Designing fit-for-purpose regulation for evolving healthcare systems

Country report: **Kenya**

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Table of Contents

List of Abbreviations

CAK	Competition Authority of Kenya.
COC	Clinical Officers Council
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
KMPDB	Kenya Medical Practitioners and Dentists Board
KNDI	Kenya Nutritionists and Dieticians Institute
NCK	Nursing Council of Kenya
PHOTC	Public Health Officers and Technicians Council
PPB	Pharmacy and Poisons Board.
PPP	Public Private Partnership
PSK	Pharmaceutical Society of Kenya
RPB	Radiation Protection Board

Chapter 1: Methods

1.1. Landscaping

A landscaping exercise was conducted to identify 'hot topics' in terms of recent changes in Kenya's healthcare market. These included market structure changes, developments in financing mechanisms, and innovations in service delivery. Through a desk-based review of media, business and academic literature, a host of new developments were identified. Following discussion with the research team, three topics were chosen to study in more detail: consolidation (pharmacy chains); e-pharmacy, and public private partnerships in health.

1.2. Key informant interviews

A set of key informant interviews were conducted in order to explore the three topics in more depth. The purpose of these interviews was to learn more about the nature of each topic, the scale and scope of each phenomenon, and the impact they have had on the health economy. Further, we explored the regulatory issues associated with each topic, focussing on the nature of the regulatory response, including regulatory structures and processes. Finally, we sought to identify the regulatory gaps and challenges associated with each new topic, as well as any regulatory opportunities they may present. The interviews were semi-structured in nature; based on an interview guide (guided by the research questions) to ensure each interview covered comparable matters but allowed for flexibility in the discussion thus providing opportunity to cover issues that arose freely. While no effort was made to restrict the inquiry to specific geographic locations, innovations in areas under study were mainly focused around Nairobi, Kenya's capital.

No specific piloting was done for the tools. However, they were continuously reviewed to improve relevance and ensure that interviews focused on getting rich data from interviewees. For instance, once the overall regulatory mechanisms were established and confirmed, subsequent interviews focused more on understanding stakeholder views on regulatory gaps and how they can be improved.

Between September and December 2018, a total of 22 interviews were conducted with purposively selected private sector actors, health policymakers, regulatory officials, and other experts identified by the research team. These comprised the CEO Kenya Medical Practitioners and Poisons Board, Registrar Nursing Council of Kenya, Registrar Pharmacy and Poisons Board, and CEO Pharmaceutical Society of Kenya. Three interviewees (two e-pharmacy, and one PPP) refused to participate, citing lack of time. Interviews were organized and conducted in-person by AM, DO and FW, in English, and lasted between 30 minutes and 90 minutes. Verbal consent was obtained prior to commencing interviews. A note-taker was present at all interviews. 21 Interviews recorded but not transcribed, one responded declined to be recorded.

An initial set of broad, pre-defined coding categories were prepared based on the topic guide, to guide a thematic data analysis. The research team members then coded a few transcripts together to refine the codes. However, analysis also allowed for new themes to emerge from the data and the initial categories were refined again and again throughout the process.

1.3. Document review

Alongside the key informant interviews, documents were gathered relating to the topics under study. Documents reviewed included legislation and policy documents governing the Kenyan health sector. These included the Pharmacy and Poisons Act, the Kenya Medical Practitioners and Dentists Act, the Nursing Act, the Clinical Officers Act, the Public Health Act, the Radiation Protection Act, the Kenya Nutritionists and Dieticians Act, Kenya Medical Laboratory Technicians and Technologists Act and the Public Private Partnerships Act. In addition, a recent review of health-related legislation done by FW was reviewed by the team to understand the broad regulatory landscape and the role of different regulators.

Chapter 2: Consolidation

2.1. Overview of consolidation in Kenya

Kenya has a pluralistic health system, with roughly half of all healthcare services provided through the private sector. Informally, health system analysts agree that the real numbers served through the private sector are much higher, particularly when medicine retailers are considered. Pharmacies are preferred for the convenience of their location and opening hours as well as the speed of service, which avoids the need for clients to miss work, an important consideration for lower income groups.

Kenya's retail pharmaceutical sector is excessively fragmented with evidence indicating low presence of qualified staff and poor compliance to regulatory standards. The size of the Kenyan retail pharmaceutical market is poorly defined, with little reliable information on the numbers and location of pharmacies. Estimates vary but actual numbers are estimated to lie between 15,000 and 20,000. Officially, only about 5,000 pharmacies are licensed to operate.

The excessive fragmentation creates inefficiencies in practice and poses regulatory challenges. However, it also creates opportunity for consolidation. While it is common to find individuals owning two or three pharmacies, discussions with experts reveal that these do not typically operate like formal chains with unified operations and shared systems. General retail management capabilities across the sector remain relatively poor. Anecdotal evidence suggests that most pharmacies operate at a subsistence retailing level with median daily sales ranging from KES 1,000 (US$ 10) to KES 10,000 (US$100), barely enough to sustain the business. Some in informal settlements have daily sales of below KES 1,000 (US$ 10). A lack of business management expertise and support systems underlines the hand-to-mouth nature of many pharmacies.

The operations and management challenges are further compounded by difficulties accessing good credit arrangements. Experts report that most small pharmacies either have no access to credit facilities or have credit arrangements that do not extend beyond 30 days, denying them operating capital and making it hard for sustained growth. Suppliers often complain that small retailers often default, and will normally engage a different supplier when they need new stock.

Poor financial management and record keeping contribute to the problem. Traditionally, most retail pharmacies in Kenya have engaged in the sale of medicines only. However, this appears to be changing, with more pharmacies offering clinical and diagnostic services, as well as front shop merchandise such as basic toiletries and convenience items. These aim to boost sales, but only put additional strain on establishments with poor supply chain and operations management systems.

The market features described here underlie a growing interest in consolidation across the country. Retail pharmacy chains are starting to emerge but remain embryonic overall. The last five years have seen two well-established retail pharmacy chains emerge in Kenya: Goodlife Pharmacy and Haltons Pharmacy (both having more than 15 outlets). In addition, some of the older businesses like Pharmart and Malibu Pharmacy have expanded, branching out to other strategic locations.

The market share taken by pharmacy chains remains low overall. One manager we interviewed estimated it to be below 3% (and that's only using the denominator of 5,000 licensed pharmacies).

Haltons Pharmacy have 17 branches in total, with an additional two branches that they operate on behalf of private healthcare facilities. The chain started in 2013 following capital injection by Fanisi Capital, a Kenyan-owned private equity firm. The firm initially expanded to more than 100 sites, but later shrunk by closing non-performing stores across the country. Goodlife started in 2015 and

expanded with additional investment from LeapFrog, a US-based private investment firm. Goodlife presently own 46 shops distributed across two countries (41 in Kenya and five in Uganda). Their pharmacies are mainly located in large towns, most in Nairobi. The chain is targeting to have at least one pharmacy in every Kenyan county by year 2020. Dovey Pharmacy are a domestically owned chain with five branches (four in Nairobi and one in Mombasa). Malibu Pharmacy, perhaps one of the oldest pharmacies in Nairobi that is still operational, started in 1994, and remained a single business unit for many years. It has only recently expanded to seven branches.

The Kenya Pharmaceutical Association's Pharmnet is a network of individually-owned pharmacies that are operated by pharmaceutical technologists. The Kenya Pharmaceutical Association is the professional body representing pharmaceutical technologists, who operate nearly four-fifths of all licensed retail pharmacies in Kenya. Unlike the commercial chains, Pharmnet targets lower income groups, with deliberate effort to consolidate certain aspects of the smaller business establishments (for instance, pooled purchasing and quality assurance mechanisms).

There is a general belief that consolidation may help address some of the regulatory challenges linked to the private commercial pharmacies. Market consolidation may take one of many different forms, including chains, franchising, formal collaboration. Consolidation allows governments and regulators to engage the private pharmacy providers in a structured way. Consolidation raises the stake for the providers, creating strong disincentives for engaging in unlawful or unethical practices. One errant store has the potential for damaging the reputation of the entire chain/franchise. This creates opportunity for regulators to deploy newer, more effective and less costly regulatory mechanisms such as self-regulation and responsive regulation.

On the other hand, consolidation carries certain regulatory and market failure risks. In poorly controlled markets, consolidation could result in monopolies, which are inherently inefficient. Monopolists have incentive to restrict supply and raise prices, which then creates problems of poor access and inequity. While consolidation is relatively minimal in Kenya, experiences higher up the distribution chain suggest the possibility of dominant players emerging. A 2015 DFID-supported study, for instance, found that three distributors controlled between 44% and 66% of market share across four Kenyan counties (mixed rural and urban).

2.2. Regulatory overview

[Please outline the current regulatory structure and mechanisms in place for the regulation of the phenomenon, highlighting the focus of these agencies. The purpose of this section is to outline what SHOULD be happening in theory with regards to regulation].

Agency	Role/responsibility	Notes
Pharmacy and Poisons Board	PPB is the body responsible for regulating pharmacy practices and the manufacture and trade in drugs and poisons in Kenya. The Board aims to implement appropriate regulatory measures to achieve the highest standards of safety, efficacy and quality for all drugs, chemical substances and medical devices to ensure protection of the consumer as envisaged by the laws regulating drugs in Kenya.	**Regulatory Framework;** The current regulatory framework in Kenya stipulates Pharmacy and Poisons Board, established under the Pharmacy and Poisons Act, Cap 244 as the major corporate body responsible for regulating pharmacy practices. This is the Act employed by pharmacy chains and networks in Kenya. The regulatory requirements for Pharmacy chains, are more or less similar to regulation of standalone pharmacies; each outlet is regulated as an independent entity. **Inspections;** Regulatory inspections are carried out by inspectors for all pharmacy outlets as a prerequisite for licensing facilities and the requirements are the same for both chain and non-chain establishments. The inspectors have the power to carry out impromptu inspections in any chain outlet and inspect for valid licenses and registries. **Licensing; (Practitioners, Premises, Importers, Wholesalers, Distributors, Manufacturers)** PPB also has the mandate of registration, enrolment and licensing of qualified pharmacists and pharmaceutical technologists in Kenya to promote good pharmacy practices. The process which is similar for all practitioners whether working in chain or non-chain establishments involves; application made to the

		board in writing and payment of a prescribed fee upon which a certificate of registration is issued if the application is satisfactory. Additionally, there are requirements for chains to purchase their products from importers, wholesalers, distributers and manufacturers who are licensed and comply with good distributing and manufacturing practices. **Market and Quality Control;** The National Drug Quality Control Laboratory has been established under the Act for examination and testing of drugs. Additionally, legal provisions require that all pharmaceutical products on the market receive marketing authorization through registration.
Competition Authority of Kenya	CAK is mandated to enforce the Competition Act with the aim of promoting and protecting effective competition in markets and preventing misleading market conduct hence enhancing the welfare of the consumers.	The nature of consolidations employs the concept of mergers and acquisitions and CAK works to control unwarranted concentration of economic power in the market that may lead to market failure. Goodlife Pharmacy was the only pharmacy chain that had to seek clearance from CAK after they had increased their numbers through takeovers.

