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From evidence to action

Legislation, Regulation, and Consolidation in the Retail Pharmacy Sector in Low-Income Countries

Richard F Lowe, Dominic Montagu

Global Health Group, Global Health Sciences, University of California, San Francisco

Study Objective

Status of private retail pharmacy in low- and middle-income countries

- What legislative and market forces cause changes
- What are those changes
- What are the effects of, and responses to those changes
- Are there barriers to consolidation – formation of retail chains?

Consolidation – findings from OECD countries

PROS	CONS
Standardized quality	Profit driven and business focused
Improved efficiencies	Loss of the pharmaceutical environment
Encourages effective competition	Less personalized service - decrease in quality of care
Lower costs to customers	Opposition from Pharmacy Councils
Increase in pharmacists and pharmacies	Possible decrease in pharmacist accountability
Expansion of new services	Additional infrastructure investment
Increased accessibility	Potential loss of services in rural areas

Sources: Community Pharmacy Section, International Pharmaceutical Federation (FIP)
Australia National Competition Council

Could private sector retail pharmacy in low-income countries be improved by encouraging consolidation?

Study Details

Focus areas:
- Regulatory frameworks
- Legislation
- Market forces

} Identify any changes and Effects of these on retail pharmacy practice

Consolidation:
- Extent
- Barriers
- Consequences

Countries: Highly Private healthcare financing

- 23 with highest private expenditure on health (PHE) as a percent of total health expenditure (THE) in 2003 + South Africa

Sources: Peer-reviewed literature, "gray" material, pharmacy associations and websites, individuals

Country characteristics

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]
Cambodia	3	80.7	86.2	36.7
India	10	75.2	97.0	14.5
Togo	11	75.2	88.0	36.8
Nigeria	12	74.5	91.2	18.2
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
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*

Not included in table:
Guinea, DR Congo, Myanmar, Armenia, Tajikistan, Burundi, Azerbaijan, Georgia, Togo, Uruguay

What laws control private retail pharmacy?

Legislation / Regulations

- Pharmacy Act
- Drug Law
- Drugs and Cosmetics Act
- National Drug Policy, State Rules
- Law on the Management of Pharmaceuticals
- Regulation of Pharmaceutical Premises
- Ordinance on Private Medical and Pharmaceutical Practice
- Medicines and Related Substances Control Act
- National Drug Policy and Authority (Issue of Licenses) Regulations
- Pharmacy Profession and Pharmacy Practice Bill

Ownership
Practice
Prescriptions
Drug Sales

What agencies control private retail pharmacy?

Regulating Agencies

- Ministry of Health (National and Provincial)
- Food and Drug Administration
- Pharmacy Councils (National and State)
- Pharmaceutical Society
- Order of Pharmacists
- Syndicate of Pharmacists

Registration / Certification
Licensing

May also influence drug prescribing and sales

Ownership and practice: who can do what?

Restrictive Ownership Rules

CHARACTERISTIC	COUNTRY	CHAINS
Individuals only Registered pharmacist One pharmacy per pharmacist	Cambodia Cote d'Ivoire Cameroon Lebanon Vietnam	Not permitted

Additional rules (country specific)

- Pharmacist may partner with non-pharmacist (Cambodia)
- Owner must be a national (Cote d'Ivoire)
- Additional requirements for non-nationals (Lebanon)
- Site must be approved by MoH (Cameroon – up to 10 years waiting)
- Pharmacy Assistant can manage a store under owner's responsibility (Cote d'Ivoire)

No private retail chains exist

Ownership and practice: who can do what?

Moderate / Liberal Ownership Rules

CHARACTERISTIC	COUNTRY	CHAINS
Individuals, Partnerships, Body Corporates, "Legal person" Individuals must be pharmacist Partnerships must employ pharmacist at each store	Nepal	Planned
	Ghana Nigeria Pakistan Uganda	3-5
	India South Africa	>10 >7

Why are there chains in some countries and not others?

