Legislation, regulation, and consolidation in the retail pharmacy sector in low-income countries

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Abstract

Formal pharmaceutical retailing in most countries in the world is governed by regulations concerning ownership, staffing, medicines, prescriptions and prices. However, in most low and middle-income countries regulatory enforcement of these regulations is difficult or impossible constrained by limited government capacity, and complicated by the fragmented nature of pharmaceutical retail markets.

This paper documents the current status of private-sector retail pharmacy legislation and regulation in the low-income countries where private financing of healthcare is most important. We look at regulatory frameworks in 25 countries, what legislative and market forces are causing changes in the practice of retail pharmacies, and what the effects of these changes have been in recent years.

In most countries studied, pharmacy legislation and regulation is fragmented and there is sporadic and limited enforcement of regulations. Market consolidation through shared ownership, franchise arrangements, or formal collaboration, is usually impeded by ownership laws. Consolidation in South Africa has resulted from a recent legislative change, while in India it has been driven by refinement of existing legislation and changing market forces. In these two countries recent changes have permitted rapid expansion of pharmacy chains. The early effects of these chains appear to be lowered prices, greater competition, and an initial balance between newly opened stores in shopping centers and the closure of independent pharmacies.

Four main factors determine the extent to which consolidation is possible in the private pharmacy sector: 1. Legislation on ownership, 2. Regulation, licensing and registration of pharmacies, 3. Availability of qualified pharmacists, and 4. Access to finance to set up a pharmacy.

Introduction

Most health delivery in low-income countries occurs in 'mixed market' systems, with care delivered by both government and private sector providers[1,2,3]. Within this larger category of 'private providers', cost, access, speed, anonymity, and other motivations drive patient selection of provider. Private pharmacies, drug stores and drug sellers are often the first point of contact for healthcare[4,5,6,7,8,9].

Formal private sector pharmaceutical retailing in most countries, including low-income countries is governed by regulations that prescribe ownership, staffing, acceptable medicines along with sources and quality standards, and pricing and prescription practices[10]. There is considerable variation between countries in the way retail pharmacies operates. While retail chains such as Boots, Walmart, Watsons, Farmacias Similares, and Payless are common in Canada, the US, the UK, and across much of Latin America and East Asia, many countries in Europe, Asia, and Africa impose regulatory limits on pharmacy ownership, prohibiting chains and discouraging franchises.

The great difference between the market for pharmaceuticals in Europe and the market for pharmaceuticals in low-income countries is regulatory capacity. German oversight of the country's 21,500 pharmacies is effective at assuring that medicines are dispensed by qualified and registered pharmacists and the sale of illegal, out-of-date, or non-prescribed medicines is prevented. In most low- and middle-income countries, regulatory oversight is constrained by governments which lack the enforcement staff, budgets, or efficient regulatory and judicial framework that exists in developed countries[11,12]. Regulatory inspections are few, enforcement is weak and infringements common[13,14,15,16]. Enforcement is made particularly difficult because the pharmaceutical retail market in most low-income countries is highly fragmented: the number of formal pharmacies is small compared to the many different types of retailers, such as dispensing doctors, medicine sellers, drug sellers and general stores that also sell a variety of drugs and healthcare remedies[13].

The result is widespread unregulated and sometimes illegal sale of restricted medicines, often without prescription and often by

unqualified staff [17,15,18,16,19,20]. In most low-income countries there is little, if any, quality control and retail prices are inflated and highly variable according to what each patient will pay[21,22,23]. Pharmacists working in these countries often complain that they are not viewed or valued as health care providers but merely as retailers or businessmen[24,25,26]. All of these factors are especially detrimental to the poor who, due to limited access and information, often have few choices when buying medicines.

This paper documents the current status of private-sector retail pharmacy legislation and regulation in those low-income countries where private healthcare plays a particularly important role. We look at regulatory frameworks in these countries, what legislative and market forces are causing changes in the practice of retail pharmacies, and what the effects of these changes have been in recent years.

Focus of study

We focused this study on 24 low- and middle-income countries (LMIC) having the highest private expenditure on health (PHE) as a percent of total health expenditure (THE) in 2003. The 23 countries were examined and South Africa was included because of recent legislative changes in its retail pharmacy regulation. South Africa ranks 36th in terms of PHE as a percentage of THE.

