuticals and related products using an open tender system. MEDS is a nonprofit making mission based medical supply facility which procures pharmaceuticals and related items for faith based organizations and some donors.

Procurements are based on prequalification of suppliers. The two agencies procure both propriety and generic products giving preference to drugs listed in essential drug list.

The government pharmaceutical supply system has a central medical store at national level and 8 public warehouses.⁶

2.5 REGULATION AND POLICY FRAMEWORKS

2.1.5.1 REGULATION

PPB is a semi autonomous body that was established as a regulatory authority under the pharmacy and poisons Act Chapter 244 of the laws of Kenya. The board regulates pharmaceutical services in Kenya. It is responsible for market authorization of pharmaceutical products, regulatory inspection; inspect premises where pharmaceutical are performed. Inspection is a pre requisite for licensing of facilities.⁸

Licensing is legal provision requiring that manufacturers to be licensed and comply with Good Manufacturing Practices. There is also a legal provision requiring importers, distributors and wholesalers to be licensed. Pharmacist and private pharmacies are supposed to be registered.⁸

PPB also controls advertising and promotion of prescription medicines, clinical trials, import control, market control and quality control.⁸

2.1.5.2 POLICY FRAMEWORK

Aspects of policy deals with selection of essential medicines, medicine financing, medicine procurements, medicine distribution, medicine regulation, pharmacovigilance, rational use of medicines, human resource development and research.⁷ The Kenya Pharmaceutical Policy was updated in 2010. The Kenya Health Policy was developed in 1994.

2.1.6 MANUFACTURING COMPANIES IN KENYA

Kenya has capacity for manufacture of pharmaceuticals for local and regional markets. There are about 30 pharmaceuticals companies which include local manufacturing companies and large multinational corporations. The local industry produces primarily generic medicines which are

generally affordable .^{6,11} This offers great potential for Kenya to attain self sufficiency in essential medicines and serve the export market.

2.4 STUDY OBJECTIVES

2.4.1 General Objective

To assess the impact of devolved government framework on structure and functions of pharmaceutical sector.

2.4.2 Specific Objective

1. To compare components of pharmaceutical services in pre-devolution and post devolution Kenya.
2. To analyze challenges that face devolution of pharmacy services

3. CHAPTER THREE

3.1 METHODOLOGY

3.1.1 STUDY DESIGN AND FRAMEWORK OF ANALYSIS

The study used an analytical framework to compare the degree of decentralization of various pharmaceutical functions. Modified decision space analysis adapted from Thomas Bossert was used.¹² Decision space is a form of principal-agent approach in which the principal set the goals and the agent is responsible for implementation of principal's objectives. A range of effective choice is allowed by principal to be utilized by the agent.

Table 1. Decision space map

Function	National Government	County Governments	Performance as at September 2013
Financing Source of revenue			
Human resources Salaries Hiring of staff			
Regulation Product assessment and registration Inspection of manufacturing and distributors Quality control Market control Licensing of premises. Licensing of persons and practice			
Policy making			

3.1.2 MATERIALS AND DATA COLLECTION METHOD

A variety of textual sources including the constitution, statutes, policy documents were reviewed determine degree of administrative freedoms for the county governments in the management of pharmaceutical services.

RESULTS AND DISCUSSION

IMPACT ON THE STRUCTURE OF PHARMACEUTICAL SECTOR

The structure pharmaceutical sector changes from a one tiered system in pre-devolution to a two tiered system in post devolution. This results from two forms of governments, National Government and County Governments. At National Government, pharmaceutical services will be under Ministry of Health. Ministry of Health will oversee National referral hospitals, Pharmacy and Poisons Board, Kenya Medical Supplies Authority and training institutions.

At county level their will county pharmacies.