2.3. Regulatory gaps and opportunities

Retail pharmacy consolidation is in its infancy in Kenya. This section looks at the key features of consolidation in the Kenyan retail pharmaceutical market, highlighting regulatory opportunities and challenges linked to the existing models.

The consolidation models explored are the chain and association models, further subclassified to allow a more detailed examination of the opportunities and challenges. We classify pharmacy chains into two broad categories based on the respective pathways taken towards expansion: those that grew/expanded organically without major changes in ownership or identity/name (organic growth pharmacy chains) and those that emerged or expanded as a result of some form of merger or takeover, or other forms of association with external partners (inorganic growth pharmacy chains). We include a third group of pharmacies consolidated through a professional association initiative.

2.3.1. Consolidation models in pharmacy

2.3.1.1. Organic growth pharmacy chains

This refers to retail pharmacy chains that have grown from one site to more than two branches bearing the same exact ownership and identity. The expansion is typically aimed at increasing the business footprint to meet growing client needs, especially those covered by private insurance firms.

> *'A' Pharmacy started in 1994 as a single store … and has been growing but last year is when we began aggressive expansion and we want to focus in towns outside Nairobi since there are no pharmacies that do insurance. The insurance companies wanted to extend that partnership outside Nairobi…… we are opening more shops due to demand especially from the insurance companies.*
>
> **Pharmacy chain manager**

Because of their slow growth, organic growth pharmacy chains did not appear to have strong views against the fact that the regulatory framework was generic and not specifically designed for pharmacy chain businesses. They were okay with the fact that each store was regulated independently and that establishing additional stores followed the same exact process as setting up a store as a new entrant. One operator even felt that there was an advantage to this; the fact that an impropriety at one store would not affect/lead to sanctions for the other stores.

> *They (regulations for chains and standalone pharmacies in Kenya) are the same, and they should be the same.*
>
> **Pharmacy chain manager**

> *Another advantage is that outlets are penalized individually even if they are owned by chains and this does not affect other outlets hence there is risk management.*
>
> **Pharmacy chain manager**

However, a regulatory manager noted that the opposite could also apply. Clients could sue a chain following a bad experience at one store. The risk of reputational damage could not be overlooked, particularly in the present day where complaints lodged through social media spread fast, and may adversely affect business at other stores.

2.3.1.2. Inorganic growth pharmacy chains

Inorganic growth refers to expansion resulting from external injection of capital. The typical scenario entails a private equity firm or other investor negotiating/seeking out viable existing businesses, buying them out, then setting out on an expansion plan to increase footprint. Viable firms would usually be small businesses with a couple of branches. Investors may opt to retain the original pharmacy name or rebrand to a new identity.

One chain adopted a greenfield expansion strategy, looking for newly developed real estate and booking pharmacy space, then setting up new shops. They felt this a more cost-effective model; business goodwill payments tend to be generally very high in Kenya. The chain had prefabricated fixtures which allowed rapid set-up of new branches. The chain's target market is mainly the lower and upper middle-class, with shops in malls, streets downtown and in residential estates.

Another chain entered the market through buying out existing pharmacies owned by different companies and rebranding them. The shops are mainly located at upmarket locations, although the company hopes to expand more towards the lower middle-income groups.

> *We target everybody, we are a shop for all Kenyans although if you are to say in a marketing perspective we have been focused recently in targeting professional women between the age of 20-55 purely as a marketing platform for our beauty range and being that women are a core in the society and if you get them everybody else will come into play. But essentially, we are not restricted in our services. Over the years we have expanded since we started in the higher end market but as we expand further our clientele is expanding to be all encompassing.*
>
> **Pharmacy chain manager**

Chains in the inorganic growth category share certain features. First, they often set out to offer a broad range of services beyond pharmaceutical dispensing. They usually include diagnostics, drug information and counselling services, and front shop sales (toiletries, cosmetics and beauty products). Some services pose little regulatory risk, for instance, front shop products. Others pose bigger challenges mainly due to the lack of clarity on regulatory arrangements required, for instance, biological sample collection, immunization, and some lab testing services (blurred boundaries between diagnostic tests requiring a licensed laboratory and point of care testing that may even be done by patients themselves).

Some chains provide blood pressure, blood sugar and body mass index measurement as a standard, among other tests.

> *We are primarily a pharmacy, so, we offer pharmacy services which have other professional services like blood pressure testing, blood sugar testing, professional medication counselling and dispensing services. We also double up like a beauty hub so we have beauty advisors and skin care in our shops. We have also partnered with a lab and we are a collection center in seven of our outlets where we have lab techs. In comparison to standalones we definitely offer a better range of beauty and personal care services that we don't find in other pharmacies, but in terms of dispensing we are pretty similar.*
>
> **Pharmacy chain manager**

2.3.1.3. Professional association pharmacies

This refers to a strategy where pharmacy businesses owned by members of a same professional association consolidate certain aspects of their operations. Presently, there is an ongoing effort by the

Kenya Pharmaceutical Association (KPA), the professional body representing pharmaceutical technologists, to expand the Pharmnet Initiative. Estimates suggest that technologists (who are by default KPA members) operate over 70% of licensed retail pharmacies in the country.

The model entails registering pharmacies that are owned/operated by pharmaceutical technologists into the Pharmnet network. The initiative's goals and value preposition remain unclear, but include plans to enforce uniform branding to increase recognition, introducing some kind of quality assurance mechanisms and (eventually), pooled purchasing. Since being registered in 2014, the initiative is yet to gain traction; little has happened beyond putting the Pharmnet logo on some pharmacies (below).

Source: victormatara.com

The main challenge remains reconciling professional autonomy wishes with business growth and expansion plans. This includes Pharmnet's plans for pooled purchasing, which will require that pharmacy owners delegate some of their roles.

2.3.2. Regulatory opportunities and risks

There are opportunities for regulators when markets consolidate.

First (especially for inorganic growth pharmacies), most funders will want to follow local legislation, and will typically carry out due diligence on who they are buying out and ensure they are legitimate and compliant. Pharmacies considered will usually be businesses of good repute. No fund manager would want to put money in an illegitimate or questionable business. Regulators have the opportunity to work with such funders from the start to create businesses that are not just compliant, but ones with good dispensing practices and strong quality management systems. These can serve as centres of excellence, reference points where regulators can send prospective pharmacy operators to copy.

The benefits extend to inspections for practice. A well-run retail pharmacy chain will typically have internal quality assurance systems for ensuring its services are standardized and client focused. The regulators can establish mechanisms for assessing compliance at the central level, including checking through reports from individual stores and assessing for evidence of compliance to good dispensing practices and other standards. In addition, externally funded chains are more likely to have internal

audit mechanisms and risk management strategies to guard investment and ensure longevity. Regulators can partner with the chains management to understand what works well, what does not work well and poses risk, and what can be improved for patient safety and better quality.

> *There is a PPB checklist (for quality audit) which is quite old, but we also have our own internal quality standard checklist which is not a PPB requirement.*
>
> **Pharmacy chain manager**

The chain store operators felt that having well managed internal quality and process control mechanisms makes it easier and cheaper for regulators to enforce standards.

> *It is also easier to concentrate on chains than standalones since one branch can stand as a representation of others.*
>
> **Pharmacy chain manager**

> *It is actually easier (to regulate chains) because for instance we have 19 stores and instead of going to each of the individual shops it is easy to come to our head office who will disseminate the information as opposed to dealing with all of them. With chains it is also easier to implement the rules because there is an internal corporate structure that ensures you are following regulations.*
>
> **Pharmacy chain manager**

> *Like for us we have our own internal regulation, so we are also a center of excellence for the Pharmacy Board. It is also easier for us to implement specific practice guidelines because we are one and we have regular trainings of our staff.*
>
> **Pharmacy chain manager**

The operators agreed that brand recognition was a major factor driving growth of pharmacy chains. Increased recognition meant better opportunities for funding from financing institutions and more opportunities for partnering with reputable training institutions.

> *Yes (we are disrupting the market), for instance universities want to bring their students here to do their attachment, for example, the University of Nairobi and Kenyatta University.*
>
> **Pharmacy chain manager**

These kinds of partnerships increase the credibility of retail pharmacies, particularly in a country where the majority of pharmacies are known to be operating unlawfully.

One pharmacy chain said they pay license fees on behalf of their pharmaceutical personnel, specifying to the regulator the station of work where the respective staff are based. The chain's manager argued that the regulator has the benefit of not just receiving license fees in good time and without hustle, but also knowing where the licensed personnel are working. This makes it easier for regulators to carry out their mandate.

> *There is also the annual renewal for all licenses for all pharm techs which is not a requirement by PPB (not a requirement by the regulator for employer to pay license fees for their staff and*

license them to a particular establishment) but in our chain each pharmtech is registered at their point of practice.

Pharmacy chain manager

However, presently, there are no differences between regulation of chain stores (or other forms of consolidation) and single business units. There was a feeling that regulatory enforcement was weak and unsupportive overall, and that inspections were only done to check for licenses or follow up on complaints. No formal reports were issued to guide any improvement, which from a chain business perspective meant they (pharmacies) had to establish their own improvement mechanisms.

When they inspect they don't issue a formal report hence most of the feedback is received when there is a problem which is rare. There is no much interaction between us and the inspectors other than when we pay for the license or when they find there is something out of order.

Pharmacy chain manager

There were also concerns over how well planned and scheduled the inspections were. The regulator was reported to inspect establishments located closer to their offices more frequently. One chain, for instance, reported that their store in the area where regulator officers are located received regulatory visits roughly once every month. On the other hand, the vast majority of pharmacies were either only rarely visited, or never visited at all.

They (inspections) are ad hoc inspections and not all of them (pharmacies) are inspected. Or rapid response when something goes wrong. There should be a change to have scheduled inspections where every pharmacy knows that every quarter whether it is planned or not there will be an inspector, that would work well. I know some pharmacies that have never seen them, they don't even know the inspectors.

