PHARMACEUTICALS IN SOUTH AFRICA – AN ENQUIRY

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TABLE OF ABBREVIATIONS

BHF	The Board of Health Care Funders
CMS	Council of Medical Schemes
COP	Corporate Owned Pharmacy
DoH	Department of Health
DSP	Designated Service Provider
ERP	External Reference Pricing
FFS	Fee for Service
GP	General Practitioner
HASA	Hospital Association of South Africa
HPCSA	Health Professions Council of South Africa
HSF	Helen Suzman Foundation
HTA	Health Technology Assessment
ICPA	Independent Community Pharmacy Association
IOP	Individually Owned Pharmacy
IHD	International Healthcare Distributers
MARSA	Medicines and Related Substances Control Act
MCC	Medicines Control Council
MSR	Medical Scheme Rates
NHA	National Health Act 61 of 2003
NHI	National Health Insurance
NHRPL	National Health Reference Price List
OPD	Out-Patients Department
OTC	Over the Counter
PAJA	Promotion of Access to Just Administration Act 3 of 2000
PIT	Personal Income Tax
PHC	Primary Health Care
PBM	Pharmacy Benefit Manager
PMB	Prescribed Minimum Benefits
PPI	Produce Price Index
PSSA	Pharmaceutical Society of South Africa
RAMS	Representative Association of Medical Schemes
RPL	Reference Price List
SAMA	South Africa Medical Association
SEP	Single Exit Price
SEPA	Single Exit Price Adjustment

In August 2013, the Southern Gauteng Branch of the Community Pharmacist Sector of the Pharmaceutical Society of South Africa approached the Helen Suzman Foundation to produce an independent report on the impact of legislation allowing for the open ownership of pharmacies in the country. In November 2013, the first grant to the HSF was awarded and research commenced. Detailed terms of reference have never been fully specified in writing. Rather, the scope of the project has been discussed in several meetings.

In the process, the following points have become clear:

1. The ownership issue is embedded in a wider legal framework regulating pharmacies. In particular, the legislation establishing prices at which pharmaceuticals pass along the supply chain to retail pharmacies and determining upper limits to dispensing fees creates a framework within which competition between pharmacies plays out. In addition, regulation of licensing of new pharmacies is relevant, as well as competition law and the outcomes of specific legal actions. The actions of medical aid schemes are also important. In general, what one is faced with is competition in a highly regulated market, the scope and fairness of which needs to be assessed.

2. The international experience with respect to pharmacy ownership is relevant to South African policy choices. Evidence from different parts of the world and from countries at different levels is considered.

3. A useful way of identifying stresses in the current system of supply of pharmaceuticals to the public is focused interviews with key agents in the supply chain.

4. While an understanding of the history shaping current circumstances is important, a prospective approach is invaluable. Government policy is to weld the components of the health system into a better functioning and coherent whole. Since the supply of pharmaceuticals is one of the components of the health system, opportunities exist to help shape the future. In particular, the possibilities for servicing both rural areas and poorer parts of urban areas need careful consideration.

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CHAPTER 1:

AN INTERNATIONAL SURVEY OF PHARMACY OWNERSHIP LAW

Introduction

The debate about pharmacy ownership rules in South Africa focuses on the legal framework governing pharmacist owned community pharmacies and corporate pharmacies. Many other countries have had to deal with the same issue and the South African debate would be enriched by an account of (a) pharmacy ownership rules elsewhere and (b) studies of the impact of the rules on the provision of pharmaceuticals and related services.

It is important to note at the outset that ownership rules are only one source of pressure on pharmacist owned community pharmacies. Figure 1, taken from a study by Wessels and Luiz[1] illustrates the point. The effect of pharmacy ownership rule depends on the entire policy and practice surround.

Pharmacy ownership rules

The world will be divided up here into the following categories:

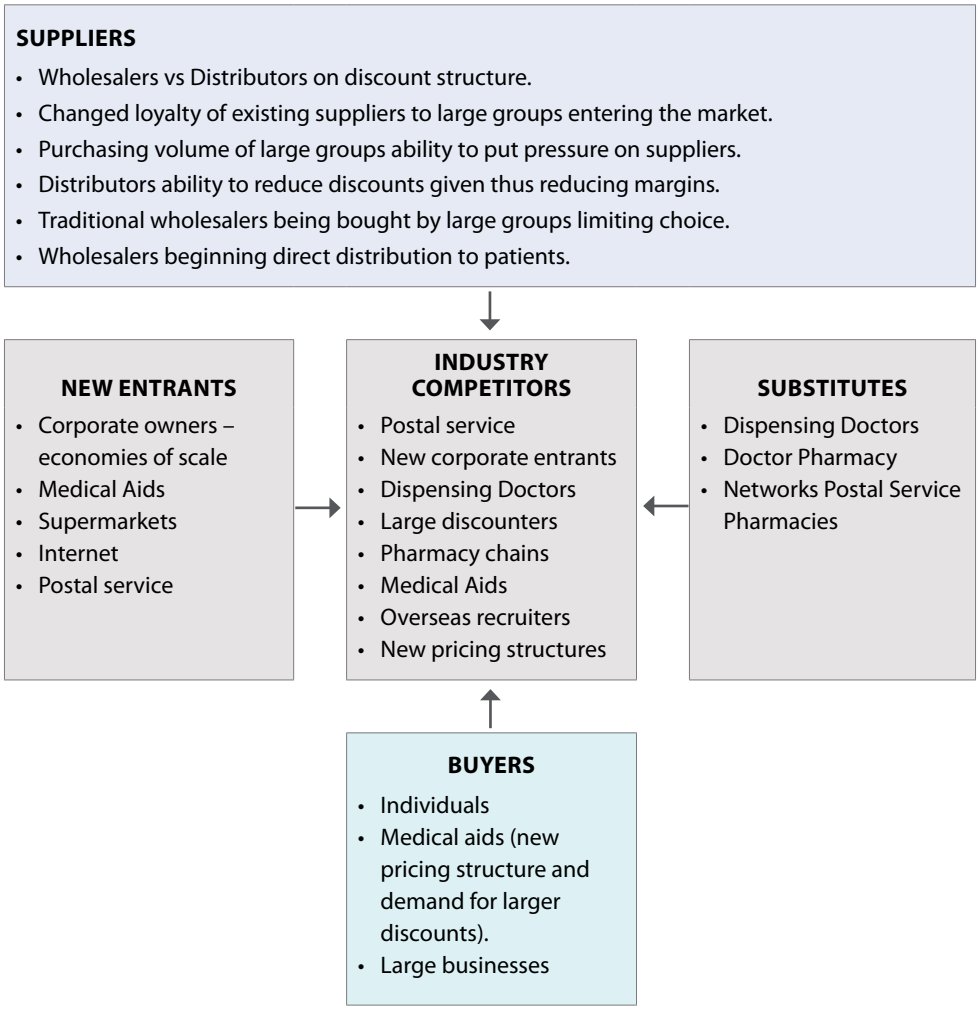
The United States
Europe
Australia, New Zealand and Canada
High Income Asia
Low and middle income countries

The United States

Regulation of commerce (other than interstate commerce) is a state rather than federal matter, so pharmacy ownership rules vary across the country. A complete account would be impossibly lengthy, so a focus on particular issues will be presented.

North Dakota has a unique set of pharmacy ownership rules within the United States. They are contested and were the subject of a pharmacy ownership initiative held on 4 November 2014. This initiative sought to remove the requirement imposed by state legislation in 1963 that majority ownership of pharmacies in the state be held by registered pharmacists, ruling out pure corporate ownership, though partnerships between corporates and pharmacists are possible.[2] The legality of the North Dakotan statute has been tested in the courts and upheld. The state legislature has refused to change the legislation, so opponents have assembled the necessary support to have the matter considered directly by the state electorate. The initiative was defeated, with 59% of voters voting against.

Figure 1 – The stake holders in the retail pharmacy market



Closest to North Dakota is Michigan which has a law requiring that 25 percent of pharmacy stock ownership must be held by pharmacists. Elsewhere, restrictions on corporate ownership are less stringent. Conflicts of interest when prescribers of medicine have ownership stakes in pharmacies have been an issue in the United States. California, Rhode Island, New Hampshire and Pennsylvania have had laws restricting prescriber ownership, though California repealed its restrictions in 1996 and Rhode Island in 2002.[3]

1 Martin Wessels and John Luiz, The future of the South African retail pharmacy industry in the light of international experience and the changing health care market, SAJEMS NS 6 (2003)
2 There are some exceptions to the rule, notably in relation to hospital pharmacies
3 Stephanie Haarsager, North Dakota's pharmacy ownership law: an analysis of the strictest pharmacy ownership law in the United States, North Dakota Law Review, Vol 86

Haarsager provides a useful summary of the issues in North Dakota. The debate around the ownership law has focused on three issues: rural access, price and service quality, and economic impact. Proponents of repeal of the law have argued that it would increase rural access. Delivery of pharmacy services to rural areas is an issue everywhere and it has been difficult in rural North Dakota to locate pharmacists able to cover routine hours, evenings, nights, weekends, vacations and sick time. Corporate suppliers such as Walmart are sometimes open round the clock every day of the week. The North Dakota Telepharmacy Project has been developed to fill the gap. It works by establishing a pharmacist staffed central order entry site that provides supervisory pharmacist oversight to a pharmacy technician located at the remote telepharmacy site. The pharmacy technician then processes prescriptions and enters them on computer. The pharmacist then dispenses them and the product is delivered to the patient's doorstep. It is arrangements such as this that are likely to deliver services to patients in rural areas, since corporate entry would be limited by market size. Moreover, comparison between North Dakota and South Dakota shows that there are more local pharmacies in North Dakota and they are spread more evenly throughout the state.

On price and service quality, a study by from the University of North Dakota found that drug prices would decrease if the ownership law were repealed. However, another study found that average prescription drug prices in North Dakota were among the lowest in the country and *Consumer Reports* found that prices for four common drugs at major chains were more expensive than the same drugs available from independent pharmacies.

On economic impact, the University of North Dakota study found potential gains in output, employment and tax revenues associated with repeal of the law. However, another study found that repeal of the law would result in the closure of 70 independent pharmacies employing about 600 people with a reduction in local and state revenue.

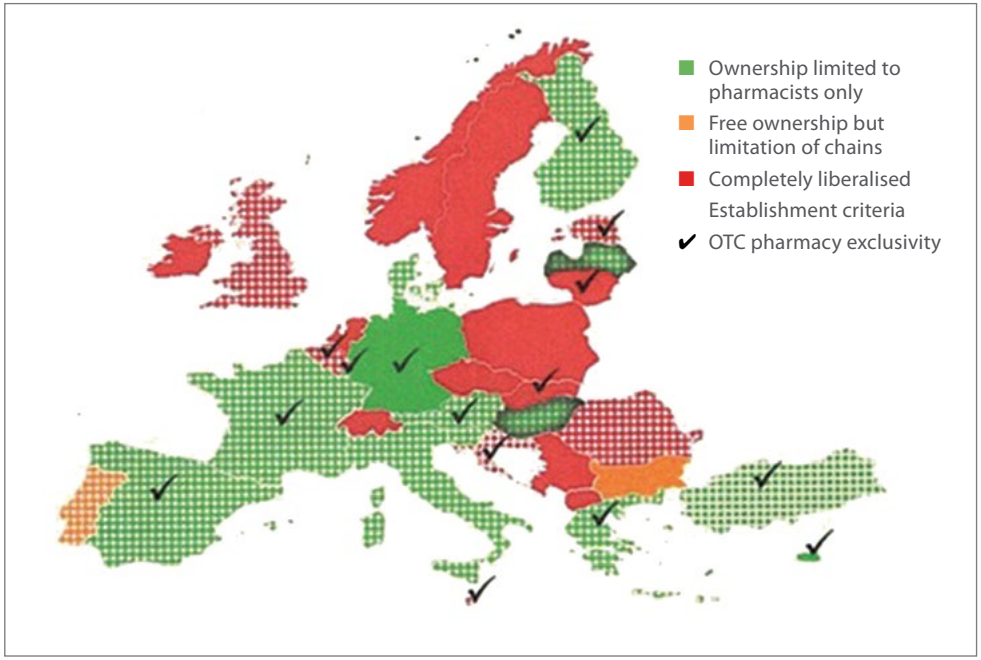
A study by the Rural Policy Research Institute's Centre for Health Policy Analysis at the University of Iowa found that from March 2003 to December 2013, there was a loss of 924 (12%) independently owned rural pharmacies in the United States, the most drastic loss occurring between 2007 and 2009.[4] Four hundred and ninety rural communities that had one or more retail pharmacy in March 2003 had none in December 2013. This change was not ascribed to ownership rules, but to changes in Medicare rules.

In 2007, the House of Representatives in the US Congress conducted a hearing on the impact of anti-trust laws on community pharmacies and their patients.[5] The issue was whether independent pharmacies should be allowed an exception from horizontal collusion rules in order to allow them to band together to press for better reimbursement rates from pharmacy benefit managers (PBMs) employed by health insurers. The proponents of the exception claimed that the PBMs had substantial market power and imposed low reimbursement rates on community pharmacies, driving many of them out of business. Moreover, it was claimed, that PBMs were running mail order pharmacies in direct competition with independent pharmacies, creating a conflict of interest. The opponents pointed to a study that an exception would cost consumers $30 billion in increased prices, that anti-trust waivers are inefficient and an inappropriate way to deal with the problems of independent pharmacies and that PBMs are competitive. In the nature of US Congressional hearings, there was not resolution of the issues in the record.

Europe

Pharmacy ownership rules are diverse across Europe as Figure 2, taken from the Pharmaceutical Journal illustrates.[6] Appendix 1, published by the Pharmaceutical Group of the European Union sets out the systems in EU countries.

Figure 2 – Map of pharmacy ownership systems in Europe



4 RUPRI Centre for Health Policy Analysis, Update: Independently owned pharmacy closures in rural AMERICA, 2003-2013, Brief 2014-7, June 2014
5 Hearing before the Task Force on Antitrust and Competition Policy of the Committee on the Judiciary, House of Representatives One Hundred and Tenth Congress, 18 October 2007, Serial Number 110-85
6 Royal Pharmaceutical Society, The Pharmaceutical Journal, The challenges we share with some EU countries: what can we learn? Supplements, 11 February 2014

European diversity is underpinned by a judgment of the European Court of Justice delivered in May 2009.[7] In the cases under consideration, the rights of Germany and Italy to exclude non-pharmacists from ownership of pharmacies were contested. The Court found that such exclusion was a restriction on freedom of establishment and free movement of capital. However, it also found that these restrictions were justified by overriding reasons in the general interest, namely the objective of protecting public health and, more specifically, the objective of a reliable and high quality supply of medicinal products to the public. It highlighted the discretion of member states to determine the level of protection which they wish to afford public health and the way in which that level is to be achieved. The Court found that the rule on exclusion of non-pharmacists was appropriate to the objective and that it did not go beyond what is necessary to achieve the aim.

Recent developments in selected countries follow:

Restrictive ownership

Germany

Recent developments in Germany have been described as follows:

> Traditionally, the prices of pharmaceutical products were fixed in Germany. Pharmacists could only compete with others by offering good consultation services to their clients and they could not transfer their innovative concepts to other pharmacies because each pharmacist was allowed to operate only one pharmacy. Mail-order business was also prohibited.
>
> Since 2004, pharmacy owners have been allowed to operate up to three further public pharmacies (so-called branch pharmacies) in addition to their main pharmacy. At the same time, mail-order purchases have become possible. The only major restriction that has not been abolished is the prohibition of third-party ownership, i.e. only professional pharmacists with a university degree in pharmaceutics and an additional internship are allowed to own and run public pharmacies.[8]

Austria

Co-ownership of pharmacies is allowed in Austria provided that the managing pharmacist (the licensee) holds more than 50%. Each pharmacy is allowed to run at least one branch. Internet pharmacies are not allowed. Establishment rules for community pharmacies take geography into account and new pharmacies have opened in small communities over the past decade. Dispensing doctors are more common in Austria than in other European countries.

Denmark

Pharmacy ownership in Denmark is restricted to pharmacists and multiple ownership is not allowed. There is an equalization scheme among pharmacies to subsidise small scale pharmacies in rural areas. Only one internet portal, operated by the Association of Danish Pharmacies, sells prescription medicines.

Finland

Neither multiple ownership nor vertical integration is allowed. A private pharmacy is allowed to own up to three branch pharmacies. In rural areas, pharmacy service points may be established by a supervising pharmacy. These service points may dispense only a limited range of OTC medicines. Pharmaceutical wholesale is organised as a single channel system.

Spain

Spain has no dispensing doctors and no branch pharmacies. Co-ownership is allowed if 51 percent is in the ownership of a pharmacist. Multiple ownership is forbidden, so there are no pharmacy chains. Geographic and demographic establishment are centrally and regionally controlled. One region liberalized in 2000 and the result was the establishment of more pharmacies, a decline in profit margins and the closure of some.

France

Ownership is restricted to a single pharmacy (chains are therefore non-existent). A pharmacist can own minority shares in several other pharmacies (less than 49%). Only pharmacists can own a pharmacy. Pharmacies can nevertheless form groups/co-operatives

Italy

Pharmacists cannot own more than four outlets in the same province. Only pharmacists are permitted to own and manage pharmacies. Wholesalers are not permitted to acquire a share in pharmacies

In general, there has been little change in these countries, apart from modest liberalisation in Germany.

Liberalising countries

Norway

In 2001, ownership and establishment of pharmacies were liberalized. Since then there has been no limit on the number or location of pharmacies and no professional requirements for the ownership of pharmacies. Since 2003, a limited range of OTC medicines have been allowed to be sold outside pharmacies. Over 80% of pharmacies are now owned by three chains, each vertically integrated with a pharmaceutical wholesaler. No pharmacy chain is allowed to own more than 40 percent of all pharmacies.

Sweden

Up until 2009, all community pharmacies were state-owned by the public company Apoteket AB Following liberalisation, about two thirds of all pharmacies are in the hands of private companies. The rest are still owned by Apoteket, which also provides about 900 representatives

7 C-531/06 Commission v Italy and C-171/07 and C-172/07 Apothekekammer des Saarlandes a.o. v Saarland
8 Jorg G Heinsohn and Steffen Flessa, Competition in the German pharmacy model: an empirical analysis, BMC Health Services Research, 2013 (13)

in rural grocery stores. There are neither dispensing doctors nor branch pharmacies. The sale of OTC medicines outside pharmacies has been allowed since 2009. In the first year after liberalisation, around 200 new pharmacies were established. Large chains have appeared.

Netherlands

Multiple pharmacy ownership was first allowed in 1987. Since 1999 it has been possible for non-pharmacists to own pharmacies. 32% of pharmacies now belong to chains. There have never been statutory geographic or demographic restrictions on the establishment of pharmacies.

Lightly regulated ownership

England

Pharmacy chains and vertical integration are allowed. Under certain circumstances, doctors can dispense prescription medicines. Owners of 39% of community pharmacies own up to five pharmacies. Owners of the remaining 61% own six or more pharmacies. There has been liberalisation of entry requirement since 2005.

Ireland

Ireland has always had a highly liberalized pharmacy sector, in particular with regard to the establishment and ownership of pharmacies. Pharmacy chains and vertical integration are allowed. The number of pharmacies in chains has been rising in recent years, but Ireland still has a large number of individual pharmacies. Internet sales of OTC medicines has been allowed since 2006. Some OTC medicines may be sold outside pharmacies. There are a few dispensing doctors, mainly in rural areas.

In general, a study conducted in 2012 on behalf of the Association of Danish Pharmacies[9] concludes the following:

> Liberalisation in the pharmacy sector can have consequences, which might impede a good and equitable access to medicines, such as
>
> - an uneven spread of community pharmacies within a country;
> - the dominance of some market players, for example wholesalers and distributors; and
> - the economic pressure to increase pharmacy turnover through the sale of OTC medicines and non-pharmaceuticals.

In western Europe, one can identify the Anglo-Irish-Dutch model, which is similar to the US in which ownership can be separated from operations. Sweden and Norway have liberalized and, because the old government network was limited, liberalisation has brought both new locations and consolidation into a handful of pharmacy groups. Continental Europe has inherited a historical guild system. In these countries, there are many smaller pharmacies, high pharmacy density and low generic penetration.

Formerly communist countries

Latvia

A pharmacy shall be established in the form of a pharmacist's practice, a joint practice or a company. A company may own a pharmacy, if at least one of the following conditions are observed:

1 not less than 50 percent of capital shares (shares) of a capital company are owned by a pharmacist;
2 at least half of the members of the board of a capital company (executive institution) are certified pharmacists; or
3 a pharmacy may be established by a pharmacist's assistant in an area where the number of inhabitants does not exceed 4 000 and there are no other pharmacies or pharmacy branches within a radius of five kilometres. A company established by a pharmacist's assistant may operate, if not less than 50 percent of capital shares (shares) of a capital company are owned by the pharmacist's assistant. A special permit is issued for the operating of a pharmacy for five years.

A pharmacy may open branches in areas where the number of inhabitants does not exceed 4 000 and there are no other pharmacies or pharmacy branches within a radius of five kilometres.

Lithuania

There are no restrictions on the number and locations of pharmacies and these are often located in supermarkets. In rural areas, medicine is sold at PHC facilities. About 80% of pharmacies are chain pharmacies and most of the chains are vertically integrated with wholesalers. Online pharmacies will be permitted soon.

Hungary

Pharmacy licenses are controlled by geographic area. A pharmacist may not own more than four pharmacies. By 2018, pharmacists must own a majority share in all pharmacies currently owned by foreign investors. Dispensing doctors may sell prescription medicines in areas where no pharmacies are available. A small number of pharmacies are permitted to sell medicines online. Chains have existed, but all chain pharmacies have to sell majority ownership by 2017, or pass the controlling rights to pharmacists. The state will have a pre-emptive right to purchase stakes in pharmacies which employees and other pharmacists do not want or are not able to buy.

Czech Republic

Any person has the right to own a pharmacy. Chains are permitted.

Slovakia

Ownership and geographical distribution of community pharmacies are not restricted by any rules. Internet pharmacies are operating and are linked to community pharmacies.

9 Sabine Vogler, Danielle Arts and Katharina Sandberg, Impact of pharmacy deregulation and regulation in European countries, Vienna, 2012

Bulgaria

The major wholesale distributors in Bulgaria also own (or control) pharmacy chains. This practice carries over from the communist era. Privatization and new starts increased the number of wholesalers to an estimated 300 in 2000, and the number of pharmacies to nearly 3 000 by 2003.

Ukraine

There is no restriction on the number of retail outlets, though online sale is not allowed. In Eastern Europe the pharmacy industry is still in transition, with extreme free market approaches in some countries and limited or ineffective regulation in others.

Russia

Retailing of medicine is carried out by pharmacy institutions, individual entrepreneurs licensed to carry out pharmaceutical activity, medical organisations having a pharmaceutical license, and centres of general medical practice in rural areas without a pharmacy. Private ownership of pharmacies is greater than public in almost all regions of Russia.

Australia, New Zealand and Canada

Australia

Section 66V of the Public Health Act specifies an owner of a pharmacy must be a pharmacist or a complying pharmacy corporation. A complying pharmacy corporation must have pharmacists only as directors, have voting rights at a general meeting restricted to pharmacists and have shareholders in the corporation consisting only of pharmacists and their close relatives. This position has been maintained by the government, despite recommendation from a 2013 Competition Policy Review.

New Zealand

Company ownership is the most common form of pharmacy ownership. The majority of the share capital must be owned by an individual pharmacist or pharmacists. This pharmacist or these pharmacists must have effective control of the company at all times. For example, this may be reflected by the classes of shares held (if applicable), the ability to appoint directors to the board and the ability to control the board of directors to the board. Any company or individual may have the majority shareholding in up to five pharmacies.

In both Australia and New Zealand franchise-based systems are leading to chains and models of multiple ownership.

Canada

No person other than a pharmacist or a complying corporation may own or operate a pharmacy. A complying corporation must have pharmacists as a majority of directors. It is possible to have chains. One company has more than 1 000 locations, with pharmacists as licensed associate-owners combining independent business ownership, professional practices and co-operative services under one brand, with the support of a corporate entity.

All three countries have restrictive pharmacy ownership rules.

High income economies in Asia

Japan

The establishment of a pharmacy requires the approval of the governor of the prefecture in which it is located. Permission has to be renewed every six years. There is no regulation that imposes restrictions on the locations where pharmacies may be located.