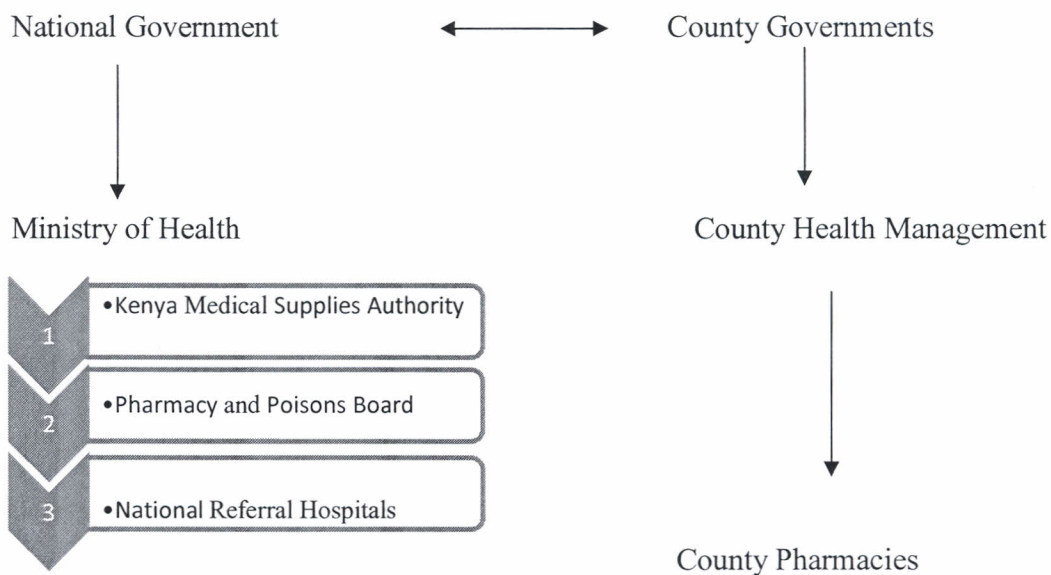


Figure 1 Structure of Pharmaceutical Sector

IMPACT ON THE FUNCTIONS

Human Resource

The Constitution provides for devolution of the management of healthcare services to the county governments. The county governments are constitutionally mandated to hire and supervise their personnel in the pharmaceutical sector (see Table 1). Nevertheless, the national government also retains slight control of human resource in the health sector. For instance, hiring of pharmacists in the Referral Hospitals and national policy and regulatory bodies will remain with the national government. Currently, the country is grappling with unequal distribution of pharmacists and pharmaceutical technologists to various regions of the country. This trend transcends across all health-related professions. Basically, most pharmacists and pharmaceutical technologists are posted in big hospitals, effectively abandoning small health centers and local dispensaries. Although this is widely attributable to the availability of requisite health facilities, it certainly stifles the provision of quality healthcare in the rural Kenya. Notably, healthcare needs are specific to various regions or communities and thus leaving the responsibility to the national government would certainly result in such a failure. This is the reason devolution of human resource to the county government came as a relief to Kenyans. Indeed, the speculated success of the county governments was premised on the belief that following minimum staffing norms would significantly reduce disease burden on the rural folk and ease the workload currently born by health workers in the country. This is because the health workers would be able to negotiate with their county government leaders with a view to coming up with acceptable terms of service. Eventually, the country would end up with a health system that responds to the needs of the society and a work force that is sufficiently motivated to deliver the best healthcare. In addition,

the current misfits would be given specific remedies instead of general attempts that have failed in the past.

Considering that county governments are yet to develop adequate capacity, there is need to define what roles the national government must undertake during the transitional period. For instance, it should help county governments to institutionalize staffing norms and develop elaborate schemes of service for their health staff. In addition, the national government should continue to support higher learning institutions in healthcare as well as in-service training of staff to keep them abreast with current trends in healthcare. This entails supervision of sub-specialized skills and the development of national guidelines to ensure that pharmacists and pharmaceutical technologists attain the necessary skills. This may include the use of incentives to retain skilled labor in public service. However, there is a school of thought that deployment of healthcare personnel should be reserved for the national government. This is based on the logic that certain counties will be logistically in a better position to employ the best personnel in pharmaceutical cadre than others. As a result, marginalization that is supposed to be solved by devolution will reign supreme. It will be interesting to see industrial strikes by pharmacist and other health personnel within certain counties. Notably, this school of thought argues for the creation of a National Health Service Commission to rationalize deployment of personnel in pharmaceutical sector.