Pharmacy chain manager

Some operators felt that the regulator should make regulation work better for those operating chains, arguing that this would benefit both the regulator and the operators.

When I joined I sought to find whether there is anything specific for chains and I couldn't find so there is need to look at the regulation. Now that chains are becoming more companies are having more than one pharmacy the stakeholders need to look further into this.

Pharmacy chain manager

…..the free operating independents (standalone pharmacies) when doing something gross you come for inspections and they run away, if you come the following day you find that what was a pharmacy yesterday is a hardware today and you don't know the owner because they are not being regulated, but if a network member does that they can be easily fished out.

National stakeholder

The regulators agreed, noting that organized businesses have structures in place for continuous improvement, and tend to be easier to regulate.

> *They (consolidated pharmacies) have their code of conduct so services tend to be standardised and they are easily regulated because already they are an organised group.*
>
> **Pharmacy regulator**

There was a feeling that the way the regulator approaches/treats you is highly dependent on how recognizable one is as a brand, and whether the regulator felt you could be trusted to operate properly without close monitoring. Networked pharmacies, for instance, were reported to have gained strong visibility because of the large number of technologists in the market, despite (by the management's own admission), its slow pace of deploying practice and quality management systems.

> *However being part of a network influences the way policy makers look at you and anyone coming into a store already has a copy of our guidelines and at that point in time even PPB didn't have a guideline to do inspections and whenever they come they know that we operate under certain standards hence it influences the way they view you. When everyone else is running because PPB is coming, a member will be waiting to welcome them because these are professional colleagues which is a benefit to the regulator.*
>
> **National stakeholder**

There were suggestions that since chains operated more openly, and were more visible to regulators, regulatory frameworks should be adjusted to allow to offer a wider range of services, including immunization and selected primary healthcare services.

> *We are moving towards immunization services, but it is something that is grey as far as regulation is concerned. As far as science is concerned it is neither here nor there because regulation tells you not to give an injection at the pharmacy or to a diabetic patient but the same patient is able to inject themselves at home. If they can do it out there why not place a designated place in the pharmacy so as to enhance medicine therapy management.*
>
> **National stakeholder**

There were some complaints that chains are disadvantaged because they sought to comply with the laws. Some pharmacy operators observed that the market was full of unlicensed providers whose costs of operations were generally low, and who were engaging them in unfair competition.

> *Compliance has a cost and you find pharmacies where the people dispensing are not licensed. So, if someone is not licensed they end up paying less than us who are compliant which brings about unfair competition-as a minimum anyone dispensing should be a pharmtech.*
>
> **Pharmacy chain manager**

Another challenge reported was the inability of the local suppliers to meet the growing demand for medicines by chains, yet the regulatory framework did not allow them (as a retail chain) to engage in distribution.

Due to our size, we are getting challenges in supply for healthcare commodities such that the local distributors cannot supply our orders sufficiently and that is where regulations should come in to support future supply chains because if we were to set up our own supply chain we will need to have the regulations to allow people to do that. With the current regulation it is difficult to retail and distribute at the same time.

Pharmacy chain manager

Yet, some argued that the requirement that retailers must not engage in wholesale business was very poorly enforced, only serving to punish legitimate pharmacy chain businesses. One operator complained that there were wholesalers who were engaging in retail business, thereby giving them unfair competition (the said wholesalers were engaged in unlawful practices, but not sanctioned).

They don't (regulate competition) because we have pharmacies in town … who are meant to be wholesalers, but at the same time they do retail business, so they are able to give wholesale prices to retail clients. That is where regulation again is a bit wanting by the board (Pharmacy and Poisons Board).

Pharmacy chain manager

There was lack of clarity on whether there was a statutory need for a pharmacist to be overall superintendent. Wholesale businesses require a pharmacist to be in charge partly because of the volumes they sell. Retail pharmacies may have a pharmacist or a pharmaceutical technologist in charge. What was not very clear was whether the chains are/should be treated like any other individual retail pharmacy store.

It is not clear whether if you have a chain of pharmacies and each store is licensed whether you need a pharmacist, the people we currently have are pharmtechs (pharmaceutical technologists) so my understanding is wholesalers must license under a pharmacist, retail shops can license under a pharmtech but it is not very clear (on chains). Chains (typically) get pharmacists but I don't think it is a regulatory requirement.

Pharmacy chain manager

The other complaint raised was the poor control of the number of pharmacies operating within a specified geographic location. Presently, Kenyan laws do not restrict the number of pharmacies in an area. However, the regulator said that this was likely to change starting January 2018, when new pharmacies may not be licensed within a certain radius of existing ones.

The Pharmacy and Poisons Board's regulatory mandate is limited to regulating aspects linked to professional practice and medicine quality. Competition is regulated by the Competition Authority of Kenya (CAK). From the interviews held, it appears CAK has yet to flag concerns over emergence of monopolies in the retail pharmaceutical industry. Only one chain reported having been forced to get clearance from CAK when they were taking over existing standalone pharmacies.

Yes they do (state regulating for competition), but not under PPB but under Competition Authority of Kenya. We have a few takeovers in Nairobi so CAK was concerned with our monopolization of Nairobi, prior to the bill going through we had to get clearance from CAK.

Pharmacy chain manager

Overall, chain operators expressed willingness to work with regulators to promote practice and keep out quacks and unlicensed providers. In a sense, the regulator and the chains business operators have a shared goal of ensuring only legitimate businesses operate, which has direct benefit to the consumers.

> *More forums and interactions with our regulators. There should be equal enforcement of the regulation for all. As a minimum have pharmtechs dispensing drugs, not just anyone. Make sure the drugs being dispensed are the right quality and there are no counterfeit drugs (whether in terms of how it came into the country or the component) since when they don't have the right efficacy people don't get well.*
>
> **Pharmacy chain manager**

2.4. Information gaps

The size, number or volumes of sales in the retail pharmaceutical industry is largely undocumented. There are no exact figures on the volumes of consolidated pharmacies as compared to standalones, especially considering some pharmacies are operated under different names but under the same ownership (this happens at times when one pharmacy wants to act a supplier to another pharmacy, but do not want the regulator to know that it is the same business doing wholesaling and retailing). PPB does not register chains as chains, each outlet is registered as a standalone, there is no documentation of the number of chains in Kenya, and the number of outlets in each chain. Using the lose definition of a pharmacy chain as any establishment with more than one, it is quite possible that we have a lot more chains than is reported.

2.5. Research questions arising

It is quite clear that consolidation brings in order and opportunity for more responsible practice and self-regulation. In a country where regulatory enforcement is weak, this provides opportunity for innovative regulatory thinking. It is likely that alternative regulatory mechanisms such as risk based and responsive regulation may work in the presence of organized structures, and may provide cheaper and more effective solutions to the regulatory enforcement gaps.

Chain pharmacies are generally receptive to regulatory mechanisms. They have internal mechanisms of self-regulation, and have more to lose when any one outlet engages in a unlawful practices. Use of alternative regulatory mechanisms such as risk based and responsive regulation may lead to better outcomes of regulation. There is limited information that compares standard regulatory mechanisms of consolidated providers to risk based and responsive regulatory mechanisms in lower- and middle-income countries like Kenya where regulation is not fully implemented.

Chapter 3: E-pharmacy

3.1. Overview of e-pharmacy in Kenya

Kenyans are known to be techno-savvy, with reports indicating that the mobile phone coverage is higher than the African average. The country has pioneered game-changing innovations and e-commerce platforms that have contributed to major changes in the way business is done across the continent. It is therefore not surprising that e-health is a major point of interest for Kenyan businesses.

Over the last decade, healthcare enterprises have expanded the use of technology. Examples include automation of selected operations at healthcare facilities, migration to electronic health record keeping, use of barcoding and radiofrequency identifiers for patient identification, use of computer aided platforms to access diagnostic imaging specialist services, and, increasingly, use of mobile phone powered applications in delivering essential services by community health workers. While these innovations carry promise, their application has mainly been restricted to higher end establishments like private hospitals, which are few overall and serve limited proportion of the population.

One e-health industry with potential for major disruption is the e-pharmacy. Since the first e-pharmacy business was formally registered in Kenya in 2013, the sector has seen at least eight other firms emerge, each having its own unique model. The growth is relatively slow, with clients expressing preference for physical pharmacies. However, those in market expect e-pharmacy to grow in time.

> *"The sales are quite good but it takes a lot of marketing, people are not entirely familiar with this concept and they still prefer the physical pharmacy. The concept is however picking up with time, but it is a bit slow."*
>
> **E-pharmacy manager**

While details of the market share occupied by e-pharmacy remain unclear, most people interviewed agreed it was a rapidly growing industry. At present, the e-pharmacy business is almost exclusively limited to urban settings, with majority operating in Nairobi and its environs. Some businesses have boosted sales volumes through their e-pharmacy component, for instance one pharmacy chain reported that nearly half of sales in one of their branches came from online sales.

The Kenyan retail pharmaceutical sector is regulated by the Pharmacy and Poisons Act (Cap 244 of Kenyan Laws), a legislation that predates the country's independence and remains outdated, despite numerous amendments over the years. There are plans to repeal the legislation and replace it with two separate laws, one for pharmacy practice and another for medicines regulation.

At present, there are no statutory provisions that directly govern e-pharmacy business in Kenya, perhaps reflecting the undefined nature of the business and market currently. What exists currently is regulation of pharmacy premises and/or warehouses where medicines are stored, whether by physical pharmacy operators or by e-pharmacy operators. However, regulating practice in this way ignores a relatively large space occupied by entrepreneurs, some of whom are operating e-pharmacy businesses without any physical location or warehouses. What this means is that there are aspects of e-pharmacy business that may not be subject to regulation under Cap 244 and may not even be under any kind of regulation. While this lacuna presents opportunity for technology innovators and start-ups

to enter the market and test fresh ideas, it does little to protect the public. Even well-meaning e-pharmacy investors may not fully appreciate the risks that certain elements pose to patient safety and quality, and, may not get the opportunity to engage experts and regulators to guard against these.

Risks may come in many different forms, including inappropriate sale of medicines to wrong groups (e.g. a harmless over-the-counter product may interact with other products and cause harm), poor storage/handling of medicines, and problems of labelling, packaging and transportation of medicines.