Consolidation

South Africa

Major legislative change in 2003

- Non-pharmacists ownership permitted
- Registered pharmacist must be present in each pharmacy

Outcomes

- Rapid introduction of pharmacies in grocery and retail outlets
  - Clicks – 130 dispensaries (700 stores overall)
  - Dis-Chem – expansion through franchising (retailers and pharmacists)
  - Pick n'Pay – "one-stop" pharmacies and clinics
- Pressure on independent pharmacies – some likely closures
- First four years after change, 15% increase in pharmacy numbers
- Prices vary: affected by a separate law enacted in 2003

Consolidation

India

Changing environment

- From late 1990's increasingly Liberal interpretation of pharmacy laws
- Social and economic changes
  - economic liberalization
  - growing middle class

Outcomes

- Formation of hospital pharmacy chains in mid 1990's
- Rapid expansion into private grocery and retail sector late 1990's
- Price competition – many large chains offering permanent reductions on products

2007: 12 firms with chain plans

2008: 1500-2500 stores in chains

Responses to retail chains

India - formation of de facto chains

All India Organization of Chemists and Druggists

Gather many of the 500,000 independents into a single entity

- Coordinate direct purchasing from drug companies
- Lower prices through a common system
- Standardize and share logistics

Retail and Dispensing Chemists Association

Organize 5000 individual pharmacies

- Adopt shared management practices
- Customer loyalty schemes
- Modernize stores – electronic records / AC
- Work with wholesalers to prevent stock-outs

2500/500,000 (0.5%) chain pharmacies provoked this strong response from independent pharmacies

What are barriers to consolidation?

1. Legislation

- Complicated regulatory frameworks are the norm
- Ownership limited to pharmacists
- Ownership limited to one pharmacy

2. Personnel

- Shortage of degree-level pharmacists
  - Flouted by "mom and pops" but corporations dare not disobey

3. Financing

- Often difficult for new pharmacists to get financing to open stores

The Philippines: the downside to consolidation

Drug prices

- 6-8 times higher than elsewhere in Asia
- Higher in rural areas
- Generic drugs < 4% total market

Combination of factors

1. Monopoly: Mercury Drug Corporation
    - ➢ 450 stores; movement into general retail
    - ➢ sell up to 60% of all drugs; set commercial price for many drugs

Conclusions

- Regulatory barriers to pharmacy consolidation are the norm in LICs
- Costs and benefits of consolidation are poorly documented.
  - Anecdotal evidence :
    - lower prices to consumers
    - risks of monoplies
    - increased numbers of pharmacies
    - poor quality services
- Human resources and access to financing remain barriers to pharmacy expansion

Why look at pharmacies?

Low- and middle- income countries

Mixed market health system

Government → Free / low cost, Quality assurance, Specialist drugs, Linked to physician

Private Sector → Cost, Access, Speed, Anonymity

Motivators for provider selection

Pharmacies, drug stores, drug sellers

- first point of contact with health system
- service is often poor
- high prices and low quality medicines

What determines the presence of retail chains?

Nepal

- No legal barriers to chain formation
- Ownership laws allow some without pharmacy degrees to practice and own

→ **Chains planned by pharmacists and investors in Nepal**

Ghana, Nigeria, Pakistan, Uganda

- Legal clauses – In Ghana, supervising pharmacist may be part-time
- Retail sector becoming established

→ **Small Retail Chains (3-5 per country)**

- <7 stores per chain
- City locations / Up-market areas serving the wealthy

Still legislative barriers

- In Uganda partnerships, only one partner must be pharmacist and Ugandan
- Nigeria – all partners must be pharmacists

Expansion still more vertical than horizontal

Private sector retail pharmacy

General governing regulations

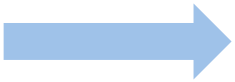
Ownership; Staffing; Pricing; Prescriptions

Low- and middle-income countries

- poor regulatory and judicial frameworks
- staff shortages
- lack of financial resources
- fragmented industry – many informal sellers

Poor oversight

Few inspections
Weak enforcement
Infringements common



Detrimental service to the poor

- Unqualified staff
- Medicines without prescriptions
- Restricted medicines sold
- Fake and low-quality medicines
- Inflated and variable prices
- Pharmacist = businessman