South Korea

No person other than a pharmacist may establish a pharmacy and a pharmacist may establish only one pharmacy. Every pharmacy founder must manage the pharmacy in person. This is the most restrictive ownership law of all.

Taiwan

Pharmaceuticals may be sold by individual pharmacists or pharmaceutical companies. Online pharmacies are not allowed.

Low and middle income countries

A study by Richard Lowe and Dominic Montagu of the Global Health Group in 2009[10] placed a number of low and middle income countries in categories by ownership rules as follows:

Individual ownership only by a registered pharmacist and only one pharmacy per pharmacist:

- *Cambodia* (may partner with a non-pharmacist)
- *Cote d'Ivoire* (owner must be a national; pharmacy assistant can manage a store under owner's responsibility)
- *Cameroon* (site must be approved by the Ministry of Health)
- *Lebanon* (additional requirements for non-nationals)
- *India* (increasing liberalisation from the late 1990s, with the formation of chain and of the All India Organisation of Chemists and Druggists which co-ordinate direct purchasing from manufacturers)
- *Philippines* (very high drug prices, compared to the rest of Asia. A single company sells up to 60% of all drugs)[11]

Further details can be found in Appendix 2.

In many low and middle income countries, regulatory oversight is deficient. Furthermore, the number of formal pharmacies is small, compared with dispensing doctors, traditional medicine sellers and general stores.

10 Legislation, regulation and consolidation in the retail pharmacy sector, Southern Medical Review, 2009
11 Further details can be found in Appendix 2.

China

Most pharmaceuticals are distributed through public and private hospitals. Individual and chain pharmacies are growing and about 20% of pharmaceuticals are now dispensed by them. OTC medicines are much more available through a variety of privately owned retailers than prescription medicines.[12]

Appendix 3, taken from the International Federation of Pharmacists 2009 Work Force Report (Table 3) contains brief descriptions of community pharmacy ownership in countries not covered in Appendices 1 or 2.

Peru

The retail sector has changed remarkably in the last decades. In the 1990s the number of drugstores was just over 3 000, whereas nowadays this number exceeds 24 600. In the mid 90's the share of the business of independent drugstores was of around 86%, whereas in 2011 almost 60% of the business was conducted by retail chains.

Turkey

Some wholesalers are permitted to retail. Individual pharmacies are subject to geographical regulation.

General considerations

Lowe and Montagu comment on trends as follows:

> Liberalisation 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. Even where chains are restricted, as is the case in much of mainland Europe, franchise contracts are being used to create de-facto chains. 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. Where chains have formed they appear to have been facilitated by the existence of an urban middle-class market, but also by legislative change, as in India and South Africa.

John Strong[13] observes:

> The way the pharmacy sector is organized and regulated has been considerably influenced by historic developments, traditions, and cultures. What works well in one country is not necessarily successful in another country.

He goes on to add that gradual liberalisation has the following consequences

1. Deregulation means you tend to get new entrants with new strategies. New entrants often target specific customer segments, such as the price-driven consumer, by starting warehouse-type models. But, the low-price volume driven drugstore requires low costs and scale, which means that many of these new entrants will fail. In pharmacy retailing, there appears to be only a limited market for heavy discounters, with very few players in the long run.
2. Technology can also drive entry (especially through online activities), but these new/emerging channels are often best adopted by incumbents willing to be smart and flexible.
3. Incentives to control costs and to improve productivity are not just driven by discounters or technology. Deregulation has generally meant that prices fall faster than costs, so margins are squeezed. This will be especially true in pharmacy, as core dispensary reimbursements from governments and third-party PBMs are falling dramatically.
4. The increased financial pressures will put more pharmacies under financial strain, with external capital funding becoming less available and carrying harsher terms. An increase in bankruptcies is likely, spurring industry consolidation.
5. Industry consolidation also will take place through increasing mergers and organisational affiliations. Both scale and scope economies become more important. As a result, becoming part of a pharmacy network has much more value, spurring deepening franchise models which can link suppliers, wholesalers, and retail pharmacies.

Lowe and Montagu summarise the pros and cons of chain retail services as follows:

	Pros	Cons
1	Standardised quality	Profit driven and business focused
2	Improved efficiencies	Loss of the pharmaceutical environment
3	Encourages effective competition	Less personalised service – decrease in the quality of care
4	Lower costs to customers	Opposition from Pharmacy Councils
5	Increase in pharmacists and pharmacies	Possible decrease in pharmacist accountability
6	Expansion of new services	Additional infrastructure development
7	Increased accessibility	Potential loss of services in rural areas [14]

12 Appendix 3, taken from the Internation Federation of Pharmacists 2009 Work Force Report (Table 3) contains brief desciptions of community pharamcy ownership in countries not covered in Appendices 1 or 2.
13 John S Strong, Rethinking strategy in pharmacy and drugstore retailing, Babson Executive Education, 2013
14 These broad brush points should be qualified as follows:
1. Standardisation of quality depends on the quality control environment, especially in relatiion to prescription medicines. All pharmacies are profit driven, but chains have options that individual pharmacists do not.
2. Loss of the pharmaecutical environment depends on the limits to product diversification on individual pharmacies.
3. None.
4. None.
5. Decrease in pharmacist accountability depends on the extent to which pharmacies are subject to accounting for medicines bought and dispensed and whether regular inpections are carried out.
6. Additional infrastructure development depends on the extent of new construction undertaken by chains.
7. Chains may offer longer opening hours.

Conclusions

There are three main conclusions:

1 Ownership rules vary round the world from extreme restriction to free market systems. Ownership cannot be captured by a single indicator. Dimensions to be considered are:

- Restriction of ownership to pharmacists;
- Whether adjunct professionals (assistants or technologists) can own and operate a pharmacy;
- Whether chains are allowed;
- Degree of possible corporate ownership: complete, majority, minority or none;
- Whether only one or more than one pharmacist can be owned by a single owner;
- Whether branch pharmacies are allowed;
- The degree and nature of franchising;
- Rules governing dispensing from public and private hospitals;
- Whether there are geographic or demographic restrictions on where pharmacies may be located;
- Restriction of ownership to nationals;
- Special dispensations for rural areas;
- The degree to which online pharmacies are allowed; and
- Restriction on physician ownership.

2 Inherited ownership rules are tenacious, with an overall moderate trend to open ownership over the last thirty years. Liberalisaton of ownership in South Africa has been matched by relatively few countries over the same period: Norway, Sweden and some Eastern European countries, though the situation in Eastern Europe is far from stable. China is moving towards liberalisation.

3 Pharmacist profit margins are being squeezed by governments and benefit managers, impeling industry consolidation and network formation including franchises, even in countries with restricted ownership rules. This development, rather than ownership, is the main determinant of pharmacy profitability.

APPENDIX 1 – EUROPEAN OWNERSHIP RULES

Pharmacy Ownership and Establishment

OWNERSHIP – information on who is entitled to own a Pharmacy. Reference should be made if ownership is for a single person and/or a partnership of two or more people. Information should be provided on the qualifications or specific requirements the candidate to ownership must have and fulfill. Information should be provided on how many pharmacies one person or partnership may own. Information on partnership specificities should be provided (e.g. only pharmacists, mix of pharmacists and non-pharmacists; if one pharmacist already owning a pharmacy can be part of a partnership; etc.). Information on how ownership and management of the pharmacy is linked, if at all. Recent changes in legislation should be mentioned.

ESTABLISHMENT – information if there area or not specific geographical and demographic criteria; if yes which ones. This information is related to the opening of new pharmacies. Reference should be made to who is responsible for issuing the license and what criteria are used for that (e.g. public tender). Information on conditions to retrieve the license by the issuing body or pass it to others should also be provided. If relevant, more information could also be provided on transfer of pharmacies from one place to another and what conditions are required to do so. Recent changes in legislation should be mention.

APPENDIX 1 – EUROPEAN OWNERSHIP RULES

Country	Ownership Criteria	Establishment Criteria	Additional comments
Austria	Pharmacists or partnerships wherein the pharmacist must own at least 51 %	A number of preconditions must be fulfilled to establish a new pharmacy, including the existence of a physician's surgery in the neighbourhood, a minimum distance of 500 meters to the next existing pharmacy and the requirement that each of the existing neighbouring pharmacies still has a potential of at least 5 500 people to supply.	Only a qualified pharmacist with 5 years professional experience in a pharmacy, EU/EEA nationality and good command of German can apply for a licence to establish a pharmacy. One pharmacist can only have one licence. The pharmacist holding the license must have the exclusive power of management and of representation and must own more than half of the enterprise. This means that non-pharmacists can own up to 49% of a pharmacy.
Belgium	Pharmacies can be owned by anyone (pharmacists or not, partnerships, companies)	There are criteria for the establishment of new pharmacies, which seek to avoid over-concentration of pharmacies in certain areas and to guarantee to meet the needs of people living in isolated areas. Depending on whether a commune has more than 30 000, 7 500- 30 000 or less than 7 500 inhabitants the number of pharmacies cannot be higher than the figure obtained by dividing the number of inhabitants by 3 000, 2 500 and 2 000 respectively.	Since 1994 there is a moratorium on the opening of new pharmacies which means that the total number of pharmacies in Belgium cannot rise above the figure of 1994.
Bulgaria	Non-Pharmacist	There is no establishment criteria.	On the 31 July 2008 the Bulgarian parliament passed a new law, which gives every individual the right to open a pharmacy. Until now only a graduate pharmacist had the right to open pharmacies. The ban for vertical integration was abolished except for compounding pharmacists. Now everyone can own a pharmacy, also a person or a company active in manufacturing, wholesaling and retail, but a compounding pharmacist. MPs also decided not to allow company or persons to own more than four pharmacies. This should limit the establishing of pharmacy chains.
Croatia	Pharmacies can be owned by anyone. However the manager of the pharmacy must be a pharmacist	There is a demographic criterion for pharmacies of 1 pharmacy per 3 000 insurants. Every following pharmacy for 5 000 insurants on every 200, 300 or 500 meters depending on the number of insured persons. Insurants must be registered at the Croatian Institute for Health Insurance, the only obligatory insurance body in Croatia. Exceptionally, new pharmacies can be opened regardless of demographic and geographic criteria in the city area only if the nearest pharmacy is opening on 3 000 meters of the air distance. New pharmacies can also be opened regardless of the number of pharmacies in new populated areas when they have more then 500 flats or more then 1000 inhabitants on 500 meters from the first nearest pharmacy. New pharmacies can be opened in tourist towns on 1 000 meters of air distance from the nearest pharmacy.	A pharmacist can own a single pharmacy. Any private or legal person can establish a pharmacy chain comprising at least two pharmacies as long as a pharmacist is employed as the manager of each pharmacy.

APPENDIX 1 – EUROPEAN OWNERSHIP RULES continued

Country	Ownership Criteria	Establishment Criteria	Additional comments
Cyprus	Pharmacist or partnership of pharmacists must own at least 51% of a pharmacy	The Pharmacy Board is responsible for awarding pharmacy concessions. Legally defined criteria exist for the awarding of concessions. There are no demographic or geographic criteria laid down for the pharmacy network.	Each pharmacist can only own one pharmacy; therefore associations of pharmacies are not permitted.
Czech	Non-pharmacist can own a pharmacy	Pharmacy concessions are awarded by district authorities, but the Czech Chamber of Pharmacists and the State Agency for Medicine Control are also involved. There are no demographic or geographic criteria laid down for the pharmacy network.	Anyone can own a pharmacy. Pharmacy chains are permitted and exist. Any pharmacy not owned by a pharmacist must have a professional representative who is a qualified pharmacist with a minimum of five years professional practice. 60% are pharmacist owned. The three big wholesalers own chains of pharmacies in the Czech Republic.
Denmark	Pharmacists (State license)	The authorities publish vacant licenses, which pharmacists can apply for. The license is granted to the best qualified pharmacist and is linked to a delimited geographical area.	Any qualified pharmacist from an EU/EEA country can own a pharmacy.
Estonia	Non-pharmacist can own a pharmacy	From 1 January 2006, a new measure was approved introducing geo-demographic criteria. According to it new licenses will not be granted to pharmacies and subsidiary pharmacies in towns, where there are less than 3 000 inhabitants per a community pharmacy. In addition community pharmacist cannot change their location. However, this rule is not applied if the new location is placed within 500 metres from the old one. For non urban pharmacies, a new pharmacy or subsidiary pharmacy could be opened if there is 1 kilometre from an existing pharmacy. The same rule applies to change the location of a pharmacy or a branch pharmacy.	Any natural person, legal person, the state or local government entity can own a pharmacy and an association of pharmacies is possible in various forms. Pharmacy chains are permitted and exist. Around 80% of pharmacies are influenced by two large pharmacy chains. A pharmacy requires an operating licence and the operating licence is only given to a qualified pharmacist with at least five years professional experience. The Ministry of Social Affairs grants activity licences.
Finland	Pharmacists (State license)	The authorities publish vacant licenses, which pharmacists can apply for it. The licence to the best qualified person is linked to a delimited geographical area.	Any qualified pharmacist from an EU/EEA country can own a pharmacy.

Country	Ownership Criteria	Establishment Criteria	Additional comments
France	Pharmacist or partnership of pharmacists	On 23 November 2007 a new law on the social security system was adopted in France. Article 59 of this law focuses on the establishment criteria for the opening of new pharmacies and for the transfer of existing pharmacies. The new law has the following objectives: - to limit drastically pharmacy creations - to encourage pharmacy mergers and transfers The new law states that creations will not be possible during two years (01.01.2010). After that, a creation will only be possible in the towns where there is no pharmacy or in deprived areas. For those limited cases, the population criteria will still apply, but the law raised the criteria: 2 500 inhabitants for the first licence and then further pharmacies can be opened for every additional 3500 inhabitants. Before the criteria was 1 pharmacy per 2 500 inhabitants in rural areas and 1 pharmacy for 3 000 inhabitants in urban areas.	A pharmacy can be owned by an individual pharmacist or a company in the form of a partnership of pharmacists. The new law also encourages pharmacies' mergers. With the new provisions, licences will be frozen during 5 years as a minimum for merging pharmacies, which will concretely make it difficult for the population criteria to be met in the near area. The objective is that the merger does not encourage the creation of a third competing pharmacy in the area. Finally, transfers and groupings will be possible between pharmacies located anywhere in France, (before it was only possible with pharmacies located in the same "département"), provided the supply of the population in the area of origin is not damaged.
Germany	Pharmacist or partnership of pharmacists	There are no demographic or geographic criteria for the establishment of pharmacies.	Any pharmacist can own a pharmacy and one pharmacist / one partnership can own up to 3 branch pharmacies in addition to his main pharmacy. These branch pharmacies must be located in the same or adjacent district. The partnership of pharmacists can have more than 2 people.

APPENDIX 1 – EUROPEAN OWNERSHIP RULES continued

Country	Ownership Criteria	Establishment Criteria	Additional comments
Greece	Pharmacist or partnership of pharmacists; each pharmacist can own one pharmacy, plus a minor stake in just another pharmacy.	There were no restrictions on the establishment of new pharmacies until 1997, resulting in only 900 inhabitants per pharmacy, which prompted the Greek Government to introduce geographic and demographic criteria to maintain high quality services and regulate accessibility. The new law establishes the following criteria: a) In municipalities and municipal or communal districts with a population of up to one thousand five hundred (1 500) only one pharmacy license may be granted. b) In municipalities and municipal or communal districts with a population of one thousand five hundred and one (1 501) or more, a ratio of one thousand five hundred inhabitants per pharmacy is required. The newly established pharmacies must have a distance from the current pharmacies: - A hundred meters in municipalities and municipal or communal districts with a population of up to five thousand (5 000) inhabitants - A hundred and eighty meters in municipalities and municipal or communal districts with a population of between five thousand and one (5 001) and a hundred thousand (100 000) inhabitants - Two hundred meters in municipalities and municipal or communal districts with a population of between a hundred thousand and one (100 001) and two hundred thousand (200 000) inhabitants - Two hundred and fifty meters in municipalities and municipal or communal districts with a population of more than two hundred thousand and one (200 001) inhabitants	
Hungary	Non-pharmacist can own a pharmacy, but pharmacists must own majority shares by 2018	There are geographical and demographical criteria to open a new pharmacy.	
Ireland	Non-pharmacist can own a pharmacy	The establishment of a new pharmacy is subject to some legal controls but none of these regulate the location of where a new pharmacy may establish. They mainly relate to notifying the Pharmaceutical Society of Ireland of its establishment and details of its operation, including details of the pharmacist(s) operating it.	Pharmacists, non-pharmacists and companies can own pharmacies, but each pharmacy must appoint a qualified pharmacist to manage the pharmacy. From 1996 there were regulations governing the granting of public health contracts for new community pharmacies, which specified population and distance criteria for the location of new pharmacies. These criteria were abolished in January 2002.

Country	Ownership Criteria	Establishment Criteria	Additional comments
Italy	Private pharmacy: Pharmacist or partnership and cooperatives of pharmacists Municipal pharmacy: can be managed by companies, and wholesalers as well	A pharmacist wishing to establish a new pharmacy must obtain a license granted by the regional authority. There are demographic and geographic criteria for obtaining a license including the requirement for a new pharmacy to be at least 200m away from any existing pharmacies. For towns up to 12 500 inhabitants the regional authority must give a license for opening a new pharmacy for every 5 000 inhabitants, while for towns with a population of more than 12 500 one license is given every 4 000 inhabitants. However, the regional government can bypass the general principle of only one pharmacy per town in the case of particular situations pertaining to the topography of the territory and its road conditions.	Only qualified pharmacists can own pharmacies.
Latvia	Only pharmacist may own a pharmacy. (This regulation comes into force up from 01.01.2011)	Both geographical and demographical criteria existing.	The Latvian law of pharmacy establishes ownership criteria to be implemented by 01.01.2011 According to a law approved in 2003 by 2011 there will be three kinds of pharmacies: 1. A general type pharmacy: Only a pharmacist or a local government may own a general type pharmacy 2. Closed-type pharmacies or pharmacies of medical treatment institutions. These pharmacies will not distribute medicines to the public 3. Veterinary pharmacies. Veterinary pharmacies are permitted to distribute only means of medical treatment intended for animals, including veterinary medicinal and veterinary pharmaceutical products, as well as goods intended for animal care
Lithuania	Pharmacist or partnership of pharmacists (if the owner is a company, pharmacists must represent at least ¾ of the members of the company's Board)	There are no demographic or geographic criteria for the establishment of pharmacies.	Only pharmaceutical specialists may act as a pharmaceutical specialist and practice pharmaceutical activities. Companies or their branches that practice pharmaceutical activities have to be managed by a licensed pharmacist. If the Board (collegial management body) is formed in the company, that practice pharmaceutical activities, ¾ members of the Board have to be pharmacists. Associations of pharmacies are possible and pharmacy chains exist. Municipalities award concessions to open pharmacy according to Ministry of Health criteria. The Ministry of Health can withdraw a concession for violations of the necessary criteria. Pharmacy ownership was deregulated by the constitutional court. The largest pharmacy chain "Europharmacy" has 200 outlets.

APPENDIX 1 – EUROPEAN OWNERSHIP RULES continued

Country	Ownership Criteria	Establishment Criteria	Additional comments
Luxembourg	Pharmacist or partnership of pharmacists	Any pharmacist wishing to establish a new pharmacy must obtain a concession from the state. Demographic criteria of one pharmacy per 5 000 inhabitants must be met.	
Malta	Non-pharmacist can own a pharmacy (but the manager has to be a pharmacist)	Since 1996 the awarding of new concessions is subject to the agreement of a standing committee comprising representatives of the Malta Chamber of Pharmacists, non- pharmacist owners and the Ministry of Health, who take geo-demographic criteria and the needs of the local population into account.	The February 2003 Medicines Act entrenches the principle of geo-demographic organisation in the legislation with the added provision for enforced consultation of stakeholders on any changes to the legislation and regulations. Any person can own a pharmacy, but each pharmacy must nominate a qualified licensed pharmacist as its managing pharmacist. Association of pharmacies is possible via corporate chains or purchasing cooperatives (where the owners are pharmacists). The Ministry of Health is responsible for awarding pharmacy concessions.
The Netherlands	Non-pharmacist can own a pharmacy	There are no restrictions on the opening of new pharmacies.	Pharmacists, non-pharmacists and companies can own pharmacies. Each pharmacy must appoint a responsible pharmacist to manage the pharmacy.
Norway	Non-pharmacist can own a pharmacy (with some exceptions)	There are no establishment criteria.	Since March 2001 anyone can own a pharmacy except for the pharmaceutical industry, medical doctors or others with prescribing rights. Pharmacy chains can be established and companies can own pharmacies. All pharmacies have a contract with the National Insurance Scheme that makes a settlement-agreement. Since the changes in 2001, the DoH no longer assess and direct where and when new pharmacies are to be opened.
Poland	Non-pharmacist can own a pharmacy	There are no demographic/geographic criteria for pharmacies. Pharmacy concessions are awarded by the regional pharmaceutical inspectorate and the granting of a concession requires a pharmacy to have a licensed pharmacist as the pharmacy manager.	There are no limitations on pharmacy ownership. Pharmacy chains and pharmacy partnerships are permitted and exist. Pharmacy chains were limited to 10% market share, which changed in 2004 to 1%. The new law is not however retrospective; so existing chains will not have to divest of pharmacies.

Country	Ownership Criteria	Establishment Criteria	Additional comments
Portugal	Non-pharmacist can own a pharmacy	On the 31st of August the Decree-law n. 307/2007 was published that establishes the new legal regime of community pharmacies, which will be in force in two months since its publication (1st of November). The decree-law states the principle of free pharmacy establishment (article 3). However, the demographic and geographic setting criteria will be maintained and regulated in the incoming months with the foreseen changes: a) Geographic criteria: the minimum distance between two pharmacies will be reduced from 500 meters to 350 meters; the 100 meters from a healthcare centre or hospital is maintained; b) Demographic criteria: the capitation needed for opening a new pharmacy will decrease from 4 000 to 3 500 inhabitants.	As set by the Decree-Law n. 307/2007, which will be in force in two months since its publication (1st of November). - pharmacies can be owned by anyone except for health professionals with prescribing right (i.e. doctors); associations representing pharmacies, wholesalers and the pharmaceutical industry, as well as unions of the respective workers; wholesalers; pharmaceutical industry; private prescription centres (hospitals, clinics); third-payers or co-payers of medicines; - The technical direction of the pharmacy will continue to be ensured by a pharmacist; - No individual owner, company or group of companies can directly or indirectly own, operate or manage more than four pharmacies. - The public tender of concession to open a new pharmacy is maintained; - The transfer of a pharmacy within the same municipality is possible and will be regulated in the incoming months.
Romania	Pharmacies can be owned by anyone.	The opening of pharmacies is loosely regulated by the Ministry of Health and requires the pharmacy to meet certain criteria. These criteria are legally defined but some of them change frequently.	The ownership of pharmacies is not defined in law. Anyone can own a pharmacy as long a pharmacist is employed as the head of the pharmacy.
Slovakia	Non-pharmacist can own a pharmacy		No limits regarding ownership and establishment.
Slovenia	Pharmacist	There are demographic criteria for pharmacy network of one pharmacy per 5 000- 7 000 inhabitants and one pharmacist per 2755 inhabitants.	The Act on Pharmacy Activity allows for private persons or public institutions to own a pharmacy. An association of pharmacies is possible only through a public institution. Municipalities are responsible for awarding pharmacy concessions, which can only be granted to a pharmacist. There are 82 privately owned pharmacies, others are owned by local authorities. Pharmacies can be owned by pharmacists or local authorities.
Spain	Pharmacist or partnership of pharmacists must own at least 75% of a pharmacy	The opening of a new pharmacy is regulated depending on criteria of number of inhabitants and of distance between community pharmacies. Each Autonomous Community fixes its rules according to geographic and demographic circumstances.	The pharmacist must register in one of the 52 Official Colleges of Pharmacists of Spain, one for each province.