The risks extend beyond the quality of products sold. Market failures may occur in the absence of proper regulation. Information asymmetry and negative externalities may occur. An example of a problem occurring due to poor information is acquisition and trade in products whose sources are not clearly defined. This is more likely to happen in an unregulated environment, especially where new entrants try to gain market share by beating the prices of existing businesses. A negative externality may involve improper disposal of expired or contaminated medicines, which pose safety risks to communities and the environment. E-pharmacy businesses that operate outside of formal regulation are unlikely to follow due procedures when it comes to handling pharmaceutical waste, something that is tightly regulated within the formal sector. Finally, e-pharmacy providers operating under the radar (which happens when one is unsure about regulation) are less likely to engage in pharmacovigilance activity, a major public good initiative that is promoted through formal regulation. Such providers are less likely to actively engage users beyond the sale of the product, and, may not report adverse reactions and other sentinel events that they may be informed of by users.

On the other hand, expansion of e-pharmacy presents opportunity for early adapters to engage regulators and work on developing regulation that protects their business and serves public interest. Interest group theories of regulation observe that regulation can benefit industry if they become involved in formative stages. Early adaptors have the opportunity to drive the process of getting stakeholders together to discuss ways of regulating e-pharmacy business. Aside from ensuring their voice is heard and thoughts considered, the creation of a regulatory framework would help protect existing players through creating some barriers to entry. New legislation often gives existing businesses some time to prepare and comply, a courtesy that never extends to new entrants coming after enactment. However, policy should also guard against the risk of regulatory capture, which may happen if those in the business are allowed too much room to dictate provisions of the new legislation.

The rapid growth of the e-pharmacy industry presents new opportunities for expanding access to medicines, managing the quality of medicines and practice, and increasing transparency in pricing of medicines (thus allowing price comparison). On the other hand, it carries significant risk, if poorly regulated. The government has a duty to bring stakeholders around a table to discuss how best to regulate the industry to both encourage its growth and protect public good. These discussions will need to build on a detailed understanding of the e-pharmacy models in the country, risks and opportunities for regulation, and what the likely consequences are if policy solutions are not sought in good time. This section discusses these and other factors relating to regulation of e-pharmacies.

3.2. Regulatory overview

Agency	Role/responsibility	Notes
Pharmacy and Poisons Board	The major body responsible for regulating e-pharmacy practices in Kenya. This includes inspection of premises, regulation of advertisements and licensing of premises and practitioners.	**Regulatory Framework;** Currently there is no framework regulating e-pharmacies in Kenya, they are regulated as physical pharmacies **Inspections and licensing;** Absence of regulations guiding the registration and licensing of online platforms has created fear of the unknown. Prior to setting up shop, each investor is required to present their concept, and innovation to the Pharmacy and Poisons board. If the idea resonates well with the board, the online platform is issued a letter of no objection Those with a physical presence, the physical location is licensed as a physical pharmacy. The warehouse is inspected as a prerequisite before they are licensed. Additional online inspections are carried out to monitor dispensing practices from e-pharmacy platforms. **Medicine Advertisement and promotion;** E-pharmacy platform sales are directly affected by their marketing. Currently, provisions require the pre-approval of medicines advertisements and promotional materials before they are displayed on any e-pharmacy platform. Direct advertising of prescription medicines to the public is prohibited.

3.3. Regulatory gaps and opportunities

The e-pharmacy business models in Kenya are diverse. Any meaningful discussion on their performance and/or regulation must consider this. In this section, we define the key features of the e-pharmacy models in Kenya and highlight regulatory opportunities and challenges that accompany each model. The classification is both conceptual and operational, thus allowing a detailed discussion of potentially important aspects to be considered when discussing regulation of the sector.

We classify the e-pharmacy businesses in three broad ways: provider-facing versus consumer-facing models; pure e-pharmacy businesses versus hybrid models (brick-n-mortar pharmacies with an e-pharmacy component); and compete models versus cooperative models.

3.3.1. Provider-facing versus consumer-facing models

By default, e-pharmacy businesses appear to target end-users (consumers of medicines) rather than other players in the supply chain. The e-component is mainly aimed at removing information and geographic access barriers that consumers face.

However, there are e-pharmacy models that are designed to support providers, and by extension, support consumers through better quality products at lower cost.

Group purchasing organizations (GPOs) aggregate purchase requests from members and negotiates prices from reputable suppliers for quality assured products. It provides a platform that allows members to access competitive prices for quality products. Such organisations do not purchase or stock any medicines, and do not, therefore, have a warehouse where physical activity takes place. According to the management of one such business, all their products are sourced from reputable and licensed manufacturers and distributors. They supply independent pharmacies, chains and franchises, hospitals, clinics and other types of providers.

> *Our system has four categories; innovator brands, multinationals branded generics, local branded generics and unbranded generics and what we put up is all of quality but different price (cheapest and second cheapest) points based on the distributors*
>
> **Provider-facing e-pharmacy manager**

Provider facing models are designed to enhance the experience of the providers, by providing cheaper products, training for providers and access to credit facilities. They also provide documentation systems that support providers in tracking sales, and making plans for the future

> *We also provide credit guarantee on behalf of our members to our suppliers and they will be confident that they will get paid and also because of the assurance they are able to extend favourable commercial terms. We also build our members capacity by doing trainings on business skills, planning and credit management and also on the technical side we train them on inventory management, rational use of drugs. To date we have trained over 600 practitioners. There is also price transparency to the last mile dispenser and after that we are*

able to get data and advise our members on trends in terms of procurement and inventory management but also upstream for the distributors and manufacturers to be able to do volume forecasting.

Provider-facing e-pharmacy manager

Regulatory Gaps and Opportunities

Provider facing e- pharmacy models have some form of consolidation, and offer similar advantages to consolidation of providers; economies of scale leading to better pricing and self-regulation initiatives making regulation easier. Unlike consolidated providers, they are generally risk averse as they do not brand the facilities that they serve.

One provider-facing e-pharmacy has conducts rigorous client screening that includes background checks, inspections and confirmation of licenses. They reported to only work with registered pharmacies that have a registered pharmacist or pharmaceutical technologist that is dispensing medication. They keep a record of their clients' valid licenses and send reminders when licenses expire.

The way we set out our model was to sanitise the private sector market. We are pushing for our members to be licensed, they pay on time and purchase from legitimate people. With consolidation you have a database of many people and because we also provide other levels of guarantee like credit we have very elaborate [client screening].

Provider-facing e-pharmacy manager

A second regulatory opportunity is presence of an internal quality control system that ensures providers, and in the long run consumers get quality affordable products. The preselection criteria for distributors is thorough; distributors must provide valid licenses. The distributor premises are inspected to ensure they adhere to stipulated storage and transportation requirements.

We have gone ahead to handle quality upstream where at our distributors level we do random checks and sampling for quality checks and downstream we are looking at introducing a device that checks on quality at point of sale, it is in pilot right now so that the dispenser can also check on quality.

Provider-facing e-pharmacy manager

One challenge with this business model, is the regulatory requirements for dispensing medicines; only Pharmacists and Pharmtechs are allowed to dispense medicines. This has locked out of a greater percentage of the target market of provider facing e-pharmacies given that they cannot work with nurse-led or doctor-led private clinics as most of them do not employ a pharmacist or pharmaceutical technologist. A significant percentage of primary healthcare (PHC) facilities in Kenya, including government owned PHC facilities do not employ pharmacists or pharmaceutical technologists.

The institutions that exist that are dispensing are way more than the current registered pharmacists and pharmtechs and there are some institutions that have many outlets (against few pharmacists) so there is a gap. We are moving to UHC and we don't have enough facilities

nor personnel and if they were to be shut down (pharmacies that are not regulated) a lot of them would be shut down, more than 50% of them (Requested this part to be off record)

Provider-facing e-pharmacy manager

A provider-facing e-pharmacy manager reported challenges with the coding of medicines especially on digitized formats where different distributors, and providers use different coding mechanisms to register their drugs making it difficult to track products through the supply chain.

In Kenya we are very adaptive to technology but the one thing that is failing us right now is there is no standardisation, there is no coding and you cannot track. The biggest problem we have been getting is that every time I change my catalogue it takes a while to be able to map all the products because each provider has their own codes and our system also generates its codes. If we could get standardised codes for all drugs available in this country, a massive transformation will be seen in the way healthcare is delivered and tracked.

Generally, provider facing e-pharmacies have minimal regulatory risks. However, just like any other consolidated model, an online platform that aggregates retailers and controls the data on pharmaceutical consumption poses a risk of monopolistic tendencies leading to market failure. One such business has a pre-selection criterion for distributors and for each category of drugs they display the prices and products of two distributors, the cheapest and the second cheapest. Monopoly may not be a challenge as of now, as they control a small percentage of the market, but overtime, it may be significant. The risk for monopoly is even higher as their model is geared to augment the relationship between the retailer and the distributor, and at the same time augment the relationship between the distributor and manufacturer/importer, in the long run, they may have control over a good portion of the pharmaceutical chain, right from the manufacturer to the end user.

We have just scratched the surface. Right now the market size is about 900 million dollars in total for pharmaceuticals and the private sector would account for about 40% of that and we are looking at grabbing a decent proportion of that. We are in the process of member enrolment and also training members on how best to use the system.

Provider-facing e-pharmacy manager

They are however keen that their model does not result in monopolistic tendencies, they mentioned that it is in their core mandate to avoid this. The catalogue is reviewed every 6 months to allow for other distributors to competitively bid to be sell their products on the platform.

It (Monopoly) is a possibility but the way our model is to discourage that and encourage more price negotiations. Every six months we send out the RFQ to a group of distributors and we don't interfere with the relationship between distributors and members we only enhance it. We started with the distributors because they were easier to deal with because they were not enough aggregated volumes, the big conversation however is with the manufacturers. Our model is not a monopolistic maximisation model, it is exactly the opposite.

Provider-facing e-pharmacy manager

Provider Facing Models that lack a physical presence are perceived to present greater regulatory challenges. Regulators are unclear on the most effective way of regulating such establishments.

> *We presented what we are doing but from a regulatory point of view a group purchasing organisation that is aggregating dispensers did not exist and we also don't stock or distribute products, the only place we could fit is like a distributor but without product. The inspections are done annually, we renewed our license in March but they came for inspections last week.*

Provider-facing e-pharmacy manager

Overall, provider facing e-pharmacy models are deemed to pose less regulatory challenges and more regulatory opportunities. Pharmacy and Poisons Board noted that they do not visualize any major regulatory gaps with e-health solutions at the distributor level.

Consumer-facing models, on the other hand, carry significant regulatory risks, as they are designed to serve end-users directly. This is the most common model in Kenya. However, there are notable variations in business models, ranging from establishments that stock medicines and supply directly based on e-orders, to those that merely serve as a link between independent pharmacies and clients. Among those with a physical presence, some have pharmacies that also serve walk-in clients, while other only have a warehouse, where no retail activities take place. (Risks and regulatory challenges of consumer facing e-pharmacy models are discussed exhaustively in the other model classifications).