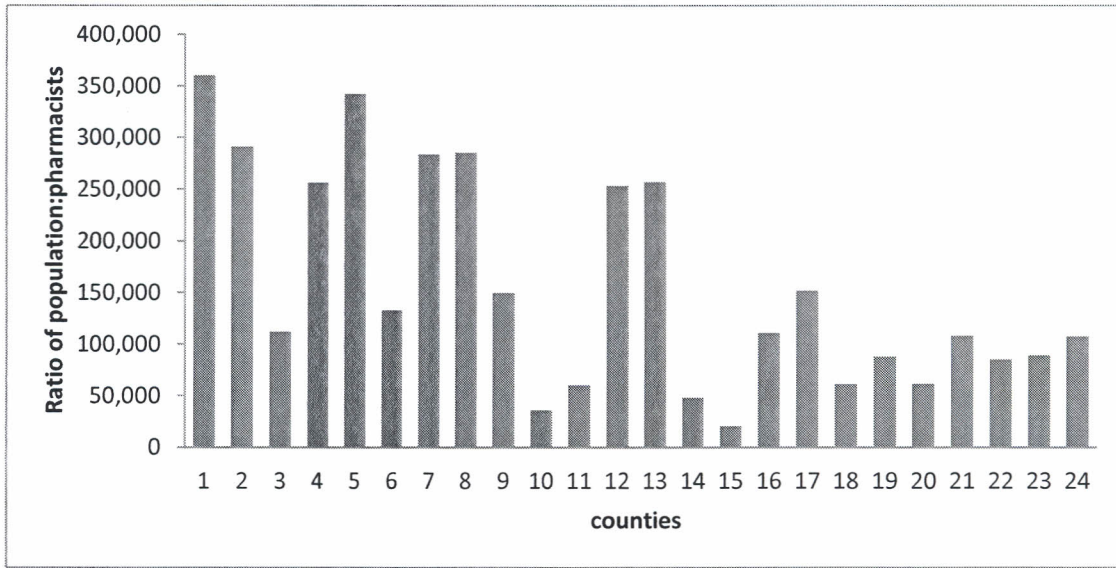


Figure 2 Population to pharmacists ratio

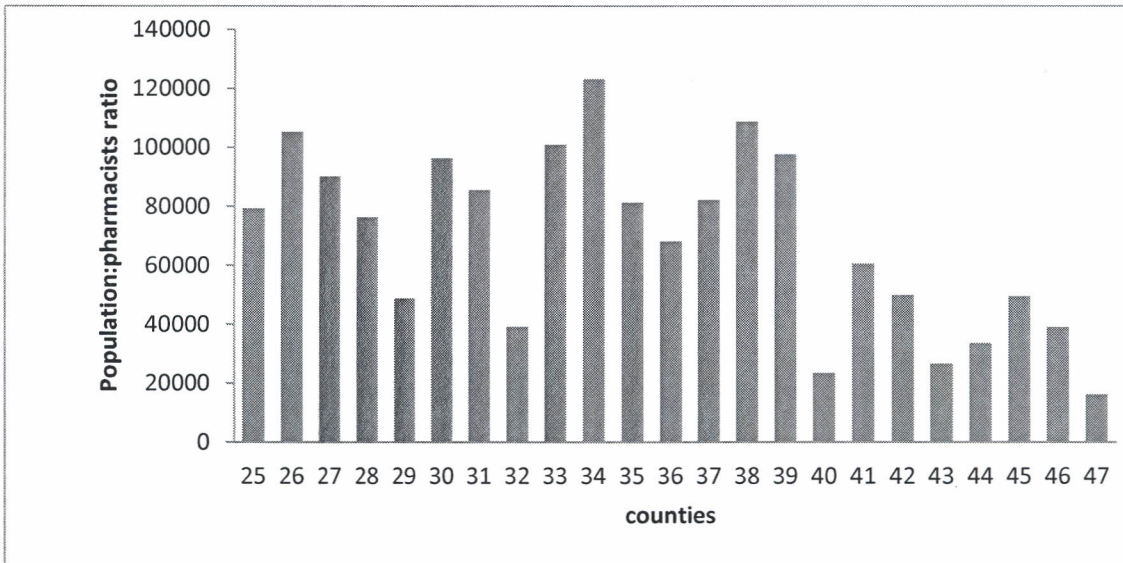


Figure 3 Population to pharmacists ratio

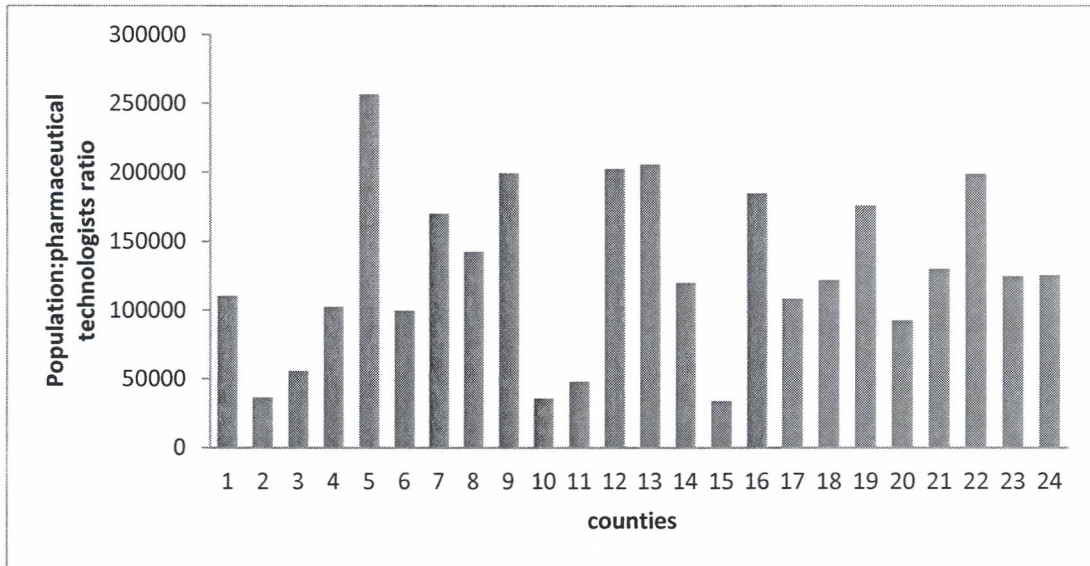


Figure 4 Population to pharmaceutical technologists ratio

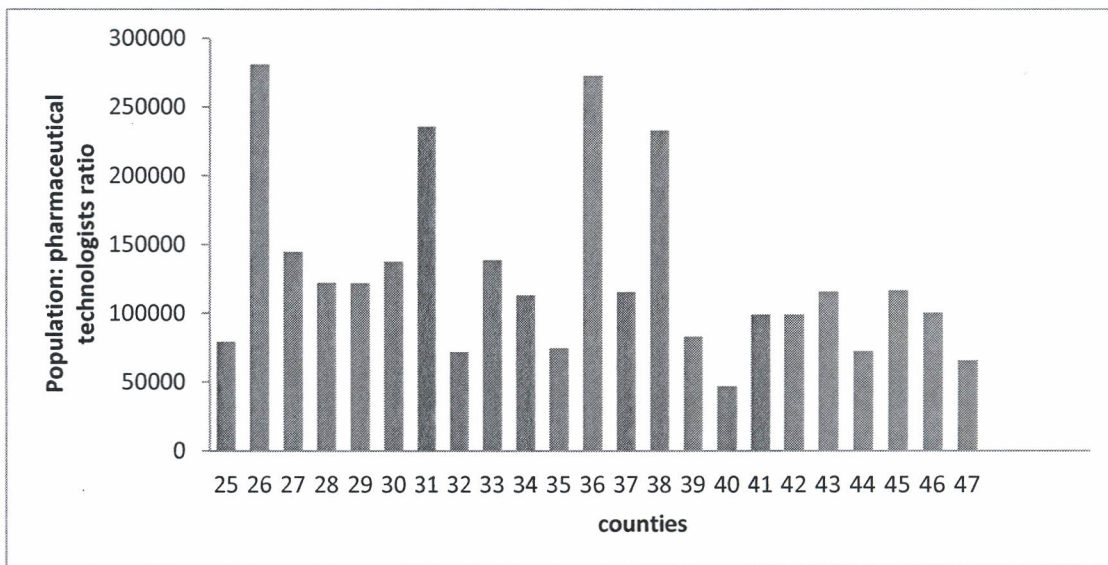


Figure 5 Population to pharmaceutical technologists ratio

KEY

1 Wajir	17 Kericho	33 Kilifi
2 Marsabit	18 Tharaka Nithi	34 Meru
3 Samburu	19 Kirinyaga	35 Uasin Gishu
4 West pokot	20 Elgeyo Marakwet	36 Trans Nzoia
5 Mandera	21 Kwale	37 Kisii
6 Laikipa	22 Nyandarua	38 Bungoma
7 Narok	23 Garissa	39 Kisumu
8 Turkana	24 Nandi	40 Kakamega
9 Nyamira	25 Baringo	41 Embu
10 Isiolo	26 Siaya	42 Machakos
11 Taita Taveta	27 Bomet	43 Nyeri
12 Migori	28 Kajiado	44 Mombasa
13 Kitui	29 Busia	45 Kiambu
14 Tana	30 Homa Bay	46 Nakuru
15 Lamu	31 Murang'a	47 Nairobi
16 Vihiga	32 Makueni	

Pharmaceutical Financing

Before devolution of healthcare, there were several documented sources of revenue for the health sector. These included budgetary allocation to the Health Ministry which was centralized and other decentralized revenue sources like the Health Sector Services Fund (NSSF), Hospital Management Services Fund, Local Authority Transfer Fund (LATIF) and the Constituency Development Fund (CDF). But with the coming of devolution, some of these decentralized funds have been scrapped off. They have been effectively replaced with revenue sources like budgetary allocation to health ministries