APPENDIX 1 – EUROPEAN OWNERSHIP RULES continued

Country	Ownership Criteria	Establishment Criteria	Additional comments
Sweden	Non-pharmacist can own a pharmacy (except prescribers and pharmaceutical industry)	Free establishment.	In 2009 the whole pharmacy system was deregulated and 65% of the state owned pharmacies where sold out. 466 were sold to 4 chains and 150 are going to be sold to private, independent owner. Free ownership (except for pharmaceutical industry and prescribers) and free establishment.
Switzerland	Non-pharmacist can own a pharmacy	There are no restrictions on the establishment of new pharmacies or drug stores.	It is possible to own more than one pharmacy.
Turkey	Pharmacist	There is no regulation regarding pharmacy location, geographical distribution and the total number of pharmacies in the country.	Chain pharmacies are not allowed in Turkey.
United Kingdom	Non-pharmacist can own a pharmacy	There are no restrictions on the establishment of new pharmacies, but to obtain a contract to dispense National Health Services Prescriptions (which amount to 80% of turnover of an average pharmacy), a pharmacy owner must apply to the local NHS administrational body (Primary Care Organisation). The PCO will decide if a new contract is necessary or desirable for the proper provision of NHS pharmaceutical services. In England the PCO must also consider whether a new contract would be to ensure choice and competition the local health economy.	Anyone can own a pharmacy, including pharmacists, non-pharmacists and companies. In each pharmacy there must be a pharmacist in personal control at all times when the pharmacy is open. In addiction each company must appoint a superintendent pharmacist who is responsible for ensuring all legal and ethical requirements of pharmacy practice.

APPENDIX 2 – LOW INCOME COUNTRIES OWNERSHIP RULES

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 recognised 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.	B.Pharm (4 year degree) or Dip.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 organisation' or "not-for-profit organisation")	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 organisations	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
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 recognised 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

APPENDIX 3 – COMMUNITY PHARMACY OWNERSHIP IN OTHER COUNTRIES

Key:
RP – Restricted to pharmacists RH – Restricted to health care professionals U – Unrestricted O – Other

Country	Pharmacy ownership	Policies and restrictions
Albania	U	Each pharmacy must employ a pharmacist as its technical director. Can own more than one pharmacy
Argentina	O	Varies by province. Pharmacists, limited liability companies and partnerships permitted to own pharmacies. Limit one pharmacy per pharmacist. Partners cannot be involved in more than three companies that own pharmacies.
Brazil	U	Can own more than one pharmacy.
Chile	U	Can own more than one pharmacy.
Chad	RP	Only pharmacists can own pharmacies. Limit of one pharmacy per pharmacist.
Colombia	U	A pharmacist or medicine dispenser must be employed as the pharmacy director. Medicine dispensers should have a minimum of ten years pharmacy experience and have support letters from two pharmacists or physicians.
Costa Rica	U	Can own more than one pharmacy.
Egypt	RP	Restrictions on number of pharmacies a pharmacist can own.
Ethiopia	O	Pharmacy should have a licensed pharmacist that is legally and professionally responsible. Can have more than one pharmacy.
Iceland	U	Companies cannot hold more than the majority market share in order to promote competition.
Indonesia	RP	Restrictions on pharmacy ownership.
Iraq	RP	Ownership restricted to pharmacists. Cannot own more than one pharmacy.
Israel	U	Physicians cannot own pharmacies. Can own more than one pharmacy.
Jordan	U	Pharmacies should employ at least one full time pharmacist that is not designated as a responsible pharmacist in any other pharmacy. Pharmacists working in the public sector cannot own private pharmacies but can be a shareholder.
Kenya	O	Ownership restricted to pharmacists and pharmaceutical technologists. Pharmaceutical technologists must have worked for at least six years in order to own a pharmacy.
Kuwait	O	Only pharmacists with a Kuwaiti pharmacist license may own pharmacies with the exception of pharmacies in supermarkets and private hospitals. Can own more than one pharmacy.
Mali	RH	Each pharmacy must employ a pharmacist.
Mexico	U	Can own more than one pharmacy.

Key:
RP – Restricted to pharmacists RH – Restricted to health care professionals U – Unrestricted O – Other

Country	Pharmacy ownership	Policies and restrictions
Macedonia	U	Can own more than one pharmacy.
Rwanda	RP	Pharmacy ownership restricted to pharmacists. Limit of one pharmacy per pharmacist.
Serbia	U	Pharmacies are also owned by the state. Can own more than one pharmacy.
Singapore	U	Can own more than one pharmacy.
Sudan	U	Each pharmacy must employ a responsible pharmacist. Can own more than one pharmacy.
Syria	RP	Pharmacy ownership restricted to pharmacists. Limit of one pharmacy per pharmacist.
Tanzania	U	Each pharmacy must be supervised by a pharmacist. A pharmacist cannot supervise more than one pharmacy. Can own more than one pharmacy.
Turkey	RP	Pharmacy ownership restricted to pharmacists. Limit of one pharmacy per pharmacist.
Uruguay	U	Any person can own a pharmacy provided that they are not a doctor, dentist or veterinarian.
Zimbabwe	RP	Pharmacists must own at least a 51% stake in a pharmacy. Can own more than one pharmacy.

CHAPTER 2:

OWNERSHIP OF PHARMACIES IN SOUTH AFRICA

Introduction

The Pharmaceutical Society of South Africa (PSSA) and the Independent Community Pharmacy Association (ICPA) have been much exercised in recent years about legislation concerning the ownership of pharmacies. An amendment to the Pharmacies Act passed in 1997, allowed corporations to own pharmacies. Prior to that amendment, pharmacies could be owned only by qualified pharmacists.

Annexure A sets out current law relating to ownership. Annexure B contains a description of the effect of litigation.

The PSSA and ICPA believe that the extension of ownership was not justified and have consistently opposed it. However, they have not succeeded in getting the legislation reviewed.

A number of arguments swirl around the ownership issue. Some are more relevant and persuasive than others. The purpose of this chapter is to disentangle the arguments and assess them.

Hansard

On 23 October 1997, the Minister of Health said the following during the second reading of the Pharmacy Amendment Bill:

> This Bill seeks to improve access to pharmaceutical services by removing the restriction that provides that only people registered as pharmacists may own pharmacies. If this Bill is passed, it will be possible for people who are not pharmacists to own pharmacies. Thus business people and other prospective entrepreneurs with the necessary capital will be able to open pharmacies in their underserved areas and provide vitally required pharmaceutical services. This will happen on condition that the pharmacy is under the supervision of a qualified pharmacist.

This has sometimes been taken as a commitment by the Minister that lay ownership of pharmacies should have been concentrated in areas not served by pharmacies at the time of the passing of the Amendment. Does the passage support that reading and, if so, what are the consequences?

At present there is no requirement to make existing pharmacies aware of where a pharmacy is being opened. This contradicts what was proposed in Hansard. The application of the principle in Hansard would require that the issuing of new licenses, whether for corporate or individually owned pharmacies, should be preceded by advertisement thus giving opportunity for objections by existing pharmacists in the areas concerned.[15]

That said, there is nothing in the cited paragraph to suggest that corporate pharmacies should be restricted to areas underserved at the time of the Amendment, nor was any such restriction incorporated into the Amendment. So there are no legal grounds for regarding licenses issued to corporate pharmacies in urban areas as invalid on the basis of this speech. At most, speeches in Parliament may be considered if courts find that there is uncertainty about the purpose of legislation. There is no such uncertainty in the Amendment, which opened ownership throughout the country without geographical restriction.

Professionalism

A document entitled *Why the Pharmaceutical Society believes in ownership of pharmacies by pharmacists* makes the point that:

> The members of this profession, whether in practice or employment, must be independent in thought and outlook. They must be willing to speak their minds without fear or favour. They must not allow themselves to be put under the control of any person or organisation which could impair their independence… Professional standards should not be compromised by financial considerations, and only a pharmacist can ensure pharmaceutical services, and the conditions under which they are offered, in the best interests of the public.

Members of a profession can work independently or in the employment of an organisation. This is true for attorneys, accountants, engineers and members of other professions. Whether independent or employed, a professional has the obligation to adhere to professional standards. No employer can require otherwise and, indeed, may often depend on professional judgement to carry on their business. The appropriate action in the case where an employer flouts professional standards is a report to the relevant professional council. The personal cost of a professional opposing his employer may be considerable, but this cannot rule out the employment of professionals by organisations.

15 Regulation 7 of the Regulations dealing with the Ownership and licensing of pharmacies (GN R553 of 2003).

Principal-agent issues

In situations in which a principal relies on an agent to carry out functions on his behalf, the issue of alignment of the interests of the principal and the agent arises. In the case of an individually owned retail pharmacy, the principal and the agent are identical, and the pharmacist will always be concerned with the reputation of the business, in considerable part a function of the quality of advice and service given.

In the case of a corporately owned pharmacy, there is a separation between principal and agent. The principal has an incentive to economize on the services of pharmacists, and to use pharmacist assistants where possible. The result may be restrictions on the quantity and quality of advice given. Countervailing factors include:

- consumers can often (but not always) choose to use individually owned pharmacies in their search for suitable advice;
- all pharmacists and pharmacist assistants in South Africa are obliged to offer generic equivalents to prescribed medicines, in cases where generics are available. This amounts to advice on price; and
- there is an important difference between prescription and OTC medicines. In the case of prescription medicines, the consumer generally relies on his confidence in the prescriber. In the case of OTC medicines for ailments for which a prescriber has not been consulted, the consumer will often want the advice of a pharmacist.

An associated issue is whether pharmacists should be able to charge for professional advice. This would create more problems than it solves, in many cases requiring two transactions rather than one when consumers buy medicine. Moreover, advice in individually owned pharmacies is often effectively costed in to a somewhat higher price for medicine.

International experience

The analysis of international experience leads to four conclusions:

1. There is a wide diversity of ownership regimes around the world. The most restrictive standard which requires that only a pharmacist must own pharmacies, and that each pharmacist may own only one pharmacy. At the other end of the spectrum, there is free entry by any entity into pharmaceutical distribution.
2. Ownership regimes change infrequently. There has been a limited trend towards liberalisation of pharmacy ownership, but changes have occurred in a small number of countries, of which South Africa has been one. There has been some instability in ownership regimes in the formerly communist countries of Eastern Europe, as these countries have struggled to come to terms with a general and significant change in economic system.
3. In some situations, for example in Australia and North Dakota in the United States, initiatives to liberalize ownership have been successfully resisted. Stability is an outcome of vested interests clustered around an existing regime. Change in ownership rules are usually accompanied by political change; for example, the end of social democratic hegemony in Scandinavian countries. In the South African case, individual retail pharmacies were unable to resist pressures from corporates wishing to enter the market, and a belief by the government that more competition in the sector was desirable. The pressures for continuation of the existing system will be the greater, because vested corporate interests now exist.
4. In considering an appeal for greater liberalisation in Europe, the European Court of Justice held that (a) excluding the possibility for non-pharmacists to operate pharmacies or to acquire stakes in companies or firms operating pharmacies constitutes a restriction on the freedom of establishment and the free movement of capital, but (b) that the restriction can be justified by the right of a member state to take the view that it is necessary for reliable and good quality provision of medicinal products to the public. Essentially, this judgement allows the coexistence of different ownership regimes in Europe; the pattern found around the world.

It cannot be claimed that international experience supports the superiority of any one ownership regime.

Pricing power

It often happens that, where corporates are permitted to own pharmacies, a limited number of them become dominant. This creates an oligopolistic situation in which pricing power may emerge at the expense of consumers. Against this:

- individually owned retail pharmacies continue to offer competition with the corporates; and
- in many jurisdictions, retail prices are regulated. Thus in South Africa, the SEP removes pricing power from private pharmacies and places it in the hands of the state.

Horizontal collusion

There have been cases where corporates have used their size to induce mall owners to terminate the leases of smaller, individually owned pharmacies. This amounts to horizontal collusion in restraint of trade. The recourse is legal action, but this can be prohibitively expensive, and the remedy may only come when irreversible damage has been done.

Vertical integration

In general, vertical integration is regarded as a smaller threat to competition than horizontal collusion. It may affect the points along the supply chain at which profits are taken, but the relevance of this distribution is not clear on the final price in any system – particularly in a system where the price to consumers is regulated. The more serious threat from vertical integration in the South African system is a set of dealing arrangements between manufacturers, importers, distributors, wholesalers and corporate pharmacies that shuts out the ability of individually owned retail pharmacies to purchase some product lines. This configuration is anti-competitive and undesirable. It could be remedied by the imposition of a requirement that distributors and wholesalers be required to sell any medicine in which they deal to any pharmacy on request. [See chapter 6 for a full discussion on this topic.]

Medical aid schemes and pharmacies

Medical aid schemes have an incentive to contain costs. In the case of open medical aid schemes, this incentive is created by competition for membership. In the case of restricted access schemes, often company-based, medical aid costs may be partly or wholly borne by companies as part of remuneration packages.

In pursuit of the containment of pharmaceutical costs, medical aid schemes often enter into agreements with retail pharmacies. These agreements designate pharmacies at which medical aid members may obtain medicines without the imposition of a levy, or the imposition of the lowest possible levy. The quid pro quo is an agreement by pharmacies to dispense medicines for a fee below the ceiling imposed by law. Large medical aid schemes may have considerable power to impose low dispensing fees. The pattern of demand across pharmacies is affected, especially in cases where corporates are chosen over individually owned pharmacies.

The remedy against uncompetitive behaviour by medical aids would be a requirement that they offer the same deal to any pharmacy that is interested in it. This avoids shut-outs associated with these agreements. Of course, any pharmacy should remain free to sign up or not, in light of its own commercial judgement.

Licensing of new pharmacies

South African law requires that pharmacies be able to raise objections to the granting of new licenses on the grounds of the geographical distribution of existing pharmacies. The rationale is the avoidance of over-trading, where the setup costs for pharmacies is considerable.

It appears that the advertising of applications for new licenses is insufficient, with existing pharmacies discovering the granting of new licenses only when a new pharmacy opens. The remedy is for a uniform and fully publicised procedure for the publication of applications to be introduced, with adequate time for individual pharmacies to prepare their objections.

National Health Insurance and pharmacies

The National Health Insurance White Paper was released on 11 December 2015. It states that the NHI will accredit and contract with private retail pharmacies based on need. Accredited retail pharmacies will be able to order drugs from nationally agreed pharmaceutical contracts and will be required to dispense such drugs to NHI patients at subsidised prices. The NHI Fund will then reimburse the cost of the subsidised drugs as well as a pay a capitated administration fee to the retail pharmacies. Medicine collection points will be established in communities – for example, in schools, churches and community pharmacies. The Department of Health (DoH) has implemented the Centralised Chronic Medication Dispensing and Distribution programme, consisting of two components: Central Chronic Medicines Dispensing and Distribution and Pick-up Points. All these developments create new opportunities for retail pharmacies.

Conclusion

There are three possible ways forward:

1. *Simple maintenance of opposition to lay ownership of pharmacies by the PSSA and ICPA*. The almost certain consequence of this approach will be maintenance of the present position of disagreement with the government, especially in the absence of a knock-down argument for change back to individual professional ownership only.
2. *A focus on unreasonable ways in which individually owned pharmacies are placed at a competitive disadvantage*. This chapter has identified several of these, and identified remedies for them. The remedies suggested would be in the public interest, and should be urged on that basis.
3. *A search for a new policy framework to extend pharmaceutical distribution*. This would be in line with the fundamental National Health insurance goal of provision of essential health needs for everyone. There is an opportunity to become pro-active by developing business proposals and pursuing them with government.

ANNEXURE A

Ownership and licensing of pharmacies – GN R553 of 2003

This is a layout of the regulations which relate to the various pharmacy types and their operations.

1. Regulations dealing with Ownership

1.1. Community Pharmacy

'community pharmacy' means a pharmacy wherein or from which some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to the general public or any defined group of the general public, but excludes an institutional pharmacy;

Regulation 6, subject to the provisions of regulation 7.

1.2. Institutional Pharmacy

'institutional pharmacy' means a pharmacy situated in a-

(a) public health facility, wherein or from which some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to the general public requiring pharmaceutical services, medical or surgical treatment, nursing or other health care from or at that public health facility; or

(b) private health facility, wherein or from which some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services, medical or surgical treatment, nursing or other health care from or at that private health facility;

Regulation 3 as it relates to public health facilities.

Regulation 4, subject to the provisions of regulation 7, as it relates to private facilities.

1.3. Manufacturing Pharmacy

'manufacturing pharmacy' means a pharmacy wherein or from which some or all of the services as prescribed in terms of regulation 16 of the Regulations Relating to the Practice of Pharmacy are provided and which shall sell medicine only to the wholesale or retail sector or to the State;

Regulation 2, subject to the provisions of regulation 7(a).

1.4. Wholesale Pharmacy

'wholesale pharmacy' means a pharmacy wherein or from which some or all the services as prescribed in terms of regulation 17 of the Regulations Relating to the Practice of Pharmacy are provided and which shall sell medicines only to the retail sector or to the State.

Regulation 2, subject to the provisions of regulation 7.

1.5. Consultant Pharmacy

Regulation 5.

2. Conditions for the ownership of pharmacies

Regulation 7 sets out the conditions for ownership of pharmacies as follows:

(1) A person who may own a pharmacy in terms of section 22A of the Act and who applies for a licence in terms of section 22 of the Act shall provide the Director-General with-

(a) proof that such person is able to comply with standards of Good Pharmacy Practice as determined by the council, and where applicable, Good Manufacturing Practice or Good Distribution Practice as determined by the Medicines Control Council, a body established in terms of section 2 of the Medicines Act; and

(b) an undertaking that such person shall comply with standards referred to in paragraph (a).

(2) The person referred to in subregulation (1) must satisfy the criteria for the determination of a need for the pharmaceutical service in respect of an area for which the application is made, which includes but is not limited to-

(a) the location of the premises applied for;
(b) the benefit to members of the specific community which the pharmacy intends serving;
(c) the nature and extent of the pharmaceutical service to be provided;
(d) a statutory requirement for the location of a pharmacy within a private or public health facility;
(e) the approximate number of the population to whom a pharmaceutical service will be provided;
(f) the relationship between the proposed pharmaceutical service and existing services and facilities;
(g) the extent of the provision of services to persons outside the service area and the extent and nature of the availability of pharmaceutical services in the nearby areas;
(h) any special care needs of the community to be served;
(i) an inspection report by the council of the premises.

3. Licensing of pharmacy premises

Regulation 8 deals with the licensing of pharmacy premises as follows:

(1) A person desiring to own a pharmacy in terms of section 22A of the Act shall-

(a) submit to the Director-General:

(i) a duly completed application on a form approved by the Director-General; and

(ii) acceptable documentary evidence that the applicant complies with the applicable conditions contemplated in regulations 2, 3, 4, 5, 6 and 7; and

(b) pay the application fee as determined by the Director-General.

(2) Notwithstanding subregulation (1), the Director-General may request the assistance of the council in determining whether a person contemplated in subregulation (1) complies with the conditions for ownership in respect of a specific pharmacy.

(3) If the Director-General is satisfied that the application in terms of subregulation (1) and other documents submitted in support of such application, including an inspection report of the premises from the council, complies with the provisions of these Regulations, he or she may issue a licence, subject to conditions as he or she may determine, for each one of the premises wherein or from which such pharmacy business may be conducted.

(4) A person who is a holder of a licence issued in terms of subregulation (3) shall, within 30 days from the date of issue of such licence, but prior to the provision of any pharmaceutical services from the premises specified in the licence, notify the council thereof on the form approved by the Director-General.

(5) The council shall on receipt of the notification referred to in subregulation (4), and on payment of a recording fee as determined by the council, record the name, address, date of licence and licence number.

(6) A licence issued in terms of subregulation (3) shall not be transferable to a person not authorised in terms of the Act to own a pharmacy.

4. Withdrawal of a licence

Regulation 9 deals with the withdrawal of a licence as follows:

The Director-General may withdraw a licence issued in terms of regulation 8(3) if the person issued with such a licence-

(a) has failed to comply with any of the conditions of ownership or the licensing requirements in terms of the Act and these Regulations;

(b) disposes of the whole or any part of his, her or its interest in a pharmacy or the body corporate that owns such pharmacy to any person not authorised to own a pharmacy or have any direct or indirect beneficial interest in a pharmacy;

(c) contravenes any provision of the Act, the Medicines Act or any other legislation applicable to such pharmacy;

(d) is sequestrated or liquidated;

(e) fails to pay any fees payable in terms of the Act and these Regulations;

(f) fails to comply with the registration or recording requirements prescribed in terms of the Act;

(g) being a pharmacist, has been suspended from practising as a pharmacist or if such person's name has been removed from the register in terms of section 45(1) of the Act and such name has not been restored in the register;

(h) is not carrying on the business of a pharmacy or the pharmacy is not in operation;

(i) fails to comply with Good Pharmacy Practice or Good Manufacturing or Distribution Practice referred to in regulation 7(1)(a).

ANNEXURE B

Litigation

The cases provided, and more importantly the cases available, would suggest that no substantial application has been brought to change the Constitutional jurisprudence. *New Clicks* is still the case that needs to be met.

1. Courts

   The following cases were adjudicated upon by superior courts. These judgments form part of the body of precedent that must be referred to if one is to correctly interpret the law. The only concern is that the body contains very limited substance.

1.1. New Clicks South Africa (PTY) Ltd v Tshabalala-Msimang and Another NNO; PSSA and Others v Tshabalala-Msimang and Another NNO 2005 (2) SA 530 (C) [August 2, 2004]

1.2. Affordable Medicines Trust and Others v The Minister of Health and Others 2006 (3) SA 246 (CC) [March 11, 2005]

1.3. Minister of Health and Another NO v Ne Clicks South Africa (PTY) Ltd and Others (Treatment Action Campaign and Another as Amici Curiae) 2006 (2) SA 311 (CC) [September 30, 2005]

1.4. The Hospital Association of South Africa (HASA) Ltd v The Minister of Health 2010 JDR 0857 (GNP) [July 28, 2010]

1.5. Clicks Retailers (PTY) Ltd and Albert Sibanyoni N.O. and Others 66710/2013 [October 31, 2013]

2. Competition Commission

2.1. The Competition Commission and the HASA and Another 24/CR/Apr04 [26 April 2004]

2.2. The Competition Commission and the Board of Healthcare Funders of Sothern Africa 07/CR/Feb05 [3 March 2005]

2.3. Mergers and Acquisitions

Below is a list of mergers within the pharmaceutical sector that have been decided upon by the Competition Tribunal:

- http://www.comptrib.co.za/cases/large-merger/retrieve_case/247
- http://www.comptrib.co.za/cases/large-merger/retrieve_case/288
- http://www.comptrib.co.za/cases/large-merger/retrieve_case/982
- http://www.comptrib.co.za/cases/large-merger/retrieve_case/1260

CHAPTER 3:

SOUTH AFRICA'S TARIFF SETTING PROCESS HISTORICAL TIMELINE

Date	Document released or process started
Pre 1993	Regulated medical scheme benefits: PMBs were a percentage of services regardless of diagnosis eg: 80% of GP fees. Open schemes couldn't under-price occupational schemes without providing less benefits – thus they lobbied for the removal of minimum benefits.
Up until 1994	Private healthcare sector evolved on a FFS system. As medical schemes paid the price of medical care etc, the patients were not price sensitive and doctors and specialists did not compete on price as a change in price would not affect demand. Medical schemes thus began to negotiate tariffs on a collective basis. RAMS negotiated a set of statutory FFS tariffs which were published in the Gazette each year. This was abolished in 1994 in amendments to the regulations of the then Medical Schemes Act. Important to note is that RAMS represents administrators and not medical scheme members and thus their decisions do not necessarily advantage patients. Collective bargaining thus left out key stakeholders and as there was no deal-breaking mechanism, if the process of negotiation broke down, practitioners could just charge whatever they wanted.
1994	As a result RAMS shifted from negotiating an actual set of FFS prices to 'negotiating' reference prices. Medical Schemes had to then negotiate their own prices separately but could use the reference price as a guide. SAMA began publishing a competing reference price schedule for GPs and specialists. SAMA tariff schedule prices were higher than the RAMS prices. Doctors sat together to agree on these SAMA tariffs which amounted to horizontal collusion against the general public. If doctors used the RAMS tariff schedule they would be reimbursed directly by medical schemes using bulk billing. If doctors used the SAMA rate (which was higher) medical schemes forced doctors to bill through the patients. Patients could then claim back from the medical schemes. There are no minimum benefits and medical schemes are risk rating. Open medical scheme environment rapidly expands. Medical schemes are negotiating directly with hospitals and specialists and doctors are contracted in or contracted out.
Prior to 2003	Tariff negotiations between private hospitals and medical scheme funders took place collectively. HASA represented private hospitals and BHF represented medical schemes.
2004	Competition Commission outlaws 'collective bargaining' (centralised reference tariff schedules produced by BHF, HASA and SAMA) saying that it amounts to pricing collusion and anti-competitive behaviour. Parties involved signed separate consent agreements with the Competition Commission to negotiate individually in the future.
Post Competition Commission action	As per Competition Act of 1998 and action taken by Commission, private hospitals and funders had to undertake annual negotiations individually and not collectively. Result of Competition Commission action: Medical Schemes were theoretically required to negotiate general reimbursement prices with every single medical service provider. Hospitals consolidated into three major groups. It is a moot point whether this created a negotiating power imbalance with the less concentrated medical schemes but it is thought that such consolidation eliminated the possibility of price competition.