Average PHE as a percent of THE for the 24 countries was 74% and average expenditure on pharmaceuticals as a percent of THE was 35% (Table 1). Private expenditure on pharmaceuticals was almost five times greater than government expenditure on pharmaceuticals, likely indicative of both higher volumes purchased with private funds and higher prices in the private sector where such purchases mostly take place.

Table 1. Twenty-four selected countries and indicators for expenditure on health

Country	Rank	Private expenditure on health (PHE) (% of total expenditure on health) [1]	Out-of-pocket expenditure on health (% of private expenditure on health) [1]	Total expenditure on pharmaceuticals (% of total expenditure on health) [2]
Guinea	1	83.4	99.4	21.3
DR Congo	2	81.7	100.0	19.9
Cambodia	3	80.7	86.2	36.7
Myanmar	4	80.6	99.7	16.0
Armenia	5	79.8	80.6	52.6
Tajikistan	6	79.2	100.0	13.4
Burundi	7	76.7	100.0	29.8
Azerbaijan	8	76.2	96.8	7.8
Georgia	9	76.1	98.2	39.1
India	10	75.2	97.0	14.5
Togo	11	75.2	88.0	36.8
Nigeria	12	74.5	91.2	18.2
Uruguay	13	72.8	25.0	17.1
Côte d'Ivoire	14	72.4	90.5	17.5
Pakistan	15	72.3	98.0	27.1
Nepal	16	72.2	92.2	29.9
Vietnam	17	72.2	74.2	41.0
Cameroon	18	71.1	98.3	44.5
Lebanon	19	70.7	79.4	21.2
Uganda	20	69.6	52.8	15.4
Bangladesh	21	68.7	85.8	37.9
Paraguay	22	68.5	74.6	38.9
Ghana	23	68.2	100.0	32.8
South Africa	36	61.4	17.1	12.3

[1] Data from World Health Report 2006. Annex Table 3 Selected national health accounts indicators: measured levels of per capita expenditure on health, 1999–2003. World Health Organization, 2006, Geneva.

[2] Data from the World Medicine Situation 2004 Report, World Health Organization, 2004, Geneva

Table 2. Retail Pharmacy Legislation in a selection of low- and middle-income countries

Country	Ownership / Practice Legislation	Pharmacy Registration / Licensing	Drug sales / Prescription Legislation
Cambodia	Law on the Management of Pharmaceuticals 1996	Ministry of Health	
India	Pharmacy Act 1948 Food and Drug Administration India (FDA)	Food and Drug Administration India (FDA) (licensing). State Pharmacy Councils (Registration) reporting to National Pharmacy Council	Pharmacy Act 1948 Drugs and Cosmetics Act 1940
Nigeria	The Pharmacists Council of Nigeria Act 1992. Registration of Pharmaceutical Premises Regulations, 2005	Pharmacy Council (Registration)	National Agency for Food and Drug Administration and Control (NAFDAC)
Côte d'Ivoire	Pharmacy in Public Health of Cote d'Ivoire, "Draft of the Manual of Procedures of System of Management and Quality of Pharmacy in Public Health, February 2007. Directorate of Pharmacy and Medicaments	Administration of Pharmacies and Medicines, Ministry of Health. Order of Pharmacists. Syndicate of Pharmacists	
Pakistan	Pharmacy Act XI 1967	Pharmacy Act XI 1967	Drugs Act 1976. National Drugs Policy State regulations (Northern Area Drug Rules, Punjab Drug Rules)
Nepal	Drug Registration and Regulation	Department of Drug Administration	Drug Act 1978
Vietnam	Law 34-2005-QH11 of the National Assembly14 June 2005 on Pharmacy Ordinance on Private Medical and Pharmaceutical Practice 2003	Provincial-level Departments of Health issue "eligibility" and "practicing" certificates	Vietnam Drug Policy. Ministry of Health
Cameroon	Drug Law 1980	Administration of Pharmacies and Medicines, Ministry of Health	Republique Unie du Cameroun (RUC). 1980. Law No. 80/ 10 of 14 July 1980: To Regulate the Practice of Pharmacy
Lebanon	Law No. 367 1st August 1994 on the practice of the profession of a pharmacist	Directorate of Pharmacy, Ministry of Health	Law No. 367 1st August 1994 concerning the practice of the pharmacy profession
Uganda	National Drug Policy and Authority (Issue of Licenses) Regulations 1995 Pharmacy and Drugs Act 1971	National Drug Authority (Licensing) Pharmaceutical Society of Uganda (Registration / Certification)	National Drugs Policy and Authority Stature 1993. Pharmacy and Drugs Act 1971 (to be replaced by Pharmacy Profession and Pharmacy Practice Bill 1999)
Ghana	Pharmacy Act 1994	Pharmacy Council (Registration)	Pharmacy Act 1994 (also referenced in National Drugs Policy (2nd ed.) 2004)
South Africa	Pharmacy Act 153, 1974. Amended 1997, Enacted 2003	Director General of Health, Department of Health (Licensing) Pharmacy Council (Registration)	National Drug Policy 1996 Medicines and Related Substances Control Act 1965 (amended 1997)