in both the national and county governments, donor funds from developing partners, charitable organizations and the Equalization Fund that will be managed by the national government. Moreover, county governments will be mandated to collect taxes towards provision of healthcare through legal provisions that will be legislated by the respective county assemblies. Financing pharmaceutical sector will be health financing.

Procurement and Distribution

Counties are mandated by the Constitution 2010 to establish their own county pharmacies. County pharmacy will be the supplier of medicines in a county. However, according to the proposed Health Bill 2013, KEMSA should remain the chief supplier of medicines for both the National Government and County Governments.

Noting that policy issues remain with the National Government, there will be need for it to provide guidelines for procurement, purchase, distribution and management of medicines. These should be implemented in such a way that it complies with the demand-driven procurement system as it is purported to be the best way for procurement. In addition, the National

Government should support the county health systems in establishing the requisite capacity to carry out these mandates, including inventory management.

Training institutions

There are registered universities and colleges that offer degree and diploma in pharmacy respectively. The universities include: Mt. Kenya University (which offers both degree and diploma courses), University of Nairobi, Jomo Kenyatta University of Agriculture and Technology and Kenyatta University.

Colleges that offer Diploma in Pharmacy are: Kenya Medical Training College, Rift Valley Technical Training Institute, Kisii University College, Nyanchwa Adventist College, Outspan Medical College, Gussi Institute of Technology, Equator School of Health Sciences, Thika Technical Training Institute, St. Joseph's Medical Training Institute, Royal College of Science and technology, Nairobi Institute of Business studies, Mombasa Technical Training Institute, African institute of Research and Development, Nyeri Technical Training Institute, Kenya School of Medical Sciences and Technology, Tracom College, Menengai Medical and Training College, Nairobi Technical Training Institute, Kabete Technical Training Institute, Rift Valley Technical Training College, Rift Valley Technical Training Institute, Kenya Polytechnic College, Eldoret Polytechnic

Of the four registered universities, its only University of Nairobi that has already produced pharmacists in the job market. This has partly contributed to inadequate number of pharmacist available for the public sector. There are 24 registered colleges that offer Diploma in Pharmacy. However, most of them are located within major towns such as Nairobi, Nakuru, Kisii, Eldoret,

Mombasa and Nyeri. Despite the number of registered colleges, the number pharmaceutical technologists practicing in public sector is not sufficient.