Date	Document released or process started
January 2004	BHF tariff is discarded. Until 2004, the BHF published its own list of recommended tariffs, which was compiled by means of negotiation between the BHF and the South African Medical Association. The BHF list was ruled as being in contravention of the Competition Act, which regulates activities between businesses and organisations that should be competitors. To mitigate the logistical problem created by the Competition Commission action, the NHRPL was designed by the Council for Medical Schemes on behalf of the DoH, and was first published in 2004. It was designed as a stop gap and damage control, not as a long term intervention. The CMS was allowed to do this as it derived no commercial gain from establishing the tariff schedule and therefore fell outside the jurisdiction of the Competition Act. The CMS was also allowed to publish research papers and so could thus publish a tariff schedule as research. The list did not contain negotiated prices; it was compiled by gathering submissions from all disciples of health service with suggestions regarding the actual cost of running a practice. So it was cost analysis. The NHRPL does not always reflect the actual prices that may be charged at medical practices. Therefore, its rates are more of a guideline for practitioners and medical aid schemes around which they can calculate tariff structures and design
January 2004	In the same way that doctors are not bound by the NHRPL, medical aid schemes are free to calculate their own MSR. Each medical aid scheme tends to use its own MSR, which is created using the NHRPL as guidelines! Medical service providers with market power deviated from the NHRPL, when it suited them without any market penalty.
February 2005	"Settlement agreement between the Competition Commission and Board of Healthcare Funders in regard to alleged contravention of section 4(1)(b)(i) of the Competition Act 1998.
2006	The NHRPL was determined by the CMS in conjunction with the DoH and published by SAMA in the Doctors Billing Manual alongside the HPCSA and Competition Fund tariff. The 2006 NHRPL was adopted by the HPCSA as the Ethical Tariff. Amendments to the National Health Act included enabling provision which would allow the DoH to publish regulations and tariffs. The DoH wanted control over the CMS tariff setting process. The NHRPL process was handed over to the DoH and became the RPL which was hamstrung by the conflicting roles it was expected to play by key stakeholders. It also permitted providers, with permission, to collude in the setting of prices and the determination of code structures that would ultimately be charged as balance-billed amounts to patients rather than schemes. A tariff schedule was never published by DoH.
23 July 2007	Government Notice No: R681: The DoH subsequently published "Regulations relating to the obtainment of information and the process of determination and publication of RPL
24 November 2008	HPSCA Ethical Tariffs are scrapped.
September 2008	"Summary Report of the Advisory Committee to the Director General of Health" An analysis/evaluation of the Stakeholder submissions for the 2009 NHRPL and suggestions for a way forward and for future submissions.
December 2008	HPCSA stops publishing its suggested rates.
28 July 2010	Gauteng High Court (North Gauteng Division, Pretoria) declared RPL null and void/invalid. It also struck down the regulations: "The promulgation, by the Minister of Health on 23 July 2007, under GN681, and purportedly in terms of the powers afforded her by section 90(1) of the National Health Act, No 61 of 2003 of the Regulations Relating to the Obtainment of Information and the Process of Determination and Publication of RPL is hereby reviewed and declared invalid and is set aside together with the Regulations."

Date	Document released or process started
28 October 2010	"The Determination of Health Prices in the Private Sector" Discussion Documents Key issues: • how to make a legal price tariff • all stakeholders needed to be brought together • would also negotiate balance billing • would not affect medical scheme negotiations with selective contracting • only applies to FFS environment • avoids a public body setting an administered price • funders and providers thus negotiate together. If there is a disagreement the process goes into final contract arbitration. The arbitrator/regulator would then choose between the bids rather than taking a decision on the price. This creates an evidence-based incentive for funders and providers as well as an incentive to conclude negotiations without going to arbitration. There is no appeal process, the arbitrator's decision is final. This brings all parties together and thus factors in the household budget. This type of negotiation is preferable to the "biggest-fist" type negotiation eg: where employers have power because they can cut income and workers have power because they can strike and halt operations. Those types of negotiations can be very destructive. It is also opposite to conventional central bargaining where the incentive is to hide information and outside pressure can be applied.
2011	Two meetings are held by the DoH. Anban Pillay is in charge of this process. Nothing happens after March 2011.
January 2012	"Private Practice Review: January 2012 Medical Scheme Tariffs"
21 July 2012	"Proposal for Ethical Tariff 2012: SAMA's proposal for an ethical tariff based on a single Rand Conversion Factor"
2012	Pressure to do something about so called overcharging in the private sector. It is envisaged that the NHI will contract with private providers in order to survive and therefore private sector pricing become an issue for the realisation of NHI and not in and of themselves. There is also lobbying by the BHF to reduce PMBs and allow gap cover. Hospitals and doctors become the enemy in the eyes of the Minister of Health. MoH starts looking for other bodies to help solve the problem. The Competition Commission starts to talk about a market enquiry to resolve issues. HPSCA publish the Guideline Tariffs using the 2006 NHRPL as a baseline with an inflator of 46.66%
2012	They have enabling provisions to publish tariff schedules. The 2006 NHRPL was never challenged in terms of any legal process. "Guideline Tariffs – What you need to know." The tariffs were published without consultation and there was an immediate backlash
7 August 2012	HPCSA announced that the Board had determined Guideline Tariffs for medical and dental practitioners, which were to be published in the *Government Gazette*.
15 August 2012	Press Release: "Delay in publication of Guideline Tariffs for Medical and Dental Services Announced" (following concerns raised by practitioners)
14 September 2012	HPCSA published notice in the *Government Gazette* of 14 September 2012, indicating its intention to determine and publish Guideline Tariffs and requesting interested persons to submit their comments on the proposed Guideline Tariffs by 19 October 2012. This was subsequently withdrawn in a statement on 29 November 2012.
19 September 2012	Transcript of HPCSA and Medical and Dental Professions Board meeting at Department of Health in Pretoria to discuss proposal to publish a guideline tariff for 2012.
November 2012	HPCSA call for comments or representations: "Proposed Guideline Tariffs for Medical and Dental Professionals."

CHAPTER 4:

THE EFFECT OF PRICING REGULATIONS ON THE PHARMACEUTICAL SUPPLY CHAIN

Introduction

Over the past decade a growing uncertainty has gripped the pharmaceutical industry. The uncertainty finds its roots in the legislation and regulations surrounding the lay ownership of pharmacies and the regulation of pricing. The following Chapter seeks to provide clarity on the relevant regulatory framework as well as its implications.

Intention of the Legislature

The legal relevance of "Hansard" in a challenge on the Act and Regulations?

"Hansard is a substantially verbatim report – with repetitions and redundancies omitted and obvious mistakes corrected – of parliamentary proceedings. It is named after an English printer, L Hansard (1752 – 1828) and his descendants, who compiled the reports until 1889." [16]

1. How Law is made in South Africa

- https://pmg.org.za/bills/explained/
- http://www.parliament.gov.za/live/content.php?Item_ID=1843

1.1. Does Hansard fall within the ambit of PAJA?

1.1.1. PAJA defines an administrative action to the exclusion of the legislative functions of Parliament, a provincial legislature or a municipal council.

1.1.2. Legislative functions can be deduced from section 43 of the Constitution which distinguishes between three spheres. Section 44 provides for the Legislative Authority of the National Assembly and the National Council of Provinces. Sections 55 and 56 of the Constitution define the National Assembly's Powers to, inter alia, *"consider, pass, amend or reject any legislation before the Assembly"* and to receive submissions from interested parties.

1.1.3. It is thus clear that the procedures concerning a Bill's development into an Act form part of Parliament's legislative functions. Hansard, as discussed above, is an edited recording of these legislative functions.

1.1.4. An edited recording of debates/deliberations which preceded a decision, which constituted an administrative action, could be utilised to assist a review. The recording could show that:

1.1.4.1. The administrator who took it was biased or reasonably suspected of bias;

1.1.4.2. The action was taken for an ulterior purpose or motive;

1.1.4.3. The action was taken because irrelevant considerations were taken into account or relevant considerations were not considered;

1.1.4.4. The action was taken arbitrarily or capriciously;

1.1.4.5. The action itself is not rationally connected to the purpose for which it was taken; or

1.1.4.6. The action itself is not rationally connected to the information before the administrator.

1.2. It becomes clear that Hansard would not serve a purpose in matters of a litigious nature where the outcome would be a review of the legislature's decision to pass a Bill. This is as a result of the finding that a legislature's decision making process is excluded from PAJA. Where Hansard could become useful, arguably, is in cases where provisions/Act were tested in a court. The test, however, would be if the offending title passes constitutional muster or is practicable in the implementation of its subordinate legislature.

Legal Framework

This sector has been regulated for many years. However, since 2003 it has seen a progression of restrictive regulation.

1. Legislation:

1.1. Medicines and Related Substances Control Act 101 of 1965 (MARSA)

1.2. Section 22C – Licensing

1.3. Section 22G – Pricing Committee

2. Regulations:

2.1. General Regulations – GN R510 of 2003

2.1.1. Regulation 18 – Licence to dispense or compound and dispense medicines

2.1.2. Regulation 19 – Licence to manufacture, act as a wholesaler or distribute medicines

2.1.3. Regulation 20 – Period of validity of a licence issued in terms of regulations 18 and 19 and renewal of licences

2.1.4. Regulation 28 – Particulars which must appear on a prescription or order for a medicine

2.1.5. Regulation 33 – Repacking of medicines into patient ready packs

2.1.6. Regulation 38 – Pricing Committee

2.1.7. Regulation 45 – Advertising of medicines

2.2. Ownership and licensing of pharmacies – GN R553 in GG 24770 of 25 April 2003

16 Regulation 7 of the Regulations dealing with the Ownership and licensing of pharmacies (GN R553 of 2003).

3. SEP and Dispensing Fees

3.1. Transparent pricing system for medicines and scheduled substances – GN R1102 of 2005

- 3.1.1. Regulation 5 – SEP
- 3.1.2. Regulation 8 – SEP Variation
- 3.1.3. Regulation 10 – Dispensing Fee to be charged by a pharmacist
- 3.1.4. Regulation 12 – Dispensing Fee to be charged by a person registered in terms of section 22C (1)(a)
- 3.1.5. Regulation 22 – Determining Reasonableness of SEP
- 3.1.6. Regulation 23 – Considerations determining reasonableness of SEP.

3.2. Regulations relating to a transparent pricing system for medicines and scheduled substances: Amendment R1210 of 2006

3.3. Regulations relating to a transparent pricing system for medicines and scheduled substances R524 of 2009

3.4. Determination of maximum increase in the SEP of medicines and scheduled substances for 2010 GN 208 of 2010

3.5. Regulations relating to a transparent pricing system for medicines and scheduled substances: Amendment R1090 of 2010

3.6. Regulations relating to a transparent pricing system for medicines and scheduled substances: Amendment R1256 of 2010

3.7. Regulations relating to a transparent pricing system for medicines and scheduled substances: Amendment R766 of 2012

3.8. Regulations relating to a transparent pricing system for medicines and scheduled substances: Dispensing fee for pharmacist R714 of 2013

3.9. Transparent pricing system for medicines and scheduled substances: SEP of medicines and scheduled substances [SEPA] for the year 2014 R68 of 2014

3.10. Medicines and related substances Act, 1965 Regulations relating to a transparent pricing system for medicines and scheduled substances: Amendment (Dispensing fee to be charged by persons licensed in terms of section 22C(1)(a)) R264 of 2014

3.11. Transparent pricing system for medicines and scheduled substances: Information to be supplied by pharmacist GN R584 of 2011

3.12. Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) Regulations relating to a transparent pricing system for medicines and scheduled substances: Amendment (Draft Dispensing Fee to be charged by persons licensed in terms of Section 22C (1) (a) Notice 798 of 2014

4. Rules relating to the Code of Conduct

4.1. Rules relating to the code of conduct – BN 108 of 2008

Licensing and the Supply Chain

MARSA makes the sale and distribution of medicines or scheduled substances by any person not licensed to do so illegal. MARSA along with the General Regulations has created a licensing system that governs the licensing of all entities that form part of the pharmaceutical supply chain. The licensing framework is an important part of the how the pricing regulations have been implemented and it is with reference to the current supply chain that the pricing regulations need to be assessed.

The pricing regulations have, arguably, had the effect of undermining the efficient functioning of the supply chain. Fuelled by the perceptions that a large amount of vertical integration has occurred as a result of both the pricing regulation and the open ownership of pharmacies, the retail sector has most acutely suffered the impact of these uncompetitive practices.

MARSA and the General Regulations recognise a particular supply chain in respect of the sale of pharmaceuticals in the private sector. The following entities are recognised as part of that supply chain and must be licensed with the DoH.

1. Manufactures
2. Importers
3. Distributors
4. Wholesalers
5. Retailers.

MARSA does not define "distributor" or "wholesaler" but if the words are given their ordinary meaning, a distributor would be an agent or representative of the manufacturer or wholesaler, and a wholesaler is a person who trades in bulk for his or her own account. Manufacturers may either supply their products through a wholesaler, who buys in bulk, and sells to retailers in smaller quantities, or through a distributor, who acts as the manufacturer's agent, and as such deals either with retailers or wholesalers.

In terms of sections 22C (1) (b) and 22C (6) any entity requires a license to conduct business as a manufacturer, distributor or wholesaler. Regulation 19 requires importers to have a license and makes provision for licenses to be issued only to manufacturers, wholesalers and distributors. If distributors sell on their own behalf they would, in respect of such sales, cease to be a distributor, and would become a wholesaler.

Section 22H of MARSA provides that a wholesaler may only purchase medicine from the "original manufacturer" or the "primary importer" and may only sell to the retail sector. There is no definition of "primary importer" and these words are not used in any other section of MARSA. It is not clear from this or other provisions of MARSA who a primary importer is.

Summary

- MARSA and the General Regulations establish the following framework for the importation, distribution and sale of medicine.
- Only manufacturers, wholesalers and distributors, licensed to do so, may import medicines.
- Manufacturers and wholesalers[17] sell medicines for their own account;[18] Distributors sell medicines as agent or representative of the manufacturer or wholesaler.
- If medicines are imported by a person other than the manufacturer; an importer who takes ownership of the medicines bought, acts as a wholesaler.
- Wholesalers must sell the imported medicine to the retail trade.
- If medicines are imported by an importer as representative of the manufacturer, that importer is a distributor for the purposes of MARSA.
- A distributor may sell the medicine on behalf of the manufacturer, either to a wholesaler or directly to retailers.
- Distributors, wholesalers, and pharmacists may not sell the medicine at a price other than the SEP.[19]
- MARSA contemplates that wholesalers and distributors will be engaged in the marketing of medicines.[20]

Issues

- There is no distinction between importers and manufacturers.[21] This is particularly important for the pricing regulations which are discussed below.
- There seems to be no distinction between wholesalers and distributors in practice.[22] For the purposes of the pricing regulations they are treated in the same way and entitled to remuneration in terms of the same fee. The licenses for distributors or wholesales issued by the DoH are identical for all intents and purposes.[23]
- Vertical integration, in practice, facilitates a situation in which all that an entity requires is a wholesale license and they can become an importer, distributor and, as a result of lay ownership, a retailer as well. This could allow for situations in which single entities control the entire supply chain. This becomes even more relevant when importers are entitled to determine the price of medicine, which is exactly what the pricing regulations provide.
- It appears that a sizeable amount of vertical integration occurred in this industry during the early 1990's. Arguably, lay ownership allowed for even more.
- The establishment of exclusive distribution agreements by large importers / manufacturers allowed for full control over independent wholesalers and their conversion into wholly owned distribution agencies for the importer / manufacturer.
- The effects of this on market competition are exacerbated by the pricing regulations.

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17 GN R1102 of 2005 defines a wholesaler as a dealer who purchases medicines or scheduled substances from a manufacturer and sells them to a retailer and includes a wholesale pharmacy.

18 The argument throughout is the realisation of profits by role players at the end of their involvement within the supply chain. GN R1102 of 2005 defines the SEP as "the price of the lowest unit…multiplied by the number of units in the pack." As this price is set by the importer / manufacturer one notes that wholesalers are in effect excluded from making a profit as they cannot sell the unit for more than they in effect acquire it for. The question then becomes how do wholesalers make their profits? Is it possible that they absorb the logistics fee?

19 Regulation 6 of GN R1102 of 2005 holds that a manufacturer, importer or wholesaler may not charge any fee or amount other than the SEP in respect of the sale of a medicine or scheduled substance to a person other than the State.

20 General Regulation 45 deals with the manner in which marketing may be approached:

(1) The under mentioned requirements shall apply to any advertisement of a medicine.

(2) (a Medicines which do not contain a scheduled substance and medicines which contain a substance appearing in Schedule 0 or Schedule 1 may be advertised to the public; and

(b) Medicines which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 may be advertised only for the information of medical practitioners, dentists, veterinarians pharmacists and other persons authorised to prescribe or in a publication which is normally or only made available to persons referred to therein;

(c) Paragraph (b) shall not be so construed as to prohibit informing the public of the prices, names, pack sizes and strengths of medicines which contain a substance appearing in Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6.

(3) No advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine with regard to its safety, quality or efficacy where such evidence has been accepted by the Council in respect of such medicine and incorporated into the approved package insert of such medicine.

(4) A written advertisement for a medicine shall contain:

(a) the proprietary name of such medicine;

(b) the approved name and quantity of each active ingredient of such medicine in lettering having minimum legibility: Provided that, in the case of a medicine containing only one active ingredient, such lettering shall be not less than one half the size of the largest lettering used for the said proprietary name; and

(c) in the case -

(i) of a registered medicine, the registration number allocated to it in terms of section 15 (6);

(ii) of a medicine in respect of which an application for registration has been submitted in terms of section 14 of the Act, the reference number allocated to such application by the Registrar, followed by the words 'Act 101/1965)';

(iii) where a name other than the proprietary name is also used, such other name in lettering one half the size of the largest type size in which the proprietary name appears in such advertisement;

(iv) of a veterinary medicine, an indication that the medicine is for veterinary use; and

(v) of a homeopathic medicine, an indication that the medicine must be used in accordance with homeopathic principles.

(5) In the case of an advertisement for a medicine which contains more than one active ingredient, no spec reference shall be made to the specific properties of any individual active ingredient unless a reference of this nature has been approved by the Council for inclusion in the package insert of such medicine.

(6) When a medicine is advertised verbally for the first time to persons referred to in subregulation 2(b), written information, which shall include at least the information referred to in regulation S or regulation 40, shall simultaneously be given to the person to whom the oral advertisement is directed, and when the medicine is advertised orally on subsequent occasions such information shall be available on request.

21 A distinction was drawn by the SCA in this regard but it was overruled by the Constitutional Court which held that for the purposes of the pricing regulation and MARSA, no distinction could be drawn.

22 GN R1102 of 2005 defines a distributor as a person, other than a manufacturer, wholesaler or retailer, who supplies a medicine or scheduled substance to a retailer or a wholesaler. Given the definition of a wholesaler it would become clear that the distinction is frivolous and that it is far more beneficial to be a distributor – which allows for more interaction.

23 In New Clicks the Court dealt with the regulation of participants in the making and distribution of medicines and scheduled substances at para 222:

… Only manufacturers, wholesalers and distributors, licensed to do so, may import medicines. Only manufacturers, wholesalers and distributors, licensed to do so, may sell medicines. Manufacturers and wholesalers sell medicines for their own account, distributors sell medicines as agent or representative of the manufacturer, or possibly on behalf of a wholesaler. If medicines are imported by a person other than the manufacturer, an importer who becomes the owner of the medicines bought, and sells them for its own account, acts as a wholesaler for the purposes of the Medicines Act, and must have a wholesaler's licence authorising it to import and carry on business as a wholesaler. In that event the wholesaler, unless exempted under section 22H, must sell the imported medicine to the retail trade. If medicines are imported by an importer as representative of the manufacturer on whose behalf the importer sells the medicine, that importer is a distributor for the purposes of the Medicines Act. In that event, the distributor may sell the medicine on behalf of the manufacturer, either to a wholesaler or directly to retailers.

Pricing Regulations: Single Exit Price

The SEP is defined by the Transparent Pricing system for medicines and scheduled substances GN R1102 of 2005 as follows:

> "single exit price" means the price set by the manufacturer or importer of a medicine or scheduled substance in terms of these Regulations combined with the logistics fee and VAT and is the price of the lowest unit of the medicine or scheduled substance within a pack multiplied by the number of units in the pack.

Regulation 5 deals with the calculation of the SEP.[24]

Based on this definition the SEP can be broken down into the following elements:[25]

1. *The manufacturer price*
   This is the price determined by the manufacturer / importer of medicine. The subsequent annual changes need to be approved in order for the medicine to be entered on the South African Medicines Pricing Registry Database of Medicine Prices. Determination of the price at first entry is not transparent and there is no obligation on the manufacturer or importer to disclose how it is decided.

2. *The logistics fee*
   The logistics fee is a fee charged by the distributor / wholesaler (there is no distinction in MARSA or the Regulations).[26] Like the core price, this fee is not transparent. It is determined by agreement between the distributor and the manufacturer. While the fee needs to be made public as separate from the core price, it is in no way distinct from the SEP. This fee is combined with the core price and VAT to reach the SEP.

3. *VAT*
   Section 22G (3) (a) of MARSA prescribes that the SEP is the price at which medicine must be sold to all persons other than the State. An SEP must be set for every medicine sold in South Africa. This is a mandatory price control measure that must be given effect to in the Regulations. So too is the requirement of section 22G (3) (b) that all persons licensed to sell medicines, may not sell medicine at any other price than the SEP.

Section 22G does not specify how or by whom the SEP should be determined. The Regulations provide for this.[27] The definition of SEP in Regulation 2 and the provisions of Regulation 5 require it to be set by the manufacturer or importer. The Regulations provide that the SEP must be determined by the manufacture / importer of medicines in conjunction with the distributors / wholesaler.

The SEP, thus established, becomes a fixed price at which the product must be sold at every level of the supply chain.[28] The system contemplates that the medicine and scheduled substances will move along the supply chain at a price not higher than the SEP, which is the price at which the medicine or scheduled substance must enter the supply chain.

Wholesalers and distributors are entitled to a logistics fee[29] for their services and pharmacists are entitled to an "appropriate" dispensing fee[30] for their services. Wholesalers, distributors and pharmacists add components price of the medicine, and are limited to the fees they are entitled to charge in terms of the Regulations.

At the commencement of the regulations a maximum SEP was intended to be established according to a formula prescribed by the Regulations. This is a convoluted formula which attempted to set an SEP based on the average price of medicine sold in 2003. The formula was not used in determining most of the SEP's. These were published by the manufacturer and subsequently endorsed by the DoH.

The SEP may be increased once a quarter by the manufacturer subject to certain constraints (see below). The Minister may determine a maximum SEP for a particular drug. This has not been done for many drugs and there has been very little oversight and intervention in drugs prices from the DoH.

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24 Transparent Pricing system for medicines and Scheduled Substances GN R1102 of 2005
25 There are three ways in which this SEP can be altered:
1 – In accordance with Regulation 5 the SEP may only be increased annually after the initial increase. Regulation 7 states that subject to regulations 5, 8 and 9 the SEP may only be increased once a year.
2 – Regulation 8(1) deals with the extent to which the SEP may be increased, annually. Regulation 8(3) stipulates that the SEP may be increased once a quarter subject to certain conditions, most notably that the increase does not exceed the increase first published.
3 – Regulation 9 provides for an increase, greater than that provided for in 8(1), in exceptional circumstances and upon written application.
26 Transparent Pricing system for medicines and Scheduled Substances GN R1102 of 2005
27 Transparent Pricing system for medicines and Scheduled Substances GN R1102 of 2005
28 In New clicks at par 223 the Court dealt with sections 22G(2) and (3) of the MARSA provide:
(2) The Minister may, on the recommendation of the pricing committee, make regulations—
(a) on the introduction of a transparent pricing system for all medicines and scheduled substances sold in the Republic;
(b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a);
(c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.
(3) (a) The transparent pricing system contemplated in subsection (2)(a) shall include a SEP which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and scheduled substances to any person other than the State.
(b) No pharmacist or person licensed in terms of section 22C(1)(a) or wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).
29 Regulation 5(1) of the Transparent Pricing system for medicines and Scheduled Substances GN R1102 of 2005
30 S 22G of MARSA and Regulation 10 of the Transparent Pricing system for medicines and Scheduled Substances GN R1102 of 2005

Summary:

- The SEP is the price at which medicine must move along the supply chain. The sale of medicine in South Africa may not be at any price other than the SEP.
- The SEP is determined and published by the manufacturer / importer of medicine.
- The SEP is comprised of a core price, the logistics fee and VAT.
- The core price is decided upon by the manufacturer.
- The logistics fee is determined through negotiations between the manufacturer / importer and the distributor / wholesaler.
- The SEP may be increased by the importer / manufacturer once a quarter subject to certain constraints.
- The Minister may determine a maximum SEP for a particular year.