Methods

Information on countries' retail pharmacy legislation, regulation and practice was collected through multiple sources. Peer-reviewed articles were sought through searches of academic databases including PubMed, ISI Web of Knowledge, and the International Pharmaceutical Abstracts using keywords on pharmacy-related terms[i]. Gray material and non-peer reviewed articles were obtained through online searches using the search engines Google and Google Scholar with the same terms used for the databases. The websites of the World Health Organization and the International Pharmaceutical Federation were searched for relevant information and reference publications. Government, Ministry of Health, Pharmacy Council or Association or drug regulatory authority websites in each of the 24 countries were searched and where appropriate contact information was available these agencies were also contacted by either e-mail or fax. Published experts in the field were asked for additional information, both general and country-specific, and requests for information were posted on the Essentialdrugs.org website.

Much of the information included in this paper is derived from personal interviews and gray matter publications such as online newspapers and pharmacy business websites. This is a reflection of the limited peer-reviewed research regarding pharmacy legislation and regulation in low to middle income countries.

Findings

Most of the information on legislation, regulation and pharmacy practice was obtained from national Pharmacy Council or Association websites, contact with officials in those councils or in Ministries of Health, or from websites that aggregated country legislation data[27]. A complete set of information on three areas of retail pharmacy – legislation, regulation, and practice – was only found for 12 countries, 11 of these low-income, and one, South Africa, a middle-income country. One country had data on two of these areas. Four countries, Armenia, Georgia and Uruguay, and Bangladesh, had information on only one area. We found insufficient information to draw conclusions about legislation, regulation, or practice of retail pharmacies in seven countries: Guinea, DR Congo, Myanmar, Burundi, Paraguay, Tajikistan and Togo.

Legislation and regulations

We collected information on legislation pertaining to the practice of pharmacy in 12 countries (Table 2). Columns one and two list legislation pertaining to practice and ownership, and prescription and drug sales respectively. Column three indicates which agencies are responsible for pharmacy registration and licensing.

All of the 12 countries studied have an Act or Law relating to Pharmacy or Drugs. This legislation determines who is allowed to practice pharmacy, the conditions under which a pharmacy may operate, and sets out rules for prescription and sales of drugs. In almost all countries prescription medicines and restricted medicines (such as psychotropic or narcotic drugs) can only be sold or dispensed at a pharmacy by a registered and qualified pharmacist upon presentation of a prescription. In some countries ambiguous legislation permits pharmacists to treat simple and common ailments with antibiotics dispensed without a prescription[5]. Over the counter and non-prescription medicines are sold at pharmacies and a variety of drug sellers or chemical shops, and may be sold by pharmacy assistants and staff with little or no formal training.

Registering and licensing of qualified pharmacists is usually the responsibility of a national or state Pharmacists' Association or Society, or a department within the Ministry of Health or government but may also be controlled by more than one entity. The Pharmacy Act often stipulates the conditions and legal structures under which these bodies can operate.