3.3.2. Pure e-pharmacy versus the hybrid model

The other approach we used to classify e-pharmacies is whether or not they have a physical presence alongside the e-business. We refer to those e-pharmacies with a physical location (wholesale or retail establishments where interaction with clients can happen) as 'hybrid models' while the pure e-pharmacy models are those that do not have a physical establishment, save for, perhaps, a warehouse.

The study revealed a clear different in the two models, right from the point of establishment. While hybrid models typically start as brick-n-mortar pharmacies and gradually introduce e-business, the pure e-pharmacy businesses enter the market as e-commerce establishments from the start.

This historical variation in propose and strategy has direct regulatory implications. The hybrid models grow from businesses that would typically have already met (and continue to meet) regulatory requirements. These are businesses that had already achieved a certain level of success, and, are not afraid about gaining more visibility through going online. One of Kenya's oldest and most well-regarded retail pharmacy chains that has expanded into the online space feel their reputation is at risk, and appear keen on doing things right.

> *"For us if we don't maintain the quality you will not buy from us again and our reputation is at stake, so we always have to ensure that our quality is good."*

Hybrid e-pharmacy manager

For one hybrid model, adding the e-component was merely a way of expanding its footprint and meeting client demand more efficiently.

> *"[Online business] started because there were people who would sent for drugs from the UK and there was no such platform for ordering here in Kenya and as time went we incorporated the concept to the website when the demand went up last year. It has been in existence for around five years."*
>
> **Hybrid e-pharmacy manager**

Overall, the hybrid models were more upfront about engaging regulators, again, because they were already regulated. This was not the case for some pure e-pharmacy businesses, which made very little or no effort to engage the pharmacy regulator. This group felt they were merely an App for customer convenience and did not see a need to seek regulation. Some, opted to cover their bases through seeking a letter of no objection from the regulator, even though they felt they were merely an app connecting licensed pharmacies and did not need separate regulation.

> *"We are not a pharmacy, we are a technology platform, we have separate apps for customers and pharmacies. The regulators don't regulate for prices in the market but how do patients know where they can get the best price?"*
>
> **Pure e-pharmacy manager**

Opportunities and challenges for regulation

Regulatory implications are minimal for hybrid models. This is because the sources, distribution chain and storage/warehousing of the medicines is already covered under existing regulation. Additionally, pharmaceutical personnel superintending the businesses are already (in theory) well versed with regulatory requirements. The physical establishments still carry the bulk of their business, and one would expect that they would not want to risk that through engaging in inappropriate e-pharmacy practices.

However, the e-component presents additional regulatory opportunities for such establishments. All the e-pharmacy operators interviewed emphasized the importance of having strong gate-keeping mechanisms to ensure prescription medicines are dispensed only on upload of a prescription. Most private commercial pharmacies in Kenya engage in indiscriminate sell of prescription medicines (save for selected products like narcotics), partly due to the absence of an audit trail that could link back to a particular seller (verbal orders from clients are fulfilled without prescription, hence, no record). However, all e-pharmacies included in the study were found to have established some mechanisms for ensuring that those without prescriptions did not buy prescription medicines.

Pure e-pharmacy models presented bigger challenges overall. First, the bulk of their business is online, meaning there is little opportunity for regulatory oversight, as current legislation is focused on physical establishments.. The complex interlinkages may present challenges to a regulator who may prefer to have a clearer view of the movement of products down the distribution chain.

This is made worse by the fact that some of the pure e-pharmacy providers did not see the need to engage the regulator. The implication is that there is a possibility that at some point (as e-pharmacy businesses grow), clients may receive medicines from e-pharmacy establishments that the regulator may not even be aware of, let alone be regulating.

The regulator seemed to be aware and showed some concern. However, as is the case with e-commerce broadly, they were not quite sure what approach to take.

It is, perhaps for this reason, that the Pharmacy and Poisons Board provided one pure e-pharmacy business with a 'Letter of No Objection' as authorization to conduct its business, almost as if to say 'we can't really regulate you, but we are not openly opposed to your activities.'

> *"Currently the regulations regulating the e health space is hazy but we have been in the pharmaceutical industry for 12 years and we were the first company to get a letter of no objection from PPB to set up such an application in the country."*
>
> ***Pure e-pharmacy manager***

Some online only e-pharmacies reported having mechanisms for ensuring prescription medicines are only dispensed on prescription. It is not possible to select online (or even view) a prescription medicine in without entering prescription information and uploading the prescription.

> *"Usually when we verify it has to be as per the patient's indication or what they suffer from, if we are not so sure about them all prescriptions we receive are only valid if there is an address, stamp and sign of the doctor. We usually contact the doctor sometime if there are some retractions and we verify with the doctor and get in touch with the patient and inform them if the doctor has allowed for a substitution or has changed the dosage……. They have to upload the prescription for us to give the medicine and we take the original prescription upon delivery of the medicine."*
>
> **Pure e-pharmacy manager**

This level of strictness is rarely present at brick-n-mortar pharmacies in Kenya. Previous studies have shown that clients can walk-in and purchase the majority of prescription medicines without the need to show a prescription (strictness often limited to narcotic and psychotropic medicines).

Others have found even more innovative ways of ensuring medicines get to the right people, for instance, one e-pharmacy uses pharmacists on motorcycles to collect additional information.

> *"Yes, for instance we rolled out the service of coming to where client are; it involves a pharmacist who has a motor cycle, so once we get an order we do it then we dispatch it with the pharmacist who has a laptop and the finger print reader and after you have done the thumb print he explains the medicine to you, you sign the invoice and he gives you back your*

copy, I don't think there is any other organization using this approach, I think we are the first to do it."

E-pharmacy manager

A professional association manager also warned of the risk of one prescription being used at multiple e-pharmacy establishments, since prescriptions are scanned and sent. They observed that regulators must find innovative ways of ensuring that does not happen.

With an e-prescription people either use a verbal prescription over the phone or they scan and send an e-prescription, the patient can easily obtain prescription only products including controlled products from multiple pharmacies.

Professional Association Manager

There are concerns over other aspects of e-pharmacy practice that affect both the hybrid model and the pure e-pharmacy model. These include medicine quality (including during storage/stock-holding and transportation) as well as marketing and advertising.

There is lack of clarity over regulating for product quality. Business with warehouses and physical retail stores can be regulated directly. However, those that are App-based feel they do not need separate regulation, as they deal with regulated entities only.

"We are an app, so, they cannot really regulate quality because we don't do any stocking, however PPB does regulate the retail industry which must get licensing from PPB. With Livia ewe only get registered pharmacies from PPB. We are an app so they cannot really regulate quality because we don't do any stocking, however the PPB does regulate the retail industry which must get licensing from PPB. With [our business model] we only get registered pharmacies from PPB."

E-pharmacy manager

The Kenyan law regulates transportation of medicines, but only with respect to appropriate labelling and packaging (provision only applies to specific poisons, not all medicines). This means that in theory, there are no clear laws governing who or how medicines should be transported. However, the Pharmacy and Poisons Board recently drafted guidelines for transportation (draft, not approved yet). The guidelines appear strongly focused on products imported in bulk, rather than delivery of filled prescriptions to individuals within the country, although some of the provisions may apply, for instance, carrying the products in containers that control temperature (+/- 0.5°C) and humidity (+/- 5% RH) and the requirements for keeping records after delivery for traceability.

The bigger question that arose was, who should deliver the medicines to the patients? At the moment, the providers said they were using pharmaceutical technologists for prescription only medicines. However, some were no happy with this, and felt that clients who could purchase online can read instructions and use the medicine appropriately.

"People are pretty comfortable with the idea of e-pharmacy because it is far much easier and we offer consultation as well, it is like going to a normal pharmacy except the time wastage is not there. Our delivery people are also pharm-techs as well so it is like the entire pharmacy coming to you……For us it was a necessity from PPB to have delivery people be pharm-techs or pharmacists…… They have some regulations in place that is why they specify the delivery should be done by a pharmtech, they already have the idea but it is not a fixed guideline yet."

E-pharmacy manager

"At the moment the practice is that the medicines ought to be dispensed at the retail pharmacy because the patient can be couched on how to use the medicine or if it is to be delivered then it needs to be done by a pharmacist or a pharm-tech who will coach the patient on usage, now if this patient is savvy enough to use technology to place an order certainly the patient can read the label on the medicine on how to use it so it beats the purpose of using a pharmacist or pharm-tech to do deliveries. in other developed countries the deliveries is done by non-pharmacists such as school boys on bicycles and we need to get to that level."

E-pharmacy

By creating this gate-keeping process, e-pharmacies can be seen as having a higher inclination towards regulatory compliance than their brick-n-mortar counterparts.

The other opportunity is the potential to track medicine usage through prescription analysis. The e-prescriptions loaded onto the e-platforms can allow regulators to not only verify authenticity, but also gather information on appropriateness of medicine use. Pharmacovigilance and post-market surveillance is a core function of the Pharmacy and Poisons Board in Kenya. Prescription handling and storage are generally poor for brick-n-mortar pharmacies.

There are also some concerns regarding advertising. Presently, direct-to-consumer-advertising is not allowed for health and pharmaceutical services in Kenya, with the exception of a narrow range of over-the-counter drugs. However, the law is unclear on providers advertising their presence, particularly using online platforms, billboards and other highly visible platforms. The Pharmacy and Poisons Board has published Guidelines for advertising, but these are focused on product, rather than practice advertising. There is lack of clarity over how much content should be included, whether for instance, one should be limited to sharing information on the business name and where it is located, or whether services offered/expertise available can also be included as additional information to the public.

It is not uncommon to find bus stage stands or small billboards bearing the name of a retail pharmacy in Kenya. These would typically be located somewhere close to the business. However, some e-pharmacy operators are putting up billboards and other forms of advertisements but targeting the wider population (as they do not operate from a specific location), and usually with non-specific/non-controversial messages. What is unclear is the extent to which such marketing strategies pose a risk or infringe on regulation on marketing and advertising in health.

Finally, there are concerns over data security and patient confidentiality. This too remains largely unregulated within the e-pharmacy business. By creating an account and adding data, clients give providers unlimited access to information, some of it confidential, yet there is no legislation that governs security and storage of e-healthcare data. Some interviewees identified this as a priority area for regulation, even as newer models find their way into the rapidly growing market.