Issues:

- There is no transparency as to how the core price is established. Initially the core price was a reflection of prices prior to the legislative enforcement. As a result the practice has developed that enables importers and manufacturers to propose charges as they see fit. This is subject, however, only to the possibility of a price ceiling to be imposed by the DoH and relevant Council.
- There is no transparency as to how the logistics fee is established. This is very problematic in light of the above mentioned vertical integration that has occurred.
- There has been little to no intervention in the capping of SEP's.
- Distributors that are controlled by importers allow companies to shift cost between the core price and the logistics fee without it affecting their net profit on the sale of particular drug.

Increases of the SEP

Regulation 8 [31] deals with increases in the SEP. The relevant provisions of Regulations 7 and 8 are provided below.

1. Regulation 8.

1.1. The extent to which the SEP of a medicine or scheduled substance may be increased will be determined annually by the Minister, on the recommendation of the Pricing Committee, by notice in the Gazette with regard to -

1.1.1. the average CPI for the preceding year;

1.1.2. the average PPI for the preceding year;

1.1.3. changes in the rates of foreign exchange and purchasing power parity;

1.1.4. international pricing information relating to medicines and scheduled substances;

1.1.5. comments received from interested persons in terms of regulation 8(2); and

1.1.6. the need to ensure the availability, affordability and quality of medicines and scheduled substances in the Republic.

1.2. Not less than three months before making a determination in terms of regulation 8(1), the Minister must publish a notice in the Gazette declaring his or her intention to make that determination and inviting interested persons to furnish him or her in writing with any comments thereon or any representations they may wish to make in regard thereto.

1.3. Subject to the provisions of regulation 8(1), a manufacturer or importer may no more than once a quarter increase the SEP of a medicine within a year provided that –

1.3.1. (i) such increase does not exceed the SEP of the medicine or scheduled substance as first published in respect of that year;

1.3.2. (ii) the increase in the SEP is applied to all sales of the medicine or scheduled substance and not to selected categories of purchasers;

1.3.3. (iii) the manufacturer or importer notifies the Director-General of the increase in the SEP at least 48 hours prior to the implementation of such increase;

1.3.4. (iv) the SEP may not be increased as contemplated in terms of this regulation 8(3) within the period of six months beginning from the date of commencement of these regulations (i.e. six months from 11 November 2005).

2. Regulation 7. Subject to the provisions of regulations 5, 8 and 9, the SEP of a medicine or scheduled substance may only be increased once a year.

3. Having made provision for a maximum SEP it was necessary for that determination to be subject to review from time to time. The regulations address this issue by making provision for the SEP to be reviewed, both by the Minister and by the importer.

4. The purpose of regulation 8 is to establish a system in which a maximum permissible increase of the SEP would be determined on an annual basis by the Minister, but space would be left for manufacturers and importers to increase the SEP at a price below the maximum.

5. Manufacturers and importers are allowed to increase the price of medicines on a quarterly basis as long as they do not exceed the maximum allowed. This is consistent with the Pricing Committee's final report on the regulations which were submitted to the Minister. The report provides that:

5.1. "Manufacturers may reduce and increase their prices in response to competitive imperatives, as long as the price at no time exceeds the SEP that has been established for that year and that these price increases do not occur more than once a quarter."

6. There is a large amount of ambiguity as to what exactly is meant by regulation 8(1). The Minister does not determine what the SEP for the year is. What the Minister does is to determine "the extent to which the SEP" may be increased. Does this mean the

31 Transparent Pricing system for medicines and Scheduled Substances GN R1102 of 2005

Minister is to determine a percentage increase or set a maximum amount based on the fee published by the importer? This is an ambiguity noted by the Constitution Court and has yet to be remedied. [32]

7. The second ambiguity in this section can be found in regulation 8(3)(1). It is not clear what is meant by-

> "Such increase does not exceed the SEP of the medicine or scheduled substance as first published in respect of that year;"

8. Does this refer to the price set by the manufacturer? In which case it is inherently contradictory. Or does it refer to the price published by the Minister? The latter would make sense if not for the fact that it is the importer who determines[33] the SEP and not the Minister.

9. The final issue with the system governing increases is the fact that there is a direct contradiction between regulation 8(3) and regulation 7. Regulation 8(3) provides for increased to be made once a quarter and regulation 7 provides for them to be made annually.

10. As noted above there are circumstances in which an increase in SEP over the maximum can be applied for. GN R1102, Regulation 7 caps the increase of the SEP to once a year, subject to Regulations 5, 8 and 9. Regulation 8 provides for the extent to which the SEP may be increased. It further provides that an SEP may only be increased once a quarter. Here we have a consistency issue. Finally regulation 9 provides for an increase, in exceptional circumstances, that is greater than the amount in regulation 8. [34]

11. Summary

- Increases in the SEP are permitted in terms of regulation 8.
- These increases may occur once a quarter and importers are permitted to change the SEP in response to competitive demands.
- The manufactures or importers must publish any increase in the SEP.
- The Ministers must determine the extent to which an SEP can be increased for a single year.

12. Issues

- There is no transparency as to why or on what basis the SEP may be changed.
- There are blatant contradictions between regulation 8(3) and regulation 7. This noted by the Constitutional court but yet to be cured.
- There is large amounts of ambiguity as to what exactly is implied by regulation 8(1) and regulation 8(3) (1).
- There has been little to no monitoring of the situation and the establishment of maximum prices by the Minister.
- It is possible to argue that the fact that an SEP can be changed once a quarter nullifies the intended price freezes. This is however not entirely accurate as the price can only be increased to the ceiling of the originally published SEP. Any increase above this limit would be subject to the requirements of Regulation 9.

The Logistics fee

1. The regulations[35] provide for the determination of a logistics fee in the following way:

> (f) Subject to regulation 5(2) (g), the logistics fee must be determined by agreement between the provider of logistical services and the manufacturer or importer.
>
> (g) The Minister, on the recommendation of the Pricing Committee, must determine a maximum logistics fee where, in the opinion of the Minister, such a determination is necessary to promote or protect the interests of the public in –
>
> (i) ensuring reasonable access to affordable medicines;
>
> (ii) the realisation of the constitutional right of access to health care services contemplated in section 27 of the Constitution;
>
> (iii) the efficient and effective distribution of medicines and scheduled substances throughout the Republic.

2. Section 22G (2) (c) of MARSA authorizes the Minister on the recommendation of the Pricing Committee to make regulations "on an appropriate fee to be charged by wholesalers or distributors". This is given effect to by Regulations[36] 5(2)(f) and 5(2)(g) which make provision for a logistics fee to be charged by distributors or wholesalers.

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32 Refer to increases awarded by the Minister from time to time. Refer to annexure A.
33 The manufacturer/importer determines the SEP. The initial SEP was based on prices set by the manufacturers / importers and has been adjusted yearly in conjunction with the DoH.
34 Regulation 9, of the Transparent Pricing system for medicines and Scheduled Substances GN R1102 of 2005, reads as follows:
(1) The Minister may, in exceptional circumstances, authorise a manufacturer or importer, on written application by such manufacturer or importer, to increase the price of a medicine or scheduled substance by a specified amount greater than that permitted in terms of regulation 8.
(2) In considering an application as contemplated in regulation 9(1) the Minister must take into account-
(a) the nature and extent of any adverse financial, operational and other circumstances for the manufacturer or importer if the application made in terms of regulation 9(1) is not approved;
(b) the effect, if any, on the availability of the medicine or scheduled substance within the Republic if the application made in terms of regulation 9(1) is not approved;
(c) the nature of the health condition for which the medicine or scheduled substance is a registered indication within the Republic and the extent to which public health would be adversely affected should the medicine or scheduled substance become unavailable or unaffordable within the Republic;
(d) the extent to which the rights contemplated in section 27(1)(a) and 27(3) of the Constitution may be adversely affected or limited-
(i) should the SEP not be increased by the amount requested in the application; and
(ii) should the medicine or scheduled substance become unavailable or unaffordable within the Republic.
35 Transparent Pricing system for medicines and Scheduled Substances GN R1102 of 2005
36 Transparent Pricing system for medicines and Scheduled Substances GN R1102 of 2005

3. The "logistics fee" is defined in the regulations as follows:

3.1. "Logistics fee" means the fee, inclusive of VAT, that is payable in respect of logistical services;

3.2. "logistical services" means those services provided by distributors and wholesalers in relation to a medicine or scheduled substance including but not limited to warehousing, inventory or stock control management, order and batch order processing, delivery, batch tracking and tracing, cold chain storage and distribution.

4. According to the regulation, the logistics fee is to be determined in advance (by agreement) and built into the SEP. It is therefore not permissible for a manufacturer to fix different logistics fees for different wholesalers and distributors. If a manufacturer uses more than one distributor or wholesaler, services must be provided on the basis of the logistics fee published in respect of that year. If wholesalers and distributors who were not party to the original agreement are subsequently used to market the medicine, they must agree to do so on the basis of the existing logistics fee.

5. There is an important distinction between the way in which the logistics fee is determined and the way in which the dispensing fee for pharmacists is determined. The dispensing fee is a maximum fee charged by pharmacists based on a formula provided for directly in the regulations. This allows a fee to be determined by the regulations themselves. The logistics fee on the other hand is determined solely by agreement between the importer and the distributor. The fee is not transparent and until the regulations were challenged in court, it did not even need to be published.

6. The Minister is vested with the power to cap the logistics fee if, in his/her "opinion" such a determination is necessary. Once again there is very little control over this element of the SEP. A brief review of the published logistics fees shows that they are largely determined in a similar way to dispensing fees, subject to a cap . Often the importers are negotiating fees with companies they control.

7. Summary:

- The regulations provide for the establishment of a logistics fee to be charged by distributors and wholesalers.
- This fee forms part of the SEP and must be published by the manufacturer / importer.
- This fee is determined by agreement between the importer and the provider of logistic services. This can be contrasted by the manner in which the dispensing fee is to be calculated.
- There is no transparency as to how the logistics fee is determined and it may be changed once a quarter along with any changes in the SEP.
- The Minister has the power to determine a maximum logistics fee in respect of any particular medicine but only if it is considered necessary.

8. Issues:

- The fee is determined through negotiations between an importer and distributors that are often part of the same company.
- The fee does not have to bear a relation to actual logistics costs.
- There is no room for wholesalers to make use of distributors, partly because wholesalers must sell directly to retailers unless exempted from doing so (see footnote 6) and partly because the two would have to share the same fee.
- Costs can be shifted from the manufacturer's price to the logistics fee and vice versa if necessary.
- Allows chains to control the entire supply chain from manufacture to retail.

Concerns

The first concerns are as follows.

1. Concerns that the "legal" situation for licensing of pharmacies is omitted.

1.1. Section 22 and 22A of the Pharmacy Act 53 of 1974 are of importance at this junction.

1.2. Section 22A provides for who may own a pharmacy and under what conditions they may own such a pharmacy. Furthermore, the provision deals with the removal of such authority.

1.3. Section 22 deals with the licensing of pharmacies by those entitled to own them in accordance with Section 22A. It mandates that an applicant apply to the Director General in accordance with the rules and regulations. A successful applicant shall notify the council (The South African Pharmacy Council as referred to in section 2) in writing of this licence and the council is then to record the details pertaining to the pharmacy. The pharmacy is subject to the conditions imposed upon it by the Director General.

2. Concern that the Code of Conduct's inapplicability on the supply of medicines by persons authorised to dispense (section 22C of MARSA).

2.1. Rules relating to Code of Conduct as published in BN 108 of 2008 in Government Gazette 51534.

2.1.1. The preamble particularly states that these rules are published in regard to pharmacists and other persons registered in accordance with section 35A (b) (i) of the Pharmacy Act 53 of 1974, as amended.

2.1.2. Section 35A (b) (i) reads as follows:

Pharmacy practice. – With regard to the control of pharmacy practice –

(b) the council shall be entitled to make rules as to:

a code of conduct for pharmacists and other persons registered in terms of this Act;

37 GN R104 of 4 March 2011 and GN R770 of 18 September of 2012 give a breakdown of the logistics fee. In accordance with the latter medicines where the ex-manufacturer price is less than R100 (excluding VAT), the fee can be no more than 8% plus R3 (last year's draft regulations stipulated 6%). For medicines priced between R100 and R499, the fee is capped at 6% plus R4 (previously 5% plus R2). For medicines between R500 and R999, the price has been set at 4% plus R5 (previously 3% plus R5) and for those priced at R1 000 or more, the logistics fees have been capped at R54 (over last year's recommendation of 2% plus R10).

2.1.3. The persons registered in terms of this Act include all persons who have successfully received a licence in terms of sections 22A and 22 of MARSA. The Act goes so far as to state the penalties for professing to be or practicing as a pharmacist without being registered with the Council in section 29.

2.1.4. These codes are applicable and enforceable against anyone registered as, or professing to be or practicing as a pharmacist.

2.2. Section 22C of MARSA sets out the requirement of licensing.

2.2.1. Section 22C (1)(a) reads as follows:

(1) Subject to the provisions of this section-

(a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions.

2.2.2. Subsection 2 reads as follows:

A licence referred to in subsection (1) (a) shall not be issued unless the applicant has successfully completed a supplementary course determined by the South African Pharmacy Council after consultation with the Health Professions Council of South Africa, the Allied Health Professions Council of South Africa and the South African Nursing Council.

2.2.3. Subsection 5 reads as follows:

No person shall compound or dispense a medicine unless he or she is authorised thereto in terms of the Pharmacy Act, 1974, is a veterinarian or is the holder of a licence as contemplated in subsection (1) (a).

2.2.4. Section 22E deals with the suspension and cancellation of the licence. It makes specific reference to the inaccuracy or misleading nature of information provided in applications. It further notes the applicants' failure to comply with conditions as set out in the licence or provisions of this Act as reasons for suspension of cancellation of a licence.

2.3. It is clear that the code of conduct is applicable to anyone involved in the practice of a pharmacy. When read holistically it becomes, arguably, clear that the provisions relate to particular aspects of the practice of a pharmacy and thus to those who engage in those particular aspects.

3. Concern that the mention of retailers being licensed as part of the supply chain needs to be clarified in light of hospitals as well as persons authorised to dispense.

3.1. Section 22C (1)(b) of MARSA reads as follows:

22C Licensing

Subject to the provisions of this section-

(b) the Authority may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, import or export, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine.

3.2. Subsection 6 reads as follows:

No manufacturer, wholesaler or distributor referred to in subsection (1) (b) shall manufacture, import, export, act as a wholesaler of or distribute, as the case may be, any medicine unless he or she is the holder of a licence contemplated in the said subsection.

3.3. The National Health Act 61 of 2003 (NHA)

3.3.1. Definitions read as follows:

'central hospital' means a public hospital designated by the Minister to provide health services to users from more than one province;

'health care provider' means a person providing health services in terms of any law, including in terms of the-

(a) Allied Health Professions Act, 1982 (Act 63 of 1982);
(b) Health Professions Act, 1974 (Act 56 of 1974);
(c) Nursing Act, 1978 (*Act 50 of 1978);
(d) Pharmacy Act, 1974 (Act 53 of 1974); and
(e) Dental Technicians Act, 1979 (Act 19 of 1979);

'health establishment' means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services;

'hospital' means a health establishment which is classified as a hospital by the Minister in terms of section 35;

'private health establishment' means a health establishment that is not owned or controlled by an organ of state;

3.3.2. Chapter 6 deals with Health Establishments

3.3.2.1. Section 35 deals with the classification of health establishments

The Minister may by regulation-

(a) classify all health establishments into such categories as may be appropriate, based on-

(i) their role and function within the national health system;

(ii) the size and location of the communities they serve;

(iii) the nature and level of health services they are able to provide;

(iv) their geographical location and demographic reach;

(v) the need to structure the delivery of health services in accordance with national norms and standards within an integrated and co-ordinated national framework; and

(vi) in the case of private health establishments, whether or not the establishment is for profit or not; and

(b) in the case of a central hospital, determine the establishment of the hospital board and the management system of such central hospital.

3.3.3. Pharmacy Act (GRN 553 of 25 April 2003) – Ownership and Licensing of pharmacies.

3.3.3.1. The regulations define public and private health facilities:

'private health facility' means any hospital, institution or facility at which provision is made for medical treatment or health care services which is not owned or controlled by the State, and includes facilities such as a clinic, mobile clinic, community health centre, maternity home, or unattached delivery suite, convalescent home, unattached operating theatre and sanatorium but does not include a consulting room, surgery or dispensary of an authorised prescriber;

'public health facility' means any hospital, institution or facility at which provision is made for medical treatment or other health care services and includes facilities such as a clinic, mobile clinic, community health centre, maternity home or unattached delivery suite, convalescent home, unattached operating theatre and sanatorium that is owned by the State or organ of the State;

3.3.3.2. The regulations define the different pharmacy types:

'community pharmacy' means a pharmacy wherein or from which some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to the general public or any defined group of the general public, but excludes an institutional pharmacy;

'institutional pharmacy' means a pharmacy situated in a-

(a) public health facility, wherein or from which some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to the general public requiring pharmaceutical services, medical or surgical treatment, nursing or other health care from or at that public health facility; or

(b) private health facility, wherein or from which some or all of the services as prescribed in terms of regulation 18 of the Regulations Relating to the Practice of Pharmacy are provided to persons requiring pharmaceutical services, medical or surgical treatment, nursing or other health care from or at that private health facility;

'manufacturing pharmacy' means a pharmacy wherein or from which some or all of the services as prescribed in terms of regulation 16 of the regulations relating to the Practice of Pharmacy are provided and which shall sell medicine only to the wholesale or retail sector or to the State;

'wholesale pharmacy' means a pharmacy wherein or from which some or all the services as prescribed in terms of regulation 17 of the regulations relating to the Practice of Pharmacy are provided and which shall sell medicines only to the retail sector or to the State.

3.3.3.3. Ownership of manufacturing or wholesale pharmacies

3.3.3.4. Ownership of institutional pharmacies in public health facilities

3.3.3.5. Ownership of institutional pharmacies in private facilities

Any person may, subject to the provisions of regulation 7, own or have a beneficial interest in an institutional pharmacy in a private health facility in the Republic, on condition that such a person or in the case of a body corporate, the shareholder, director, trustee, beneficiary or member, as the case may be, of such body corporate-

(a) is not prohibited by any legislation from owning a pharmacy or having any direct or indirect beneficial interest in such a pharmacy;

(b) is not an authorised prescriber;

(c) does not have any direct or indirect beneficial interest in or on behalf of a person contemplated in paragraphs (a) and (b); or

(d) is not the owner or the holder of any direct or indirect beneficial interest in a manufacturing pharmacy.

3.3.3.6. Ownership of consultant pharmacies

3.3.3.7. Ownership of community pharmacies

Any person may, subject to the provisions of regulation 7, own or have a beneficial interest in a community pharmacy in the Republic, on condition that such a person or in the case of a body corporate, the shareholder, director, trustee, beneficiary or member, as the case may be, of such body corporate-

(a) is not prohibited by any legislation from owning or having any direct or indirect beneficial interest in such a pharmacy;

(b) is not an authorised prescriber;

(c) does not have any direct or indirect beneficial interest in or on behalf of a person contemplated in paragraphs (a) and (b); or

(d) is not the owner or the holder of any direct or indirect beneficial interest in a manufacturing pharmacy.

3.3.3.8. Conditions for the ownership of pharmacies

(1) A person who may own a pharmacy in terms of section 22A of the Act and who applies for a licence in terms of section 22 of the Act.

3.3.3.9. Licensing of pharmacy premises

Any person desiring to own a pharmacy in terms of section 22A.

3.3.4. There are no regulations, at the time of writing, concerning the classification of health establishments. The fact that such a distinction is mentioned in the definitions as well as section 35 make it clear that there are various entities within the public (and private) health sphere. What also becomes clear is that the lack of a definition in MARSA concerning manufacturers, importers, distributors, wholesalers and retailers becomes problematic in the context of NHA.

4. Concern that the "licence" of pharmacies was not adequately reflected as being handled in terms of the Pharmacy Act (GN 553 of 25 April 2003) and NOT the Medicines Act.

4.1. Refer to above.

5. Concern that no reference is made as to how hospitals are licenced.

5.1. Refer to above.

6. Concern that no clear distinction is drawn between private and government supply. Particular attention needs to be given to medical aid schemes which utilise state facilities as DSPs (Government thus competes with the private sector).

7. Concern that the complexity is not addressed when one takes into account export by wholesalers. Further concern that the DoH's stupidity has allowed precedent contrary to the legislation to be decided.

What follows is a compilation of concerns arising from the regulations and case law. The concerns qualify either on the grounds that they are subject to compliance or competition irregularities.

1. GN R510 of 2003

1.1. Regulation 18

1.1.1. Item 5 concerns what the Director-General must consider an application for a licence to dispense or compound. Sub item (b) requires representations by any interested party. This item presupposes publication of the process – there is however, no such publication.

1.1.2. Item 7 refers to third party representations concerning an application for a licence. This item presupposes publication of the process allowing for such representations – there is however, no such publication.

1.2. Regulation 19

1.2.1. Item 4 states what the Council must be satisfied with in order to grant an application. Sub item (c) requires that the Council must be satisfied that the applicant must be able to comply with good manufacturing or distribution practices.

1.2.2. Items 7 and 10 deal with administrative processes that could be open to compliance irregularities as a result of departmental administrative processes.

1.3. Regulation 28

1.3.1. The regulation deals with what must appear on a prescription or order of medicine. The items are open to compliance irregularities as the information to be provided is voluminous.

1.3.2. Item 2 prescribes the checking of authenticity of electronically or telephonically transmitted scripts or orders. This is subject to compliance irregularities.

1.4. Regulation 45[38]

1.4.1. The regulation deals with the advertising of medicines. The issues here are twofold – compliance as well as competition. As a result the items relating to practices are subject to irregularities.

2. GN R553 of 2003

2.1. Regulation 7 deals with conditions for the ownership of pharmacies. Item 1(a) requires that an applicant furnish the Director-General with proof that they are able to comply with the relevant Good Practice standards. This may be used to enforce compliance as the applicant is now bound by this provision.

2.2. Item 2 sets out the criteria to be met in meeting the criterion of a certificate of need. Sub item (f) is of particular importance as it requires the applicant to set out the relationship the applicant will have with other existing services. Here the issue is one of competition as there is no way to test the veracity of the applicant's averments. There should be publication of any application to allow for existing services to make their voices heard.

2.3. Regulation 8 deals with the licensing of pharmacy premises. Item 3 sets out that if the Director-General is satisfied then they may issue a licence. This process amounts to an administrative exercise and would thus be subject to Administrative Review. Furthermore the process itself is, arguably, contrary to the principles of an open and democratic society.

2.4. Of concern are the avenues available to interested parties who would like their voice heard. There is no explicit provision provided for interested third parties. The wording does make provision that certain information needs to be provided and that a decision will be made accordingly by the Director-General. The only possible recourse would be to challenge the decision made by the Director-General in terms of administrative law.

38 See footnote 17 above where Regulation 45 of MARSA is discussed and how it deals with the manner in which marketing may be approached.

3. GN R1102 of 2005

3.1. The regulations deal with the transparent pricing system for medicines and scheduled substances. Here dispense is given a particular meaning and it is this meaning that may lead to compliance and competition irregularities.

3.2. Items 10 and 12 deal with the calculation of dispensing fees to be charged by pharmacists and other persons respectively. The issues here surround compliance with the amounts, which are subject to a prescribed cap. The dispensing fee charged by dispensers, still within the prescribed caps, is now largely determined by contracts entered into with medical aids and not yearly determinations.

3.3. The items further make provision for the Minister to review the amounts annually.

4. BN 108 of 2008

4.1. These rules relate to the code of conduct as they are to be adhered to and applied to persons dispensing and compounding.

4.2. Item 1.6 deals with Professional Independence.

4.3. Item 1.6.1 highlights the unacceptable nature of collusion.[39] It further states that the patient must have freedom to choose.