Table 1. Distribution of Pharmacy Services

Function	National Government	County Governments	Performance as at September 2013
Financing Source of revenue	✓	✓	National Government
Human resources Salaries Hiring of staff	—	✓	National Government
Regulation Product assessment and registration Inspection of manufacturing and distributors Quality control Licensing of premises.	✓ ✓ ✓ —	— — ✓	National Government

Licensing of persons and practice	✓	—	
Policy making	✓	—	National government

Although counties are mandated to undertake various functions by constitution 2010, this has not been realized as National government still performs various functions meant for County governments. This is partly due opposition by various health stakeholders to devolve health services. The county budgetary allocation is also way down to meet health requirements at county level

Challenges to Devolution of Pharmacy services.

Challenges that face devolution of healthcare will directly have an impact on pharmaceutical sector. Political goodwill will have direct impact on devolution and this is bound to affect devolution pharmacy services. Going by the tug of war that has since ensued between the National Council of Governors and the Transitional Authority (National Government) over devolution funds, there is little doubt that devolution may take much longer to implement. As a result, the projected benefits to healthcare could just remain a mirage. In addition, institutional capacity is a major challenge in realizing devolved healthcare in the country. These coupled with financial challenges and poor infrastructure at the county level will certainly cripple devolution of pharmacy services at some point in time. This explains why cooperation between the two levels of governments is paramount if devolution is to succeed.

Various stakeholders in health are opposing devolution of health services. This poses a threat to devolution of pharmacy services as these services are under health sector.ssssssssss

Recommendations

Creation of proposed National Health Service Commission that will deal with deployment pharmacist in all counties based on the population in each county. This will prevent further marginalization which devolution is supposed to solve.

To increase the ratio of pharmacist to population to reach WHO standards of 1:2000, more schools of pharmacy should be created in the country. The schools should also be well equipped so as to produce pharmacist necessary skills to provider pharmaceutical care to the public.

Better remuneration and working conditions are required. This will attract more personnel to the public sector hence adequate number of pharmacists to provide pharmaceutical care will be available.

Development of policies and guidelines which influence and determine decisions and subsequent actions. Implementation of such policies will give a roadmap towards realization devolution.

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APPENDIX

Number of registered pharmacists and Pharmaceutical technologists in Kenya per county in the public sector.

	County	population	Pharmacists	Pharmaceutical technologists
1	Wajir	661,941	1	6
2	Marsabit	291,166	1	8
3	Samburu	223,947	2	4
4	West Pokot	512,690	2	5
5	Mandera	1,025,756	3	4
6	Laikipia	399,277	3	4
7	Narok	850,920	3	5
8	Turkana	855,399	3	6
9	Nyamira	598,252	4	3
10	Isiolo	143,294	4	4
11	Taita Taveta	240,075	4	5
12	Kitui	1,1012,703	4	5
13	Migori	1,028,578	4	5
14	Tana	240,075	5	2
15	Lamu	101,539	5	3
16	Vihiga	554,622	5	3
17	Kericho	758,339	5	7
18	Tharaka Nithi	365,330	6	3
19	Kirinyaga	528,054	6	3

20	Elgeyo/Marakwet	369,998	6	4
21	Kwale	649,931	6	5
22	Nyandarua	596,268	7	3
23	Garissa	623,060	7	5
24	Nandi	752,965	7	6
25	Baringo	555,561	7	7
26	Siaya	842,304	8	3
27	Bomet	724,186	8	5
28	Kajiado	687,312	9	2
29	Busia	488,073	10	4
30	Homa bay	963,794	10	7
31	Murang'a	942,581	11	4
32	Makueni	430,710	11	6
33	Kilifi	1,109,735	11	8
34	Meru	1,356,301	11	12
35	Uasin Gishu	894,179	11	12
36	Trans Nzoia	818,757	12	3
37	Kisii	1,152,282	14	10
38	Bungoma	1,630,934	15	7
39	Kisumu	968,909	16	10
40	Kakamega	1,660,651	17	20
41	Embu	516,212	22	6
42	Machakos	1,098,584	22	11
43	Nyeri	693,558	26	6
44	Mombasa	939,370	28	13

45	Kiambu	1,630,934	33	14
46	Nakuru	1,603,325	41	16
47	Nairobi	3,138,569	194	48