Ownership rules and restrictions

From legislative documents and articles about pharmacy we compiled information on ownership rules, restrictions and required qualifications of pharmacists for 12 countries (Table 3). In most of these 12 countries only qualified and registered pharmacists who hold a bachelors degree or pharmacy diploma are allowed to own pharmacies and can do so as individuals or sole proprietors. Ownership is often limited to one pharmacy per pharmacist.

In a small number of countries, a partnership or corporation is permitted to own a pharmacy but with the requirement that at least one, and sometimes all, of the partners are qualified pharmacists. These corporate entities may be allowed to own more than one pharmacy, provided again that a registered pharmacist manages each store.

Of the 12 countries studied, very few countries have retail pharmacy chains. The few chains in Nigeria, Pakistan, Uganda and Ghana are small, consisting of three to six stores each. Only two countries in our study are exceptions to this rule: India and South Africa. Both have seen tremendous growth in the number and size of chains in the past five years. In South Africa, this growth stemmed from a legislative change in 2003 that permitted corporate ownership of pharmacies for the first time. In India, liberal interpretation of laws on pharmacy licensing together with explosive growth in the retail sector opened the door to chain growth beginning in 2000, first within hospital chains, but since 2004 increasingly through stand-alone pharmacy chains and outlets located in grocery or general retail stores.

In Nigeria, ownership of more than two retail pharmacies by a corporation is permitted, provided that the partners are registered pharmacists and a licensed and registered pharmacist manages the store at all times. In Ghana, legislation permits multiple pharmacies to be owned by non-pharmacists, and a

[i] Search terms used: pharmacy, drug, medicine, chemical, seller, shop, store, retail, community, chain, private, practice, legislation, regulation.

Table 3. Ownership rules, restrictions and qualifications required for pharmacy staff

Country	Who can own	Ownership restrictions	Qualifications	Retail chains
Cambodia	Pharmacist only. Pharmacist without sufficient funds may own with another non-pharmacist	Must be Khmer. Maximum one pharmacy per pharmacist license. Locations based on commune needs	Diploma recognized by MOH. In pharmacist absence, someone who has attained suitable qualifications approved by MOH	Not permitted
India	Individuals, Partnerships or Body Corporates	Individuals must be pharmacists. Partnership and Body Corporate-owned stores must have a supervising pharmacist, often a *"signature pharmacist"*	B.Pharm (4 year degree) or D.Pharm (2 year diploma course from an approved institution followed by 500 hours of practical training over 3 months)	>10
Nigeria	Individuals or partnership	Individual must be registered pharmacist. Partnership must be with other pharmacists. Owner can register as superintendant in only one pharmacy. All stores owned must employ a pharmacist	B.Pharm, followed by 1 year internship	3-5
Côte d'Ivoire	Individuals only.	Must be registered pharmacist and be Ivorian. One pharmacy per pharmacist. Non pharmacists may not own (or manage)	Pharmacy Assistant may manage a store under responsibility of owner	Not permitted
Pakistan	Individuals and corporations	Individuals must be a pharmacist. For non-pharmacist owners (individuals and corporations), drug sales must be under continuous supervision of a pharmacist	Pharmacist (B.Pharm). Pharmacy Assistant (diploma). Persons who pass an examination in pharmacy held by a Provincial Council	2-5
Nepal	Individuals. A "legal person" (defined as 'Private Limited' or 'Public Limited' or 'cooperative organization' or "not-for-profit organization")	Individuals must be a pharmacist. "Legal person" owners: must have full-time pharmacist managing	Pharmacist (4 yr B.Pharm), Pharmacy Assistant or Technician (1.5 yr Certificate in Pharmacy), Professionalist or *Vyawasayi* (3 month course approved by Drugs Advisory Committee)	Not permitted
Vietnam	Individuals and organizations	Individual must be a pharmacist or has 5 years of professional practice	Pharmacy diploma from university, intermediate pharmaceutical school or primary pharmaceutical school, depending on pharmacy type	Not permitted
Cameroon	Individual	Individuals must be a pharmacist. Maximum of 1 pharmacy per pharmacist	B.Pharm	Not permitted
Lebanon	Individual	Must be registered pharmacist. Additional requirements for non-Lebanese	Diploma in pharmacy, over 20 and has part 2 baccalaureate	Not permitted