4.4. Item 1.6.2 states that in multi-professional practice that there is always to be professional accountability, independence and responsibility. It changes the definition to a pharmacy in sub item (i) which could result in compliance irregularities.

4.5. Item 1.6.3 deals with perverse incentives.[40] The practice becomes particularly concerning when one takes note of practices by suppliers, distributors and medical aids. The practice is broadly defined.

4.6. Item 1.6.4 deals with undesirable business practices with the crux being the patient's interests or needs.

Additional material

1. Outstanding matters that the DoH has put out for consultation, but not acted upon.

1.1. Benchmarking

1.1.1. GN R1102 Regulation 5(2)(e) requires conforming with international benchmarks.

1.1.2. GN R1211 of 2010 – Methodology for International Benchmarking of Prices.

1.1.3. GN R354 of 2014 – Comments on Transparent pricing system benchmark methodology.

1.2. List everything that has been put out for comment.

1.2.1. GN R31 of 2012 – Comments on Dispensing Fee for S 22C(1)(a).

1.2.2. GN R484 of 2012 – Comments on Dispensing Fee for Pharmacists.

1.2.3. GN R218 of 2013 – Comments on Dispensing Fee for Pharmacists.

1.2.4. GN R705 of 2013 – Comments on Annual Adjustment of SEP for 2014.

1.2.5. GN R1096 of 2013 – Comments on Dispensing Fee for S 22C(1)(a).

1.2.6. GN R536 of 2014 – Comments on Annual Adjustment of SEP for 2015.

Items 1.2.1 to 1.2.5 have been promulgated.

2. The legal basis on which infractions of the SEP can be investigated and acted upon.

2.1. Regulation 22 regulates what the Director-General may do if it is determined that the SEP is unreasonable. It merely provides that the determination, along with the reasons, may be communicated via *Government Gazette*.

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39 1.6.1 General Guidelines -
(a) Pharmacists should not agree to practise under terms or conditions that interfere with or impair the proper exercise of professional judgment and skill, that cause deterioration of the quality of professional services rendered, or that require consent to unethical conduct.
(b) Pharmacists may not collude with any person who is precluded in terms of the Regulations relating to the ownership and licensing of pharmacies from owning a pharmacy or have a beneficial interest in a pharmacy.
(c) While the closest professional co-operation between pharmacist and medical practitioner or other health care professional is to be welcomed, the pharmacist-
(i) must ensure that patients have the freedom to choose where they obtain their pharmaceutical services; and
(ii) must, whenever possible, ensure that patients have given their consent to their prescription being directed to a specific pharmacy.

40 1.6.3 Perverse Incentives
(a) A patient may be issued with prescriptions intended for dispensing at a specified pharmacy but must have the right to present it for dispensing at any pharmacy of his/her choice. A pharmacist must not approach a medical practitioner or medical practice staff to secure direction of prescriptions to a particular pharmacy. A prescription should only be sent directly from a medical practice to a pharmacy when:
(i) the patient has requested the direction; or
(ii) the patient is in residential care and has indicated his/her wish that the person providing that care may collect or receive prescriptions on his/her behalf; or
(iii) the patient has an addiction problem and receives medication in defined, pre-arranged quantities.
(b) A pharmacist shall not offer or give inducements to any person in consideration of the supply to him/her of either prescriptions or orders for medicines, devices or appliances for patients.
(c) In order to prevent perverse incentives, it is neither permissible nor ethical for a pharmacist, pharmacist intern or pharmacist's assistant to engage in the following actions-
(i) advertise or endorse or encourage the use of any health establishment or medicine, complementary medicine, veterinary medicine, medical device or scheduled substance or health related product or health related service in a manner that unfairly promotes the practice of a particular health care professional or health care facility for the purpose of improper financial gain or other valuable consideration;
(ii) engage in or advocate the preferential use of any health establishment or medical device or health related service or sell any medicine, complementary medicine, veterinary medicine or scheduled substance, if any improper financial gain or other valuable consideration is derived from such preferential use or prescription or the advocacy of preferential use by the health care professional, unless entitled by law;
(iii) referral of clients or patients to any health establishment or to other health care professionals if such referral would constitute overservicing;
(iv) accept commission or any financial gain or other valuable consideration from any person(s) or body or service in return for the purchase, sale or supply of any goods, substances or materials used by the health care professional in his or her practice;
(v) pay commission or render any financial gain or other valuable consideration from any person(s) or body or service in return for the purchase, sale or supply of any goods, substances or materials used by the health care professional in his or her practice;
(vi) charge or receive a fee for services not personally rendered by the pharmacy.

2.2. Regulation 23 sets out the considerations that the Director-General must be mindful of when determining the reasonableness of the SEP.

3. The legal basis for the relationship between medical aids and retail pharmacies.

3.1. Business interactions are regulated by common law and statute. The relationship between medical aids and pharmacies is regulated similarly.

3.2. The contractual relationship between parties is subject to scrutiny in line with the common law, statute and the Constitution.

3.3. The statutory relationship between the parties is regulated, inter alia, by the Competition Act (89 of 1998) as well as the Medical Schemes Act (131 of 1998), Medicines and Related Substances Act (101 of 1965) as well as the Pharmacy Act (53 of 1974).

4. The possible legal remedies for horizontal collusion

4.1. The Competition Act:

4.1.1. Chapter 2 – Prohibited Practices

4.1.1.1. Restrictive practices

4.1.1.1.1. Section 4 prohibits restrictive horizontal practices.[41]

4.1.1.1.2. Section 5 prohibits restrictive vertical practices.[42]

4.1.1.2. Abuse of dominant position

4.1.1.2.1. Section 7 defines a firm as being dominant if it has more than 35% of the market or has market power despite having less than 35% of the market.

4.1.1.2.2. Section 8 sets out the practices that constitute an abuse of dominance.[43]

4.1.1.2.3. Section 9 prohibits price discrimination by the dominant firm.[44]

4.1.1.3. Exemptions from application of chapter

4.1.2. Chapter 7 – Offences

4.1.2.1. Failure to comply with Act

5. Rights of retail pharmacies in relation to wholesalers and distributors.

5.1. The relationship between the various points within the supply chain is regulated by common law as well as statute. Should a problem arise, the parties will have recourse to courts, if the infringement stems from a contractual agreement or from practice regulated by legislation.

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41 (1) An agreement between, or concerted practice by, firms, or a decision by an association of firms, is prohibited if it is between parties in a horizontal relationship and if –
(a) it has the effect of substantially preventing, or lessening, competition in a market, unless a party to the agreement, concerted practice, or decision can prove that any technological, efficiency or other procompetitive gain resulting from it outweighs that effect; or
(b) it involves any of the following restrictive horizontal practices:
(i) directly or indirectly fixing a purchase or selling price or any other trading condition;
(ii) dividing markets by allocating customers, suppliers, territories, or specific types of goods or services; or
(iii) collusive tendering.
(2) An agreement to engage in a restrictive horizontal practice referred to in subsection (1)(b) is presumed to exist between two or more firms if –
(a) any one of those firms owns a significant interest in the other, or they have at least one director or substantial shareholder in common; and
(b) any combination of those firms engages in that restrictive horizontal practice.

42 Section 5 provides the following:
(1) An agreement between parties in a vertical relationship is prohibited if it has the effect of substantially preventing or lessening competition in a market, unless a party to the agreement can prove that any technological, efficiency or other pro-competitive, gain resulting from that agreement outweighs that effect.
(2) The practice of minimum resale price maintenance is prohibited.
(3) Despite subsection (2), a supplier or producer may recommend a minimum resale price to the reseller of a good or service provided –
(a) the supplier or producer makes it clear to the reseller that the recommendation is not binding; and
(b) if the product has its price stated on it, the words "recommended price" appear next to the stated price.

43 It is prohibited for a dominant firm to –
(a) charge an excessive price to the detriment of consumers;
(b) refuse to give a competitor access to an essential facility when it is economically feasible to do so;
(c) engage in an exclusionary act, other than an act listed in paragraph (d), if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain; or
(d) engage in any of the following exclusionary acts, unless the firm concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act –
(i) requiring or inducing a supplier or customer to not deal with a competitor;
(ii) refusing to supply scarce goods to a competitor when supplying those goods is economically feasible;
(iii) selling goods or services on condition that the buyer purchases separate goods or services unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract;
(iv) selling goods or services below their marginal or average variable cost; or
(v) buying-up a scarce supply of intermediate goods or resources required by a competitor.

44 (1) An action by a dominant firm, as the seller of goods or services is prohibited price discrimination, if –
(a) it is likely to have the effect of substantially preventing or lessening competition;
(b) it relates to the sale, in equivalent transactions, of goods or services of like grade and quality to different purchasers; and

ANNEXURE A – SEP AND DISPENSING FEE BREAKDOWN

Table representing the SEP Increase Cap:

Date	Title	Regulation	SEP
2010	GN 208 OF 2010	8(1)	7.40%
2014	R 68 OF 2014	8(1)	5.82%

Table showing the retail pharmacist dispensing fee (DF) cap formula:

Date	Title	Regulation	DF 1st level	DF 2nd level	DF 3rd level	DF 4th level
2003	GN R510 OF 2003	10	R 81 > (R6.30 + 46% SEP)	R 81 < (R16 + 33% SEP)	R216 < (R55 + 15% SEP)	R756 < (R131 + 5% SEP)
2006	R 1210 OF 2006	10	R 75 > (R4 + 33% SEP)	R 75 < (R20 + 6% SEP)	R255 < (R33 + 3% SEP)	R1 000 < (R50 + 1,5% SEP)
2010	R 1090 OF 2010	10	R 75 > (R6 + 46% SEP)	R 75 < (R15.75 + 33%SEP)	R200 < (R51 + 15% SEP)	R700 < (R121 + 5% SEP)
2013	R 714 OF 2013	10	R 81 > (R6.30 + 46% SEP)	R 81 < (R16 + 33% SEP)	R216 < (R55 + 15% SEP)	R756 < (R131 + 5% SEP)

Table showing the dispensing doctors and nurses dispensing fee (DF) cap formula:

Date	Title	Regulation	DF 1st level	DF 2nd level
2003	GN R510 OF 2003	12	R103 > (30% SEP)	R103 < (R30.90)
2009	R 524 OF 2009	12	R 65 > (30% SEP)	R 65 < (R20)
2010	R 1256 OF 2010	12	R 78 > (30% SEP)	R 78 < (R23.40)
2012	R 766 OF 2012	12	R 90 > (30% SEP)	R 90 < (R27)
2014	R 264 OF 2014	12	R103 > (30% SEP)	R103 < (R30.90)
2014	R 798 OF 2014	12	R105 > (30% SEP)	R105 < (R31.50)

ANNEXURE B – VARIOUS DISPENSING FEES

Medical aids also influence medicine choices and dispensing fees. They influence medicine choices by implementing medicine formularies and by requiring their members to accept generics if they are to avoid co-payments. They influence dispensing fees by a system of DSPs, the designation requiring a contract which specifies the dispensing fees payable in relation to medicines supplied to scheme members. Using a service provider other than a DSP may result in co-payments by members and even, in some cases, penalty payments as well.

The figure below indicates that contracts with medical aid schemes constrain dispensing fees more tightly than the government-set upper limit. Three popular contract specifications of dispensing fees in 2015 are shown:

Tariff A: 36% of the SEP up to a maximum of R 59.40

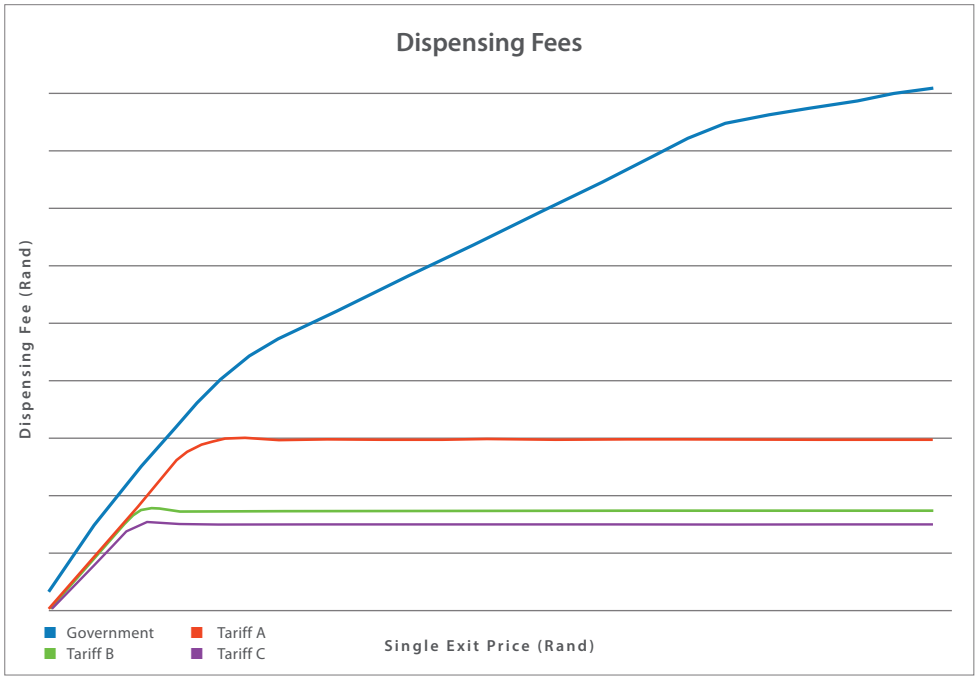
Tariff B: 34.2% of the SEP up to a maximum of R 34.20

Tariff C: 29.64% of the SEP up to a maximum of R 29.64

44 (c) it involves discriminating between those purchasers in terms of –
(i) the price charged for the goods or services;
(ii) any discount, allowance, rebate or credit given or allowed in relation to the supply of goods or services;
(iii) the provision of services in respect of the goods or services; or
(iv) payment for services provided in respect of the goods or services. 2) Despite subsection (1), conduct involving differential treatment of purchasers in terms of any matter listed in paragraph (c) of that subsection is not prohibited price discrimination if the dominant firm establishes that the differential treatment –
(a) makes only reasonable allowance for differences in cost or likely cost of manufacture, distribution, sale, promotion or delivery resulting from the differing places to which, methods by which, or quantities in which, goods or services are supplied to different purchasers;
(b) is constituted by doing acts in good faith to meet a price or benefit offered by a competitor; or
(c) is in response to changing conditions affecting the market for the goods or services concerned, including –
(i) any action in response to the actual or imminent deterioration of perishable goods;
(ii) any action in response to the obsolescence of goods;
(iii) a sale pursuant to a liquidation or sequestration procedure; or
(iv) a sale in good faith in discontinuance of business in the goods or services concerned.

ANNEXURE B – VARIOUS DISPENSING FEES Continued

The degree to which these tariffs fall short of the government maximum increases with the SEP.



It should be noted that none of these tariffs are based on the actual costs of dispensing plus a margin which represents a return on investment. The costs have three elements:

1. The cost of inventory management, ordering of medicines from suppliers, accepting them into stock and storing them.
2. The costs of accepting prescriptions from patents, advising them and dispensing to them.
3. The costs of holding medicines in inventory.

Costs in category 1 can be expected to be roughly constant by medicine, except when special storage requirements, such as refrigeration are necessary. Costs in category 2 in relation to the SEP are probably higher in relation to OTC medicines, where customers rely more on advice given by pharmacists than by doctors and other prescribers of medicine. Costs in category 3 depend directly on the SEP, and they also depend on turnover. Medicines demanded rarely have a higher inventory cost, though this may be managed in part by the size of orders placed with distributors. There are economies of turnover in category 3 costs: the faster the turnover, the lower inventory costs.

The point is this: no dispensing fees set wholly on the basis of the SEP can reflect costs adequately. Moreover, the government dispensing fee is the only one of the four which gives some recognition to the fixed costs in categories 1 and 2. The unintended consequence is that margin varies considerably across medicines dispensed.

Two other issues may be mentioned more briefly:

1. There is tension between doctors and medical aids over appropriate treatments, especially when they are expensive, and cases arise when medical advisers to medical aids call into question treatments carried out, particularly by specialists who are often more qualified and experienced than the medical advisers. These conflicts are exacerbated in cases where medical aids have considerable market power.
2. The balancing of interests between medical aids and the requirements of national health insurance are delicate, and may in part account for the long delay in publishing the government's White Paper on National Health Insurance. It is likely to be highly controversial when it appears and it will have implications for the supply of medicine to the public.

CHAPTER 5:

SOUTH AFRICAN APPLICATION OF WHO PRICING GUIDELINES FOR PHARMACEUTICALS

The World Health Organisation has published a list of pricing guidelines for pharmaceuticals. The table of these guidelines is followed by an assessment of South African capacity to implement them.

	Issues	South African Capacity to deal with issue	Adequate?
1.	**Regulation of mark-ups**		
1.1	Technical capacity	• Government has a mechanism for receiving and processing information for SEP (ceiling) determination. In the process, it considers cost information.	Yes
		• Effects of pricing on supply and distribution not analysed and contentious.	No
1.2	Data required	• Data on ceiling medicine prices published by the state.	Yes
		• Sales volumes in the private sector not collected centrally.	No
1.3	Infrastructure	• Legislation and regulations complicated and frequently revised, so not transparent.	Partly
		• Consultation via publication in the Government Gazette.	Yes
		• No mechanism used to monitor prices actually charged.	No
1.4	Methodological considerations	• Manufacturer/importer prices set by the state after submissions.	Yes
		• Logistic and dispensing charge ceilings set by formula based on manufacturer prices. No public document available on how the formula components were determined.	Partly
2.	**Tax exemptions/reductions for pharmaceutical products**		
2.1	Principles	• VAT charged on all medicine dispensed except medical services and medicines supplied by the State and provincial hospitals and local authority clinics.	Partly
		• Medical aid expenses can be partly deducted in determining personal taxable income. The rules are set out in the state budget. The aggregate amount of foregone tax is known only by SARS and the Treasury.	Partly
2.2	Infrastructure	• SARS VAT and PIT systems.	Yes
2.3	Capture of tax concessions	• Supply chain not able to appropriate tax concessions.	Yes

	Issues	South African Capacity to deal with issue	Adequate?
3.	**Application of cost-plus pricing formulae for pharmaceutical price setting**		
3.1	Technical capacity	• Cost accounting. • Market analysis. • Knowledge of manufacturing practices is the unknown third expertise.	Yes No No
3.2	Data required	• Prices of active pharmaceutical ingredients, excipients, packaging materials, and profits not fully known. • Annual increases applied by the Department. • Applications are made for price reductions by manufacturers. • No information on actual logistics and dispensing fees collected.	No Yes Yes No
3.3	Infrastructure	• Legislation mandating price setting is available. • Information system for collecting the costs of price components in the Department. No analytical data published. • Capacity to verify the information supplied by manufacturers limited or non-existent.	Yes Partly No
4.	**Use of external reference pricing**		
4.1	Technical Capacity	• Databases for medicines in other countries available.	Yes
4.2	Data required	• True negotiated prices not available.	No
4.3	Infrastructure	• Draft legislative framework for use of ERP not finalised. • Reference country choices made but not transparent how. • Procedures on how to apply ERP awaiting finalisation.	No No Partly
5.	**Use of health technology assessment/Pharmaco-economics (HTA)**		
5.1	Technical capacity	• Ability to assess or conduct statistical analyses of data. • Ability to assess or construct economic models.	Yes Yes
5.2	Data required	• Clinical data on efficacy and safety of drugs. • Price structure not available to doctors in usable form.	Yes No
5.3	Infrastructure	• Pharmaco-economics began in South Africa from 1992-1994 as result of the 'push' and 'pull' mechanism: the pull- from the Minister of Health and the managed care organisations and the push from multinational drug producers with established PE departments in US, Europe. In 1996 the National Drug Policy, stated the need for pharmaco-economics in the rationalization of the pricing structure for pharmaceuticals. To date, there is a continuing battle between the Ministry, industry and other stakeholders over the pricing of pharmaceuticals.	No
5.4	Methodological considerations	• The relationship between HTA and pricing of pharmaceuticals not worked out.	No

	Issues	South African Capacity to deal with issue	Adequate?
6.	**Promotion of use of generic medicines (6 Strategies)**		
6.1	Facilitated/accelerated market entry		
6.1.1	Technical Capacity	• None needed.	
6.1.2	Data required	• Assessments for the need for generics are found to be inconclusive.	Partly
6.1.3	Infrastructure	• Generic medicines in policies but not well defined to deal with it.	Partly
6.2	Generic substitution		
6.2.1	Technical Capacity	• Pharmacy personnel trained in appropriate substitution not always found. • Problems with not having a pharmacist on site.	Partly
6.2.2	Data Required	• None needed.	
6.2.3	Infrastructure	• Legislation to allow substitution by dispenser not available. • If substitution is to be mandated, legislation is needed to define circumstances for substitution.	No
6.2.4	Methodology	• Without legislation when and how substitution will be made, i.e. allowed, encouraged, or mandated cannot be known.	No
6.3	Promoting generic competition		
6.3.1	Technical Capacity	• Establishment of manufacturing and production facilities is lacking as there is only one generic manufacturer at present.	No
6.3.2	Data Required	• None needed	
6.3.3	Infrastructure	• Unknown if systems in place regarding number of products available. • Unknown if systems in place to allow for joint manufacturing or pooled procurement.	No
6.3.4	Methodology	• The question of whether competition will be allowed in the industry.	
6.4	IRP (International Reference Prices)		
6.4.1	Technical Capacity	• Data analysis of prices is lacking.	No
6.4.2	Data Required	• No access to prices.	No
6.4.3	Infrastructure	• Procedures on how to apply IRP non existent. • Procedures on how IRP feeds into decision-making process, possibly supported by legislation.	No
6.4.4	Methodology	• Transparency is a must for this.	
6.5	Encouraging use of generics by prescribers/dispensers		
6.5.1	Technical Capacity	• Determination of information to be provided as none is currently.	No
6.5.2	Data Required	• None needed.	
6.5.3	Infrastructure	• Establishment of clearer systems, programmes, and regulations to encourage use of generic medicines.	Partly
6.6	Encouraging use of generics by consumers		
6.6.1	Technical Capacity	• Determination of information to be provided as none is currently.	No
6.6.2	Data Required	• None needed.	
6.6.3	Infrastructure	• Promotion of use of generic medicines by government required but not being done currently.	Yes

CHAPTER 6:

COMPETITION AND REGULATION

PART 1: COMPETITION

1. Relevant sections from the Competition Act:

The Competition Act prohibits restrictive practices. Any concerted practice by firms or decision by an association of firms, is prohibited between parties in a horizontal or vertical relationship if such agreement, practice or association has the effect of substantially preventing or lessening competition in a market, unless such a party to that agreement can prove that any technological efficiency or other pro-competitive gain resulting from it outweighs the anti-competitive effect. The Act also covers abuse of dominance and refusal to deal.

Horizontal agreements / integration

Section 4(1)(a) is limited to technology, productive efficiency or other factors related to the competitive effect of restraint. The horizontal agreements that undermine the most serious of anti-competitiveness include price fixing, market division and collusive tendering.[45] Such prohibitions are carried over from the pre-1998 competition law regulations. The inclusion of the per se rule prohibiting agreements about "any other trading condition" is read narrowly to include factors that are intimately connected with price quality.

Section 4(2) states that:

"An agreement to engage in a restrictive horizontal practice referred to in subsection (1)(b) is presumed to exist between two or more firms if:

a) any one of those firms owns a significant interest in the other, or they have at least one director or substantial shareholder in common; and
b) any combination of those firms engages in that restrictive horizontal practice".

Section 4(3) deals with the presumption in subsection (2) being rebutted "if a firm, director or shareholder concerned establishes that a reasonable basis exists to conclude that the practice referred to in subsection (1)(b) was a normal commercial response to conditions prevailing in that market".

Section 4(4) goes on to define what a director means: namely one who is a director who is defined in terms of the Companies Act, a member of a Close Corporation, a trustee of a trust or a person holding an equivalent position in a firm.

Section 4(5) states that the provisions referred to above in subsection 4(1) do not apply to an "agreement between, or concerted practice engaged in by,

a) a company, its wholly owned subsidiary as contemplated in section 1(5) of the Companies Act, 1973, a wholly owned subsidiary of that subsidiary or any combination of them; or
b) the constituent firms within a single economic entity similar in structure to those referred to in paragraph (a)".

This section makes it clear as to what practices relating to horizontal agreements are prohibited and in what circumstances they are prohibited. It goes on to further define who a director is in terms of a firm which is mentioned in this section and goes on to define instances in which the section will not apply. This clarity allows for this section to be strictly adhered to. However, in certain instances some pharmaceutical companies make agreements and couch it in such terms as to subvert this section.