3.3.3. The compete versus cooperate models

New e-pharmacy businesses enter the market with one of two strategies: compete with existing establishments, or, link customers to those already offering retail pharmacy business (marketplace e-pharmacies).

Overall, compete pharmacies carry more regulatory concerns compared to marketplace e-pharmacies. For one, the former have to try and establish themselves in an already crowded market. New entrants must find ways of not only beating the prices offered by existing establishments but pulling clients away from competitors who may already have established strong relations in the past. To beat competitors, they may engage in inappropriate behaviours such as sourcing medicines of dubious quality or employing unqualified staff who may not give the quality of service desired.

On the other hand, e-pharmacies that seek to link and accelerate businesses of existing establishments may have fewer regulatory concerns (marketplace e- pharmacies), mainly due to their limited role on product management and quality assurance. One marketplace e-pharmacy, for instance, argued that their model is primarily based on trying to link clients to the nearest best priced licensed retail pharmacy.

> *[Our] app is an application that helps users get access to quality and affordable medicine at the convenience of their mobile phone*
>
> **Marketplace e-pharmacy manager**

E-pharmacies with a marketplace approach also made deliberate effort to add value to the value chain, targeting both the providers and the consumers. For instance, one business marketed its app/product to existing pharmacies as a turnkey package that would enable them to gain an online presence without incurring any costs. On the consumer side, one provider reported that they send registered customers regular reminders to promote adherence to medicines and other appropriate actions. This, they felt, had contributed to a growing base of loyal customers.

> *"Our growth has been organic but unlike our competitors you will not hear [about our business] everywhere but despite that we are growing and getting the numbers. The most important bit with applications is to get repeat customers. our customers have been coming back to use the app with a purchase rate of over 70%."*
>
> **Marketplace e-pharmacy**

3.4. Information gaps

Communications Authority of Kenya is tasked with ensuring cyber security across all industries. Their role in the healthcare space and specifically in the regulation of e-pharmacies is unclear. We were not able to schedule an interview with them.

3.5. Research questions arising

What policies and regulations are effective enough to regulate the online pharmacy space, ensuring patient safety, product quality, and locking out quacks, and at the same time accommodative enough to encourage genuine operators that provide advantages to the consumers, regulators and much needed data for the industry as a whole;

E-pharmacies offer a lot of benefits, and equally greater risks. Available regulatory mechanisms such as controlled marketing are a disincentive for legitimate online pharmacies that are willing to work with the provider, on the other hand, they allow flourishing of illegitimate online pharmacies, as there are no control measures. E-pharmacy sales volumes are fully dependent on marketing, especially so social media marketing.

More thinking is needed on how to regulate the sector. For instance, who should superintend the business, who should deliver the products, what kind of verification processes are required at ordering and delivery levels, what mechanisms can guard against the same prescription being used more than once (e.g. when the e-pharmacy platform only requires scanned prescriptions), what happens where for cold chain products and other unstable/sensitive products that require special transport arrangements etc etc.

Chapter 4: Public Private Partnerships in Health

4.1. Overview of Public Private Partnerships in Healthcare in Kenya

Universal Healthcare Coverage is one of the Kenyan government's "Big Four" goals targeted to be achieved by the year 2022. This comes at a time when Kenya has achieved the lower middle-income country status, which requires that the country be more self-reliant. Yet, healthcare in Kenya has traditionally been heavily donor dependent, with development partners and non-governmental organizations contributing up to 30% of total health expenditure. Already, the country has seen a drop in development assistance for health. To help fill gaps in healthcare financing, national and county governments are exploring innovative non-traditional financing mechanisms.

Public Private Partnerships are increasingly being seen as one vehicle to help achieve this. These partnerships aim to leverage resources, finances and expertise of the private sector to achieve key public health goals. Managed Equipment Service, a PPP-like equipment leasing model implemented by the Kenyan Ministry of Health, was the first of its kind in Africa. The project is still ongoing, but is already considered a success, creating more interest in engaging the private sector in health services.

PPPs in Kenya are regulated by the Public Private Partnership Act of 2013, a law that is strongly focused on infrastructural-type of projects, but lacking on service delivery partnerships characteristic of the health sector. The body tasked with enforcing the PPP Act is the PPP Unit housed at treasury. Ministries such as MOH have PPP nodes to provide sector specific technical advice to the treasury unit. Interviews with experts indicated that the PPP node at the MOH lacks the resources to be effective in its mandate. There have been efforts to develop a PPP strategy/framework for the ministry of health, but this has never really been completed or adopted.

> *They need to have specific regulations for specific sectors, the PPP Act is created for large infrastructure projects, it loosely regulates service level agreements when you have an NGO and a private sector coming into a public facility to provide specific services or goods.*
>
> **International Finance Manager**

PPPs present massive regulatory opportunities. The PPP Act provides a defined implementation framework for partnerships. Health Sector regulators acknowledge their role in managing PPPs, especially service delivery PPPs at implementation phase. Policies can ensure regulators are involved at project inception to cement quality and patient safety requirements in the entire process. Regulatory roles such as price regulation and equity of access can be key factors in the feasibility study of PPPs.

> *Yes, because we are involved in quality and price capping. Regulatory bodies need to give advisory services.*
>
> **Nursing Council of Kenya**

Another regulatory opportunity is the fact that PPPs already have an inbuilt self-regulation framework. The contracting documents outline key deliverables to be met and sanctions when the deliverables are not met. There already exists a continuous mechanism for inspection; the private sector implements the project while the public sector supervises the implementation.

Each aspect is obligated to meet certain key performance indicators and there is a risk of loss of reputation.

International Finance Advisor

Another regulatory opportunity stems from the need for investors to protect their investments. Most investors are keen on adhering to a specific set of standards, and quality of service. The private sector is also perceived to be better regulated than the public sector, with more severe sanctions overall. They (private sector) generally have more to lose than the public sector and would therefore strive to perform beyond regulatory requirements.

The risks for PPPs are equally high. Market failures may result from increased investment from the private sector, especially when pricing of the services is left at the discretion of the private provider. This may happen under build and operate PPP models, where the private sector is given discretion to oversee operations on behalf of the government. The goal of the private sector is return on investment. This is a big risk in a market where pricing of healthcare services is unregulated.

Another risk is the big differences in regulatory processes for public and private facilities, which become apparent when hybrid models are adopted. Public facilities, unlike private facilities, do not require formal registration or annual renewal of licenses by regulatory bodies. Public facilities undergo a one-off gazettement on opening (and this too does not always apply, as most public facilities opened by counties are not even gazetted). Private facilities on the other hand, are registered with regulators at the time of opening, and have to keep renewing premises and staff licenses every year. Sanctions for non-compliance also only apply to private facilities, yet public facilities often exhibit similar inadequacies. In the case of a hybrid model, the requirements are generally unclear, leaving a lot of grey areas. A hybrid model-type that is gaining traction in Kenya is a PPP/leasing type of arrangement where laboratory or pharmacy services at a public facility are operated by a private entity.

4.2. Regulatory overview

Agency	Role/responsibility	Notes
Public Private Partnership Unit (Treasury)	The main role of the PPP Unit is to provide technical, financial and legal expertise to the Committee and any node established under the PPP Act.	The PPP Unit at treasury is the body that majorly regulates public private partnerships in Kenya. The PPP Act is not sector specific, it provides a generic framework for regulating all PPPs, both infrastructural, service delivery and hybrid models.
Public Private Partnership Unit (Ministry of Health)	This unit is mandated to provide technical, financial and legal expertise for partnerships established under health.	The Ministry of Health in Kenya has established a PPP node under the larger ministry. The PPP node has a responsibility to provide technical advice for counties that want to engage in PPPs in the Health Sector The unit is however, not well-resourced and therefore lacks the capacity advice on transactions
Other Regulatory bodies with a role in regulating PPPs; **- Kenya Medical Practitioners and Dentist Board** **-Nursing Council of Kenya - Kenya Medical Laboratory Technicians and Technologists Board**	**KMPDB;** The major role is to regulate the practice of medicine and dentistry in Kenya. **NCK;** Responsible make provision for the training, registration, enrolment and licensing of nurses. It also regulates nurse practitioners conduct to ensure their maximum participation in the health care of the community. **KMLTTB;** The major role and responsibility of the body is to exercise general supervision and control over the training, business, practice and employment of laboratory technicians and technologists in Kenya.	Prior to entering into public private partnership arrangements, the contracting authorities undertake a sector diagnostic study and assessment to establish technical, legal and regulatory requirements. Once the PPP Unit gives a go ahead for the implementation of a project, other regulators such as KMPDB and KMLTTB are then involved to regulate for Quality and Patient Safety.

4.3. Regulatory gaps and opportunities

PPPs in Kenya are diverse. To aid analysis and understanding of gaps and opportunities, PPPs are classified into three based on their core characteristics and functions; Infrastructural PPPs, Service Delivery PPPs and Integrated Model with both Infrastructural and service delivery components. These models can be further classified into those focusing on primary healthcare and curative services, and those involving part of a health facility or an entire facility.

4.3.1. PPP models in Kenya

Infrastructural Public Private Partnerships

The private sector is contracted to build, refurbish and maintain the buildings and equipment in government hospitals. The regulation of these PPPs is well outlined in the PPP Act. This model poses few regulatory risks in terms of quality of services and patient safety. The regulatory bodies generally provide inputs into the design and organization of hospitals, but are not the key players in the regulation of construction. These models are fairly common in the healthcare in Kenya. A common example in Kenya is engaging the private sector to build facilities for the public sector to run or use.

> "*There is one in the pipeline for (construction of) four cancer treatment centres across the country*"
>
> **International Finance Advisor**

Service Delivery Public Private Partnerships

The operation and management of health facilities is contracted to the private sector. This model can involve outsourcing of the entire facility to the private sector, or part of the facility, such as Laboratory, Pharmacy or Radiology.

Integrated Public Private Partnerships

These have both a service delivery and infrastructural component. The private sector is tasked to build, or refurbish and equip a health facility, and afterwards offer clinical services. The integrated models can also involve the entire hospital, or specific departments within the hospital. An example is a partnership arrangement between a hospital and a laboratory, where the latter develop, equip and operate the laboratory on behalf of the former.

4.3.2. Regulatory gaps and opportunities

There is a strong belief that private sector involvement can help to improve the quality and efficiency of services and products provided by the government. The contracts binding these partnerships often define expected standards and outputs, and outline penalties where these are not achieved. They also have inbuilt monitoring and evaluation frameworks to ensure conformity.