Country	Who can own	Ownership restrictions	Qualifications	Retail chains
Uganda	Individuals, Partnerships or Body Corporates	Individual: must hold a pharmacist license and be a Uganda resident. Partnership or Body Corporate: one partner or director must be pharmacist and Uganda resident	B.Pharm, followed by a pre-registration examination	3-5
Ghana	Sole proprietors or corporate entities	Pharmacists and non-pharmacists permitted to own. Must be a supervising pharmacist but can be part-time	B.Pharm, 1500 hours internship (480hrs in a recognized Community Pharmacy), pass in professional exams	3-5
South Africa	Individuals and Body Corporates	Individual must be a registered pharmacist in all stores. Must satisfy a need for a new pharmacy in that area	B.Pharm (4 yr), 12 month practical training period, pre-registration evaluation, 12 months public sector community service	>7

qualified and licensed supervising pharmacist need not always be present, meaning that the store can be managed by staff with lower-level qualifications. Ugandan law permits corporations to own a pharmacy, provided that at least one partner is a pharmacist, but ownership is still restricted to two pharmacies, thus restricting any broader market consolidation. In Pakistan chains are permitted, but have not developed. Chain formation in the remaining countries in our study, Cambodia, Cote d'Ivoire, Nepal, Vietnam, Cameroon and Lebanon, is prevented by one-pharmacist-one-pharmacy laws.

Legislative change and market consolidation

South Africa

The Pharmacy Act of 1974 only allowed for a pharmacy to be owned by an individual licensed and registered in one of four categories prescribed in the Act[28]. The Act was amended in 1997,[29] and the amendments ratified in 2003. The new statute allows non-pharmacists to own pharmacies, provided that a registered pharmacist is employed to run them at all times[30,31].

Since the legislative changes a number of pharmacy chains have appeared in grocery outlets. Clicks, a large retailer focused on health, beauty, entertainment and home furnishings, began opening in-store dispensaries in some of its 700 existing stores soon after deregulation[32]. It now has over 130 such dispensaries and is adding additional services such as screening and basic health care in some of its stores. The 30 year old company Dis-Chem, the second largest pharmacy group in the country announced in June 2008 that it was planning to expand through franchising in an attempt to speed up growth in the smaller cities and retain young pharmacy graduates[33]. Franchises would not be limited to pharmacists but would also be open to retailers, in recognition of the fact that the bulk of revenues from Dis-Chem stores are derived from retail and not the pharmacy sales. A number of other grocery and general retail chains such as *Pick n' Pay* and *Shoprite* have also opened in-store pharmacies. *Pick n' Pay* has also experimented with in-store pharmacy-clinic in one store, which provides basic health care diagnostics along with full pharmacy services[34].

The change in legislation and subsequent entrance of chain stores in the retail pharmacy market has added pressure to small retail pharmacies that were already struggling[35]. It is not clear if the addition of corporate chain pharmacies has led to the closure of independent pharmacies, but it seems likely. Despite this, overall pharmacy numbers are increasing: in the first four years after ownership deregulation the total number of pharmacies in South Africa increased by 15%[36].

India: Liberalization and competition

India's two main pieces of legislation that pertain to retail pharmacy are the Drugs and Cosmetics Act of 1940 and the Pharmacy Act of 1948. The Act requires individual States to create Pharmacy Councils, responsible for keeping a register of pharmacists and information relating to their qualifications and place of practice. A comprehensive revision of the Pharmacy Act was initiated by the Pharmacy Council in 2005 and is currently progressing through parliament[37].

Pharmacy licensing is controlled by the Food and Drug Administration of India which awards a license only to a qualified pharmacist to operate. However, many pharmacies set up by non-pharmacist businessmen are able to hire a *signature pharmacist* who works part time and fulfills the regulatory requirements. These pharmacies are generally staffed by pharmacy assistants or less well-trained staff[19].