Vertical agreements / integration

In South African law, a vertical agreement is prohibited if the agreement has the effect to substantially prevent or lessen the competition in a market, unless a party can prove that any technological efficiency or other pro-competitive gain resulting from that agreement outweighs the anti-competitive effect.[46] This is as stated in section 5 of the Competition Act. The only outright prohibition is on resale price maintenance. A supplier may recommend a price as long as it is not binding. If the resale price is labelled then it must be labelled stating that it is a "recommended price". There is only one Tribunal decision on vertical restraint. There exist rulings in place regarding the procedure on dealing with vertical restraint. However these rulings are complex and there still exists ongoing controversy regarding the distribution arrangements for pharmaceutical products.

Dominance being abused in the pharmaceutical sector

Section 8(a) of the Competition Act deals with the issues of excessive pricing and is defined to mean "to have no relationship to economic value and be in excess of that value". The other prohibited practice is refusing a competitor access to an essential facility.[47]

Section 8(b) then defines what this essential facility means: "an infrastructure or resource that cannot reasonably be duplicated without access to which competitors cannot reasonably provide their customers.[48] These two practices are prohibited without considering the net competitive effects. There are a few exemptions which are listed under section 10 of the Act. These exemptions are: if that agreement or practice meets the requirement of subsection 3. The second requirement is a category of practices, if that category of agreements or practices meets the requirements of subsection 3.

45 Competition Law and Policy in South Africa MAY 2003 www.oecd.org Competition Law and Policy in South Africa South Africa aspires to a modern competition policy regime to support the fundamental restructuration of government institutions. This report by the OECD Secretariat which provides an overview of competition law and policy in South Africa was the basis of an in-depth peer review at the 2003 OECD Global Forum on Competition. Useful lessons were drawn from this first peer review of a developing country at this Forum, which gathered about 70 economies at all stages of economic development. This review is part of the OECD's ongoing co-operation with non-member economies around the world. An OECD Peer Review MAY 2003. Pages 21 and 22.
46 IBID.
47 Ibid at page 22.
48 Page 24 of the OECD Review.

Subsection 3 of the Competition Act goes on to state that the Competition Commission may grant an exemption only if:

(a) any restriction imposed on the firms concerned by the agreement or practice concerned, or category of agreements or practices concerned, is required to attain an objective mentioned in paragraph (b); and

(b) the agreement or practice concerned, or category of agreements or practices concerned, contributes to any of the following objectives:

(i) maintenance or promotion of exports;

(ii) promotion of the ability of small businesses, or firms controlled or owned by historically disadvantaged persons, to become competitive;

(iii) change in productive capacity necessary to stop decline in an industry; or

(iv) the economic stability of any industry designated by the Minister, after consulting the Minister responsible for that industry.

The Competition Act in section 8(d) (i) – (v) goes on further to list other acts which are excluded acts. These include requiring or inducing exclusive dealing, refusing to supply scarce goods to a competitor, trying or forcing unrelated contract conditions, selling below marginal or average variable cost and cornering the supply of intermediate goods needed by a competitor.

Dominance is defined in terms of markets and not in terms of firm size alone. There is a provision for general exemption based on firm size; this is to ensure that small firms will not be considered dominant in small markets. The Minister has the power to define a threshold below which the abuse of dominance prohibitions does not apply. This is based upon the turnover or assets which can be defined in either general or specific industries.

Refusal to deal

This occurs in instances where some pharmaceutical corporates own manufacturing/ importing companies. They supply medication to their retail branches only on the basis that they order more or on a larger scale than the privately owned pharmacies. This refusal to deal may create monopolies in the distribution of drugs which have no close substitutes.

2. World Health Organisation Health Pricing Guidelines for Pharmaceuticals: [49]

The WHO sets out six pricing issues:

1. The regulation of mark-ups
2. Tax exemptions / reductions for pharmaceutical products
3. The application of cost plus pricing formulae for pharmaceutical price setting
4. Use of external reference pricing
5. Use of health technology assessment (HTA)
6. Promotion of the use of generics

The position in South Africa with reference to these issues is:

1. The regulation of mark-ups is dealt with by the SEP mechanism. At present, pharmaceutical products must be supplied to retail pharmacies and other non-state dispensers at a SEP set by the Minister of Health. The schedule of SEPs for individual products is reported in a data base maintained by the Medicine Price Registry. Section 22G (3) (b) of the Medicine and Substances Related Act (SAMA) that all persons licensed to sell medicines, may not sell medicine at any other price than the SEP.

Section 22G does not state how or by whom the SEP should be determined. The Regulations (of SAMA) provide for this. The definition of SEP in Regulation 2 and the provisions of Regulation 5 require it to be set by the manufacturer or importer. The Regulations provide that the SEP must be determined by the manufacture/importer of medicines in conjunction with the distributors/wholesaler. Proposed external reference pricing might have a positive effect by lowering the cost of medicine. On the other hand, external reference pricing might lead to a price greater than the existing SEP.

The SEP, thus established, becomes a fixed price at which the product must be sold at every level of the supply chain.[50] The system contemplates that the medicine and scheduled substances will move along the supply chain at a price not higher than the SEP, which is the price at which the medicine or scheduled substance must enter the supply chain.

Wholesalers and distributors are entitled to a logistics fee[51] for their services and pharmacists are entitled to an "appropriate" dispensing fee[52] for their services. Wholesalers, distributors and pharmacists mark up the price of the medicine, and are limited to the fees they are entitled to charge in terms of the Regulations.

49 World Health Organisation Pricing Guidelines Summary.

50 In New clicks at par 223 the Court dealt with sections 22G(2) and (3) of the Medicines Act provide:

(2) The Minister may, on the recommendation of the pricing committee, make regulations—

(a) on the introduction of a transparent pricing system for all medicines and scheduled substances sold in the Republic;

(b) on an appropriate dispensing fee to be charged by a pharmacist or by a person licensed in terms of section 22C(1)(a);

(c) on an appropriate fee to be charged by wholesalers or distributors or any other person selling Schedule 0 medicines.

(3) (a) The transparent pricing system contemplated in subsection (2)(a) shall include a SEP which shall be published as prescribed, and such price shall be the only price at which manufacturers shall sell medicines and scheduled substances to any person other than the State.

(b) No pharmacist or person licensed in terms of section 22C(1)(a) or wholesaler or distributor shall sell a medicine at a price higher than the price contemplated in paragraph (a).

51 Regulation 5(1)

52 S 22G and Regulation 10

Efficiency would be improved if the schedule of approved medicines and their SEP's were available to doctors in easily acceptable form, including the ability to find alternative medicines with the same active ingredient. This would promote co-operation between stakeholders (the Department, doctors, medical aids, pharmacies and other dispensers of medicine).

The dispensing fee is subject to an upper limit set by the Minister and depends on the identity of the dispenser. The logistics fee in respect of distribution is identified as a component of the SEP, and so is VAT.

These regulations emanate from MARSA. Regulations 5, 7 and 8 deal with SEP. Regulation 7 states that the SEP may only subject to regulations 5, 8 and 9 be increased once a year. Regulation 8 and regulation 9 both deal with the conditions for the SEP. Regulation 9 deals with the increasing of the SEP.

Section 18A of MARSA deals with the supply of any medicine according to bonus system, rebate or any other incentive scheme. The provisions of this section are broadly worded and may apply to a number of transactions.[53]

Proposed amendments to Section 18A add the terms such as bonus system, rebate system, discounts and unacceptable advertising fees:

- unacceptable credit payment;
- unacceptable data fees;
- unacceptable fees paid to induce and/or encourage biased sale of a particular medicine or schedule product;
- discounts;
- formulary listing payments;
- kickbacks and perverse incentives;
- loyalty fees or similar fees or prizes or rewards;
- unacceptable marketing fees and/or co-marketing fees;
- shelf space fees;
- directors' fees, honoraria and similar compensation paid to a healthcare professional or any person who is in a position to potentially influence medicine choice, where such professional or other person actually do not perform any services or work for which they are purportedly being remunerated; and/or
- fees, enrichment of or benefit provided to a healthcare professional, administrative staff or any business enterprise or healthcare establishment in the healthcare sector which fee, enrichment or benefit is provided on the understanding that the health establishment or professional will give preference to, or encourage the purchase, sale, prescription, dispensing, use or recommendation of a particular medicine or medicines in return for such fee, enrichment or benefit other incentive scheme.

Other changes to this section include the definitions of business enterprise and a definition as to what is or is not a discount.

There are also specific definitions for the terms end-user, end-dispenser, logistical services and logistics fee cap. These definitions are important in that there is a proposed revised definition of SEP. This definition differs from the current definition concerning the application of a logistics fee and a price determined by the manufacturer or importer of a medicine to the ex-manufacturer price determined by the manufacturer or importer of a medicine or scheduled substance in terms of these regulations combined with the logistics fee and VAT and is the price of the lowest unit of the medicine or scheduled substance within a pack multiplied by the number of units in the pack.[54]

The Director-General must confirm the correctness of the SEP in consultation with the public.

The SEP must now be viewed in the calculation of the logistics fee. The SEP is now comprised of four components which are: the manufacturer's price, the logistics fee, the dispensing fee, and VAT.

Logistical services are according to the proposed amendment the following:

- receiving of medicines or scheduled substances;
- warehousing of medicines or scheduled substances;
- proper inventory control and rotation;
- taking orders from end dispensers;
- delivery of orders to end dispensers;
- provision of emergency deliveries to end dispensers where required;
- proper record keeping;
- batch tracking and tracing;
- ability to maintain cold chain storage and distribution where necessary;
- returning products to manufacturers when required; and
- having and operating a debtor's control system which conforms to accepted accounting norms.

The above need to be considered in light of the definitions of rebate, incentive and discount schemes that are stated in the draft regulations. In addition, logistical services may only be provided by logistics service providers who, in turn, must be licensed to provide such services in terms of section 22C of MARSA.

53 THE TIGHTENING OF THE NOOSE By: Neil Kirby, Director
54 Ibid Neil Kirby Article. http://www.werksmans.com/legal-briefs-view/the-tightening-of-the-noose/

Proposed amendments to the regulations also deal with:

- the manner in which the SEP for medicines is to be reflected on medicine containers;
- the adjustment of the SEP in terms of independent reviews of the prices determined by the manufacturer or logistics fee components of the SEP by the regulatory authorities;
- the increase of the SEP annually, more particularly, the criteria that the Minister of Health takes into account before allowing any increases to a SEP. Those criteria include the average consumer price index for the preceding year, foreign exchange rates, international pricing information, comments from interested and affected parties and the need to insure the availability, affordability and quality of medicines and scheduled substances in the Republic;
- exemptions and exclusions to the increase of the SEP which are intended to be provided only with reference to the criteria that the Minister may use to determine such an exemption or exclusion; and
- powers afforded to the Director-General of the DoH to obtain, from a range of persons concerned with the supply of medicine, information relating to the pricing of that medicine. This is an important change in the powers afforded to the Director-General especially in relation to the amendment of the definitions and introduction of the definition of "bonus system, rebate system or any other incentive scheme" as the power to police the introduction of such schemes is now afforded to the Director-General within the context of the SEP regulations a power that rests within the amendments proposed to regulation 22 of the SEP regulations.[55]

The issue with the draft regulations is that, although there are definitions for the bonus system, the rebate system and other incentive schemes, the definitions are lengthy, which can cause problems of interpretation. The amendments are also vague.

Prices are partly controlled by standard software systems used by many pharmacies which incorporate SEPs. There appears to be no inspection of pharmacies on price control issues.

2. Pharmaceutical products are all subject to VAT, except medicines supplied by the central government, provincial hospitals and public sector clinics.

3. See 1.

4. External reference pricing could be a possible consideration. But the system is not in place yet, so the capacity to operate an external reference pricing system has not been tested. In its absence, manufacturers and importers propose prices to the DoH at the time when they first come on to the market. Thereafter, price increases are subject to an annual cap imposed by the Minister of Health, unless the manufacturer or importer can demonstrate that a higher price is needed for a product to remain available. Manufacturers and importers can apply for temporary or permanent price decreases. The DoH can initiate investigations in cases where the price of products seems unreasonably high.

   Medicine price data bases in other countries for medicines are available. The draft regulations are not transparent on how they will be used.

   Countries which use external price referencing are, for example, Brazil, Hungary, Jordan, UAE, Iran and South Africa to name a few which were used in a Study by the WHO / HAI Project on Medicine Prices and Availability which conducted a study into external price referencing.[56] The results are as follows:

55 Ibid.
56 WHO/HAI Project on Medicine Prices and Availability Review Series on Pharmaceutical Pricing Policies and Interventions Working Paper 1: External Reference Pricing May 2011 Jaime Espin, Joan Rovira and Antonio Olry de Labry, Andalusian School of Public Health at page 15.

Table: Summary table of key case study results[57]

Country	Price Setting	Products External Reference Pricing (ERP)	Countries	Price Used	Criteria	Sources of information
Brazil	Agência Nacional de Vigilância Sanitária (ANVISA)	On patent (Category I)	USA, Canada, Portugal, Spain, France, Italy, Greece, New Zealand and Australia	Ex-factory	Minimum	Websites
Czech Republic	SUKL (State Institute for Drug Control) – maximum prices/ reimbursement prices/ Health funds – price negotiations	Reimbursable	For pricing: Estonia, France, Italy, Lithuania, Hungary, Portugal, Greece, and Spain For reimbursement: all EU countries	Ex-factory	Average	Websites; Manufacturer
Hungary	National Health Insurance Fund Administration (OEP)	Reimbursable (new active substances)	Countries in the European Union and European Economic Area	Ex-factory	Minimum	Websites; Manufacturer
Iran	Pricing Commission	On-patent and imported	Greece, Spain, Turkey and the country of origin	Ex-factory and wholesaler	Minimum	Manufacturer
Jordan	Pricing committee of the Jordan Food and Drug Administration (FJDA)	All products	Selected European countries (UK, France, Spain, Italy, Belgium, Greece and the Netherlands), the export price to Kingdom of Saudi Arabia, and the country of origin	Ex-factory price of the reimbursed price	Median	Websites; Manufacturer
Lebanon	Pricing Committee – MoH	On- and off-patent products	Region: Jordan, Kingdom of Saudi Arabia, Kuwait, Sultanate of Oman, United Arab Emirates, Bahrain and Qatar. Comparative: France, England, Belgium, Switzerland, Italy, Spain and Portugal	All	Minimum	Manufacturer
South Africa	Pharmaceutical Economic Evaluations (PEE) Directorate	On- and off-patent products	Australia, New Zealand, Spain, and Canada	Ex-factory and import	Minimum	Manufacturer
Sultanate of Oman	Directorate General of Pharmaceutical Affairs & Drugs Control	All products	Gulf Cooperation Council (GCC) countries: Kingdom of Saudi Arabia, United Arab Emirates, Bahrain, Kuwait, and Qatar	Import price CIF (cost, insurance & freight)	Minimum	Manufacturer
United Arab Emirates	Committee – MoH	All products (some exceptions)	Country of origin and Gulf Cooperation Council (GCC) countries: Kingdom of Saudi Arabia, Kuwait, Bahrain, Qatar, and the Sultanate of Oman	Ex-factory and import	Minimum	Websites; Manufacturer

The countries selected for external referencing are Australia, Canada, New Zealand and Spain.

Use of HTA in respect of pharmaceuticals involves priority-setting, selection, procurement supply system management, and benefits management including pharmaceutical formularies. The state publishes an essential medicines list which controls medicines available at public facilities. Access to generics is controlled by the MCC and what manufacturers and importers are willing to supply. South Africa has the capacity for clinical testing. However, availability of medicines is limited by a large backlog in clinical testing of new products.

57 WHO/HAI Project on Medicine Prices and Availability Review Series on Pharmaceutical Pricing Policies and Interventions Working Paper 1: External Reference Pricing at page 15 accessible on: http://www.haiweb.org/medicineprices/05062011/ERP%20final%20May2011.pdf

5. The promotion of the use of generic medicines which has several components:
   - facilitated/accelerated market entry, particularly important in light of the medicines approval backlog;
   - pharmacists, and particularly pharmacist assistants, need to be trained to be able to offer appropriate generic substitution. This then impacts on the substitution effect which means an effect caused by a rise in price that induces a consumer (whose income has remained the same) to buy more of a relatively lower-priced good and less of a higher-priced one. The substitution effect is always negative: consumers switch from spending on higher-priced goods to lower-priced ones as they attempt to maintain their living standard;[58] and
   - South Africa relies heavily on imported generics. For example, South Africa is the world's largest consumer of ARV's yet it imports almost all of its ARV's.[59] The Department of Trade and Industry seeks to promote the sector, but according to the industry the main challenges affecting its financial performance and dampening investment appetite are: (i) the impact of price controls on medicines, and (ii) regulatory delays – poor performance of the MCC.

An assessment of the role of competition in a regulated market

There are eight generic local South African manufacturers and distributors in the sector and 25 foreign originators selling drugs in the South African Market. The sector then has a large imbalance and therefore it results in a limited capacity to manufacture active pharmaceutical ingredients.

There exist two forms of competition. The first form is competition amongst different originator brand name drugs designed to treat the same or similar conditions. The second form of competition exists between generic manufacturers of drugs that are equivalent to branded drugs.

The following competition issues are of particular interest.

1. *Pricing power when no close substitute for a medicine is available*

   Pricing power will increase in this case as the consumer now has no alternative. Regulation of the SEP, especially when external reference pricing is introduced, is the only remedy for abuse of market power.

A sample of 124 active ingredients was selected from the 14 August 2015 version of the South African Medical Price Registry's data base. The following supply conditions were found:

- One originator medicine only 33%
- One generic medicine only 5%
- More than one originator, no generic 6%
- More than one generic, no originator 8%
- At least one originator and at least one generic 48%

2. *The role of medical aids in setting dispensing fees by agreement with pharmacies and its impact on competition*

   The DSP can be problematic here as medical aids then restrict choice by the consumer. On the other hand, consumers benefit from lower dispensing fees.

3. *Implications of dealing patterns which may cut retailers out of certain product lines*

   This impacts on smaller pharmacies when large vertically integrated pharmaceutical companies may refuse to deal with the smaller companies. The reason for this refusal to deal with smaller pharmacies is that the smaller companies cannot place large orders. This then leads to an anti-competitive situation as the smaller pharmaceutical companies are at a disadvantage. This problem could be removed by appropriate regulation which would be in line with the general approach to the pricing of medicine.

4. *The impact of large retailers on availability of space in malls for competitors*

   There is a trend where the bigger companies approach malls and negotiate agreements with the malls to rent a large space for their pharmaceutical companies at a lower rental per square metre than smaller retailers. Moreover, there appear to have been cases where small pharmacies have been strong-armed out of malls. This then leads to the smaller companies closing down and moving away.

   According to regulation 7 dealing with ownership of pharmacies[60], when a pharmaceutical service applies to open in a certain area the application must include, amongst other criteria, the location to which the premises is going to operate from, the benefit to the members of that community as well as the approximate number of the population that pharmaceutical service will serve. There also is a lack of oversight on this issue, even though there exists an oversight body called the South African Pharmacy Council which is there to ensure that acceptable standards of practice in the pharmaceutical sector exist.[61] This, however, is not an effective oversight mechanism as these abusive practices still occur and will continue until the Council implements an effective way to oversee and monitor the issues discussed above.

57 WHO/HAI Project on Medicine Prices and Availability Review Series on Pharmaceutical Pricing Policies and Interventions Working Paper 1: External Reference Pricing at page 15 accessible on: http://www.haiweb.org/medicineprices/05062011/ERP%20final%20May2011.pdf
58 http://www.businessdictionary.com/definition/substitution-effect.html
59 Organisation for Economic Co-operation and Development, DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS COMPETITION COMMITTEE, 05-Jun-2014 at page 2.
60 Ownership and licensing of Pharmacies GN R553 of 2003.
61 http://www.pharmcouncil.co.za/B_Prac_Overview.asp.

5. Vertical Integration Issues

1. There is no transparency as to how the manufacturer/importer price is established. Importers can apply for anything they see fit, and there has been little intervention to cap SEP's. External reference pricing may help when it is introduced.
2. There is no transparency as to how the logistics fee is established. This is very problematic in light of the above mentioned vertical integration that has occurred.
3. Combining the logistics fee with the manufacturer/importer price encourages the integration of manufactures and distributors.
4. Distributors that are controlled by importers allow companies to shift cost between the core price and the logistics fee without it affecting their net profit on the sale of particular drug.

Court cases dealing with competition issues in pharmaceuticals

Hazel Tau Case

In 2002, a range of individuals and organisations laid a complaint against two multinational pharmaceutical companies, GlaxoSmithKline and Boehringer Ingelheim, alleging that they were abusing their market dominance by charging excessive prices for their patented ARV medicines. This case is known as the Hazel Tau case.

The complainants argued that the prices charged by GlaxoSmithKline and Boehringer for certain ARV medicines could not be justified – even when taking into account the costs of production, research and development, and an appropriate rate of profit. The Competition Commission investigated the case and found solid evidence to support the complaint. It therefore decided to refer the complaint to the Tribunal on three grounds, including prohibited excessive pricing.

In order to avoid a final legal decision on this issue, GlaxoSmithKline and Boehringer entered into an out-of-court settlement with the complainants. They agreed to license generic competitors to manufacture and/or import generic ARV medicines, and to sell those medicines that were manufactured locally throughout most of Africa. This competition has resulted in lower prices for the ARV medicines in dispute.[62]

Conclusion

In a heavily regulated system, there is limited scope for competition. Competition in service is always possible. Big, vertically integrated pharmaceutical companies have market power, often as a result of loopholes in the system and lack of monitoring, to the detriment of the smaller pharmacies.

Patients, health care providers, medical aids and the government

Apart from the burden of disease, the pattern of demand for medicine is determined by the interaction between health care providers, medical aids and the government. Each has interests which compete with the others.

1. Patients want their health care problems to be dealt with as effectively as possible at the lowest possible cost.
2. Health care providers have a duty to act in accordance with their professional judgements, and a reasonable expectation that their judgements will be respected. They also have a degree of pricing power, more marked among specialists than among general practitioners.
3. In the case of mutual medical aid schemes, members have an interest in keeping their contributions as low as possible and will therefore support cost containment measures by medical aid schemes, provided that they do not compromise standards of care. In the case of medical aid schemes run by companies, the imperative for cost containment is also present, but the optimising health outcome is one which minimises absence from work. In the case of for-profit medical aid schemes, profit maximization is the objective. How this translates into outcomes for members depends on how competitive the market is. Pricing power translates into both super-normal profits and less adequate patient care.
4. Government has the most complex interests of all. It has a clear interest in cost containment, especially in the part of the health system it directly finances. It clearly desires transformation of the current bifurcated public/private system into a unitary system in which minimum standards of care increase and are not dependent on the income of patients. At times, this has led to hostility to medical aids in general as schemes of middle class risk pooling at the expense of other parts of the population. National health insurance implies national risk pooling and mechanisms have been proposed to achieve this. On the other hand, it has a duty to regulate medical aid schemes and the principal instrument it uses is the definition of prescribed minimum benefits (PMBs) which every medical aid scheme must cover.

The result is a complex system of push and push-backs in relation to the distribution of risk and benefit, as well as to unintended consequences of actions and policies at any point in time. For instance, the system of PMB has been contested continually. Inserted here is a recent HSF brief on amendments to Regulation 8 of the Medical Schemes Act, which illustrates the difficulties of rationalizing the system.

62 http://www.section27.org.za/wp-content/uploads/2010/04/Chapter14.pdf at page 463.

BRIEF ANNEXURE: THE AMENDMENT TO REGULATION 8 OF THE MEDICAL SCHEMES ACT, WHAT DOES IT MEAN? [63]

This Brief discusses the amendment to Regulation 8 of the Medical Schemes Act and what it actually means to members of medical schemes and other stakeholders.

Introduction

Regulation 8 of the Medical Schemes Act 131 of 1998 deals with Prescribed Minimum Benefits (PMBs) for a range of 270 medical conditions.[64] Every medical aid scheme must cover all these conditions. Specifically, Regulation 8 sets out rules for the payment for expenses of the diagnosis, treatment and care costs of a PMB benefit condition. These payments are met by the medical aid scheme with copayments by members under certain conditions.

A draft amendment was circulated by the DoH on 14 July 2015. Neil Nair of Principal Officer of SAMWUMED[65] has described it as follows:

> " The fundamental implication of the amendment, when passed by Parliament, shall mean that all registered healthcare providers subscribe to a regulated tariff ".