"For example if you look at MES (Managed Equipment Service), there are specific deliverables in the contract that each side agrees to. Every PPP contract no matter the type has a section on expected deliverables and if either one of them does not fulfil it is considered breach of contract and there is always a remedial action. "

International Finance Advisor

"They have clear internal mechanism of management. Some players have clear SOPs."

Transaction Advisor

The private sector and the public sector are clear that they are required to adhere to the law in their engagements. In areas where the PPP Act 2013 is not conclusive, the entities have sort additional ways of ensuring their engagement is protected by the law.

For example once the PPP unit gives a clear go ahead of a relationship, then the other partners come in and their role is to ensure the lab are run with quality in place. KENAS and the likes have their role now to accredit the labs in terms of the quality control measures. If you had a radiology arrangement, the radiation body will now come in.

Transaction Advisor

The current PPP Act is good but it has its issues, for example the MES project was not done using the PPP Act they had to use other procurement guidelines

International Finance Advisor

The investors are keen that their investment is protected under the law, for this reason, many have hesitated to invest until there is a framework to guide their investments in service delivery.

There has been interest for the last couple of years, there are efforts and initiatives towards it but it has been hard for them to execute based on the PPP framework that is not very clear.

Transaction Advisor

PPPs are also brought about to solve another key goal of regulation; equity of access. The government has limited resources and cannot reach every Kenya. The private sector on the other hand, has resources that can ensure all Kenyans have access to services. The MES project has ensured that Kenyans have access to diagnostic services that were previously unavailable.

I think it is time we embraced it, there is need because currently both National and County government cannot meet the patient demand therefore there is need for partnership where private hospitals should be accorded opportunities to offer services

KMPDB Manager

The status quo was we can run down the lab within the public sector then we set up a lab outside which was the case. It also disrupts in the sense that it streamlines procurement, supply chain and inventory management that you have a third party running supplies because the bureaucracy in the public sector is excessive but when you are dealing with a private sector player then you can cut down and improve on the supply chain. Down times were reduced. Timely results were issued to the patients

Transaction Advisor

It improves access because patients benefit from cutting edge latest technologies in private sector e.g. MRI. PPPs also benefit from the efficiencies of the private sector.

Pharmaceutical Society of Kenya Manager

PPPs are meant to make services cheaper for the clients, for example through MES people who had to come from Kisumu to Nairobi for services now don't have to because they can access those services hence it enhances equity of access

International Finance Advisor

PPPs pose some regulatory challenges. There are major differences in the regulation of public and private facilities. This leaves a lot of grey areas in the context of a hybrid model. The registration process of public facilities is not as intensive, neither are their penalties severe. There is a lot of leeway for government facilities as they are perceived to be more oriented to serving the public goods. The government is also perceived to be less stringent when regulating itself. The private sector is offering services in an area that is perceived to be highly unregulated.

The public sector tends to get away with a lot because by the time a public sector is in an area where they are the only health facility, unless there is some very serious contraventions of the regulations e.g. unlicensed workers, you cannot close such a facility. Sometimes it is very situational on how penalties are applied. The government does not also bring immediate action when it is their own facility that is not adhering to regulations.

International Finance Advisor

Public sector in my view is not regulated, it is just the governance structure that is written down e.g. how many pharmacies do we have in the county?, what are they going to be in charge of, how many technicians are we going to have and what level?. There is a difference because the public sector pharmacies are not subject to inspection by the pharmacy board and they are set to benefit since the private sector are regulated stringently.

Pharmaceutical Society of Kenya Manager

Regulatory capture- the government is both a provider and a regulator.

Transaction Advisor

The regulators are cognizant of the differences in the regulation of private and public sector, and with the support of donors are working towards a regulatory framework that cuts across. The Joint Health Inspection Checklist is perceived to bring a lot of uniformity in the inspection of public and private health facilities.

> *We are moving towards treating all facilities the same only that when it comes to fees which is charged to patients we need to moderate so that private hospitals do not charge exorbitantly. I don't think I see any gap because for us we inspect all of them and we have a checklist which is across the board*
>
> ***KMPDB***

Another risk that PPPs present is creating barriers to access, especially for models that allow the private sector to bill clients directly to recover their money. PPPs may make services too expensive for the client especially in a market where pricing is unregulated. This may limit access to services for the low-income group who rely on government facilities. The regulators recognize this as risk.

> *We are moving towards treating all facilities the same only that when it comes to fees which is charged to patients we need to moderate so that private hospitals do not charge exorbitantly*
>
> ***KMPDB***

4.4. Information gaps

Role of the MOH PPP Unit in regulating PPP in the healthcare space. We were not able to get an interview with the MOH PPP Unit. Perspective of the Private Sector in regulation of PPPs – our interview is scheduled for January

4.5. Research questions arising

There are key differences in the regulatory processes for private sector and public sector. These differences are even more apparent with the inception of hybrid models. This poses a big question on the regulation of healthcare services – Is regulation for the private sector because they are profit oriented or is it for public good?

Appendices

Appendix 1: Relevant documents reviewed

1. Pharmacy and Poisons Act
2. Kenya Medical Practitioners and Dentists Act
3. Nursing Act, the Clinical Officers Act
4. Public Health Act, the Radiation Protection Act
5. Kenya Nutritionists and Dieticians Act
6. Kenya Medical Laboratory Technicians and Technologists Act
7. Public Private Partnerships Act

Appendix 2: Final interview guides used

Interview guide consolidation operators

Topic guide for key informant interviews
Consolidation

Introduction

1. Can you tell me a little bit about the organisation that you work in and describe your role?

General description of phenomenon

2. Could you give an overview of what is happening with regards to [pharmacy/hospital/clinic] chains/franchises in [geographic setting]?
3. How would you describe the scale of chain/franchise [pharmacies/hospitals/clinics]?
    a. Eg what proportion of the market do they constitute in Kenya/town?
    b. When did we start having chains/franchises in Kenya/town?
    c. How would you describe their growth? Prompt for specific examples.
    d. What is the scope of services offered? Ie A comprehensive range or only specific services? Compare to standalones…..
4. Is your chain/franchise domestically-owned or foreign organisations?
5. Which clientele do you target mostly, and why?
    a. Prompt which SES groups.
6. Would you say your entering the market as a chain/franchise has disrupted the status quo?

Regulatory overview
NOTE: We recognise that many bodies may be responsible for regulation (Q7/8/9) but want to get a feel of the whole picture across those agencies.

7. From what I understand, the bodies responsible for regulating your chain/franchise are PPB (for pharmacies), KMPDB (for clinics/hospitals etc). Have I missed any?
8. What are the issues that these bodies seek to regulate with respect to pharmacy/clinic/hospital chains?
    - Prompts:
    a. Do they regulate for quality?
    b. Equity of access?
    c. Competition (market power, prices etc)
    d. Control of supply sources?
9. How is the regulation of chains/franchises carried out by these bodies?
    a. Can you describe the regulatory process? (Across the range of agencies)
        i. What are the processes for registration and licensing?

ii. Do you receive regulatory inspections? How often? When was the last inspection?
iii. How do they ensure that you are complying to quality standards?
iv. Do they regulate or monitor prices?
v. Do they regulate to ensure fair competition?

10. Does this differ to the regulation of non-chain establishments? And if so, how?
11. Have you ever been penalised for not conforming to regulation?
    a. If not, do you know of any chains/franchises who have been penalised? What for? How?
    b. Would non-chain establishments be penalised in the same way?

Regulatory concerns / opportunities

12. Would you say the current regulatory arrangements are suited to chains/franchises?
13. What would you say are the challenges of regulating chains/franchises?
14. Is there anything about chains/franchises that makes them harder or easier to regulate compared to standalone facilities?
15. Are there any regulatory gaps that are not addressed by the current arrangements?
16. How and in what ways could these regulatory arrangements be improved?
17. If you could change one thing about the regulation of chains/franchises, what would it be?
18. Is there anything else that you would like to add?

Interview guide e-pharmacy operators

Topic guide for key informant interviews with pharmacy operators
E-pharmacy

Introduction

1. Can you tell me a little bit about the organisation that you work in and describe your role?

General description of phenomenon

2. Could you give an overview of what is happening with regards to e-pharmacy in Kenya?
3. How would you describe the scale of this phenomenon?
    a. Eg what proportion of medicine sales do they account for? *E.g. versus physical shop*
    b. When did they enter the market?
    c. How would you describe their growth? Prompt for examples.
    d. What is the scope / type of medicines that they sell? Prescription only vs over the counter
4. Are you domestically-owned or international owned?
5. Which clientele do you target with the e-pharmacy?
    a. Prompt which SES groups and type of profession.
6. Would you say your e-pharmacy approach has disrupted the status quo? In what ways?
    a. Probe - the negative aspects of this type of service provision?
    b. What are the positive aspects?

Regulatory overview

7. In your understanding, are you regulated by any regulatory body? If yes, which one.
8. If answer above is NO, then say the following - From what I understand, you are supposed to be regulated by……would you say that is correct?
9. [For those who say they are regulated] What are the issues that these bodies seek to regulate? [For those who say they aren't regulated] Are there issues that these bodies should regulate? Prompts:
    a. Quality concerns? Eg quality of medicines, counterfeits, quality of service.
    b. Equity of access?
    c. Competition? (share of the market, prices etc)
    d. Control of supply sources?
10. Can you describe how the regulation of e-pharmacy carried out by these bodies?
        i. Processes for licensing and inspections? And frequency?
        ii. How are prescriptions validated?
        iii. Is there a way of monitoring the sale of prescription medicines? E.g. ensuring they are not sold to those without prescription?
        iv. Is there a way of assuring quality? (of service and/or medicines) How
        v. Is there a way of monitoring prices? How
        vi. IS there a way of ensuring compliance to competition law?

11. Does this differ to the regulation of normal pharmacies? And if so, how?
12. Can you be penalised if you do not conform to regulation? If so, how?
    a. Any examples of penalties?
    b. Would pharmacies with a physical presence be penalised in the same way?

Regulatory concerns / opportunities

13. Would you say the current regulatory arrangements are suited to the e-pharmacy business model? Probe – any challenges or regulatory gaps not addressed?
14. Is there anything about the e-pharmacy model that makes them easier or harder to regulate compared to physical outlets?
15. How and in what ways could these regulatory arrangements be improved?
16. If you could change one thing about the regulation of e-pharmacy what would it be?
17. Is there anything else that you would like to comment on that we have not discussed?