Beginning in the mid-1990s hospital chains began to incorporate pharmacies into their facilities, creating de-facto pharmacy chains. Their success, combined with a growing urban middle

class market and greater access to financing as India's economy liberalized, led to the creation of independent pharmacy chains, the first around1997, expanding rapidly after 2000. As in South Africa, many of these chains have been located in grocery and general merchandise stores, but chains of stand-alone pharmacies are also developing. There are estimated to be around 1500-2500 pharmacies grouped in retail chains. Although this number is still very low when compared to the estimated 550,000 pharmacies and drug sellers countrywide, it is growing rapidly[38].

Retail prices for many medicines in India are set by the state. As a result, competition by chains has successfully emphasized discounting and delivery. Since 1997, one company, Subhiksha, has opened over 1000 stores in 90 cities and sells all medicines at 10% discount from the government set-prices.

Despite the tremendous interest in this area in the last five years, there is some evidence that expansion has slowed due to the rising cost of retail real estate, an overall shortage of qualified pharmacists and rising salaries. A comparison of the projections of five of the largest groups with the actual situation shows that by early 2008 none of them had come close to opening the number of stores initially projected (Table 4)[39]. Despite challenges, in 2007, more than a dozen other healthcare firms had plans for large-scale expansion into retail pharmacy[40].

The growth of retail chains has created friction with individually owned pharmacies, prompting the latter to organize against the perceived threat from large retailers. In June 2007, the All India Organization of Chemists and Druggists (AIOCD) launched an initiative to gather many of the country's 500,000 pharmacies and drug sellers into a single corporate entity, the All Indian Origin Chemists and Distributors Limited. The goal of creating this corporation is to coordinate direct purchasing from drug companies, standardize and share logistics, and to obtain supplies through a common system at lower costs. The new organization is to be formed in collaboration with State Chemist and Druggist Associations and planned to raise Rs 250 million ($5 million USD) through issuance of shares to members[41].

At the same time a smaller organization, the Retail and Dispensing Chemists Association (RDCA), is organizing 5000 individual pharmacies and drug sellers to adopt shared management practices, including customer loyalty schemes, and modernize stores with computerized dispensing records and air conditioning[42]. The organization is also working with wholesalers to prevent stock-outs in member pharmacies[43].

Normative countries: slow growth serving the wealthy and maintenance of the status quo

The remaining countries in our study have seen no changes in pharmacy retail practice or regulation and the few chains that do exist are small. In Nigeria, Medicines Plus is a wholesale, retail chain with 30 employees[44]. Their three stores are located in shopping malls in the Lagos area, cater to wealthy clientele, and are not representative of the pharmacies used by the majority of Nigerians.

In Pakistan, although permitted by law, chain stores are still rare. The largest chain in mid-2008 was Faizal Din's Pharma Plus group, founded in 1995, with eight pharmacies in Lahore. Larger chains, operating within the government hospitals, are planned but do not yet exist[45].

In Uganda there are at least two small chains of retail pharmacies, Vine Pharmacy,[46] and Gilead Pharmacy. Each has three to five stores. A third company, Abacus Pharma, has five branches and is also a wholesaler that has expanded into Kenya and Rwanda.

In Ghana, small chains of three or four retail pharmacies began to appear in the early 1980's. These have expanded to include some supermarket-based pharmacies, but the overall market is still dominated by independent stores. Early retail chains such as Ernest Chemists Limited, Kinapharma[47] and Kama Group[48] first became wholesalers and distributors before ultimately moving into manufacturing[49].

Discussion

Effective pharmaceutical policy is an essential piece of any country's legislation, particularly given the increasingly widespread availability of inexpensive prescription medicines. In many low-income countries, formulating policies to legislate and regulate the production, approval and sales of drugs remains challenging. Differences in legislation between neighboring countries, inadequate administration and enforcement, and a lack of qualified personnel, make this a particularly difficult area for many governments[50].

Table 4. Projected and actual retail pharmacy store openings in India

Healthcare Group	Projected stores	Projected date	Stores April 2008
Fortis Healthworld	1,000	by 2012	45
MedPlus	800	by early-2008	260
Lifeken	700	by 2009	< 100
Medicine Shoppe	500	by 2010	130
Cure & Care	100	by 2008	2

This study found very little research on whether changes in pharmacy legislation and regulation in the context of increased privatization could improve the quality of practice, increase access to drugs, and lower the costs of medicines. We found few studies on the relationship between legislation and enforcement of regulations, and none that could be used as a guideline for low-income countries in the area of retail pharmacy specifically.

Consolidation has been a defining feature of the retail industry worldwide and pharmacy retailing is no exception. Chain stores are now common in the United States, the UK, and much of Asia and Latin America[51]. Even where chains are restricted, as is the case in much of mainland Europe, franchise contracts are being used to create de-facto chains[52].

Chain pharmacies have been evaluated by the Community Pharmacy Section of the International Pharmaceutical Federation (FIP),[53 54] and Australia's National Competition Council conducted a policy review on deregulation[55]. In Norway, the effects of total deregulation in the retail pharmacy industry in 2001 have been well documented[56 57]. Potential benefits and drawbacks of chain retailers highlighted by these articles are summarized in Box 1.

In comparison to high-income countries, the retail pharmacy sector in the countries examined has seen very little consolidation in recent years except for South Africa and India. Restrictive legislation, which includes allowing only pharmacists to own pharmacies and limiting the number of pharmacies that can be owned by each pharmacist, prevents consolidation in most low-income countries studies.

Where chains have formed they appear to have been facilitated by the existence of an urban middle-class market, but also by a legislative change, as in the case of South Africa, and by overall growth in the retail sector as in India. While we found no peer-reviewed research comparing the quality of services at chain pharmacies against that of independent retailers, reports from India do show that the appearance of the chains is stimulating competition, prompting some independent retailers to improve the quality of their stores and services in a bid to keep their existing customers.

Box 1. Benefits and drawbacks of chain retail pharmacies

Pros	Cons
Standardized quality	Profit driven and business focused
Improved efficiencies	Less personalized service – decrease in quality of care
Encourages effective competition	Opposition from Pharmacy Councils
Increased accessibility	Possible decrease in pharmacist accountability
Increase in pharmacies and pharmacists	Additional investment in infrastructure required
Expansion of new services	Potential loss of services in rural areas
Lower costs to consumers	

From our study, two other factors beyond ownership laws appear likely to effect consolidation where legislation allows it. First, there is a shortage of degree-level pharmacists in almost all the countries surveyed coupled with a universal requirement that professional pharmacists supervise pharmacies at all times – a law which is often flouted by 'mom-and-pop' pharmacies, but which corporate chains dare not disobey. This has almost certainly slowed pharmacy expansion in India and in many Sub-Saharan African countries. To address this, some researchers have proposed acknowledging the role that non-pharmacist drug sellers and dispensers play in the community by providing training to improve their skills[58] or by adapting legislation to match the country's enforcement capabilities[16].

The second factor which is limiting consolidation is the availability of financing for new pharmacies. This has been highlighted as a significant restriction for pharmacists in some countries[24]. Permitting non-pharmacist businessmen and corporations to own stores and employ pharmacists to manage them would appear to be an attractive option in these instances.

Conclusions

The private retail pharmacy sector is an important source of healthcare for millions of people in low-income countries. This study, although limited by the availability of data, shows that pharmacy legislation and regulation in many low-income countries is often inadequate, is largely un-enforceable, and in some cases, appears to work against the broader goals of the health system to assure affordable access to quality medicines.

Four main factors determine the extent to which consolidation occurs in the private pharmacy sector: 1. Legislation on ownership, 2. Regulation, licensing and registration of pharmacies, 3. Availability of qualified pharmacists, and 4. Access to finance to set up a pharmacy.

Experience from India and South Africa indicates that where legislation changes or where successful examples become known, market forces will quickly lead to growth in both chain and franchise operations for retail pharmacies. There remains very limited, and contradictory, evidence on the effects of this consolidation towards quality, pricing, enforcement of regulation, and responsiveness to patient needs.

Further detailed study and documentation of the impact of legislative and marketplace changes on the pharmacy sector in countries such as South Africa, India, Pakistan and in Latin America would be valuable in assisting low- and middle-income countries improve the quality of retail pharmacy.

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