Interview guide PPP

Topic guide for key informant interviews

PPP (Kenya only)

Introduction

1. Can you tell me a little bit about the organisation that you work in and describe your role?

General description of phenomenon

2. Could you give an overview of what is happening with regards to public private partnerships in Kenya?
    a. Can you describe the history of these partnerships and how they came about?

    b. Can you describe one or two PPP initiatives and explain how they work?
3. How would you describe the scale of PPPs?
    a. Eg How many are there?
    b. When did they start?
    c. What is their value / how many people are they serving?
4. What kind of services are provided by these schemes (specific services or full range)?
5. Do the services provided by these partnerships target certain clientele?
6. What are the defining features of an effective / ineffective PPP?
7. In what ways would you say this phenomenon has disrupted the status quo?
    a. What are the negative aspects of PPPs?
    b. What are the positive aspects?

Regulatory overview

8. From what I understand, the bodies responsible for regulating PPPs are X, Y. Have I missed any?
9. What are the issues that these bodies seek to regulate?
    - Prompts:
    a. Quality concerns?
    b. Equity of access?
    c. Value for money?
    d. Competition (market power, prices)?
10. How is the regulation of PPPs carried out by these bodies?
    a. Can you describe the regulatory process?
        i. What is the process for awarding contracts?
        ii. How is public interest protected?
        iii. What are the processes for licensing and inspections?
        iv. How often are regulatory inspections carried out?
        v. How is quality ensured?
        vi. How are prices monitored?
11. What are the main differences in the regulation of public and private services?
    a. How is this managed in the context of PPPs (a hybrid model)?
12. How are PPPs penalised if they do not conform to the regulatory framework?
    a. Can you give me any examples of PPPs being penalised and what for?
    b. Would purely public or purely private providers be penalised in the same way?

Regulatory concerns / opportunities

13. Would you say the current regulatory arrangements are suited to PPPs?
14. What would you say are the challenges of regulating PPPs?
15. Is there anything about PPPs that facilitates regulation compared to traditional service provision?
16. Are there any regulatory gaps that are not addressed by the current arrangements?
17. How and in what ways could these regulatory arrangements/strategy be improved?
18. If you could change one thing about the regulation of these partnerships what would it be?

19. Is there anything else that you would like to comment on that we have not discussed?

Interview guide regulators

Topic guide for key informant interviews with regulators

E-pharmacy, Consolidation, PPPs

General description of phenomenon

18. What are your thoughts about e-Pharmacy in Kenya?
    a. Would you say they account for a significant portion of the market?
    b. What is their scope / type of medicines that they sell?
19. Would you say they have disrupted the retail pharmacy sector? How?
    a. What are the negative aspects of this type of service provision?
    b. What are the positive aspects?

Regulatory overview

20. Are e-pharmacies regulated? By who?
21. In your opinion, what is/should be regulated?
    - Prompts:
    a. Quality concerns? Eg quality of medicines, counterfeits, quality of service.
    b. Equity of access?
    c. Competition? (market power, prices etc)
    d. Control of supply sources?
22. How do you (or do you intend) to regulate e-pharmacy/clinic?
        i. What are the processes for licensing and inspections?
        ii. How are prescriptions validated?
        iii. Are there mechanisms to monitor the sale of prescription medicines?
        iv. How is quality ensured? (of the service and the medicines)
        v. How are prices monitored?
        vi. How is competition law enforced?

23. Does this differ from the regulation of physical pharmacies? And if so, how?
24. Is there a way of penalizing e-pharmacies if they do not conform to regulation?
    a. Any specific examples of penalization?
    b. Would pharmacies with a physical presence be penalised in the same way?

Regulatory concerns / opportunities

25. Would you say the current regulatory arrangements are suited to the e-pharmacy/clinic business model? Probe – any challenges or regulatory gaps not addressed?
26. Is there anything about the e-pharmacy/clinic model that makes them easier or harder to regulate compared to physical outlets?
27. How and in what ways could these regulatory arrangements be improved?
28. If you could change one thing about the regulation of e-pharmacy/clinic what would it be?
29. Is there anything else that you would like to comment on that we have not discussed?

Consolidation (pharmacy/clinic and/or clinic/hospital chains)

General description of phenomenon

1. What are your thoughts about pharmacy/clinic chains/clinic chains?
2. Would you say they have (or will) disrupted the health or retail pharmacy/clinic sector? How?

    a. What are the negative aspects of this type of service provision?
    b. What are the positive aspects?

Regulatory overview

3. How are pharmacy/clinic/clinic chains regulated? Any difference with stand-alones?
4. In your opinion, what is/should be regulated?
    - Prompts:
    a. Quality concerns? Eg quality of medicines, counterfeits, quality of service.
    b. Equity of access?
    c. Competition? (market power, prices etc)
    d. Control of supply sources?
5. Are their differences between the way pharmacy/clinic chains are penalized for infringement compared to stand-alone pharmacies?
    a. Any specific examples of penalization?

Regulatory concerns / opportunities

6. Would you say the current regulatory arrangements are suited to the pharmacy/clinic chains business model? Probe – any challenges or regulatory gaps not addressed?
7. Is there anything about the pharmacy/clinic chains that makes them easier or harder to regulate compared to the stand-alones?
8. How and in what ways could regulatory arrangements for chains be improved?
9. Is there anything else that you would like to comment on that we have not discussed?

PPPs

20. What are your views about PPPs in health?
21. From what I understand, the PPPs are regulated through the PPP Act. Are there additional legislation? What about policies or guidelines?
22. Do you think there is a role for your organization in regulating PPPs in Health?
    a. Probe: Managed Equipment Service leasing
    b. Any other specific PPPs that they could regulate?

Appendix 3: Coding frame

Consolidation coding tree

1. Overview of consolidation in Kenya (2 paragraphs maximum)

- When did this start?
- What's the size like/sales volumes etc?
- What product range does it cover?

2. Regulation of pharmacy chains/franchises/associations in Kenya

- Existing regulations and regulatory bodies
- Registration and licensing processes + Ease/barriers to entry/exit
- Regulating practice (marketing, prescription filling, distribution chain/sources etc)

- Regulating practitioners (who to do what, who to own, who to dispense what product etc)
- Regulating product quality (warehousing, storage, transportation etc)
- Sanctions and penalties

3. Detailed description of consolidation in retail pharmacy in Kenya

- General features of consolidation (e.g. presence of regulatory pharmacist? Shared functions/corporate office, scope of services etc)
- Organic growing versus external funding/private equity etc (with examples, and implications on regulatory compliance, longevity and quality of service)
- Contrast smaller chains with larger chains (with examples)
- Reasons for consolidation (e.g. higher footprint? More/brand visibility? Pooled and shared resources etc?
- Approach to regulation – encouraging regulator to dialogue on regulating chains, or ignoring regulator and continuing to treat units as independent)

Benefits of consolidation

- Competition leading to improved Quality
- Internal Quality Control Mechanism/ Self-regulation
- Brand recognition
- Moving products across outlets to maximize sales (quality risk?)
- Discounts and lower prices from pooled purchasing
- Increased investment in sector (e.g. private equity/venture capital) due to removal of information barrier to entry and financial barrier to entry
- Opportunity for outsourcing pharmacy services for clinics

Risks/challenges of consolidation

- Monopoly power
- Longevity not a top priority; selling out is, for private equity funders
- Risk of chasing quick profit, based on short investment periods = inappropriate behaviour?

Regulatory gaps and opportunities

- This will be drawn from the key areas discussed under section 3 of the coding tree (i.e. there will be different challenges for the different consolidation challenges and opportunities.
- No difference with standalone regulation. Each unit treated as standalone, including licensure.
- No application of responsive or risk-based regulation, despite opportunity? (I.e. chains stand to lose if any unit messes up, meaning responsive regulation would work perfect, where

sanctions are not deployed, and where the chain is given opportunity to keep improving itself. Plus existence of management structure to take up recommendations and implement them using a clear plan.

- Tricky balance between fund investment and public good.
- Deliberate push to improve regulatory framework (chains willing regulators to do seminars and ensure minimum pharm-tech qualification)
    - This differs from standalones, whose level of risk is much lower (can close shop and go into different business….it appears chains have more to lose, hence, want fair competition). There is a clear intention to engage with the regulators, as opposed to staying below radar.

E-pharmacy coding tree

1. Overview of e-pharma in Kenya (2 paragraphs maximum)

- When did this start?
- What's the size like/sales volumes etc?
- What product range does it cover?

2. Regulation of e-pharmacy in Kenya

- Existing regulations and regulatory bodies
- Registration and licensing processes + Ease/barriers to entry/exit
- Regulating practice (marketing, prescription filling, distribu tion chain/sources etc)
- Regulating practitioners (who to do what, who to own, who to dispense what product etc)
- Regulating product quality (warehousing, storage, transportation etc)
- Sanctions and penalties

3. Detailed description of e-businesses in Kenya

- General features of e-pharma businesses (e.g. presence of regulatory pharmacist? Availability of some form of warehouse? Use of some form of technology etc)
- Provider versus client facing (with examples)
- Fully e-business or e-business plus brick-n-mortar (with examples)
- Competition strategy (compete or cooperate) with examples
- Approach to regulation – embrace or ignore (with examples perhaps?) [maybe also talk about self-regulation as an initiative for those who want to do the right thing here] – [Here, the idea of excessive regulation in the absence of proper regulation comes in]
- [Can add process maps for the key e-pharma models]

Benefits of e-pharmacy (e.g price transparency and competition, supply logistics, traceability, ease of regulating quality)

Risks/challenges of e-pharmacy (e.g. operational, demand, high barriers for genuine operators and low barriers of entry for quacks = adverse selection (race to the bottom competition), fear of the unknown can lead to overregulation etc).

Regulatory gaps and opportunities

- This will be drawn from the key areas discussed under section 3 of the coding tree (i.e. there will be different challenges for the different e-pharmacy models described – the challenges do not all apply to each model). Example, for the 'Approach to regulation' point under section 3, an opportunity for regulation might come from the fact that the e-pharma practitioners want to partner with the regulator to define the regulatory model, which makes it easier for the regulator to get things moving. The risk is regulatory capture. This is just an example.
- Opportunities and challenges will be discussed for each type of e-pharmacy model in turn, then summarized in a table at the end

PPP coding tree

1. Overview of PPP in Kenya (2 paragraphs maximum)

- When did this start?
- What's the size/Number
- Range of Services?

2. Regulation of PPP in Kenya

- Existing regulations and regulatory bodies
- Regulatory differences between the public and the private sector
- Sanctions and penalties

3. Detailed description of PPPs in Kenya

- General features
- Models of PPPs in Kenya

Benefits of PPP

Risks/challenges of PPP

Regulatory gaps and opportunities