But what the amended regulation means is not luminously clear. We have struggled to interpret it and we offer our understanding below. If we have it wrong, we would welcome correction.

Regulation 8 states (amendment in italics):

(1) Subject to the provisions of this regulation, any benefit option that is offered by a medical scheme must pay in full, without co-payment or the use of deductibles, the diagnosis, treatment and care costs of the prescribed minimum benefit conditions.

(2) Subject to section 29 (1) (p) of the Act, the rules of a medical scheme may, in respect of any benefit option, provide that— (a) the diagnosis, treatment and care costs of a prescribed minimum benefit condition will only be paid in full by the medical scheme if those services are obtained from a DSP in respect of that condition;

(b) a co-payment or deductible, the quantum of which is specified in the rules of the medical scheme, may be imposed on a member if that member or his or her dependant obtains such services from a provider other than a DSP, provided that no co-payment or deductible is payable by a member if the service was involuntarily obtained from a provider other than a DSP and:

either

> *(i) in respect of any service rendered by a health care professional who is registered with the HPCSA, medical schemes are liable for payment for services in accordance with the billing rules and the tariff codes of the 2006 NHRPL tariffs published by the Council, the Rand value of which has been adjusted annually in accordance with the Consumer Price Index as published by Statistics South Africa;*

or

> *(ii) schemes may negotiate alternative tariffs with any provider of any relevant health service for which no co-payment or deductible is payable by a member*

(3) For the purposes of sub-regulation (2) (b), a beneficiary will be deemed to have involuntarily obtained a service from a provider other than a DSP, if – (a), (b) and (c) the service was not available from the DSP or would not be provided without unreasonable delay; (b) immediate medical or surgical treatment for a prescribed minimum benefit condition was required under circumstances or at locations which reasonably precluded the beneficiary from obtaining such treatment from a DSP; or (c) there was no DSP within reasonable proximity to the beneficiary's ordinary place of business or personal residence.

(4) Subject to sub-regulations (5) and (6) and to section 29 (1) (p) of the Act, these regulations must not be construed to prevent medical schemes from employing appropriate interventions aimed at improving the efficiency and effectiveness of health care provision, including such techniques as requirements for pre-authorisation, the application of treatment protocols, and the use of formularies.

(5) When a formulary includes a drug that is clinically appropriate and effective for the treatment of a prescribed minimum benefit condition suffered by a beneficiary, and that beneficiary knowingly declines the formulary drug and opts to use another drug instead, the scheme may impose a co-payment on the relevant member.

(6) A medical scheme may not prohibit, or enter into an arrangement or contract that prohibits, the initiation of an appropriate intervention by a health care provider prior to receiving authorisation from the medical scheme or any other party, in respect of an emergency medical condition.

The logic of Regulation 8 as amended:

Expenses incurred by a medical aid scheme member for a PMB condition are met by the scheme, with or without a copayment by the member. Our understanding of the logic that the amended Regulation 8 sets up can be put as follows:

1. Does the medical aid scheme designate service providers?
   If the answer is NO, there is no copayment by the member.
   If the answer is YES, go to Question 2.

2. Was the service provided by a DSP?
   If the answer is YES, there is no copayment by the member.
   If the answer is NO, go to Question 3.

3. Was the choice of a non-designated provider voluntary (see subsection 3 above)?
   If the answer is NO, there is no copayment by the member.

63 Brief written By Arvitha Doodnath and published on Medical Brief accessible on: http://www.medicalbrief.co.za/archives/hsfs-positive-analysis-of-regulation-8-changes/

If the answer is YES, go to Question 4.

4. Has the medical aid negotiated an alternative tariff with the non-designated provider?
   If the answer is YES, there is no copayment by the member (see subsection 2(b)(ii)).
   If the answer is NO, a copayment equal to the difference to the fee charged by the provider and the NHRPL tariff is due from the member.

What does this mean for medical aid scheme members?

The regulation as amended means that in most cases, a member of a medical aid scheme will not have to make a copayment for expenses incurred for a PMB condition. The exception is when a member of a scheme with DSPs chooses a non-designated provider voluntarily and the scheme has not negotiated an alternative tariff with that provider.

Accordingly, we are puzzled by the SAMWUMED statement. We don't see that the amended regulation 8 was implying that all registered healthcare providers subscribe to a regulated tariff. For one thing, different medical aid schemes may set different tariffs for the same service when they designate service providers. Secondly, when medical aid schemes negotiate with non-DSPs, new differences in tariffs may emerge. Thirdly, non-DSPs with no medical aid scheme contracts remain free to set their own tariffs.

Rather, it seems to us that the main effect of the amendment is to establish a minimum medical aid scheme contribution (equal to the NHRPL tariff) in cases where copayments are required. This was not done by the unamended regulation 8. Of course, the amendment like the current regulation 8 means that the consumer may have to meet large co-payments under certain circumstances.[66] In a July interview with the DoH Head of Regulation and Compliance, Anban Pillay, stated that patients did face risks but he assured the Board of Healthcare Funders that consumers would be protected.[67]

Umunyana Rugege from Section 27 has observed that medical aid scheme members will no longer have the certainty as to whether their emergency, chronic conditions or cancer illnesses will be paid in full.[68] She went on to state that the Minister of Health's proposals have not been accompanied by any policy documents or analysis of the medical schemes industry. Section 27 also stated in a press statement issued on 24 July that, even though the amendment does refer to the 2006 NHRPL Tariff, this tariff was intended to be an interim measure, and, even at the time when it was introduced, it did not reflect the actual cost of providing health care services.[69]

On our interpretation, medical aid members will be able to avoid copayments if they wish to. Where service providers are designated, their use will not attract copayment. Moreover, copayments will not be required if, in an emergency, a non-designated provider has to be used. In non-emergency situations, medical aid members will have to weigh up the benefits of using a non-designated provider against the cost of copayments. This calculation will be made if a member expects superior service from a non-designated provider.

More controversy around regulation 8 and PMBs

The Genesis Medical Scheme wants the Cape Town High Court to get rid of the requirement that schemes pay for the PMB in full. Genesis states that the regulations under the Medical Schemes Act have no legal standing, since they go beyond the powers afforded to the Minister. Genesis CE Brian Watson said that "a better question to ask is: are doctors charges justified? The real issue is doctors are being given a blank cheque".[70] Some believe that Genesis has gone to Court on the basis that it faced potentially ruinous claims for PMB conditions; however this was denied by Mr Watson.[71]

The South African Private Practitioners Forum is challenging Genesis's Court application and a multitude of parties, including the Council for Medical Schemes, HASA and the South African Private Practitioners Forum have also applied to oppose such an application. Treatment Action Campaign (TAC), South African Depression and Anxiety Group (SADAG) and People Living with Cancer (PLWC) have applied to be friends of the court in this matter. These groups argue that the Minister has the power to make regulation 8 and that regulation 8 is necessary to give effect to the right to access healthcare services under section 27 of the Constitution.[72]

Dr Archer from the South African Private Practitioners Forum stated that the amendments offered protection to medical schemes at the expense of the consumer as it allowed them to limit their exposure to a reimbursement rate set in 2006 (as stated above).[73]

Conclusion

Regulation 8 and the proposed amendments have attracted criticism by various stakeholders. It seems to us that this amendment is intended to balance protection of members against the protection of medical aid schemes in light of very high claims. Will it work? Only time will tell.

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64 http://www.medicalschemes.com/medical_schemes_pmb/
65 http://www.health24.com/Medical-schemes/News/Medical-Schemes-Act-proposed-amendments-to-PMBs-20150721
66 Council for Medical Schemes speaks on PMBs by Tamar Kahn accessible on: http://www.bdlive.co.za/national/2015/07/31/council-for-medical-schemes-speaks-on-prescribed-minimum-benefits
67 Ibid.
68 Medical aid change to benefit funders by Tamar Kahn accessible on: http://www.bdlive.co.za/national/health/2015/07/20/medical-aid-change-to-benefit-funders
69 Hands off our PMBs by Section 27 issued 24 July 2015 accessible on: http://section27.org.za/2015/07/patient-groups-hands-off-our-pmbs/
70 Doctors and Genesis scheme in benefits row by Tamar Kahn accessible on: http://www.bdlive.co.za/national/health/2015/08/13/doctors-and-genesis-scheme-in-benefits-row
71 Ibid.
72 Note 5 above.
73 Ibid.

CHAPTER 7:

THE RESULTS OF A SURVEY OF THE STRESSES AND PROBLEMS IN THE DELIVERY OF PHARMACEUTICALS IN SOUTH AFRICA

The following information contains details on anti-competitive practices existing within the pharmaceutical sector. It emanates from the survey the *HSF* conducted in which we sought to understand the various players in the sector in terms of the wider supply chain of medicines.

Our samples represent the following seven categories of key players participating in the distribution of medicines to the general public within the pharmaceutical industry:

- Corporate public or private hospitals
- General public or private hospitals
- Some government hospitals
- Medical Aid Schemes
- Dispensing doctors
- Manufacturers
- Distributors/Wholesalers

All the respondents were located in Gauteng.

The table below contains details regarding the number of respondents that participated in the survey according to each category.

Clinics	**Number of respondents**
Public Sector Clinics	2
Private Sector Clinics	1
Hospitals	
Public Hospitals	2
Private Hospitals	2
Medical Aid Schemes	
Public Sector Medical Aid Schemes	1
Private Sector Medical Aid Schemes	2
Others	
Dispensing Doctors	2
Corporate Retailers	2
Individual Retailers	1
Manufacturers	2
Distributors/Wholesalers	2
Total	**19**

Listed below is the collated version of results from the surveys conducted on the various stakeholders:

Clinics – C

Public Sector clinics

a) Clinic – C1

The respondents from C1 clinic reported that the clinic keeps and dispenses medicines and that it has the authority to give prescribed medication to patients. A variety of medications are dispensed for various illnesses, which includes cases such as Tuberculosis (TB) and Human Immunodeficiency Virus (HIV). It also reported that high blood pressure and paediatric conditions are also prevalent.

The clinic is allowed to prescribe Schedule 1-4 medicines. Schedule 5+ prescriptions can only be authorised by the presiding medical doctor and not the nursing sisters at the clinic. Schedule 5+ medicines are prescribed only when a medical doctor comes to the clinic, once a week.

Referrals of cases to hospitals are not so high at this clinic. Between 10% and 20% are referred. Referrals to hospitals are either because doctors are not present to cases requiring their attention or because patients present an illness that can only be treated in hospitals. The respondents from the C1 clinic did indicate, however, that while they are only allowed to treat minor illnesses and refer major ones onto hospitals, they seldom receive bad cases that call for a referral to hospitals.

The clinic gets medicines from the provincial pharmacy, which is located in Langlaagte in Auckland Park, Johannesburg. Langlaagte is the main Provincial storehouse which dispenses medicines to local health facilities including clinics. Langlaagte receives medicines from large distributors and then supplies them according to need as indicated by the public health care facilities concerned.

The storehouse does not always have a sufficient supply of medicines. The clinic reported that running out of medicines has become a frequent occurrence and this problem impacts negatively on medical services they render. In the event that medicine is unavailable, nursing sisters at the clinic advise that they return at a later date when the clinic would have received new stock from the Provincial storehouse.

In addition, the shortage of nurses is hampering the quality of health services being rendered to the patients visiting the clinic on daily basis. The acute shortage of visiting doctors is not helping either. The clinic C1 has reported that patients are often angered if they need treatment only to find that there is a shortage of medicines. The clinic says that the shortage of medicines has been more frequent recently.

b) Clinic – C2

Like clinic C1, clinic C2 reported that it keeps and dispenses medicines. The medicines which they prescribe cater for minor conditions as well as chronic cases such as TB and Antiretroviral drugs for patients living with HIV. The clinic has the authority to prescribe these medicines immediately.

The response from clinic C2 did not indicate the type of medicines the nursing staff at the clinic can or cannot prescribe. This question was evaded by the respondent from the clinic who gave a very ambiguous response, stating that nurses are qualified according to guidelines and protocols prescribed. The same response was given in terms of the type of medicines the doctors can and cannot prescribe for patients. The response was equally evasive as to how often medicines are prescribed by doctors on duty when they are available.

Clinic C2 refers a very insignificant 0.5% of patients who report to the clinic on to hospitals. This happens in complicated cases which may require the attention of hospital health care professionals/services that the clinic does not have in the facility. As to the meaning of what complicated really entails, this was not indicated by the respondents from clinic C2 except to say that nursing sisters follow guidelines and protocols before they could refer cases on to hospitals.

The clinic receives their medicine stockpile from the Langlaagte storehouse. Just like clinic C1, these medicines do have a tendency to run out and it happens very often. The clinic did not wish to disclose the advice which they give to patients in need of medicines in the event that there is a shortage of medicines. Clinic C2 stated that they are not responsible for price determinations for medicines which are determined by the Langlaagte storehouse.

Unlike in the case of clinic C1, which reported the shortage of medicines as the key concern, clinic C2 lamented the unavailability of pharmacy assistants in their clinic as the problem. This adds to the burden on the limited nursing resources confronting the clinic.

Private Sector Clinics

a) Clinic – C3

Unlike the two clinics in the public sector, clinic C3 reported that it neither keeps nor dispenses medicines. It only gives prescriptions. The doctor is available every morning and he writes scripts for patients to buy their medicines from the pharmacy. As for the type of medicines the nursing sisters can prescribe; these are OTC medicines, such as, for example, paracetamol. Any other medication is left for the doctor to prescribe. These medicines are classified as Schedule 4 and above. In the event that the doctor is unavailable to make a prescription and the required medicine falls out of the 'OTC' cluster, the nursing staff usually recommends medicines to patients. Nursing sisters are also allowed to vaccinate patients in the event that patients request for such a service.

Similarly to the clinics in the public sector, the referral rate to hospitals is quite low in this clinic. In a month, about one or two cases are referred to hospitals and, this usually concerns cases such as cancer-related illnesses as well as complicated HIV cases.

Since the clinic only prescribes and does not dispense nor keep medicines, patients are only charged a fee for health care services used at the clinic. Prices of medicines are determined by the pharmacy and not the clinic itself. This is despite the fact that clinic C3 is under the same control as the pharmacy which is located right next to it. Unlike the two clinics in the public health sector, clinic C3 never runs out of medicines as the pharmacy located right next door is always well stocked with supplies.

HOSPITALS – H

Public Sector Hospitals

a) Hospital – H1

The respondent at hospital H1 indicated that they order medicines from Langlaagte in Auckland Park as every hospital has a depot. Langlaagte makes a direct delivery of medicines to hospitals and through the Provincial Medicines Procurement Unit as well. Medicines cannot be ordered via private suppliers, but only through Langlaagte depot and the Provincial Medicines Procurement Unit.

To keep track of stock of medicines, the hospital makes use of bin cards as well as a computerised system that tells them how much to order according to categories of medicines normally in use. While the hospital does have a system to keep pace with the dispensing of medicines in place, problems abound relating to shortage of medicines.

This makes it difficult for the hospitals to keep adequate inventory. There is a breakdown in communication between hospital management and dispensary in the hospitals, with pharmacists not being informed of termination of tenders in terms of which medicines are supplied to the province. In the event of medicines running out and no supply of medicine from Langlaagte forthcoming, the hospital borrows from other hospitals where possible. If that options fails, the hospital simply buys out.

The process of delivering medicines to the patient at hospital H1 follows the following process: for the out-patient, the doctors issue a prescription to the out-patients department (OPD). The patient then stands in the queue, scripts are found and the pharmacies dispense medication to the patient. In this hospital, outpatients are given medicines that will last them for two months, as it results in fewer shortages. In the case of the in-patient, however, wards have stock of basic medications, and other specific medicines are dispensed by the pharmacies when needed.

The general view of pharmacists at hospital H1 is that pharmacists are overworked. What they find to be particularly disturbing is the inefficient delivery of medicines, and that the process of appointment and termination of tenders either aren't adhered to or are simply too complicated to understand in full. Black Economic Empowerment requirements mean that it takes too long to appoint suppliers. All these factors adversely affect availability of medicines at the hospital. Moreover, buy-outs (purchases outside the public system) are difficult, unless backed by the motivation of a doctor. Doctors are reluctant to do that.

b) Hospital – H2

Hospital H2 has appointed a tenderer, who is responsible for the supply of its medicines. These medicines are ordered via the medical supplies department as well as the provincial medicines procurement. Unlike hospital H1, which has indicated that they only receive medicines from the provincial storehouse in Langlaagte and very rarely from private suppliers, at hospital H2 medicines can be supplied by private suppliers who are referred to as direct drug deliveries. The procedure for ordering of medicines is through the medical supply unit; however medicines are delivered directly from the company that supplies medicines.

To ensure that the hospital does not run out of hospital supplies, the bin card system is in place, similar to that used at hospital H1, which is intended to monitor the supply. A computerised system is also in place and is run alongside the bin card system, which allows the dispensary to have access to all inventories on hand. This system allows the levels to be kept in control. Orders are placed weekly.

While the system of monitoring medicines levels is up and running, it does not guarantee constant availability of medicines. The hospital reported that time and again they run out of stock. While hospital H1 cited the inefficient awarding of the tender system as the predominant reason, at H2 hospital, various reasons were cited. These include suppliers not delivering medicines on time, companies unable to honour tender agreements, shortage of active pharmaceutical ingredients at the hospital, expiry of contracts, as well as tenders not being renewed.

Concerning the issue of dispensing medicines to patients, the following process takes form at hospital H2. Generally, a patient ought to consult with a doctor, who is then written a prescription to be presented to the pharmacy/dispensary, a script is then compiled and dispensed. The hospital reported that the process works well; however, staff shortages and time constraints impact negatively on the smooth running of operations at dispensary. This is usually indicated by patients who usually complain about waiting in long queues at the pharmacy. The pharmacist advises the patients on how to make use of the medicine, the side effects associated with the usage, and the special precautions s/he must take into consideration.

Private Sector Hospitals

a) Hospital – H3

Unlike in the public sector, the pharmacy at hospital H3 is run independently from the main hospital administration and has an entirely different management system. The pharmacy rents out the space from the hospital. The hospital management appreciates the convenience of the pharmacy being located within their premises to the benefit of the patients.

The doctors have complete liberty to prescribe their medicines of choice, since they are independent practitioners. Usually pharmacies advise patients to opt for generic medicines. To this end programmes like antimicrobial stewardship have been implemented to reduce utilisation and waste. Usually in-patients are not empowered to make that decision unless they insist on a specific brand. Generally, in-patients do not pay dispensing or professional fees, whereas out-patients are required to do so.

Concerning whether the hospital was experiencing any problems with the SEP, the respondents indicated that the SEP forced the hospital to change the model in place at the time. Before the SEP was introduced, the hospital had products marked up. Now no professional fees are allowed.

Like those hospitals in the public sector, hospital H3 has indicated that at times they do encounter shortage of medicines. But the reasons and remedies are different. While problems relating to awarding of tenders are the main problems in public sector hospitals, shortages at hospital H3 are usually a result of manufacturers running out of stock of products, including vital medicines. Should the problem occur, the hospital resorts to distributors and wholesalers such as UPD, UTI, Alpha Pharm and Transpharm who depending on availability of medicines in stock, supply to this hospital.

b) Hospital – H4

Unlike hospital H3, the pharmacy at hospital H4 is owned fully by the hospital and it is not a separate entity. In addition, the pharmacy has been registered with the MCC. As to the medicines which are dispensed, the hospital has communication procedures put in place to ensure that the pharmacy orders the right type of medicines. So all medicines obtained would arise from internal communications between relevant authorities at the hospital. This also means that in the event that there is a new product in the market and the hospital needs to obtain it, internal communication channels within the hospital ensure that the pharmacy is duly notified. However, the hospital relies on the suppliers for details of the products.

In-patients at hospital H4 simply go with what the doctor has prescribed and they are not given a choice of medicines. Like at hospital H3, in-patients at hospital H4 are not charged a dispensing fee. In the event that generic medicines are available, the pharmacy usually dispenses a generic rather than an originator, unless, of course, the doctor has stipulated otherwise. Unlike in-patients, however, outpatients are required to pay a dispensing fee.

In so far as the SEP is concerned, the hospital has encountered no problems with this.

The shortage of medicines is an issue that troubles the H4 hospital as well. Like hospital H3, hospital H4 also uses UPD, UTI, Transpharm and Pharm Med for procurement of such services if these providers have a supply of medication in stock.

Medical Aid Schemes – MS

Public Sector Medical Aid Scheme(s)

Medical Aid Scheme – MS1

For medical aid scheme MS1, members are encouraged to deal with a preferred service provider even though the medical aid scheme is open to use any doctor. This scheme uses almost any doctor of which the percentage of doctors utilised amounts to 70%. It is only when patients are on a certain plan are they advised to utilise the services of a DSP. Service providers have to meet the following criteria: accessibility; quality of service; cleanliness; and must have the necessary facilities to render services to members. Additionally, medical aid scheme MS1 puts great emphasis on striking a balanced male-to-female doctor ratio.

The basis for dealing with DSPs takes considerations of the following two factors: firstly, to advise them of how of how to use the DSPs. Secondly, MS1 has people going to DSPs to inform and assist them. This includes sending communication on any information that the medical aid scheme might need.

Medical aid scheme MS1 does not make any decisions about whether originator or generic medicines should be made available to members. They leave that decision to the doctors, in spite of the fact the medical scheme does not cover originator medicines. Should an originator medicine be opted for, a co-payment is required. However, a co-payment is not required in the case of generics. Medical aid scheme MS1 can offer cover for the use of non-DSPs by members depending on the plan that members opted for. These usually are plans that (a) only assist members if they see DSPs and, (b) if it is an emergency situation and a non-DSP is used.

The following anti-competitive practices were noted by medical aid scheme MS1 in sectors of the pharmaceutical industry:

(a) Manufacturers have a relationship with doctors that bring business to them by selling their drugs as opposed to the medical aid schemes;

(b) Distributors have a tendency to take the drug straight to the market without following registration procedures; and

(c) GPs and specialists have a tendency to charge exorbitant prices that medical aid schemes are not able to cover for the price of medicines. Medical aid scheme members are then left with the impression that medical aid scheme MS1 is not able to cover medical costs as promised.

Medical aid scheme MS1 has emphasised the importance of a close relationship between medical aid schemes and pharmaceuticals, companies and providers.

Private Sector Medical Aid Schemes

Medical Aid Scheme – MS2

Medical aid scheme MS2 encourages members to deal with designated providers. The decision to use a DSP is based on a lower-cost premium benefit plan as part of the benefit, designed to contain cost and ensure access to services and service levels. Dealing with such DSPs centres is based on the following considerations: that negotiated discounted tariff structures ensure affordable access; that DSPs provide satisfactory customer service levels, appropriate risk management, and member accessibility; that DSPs adhere to scheme benefit designs such as generic medicine substitution, among other alternatives; that DSPs participate in special projects that have a bearing on costs, quality and the consumer focus; and that DSPs take considerations of management of member co-payments.

Unlike the medical schemes in the public sector, MS2 makes decisions about whether originator or generic medicines are available to members or not. These decisions are based on the following considerations: prices of medicines versus clinical outcomes, PMB requirements which stipulate the priced generics and limited benefits of members. Should members end up using non-DSPs, the medical aid scheme applies a penalty.

Medical aid scheme MS2 regards the following actions as anti-competitive:

(a) manufacturers are engaged in a perverse relationship with doctors and pharmacies that are offered incentives for dispensing their products at higher comparative prices;

(b) amongst distributors and wholesalers, the problem of unregulated logistics fees are prevalent. There is a forced associated relationship between retailers and wholesalers to access selected product lines; and

(c) corporate retailers have a pervasive relationship with corporate pharmacies that are offered incentives on SEP by being wholesalers. This allows corporate retailers to give discounted dispensing fees and gain market advantage over individual retailers.

The general concern expressed by MS2 is that the lack of statutory pricing governance on SEP is very problematic as manufacturers schedule prices at whatever price they choose. This leads to abuse, which prompts the use of DSPs who are aware of the implications of these added costs.

Medical aid scheme – MS3

Medical aid scheme MS3 encourages their members to deal with DSPs using criteria referred to as 'centres of excellence'. What these centres of excellence are and what they entail is not stated. The vagueness of the response does not shed light on the guidelines used to decide on DSPs. Dealings with DSPs are based on whether they are able to supply medical services at an affordable price. In the event that a member uses non-DSPs, the member would be required to pay a co-payment fee.

The decision as to whether originator or generic medicines should be made available to members is based on the therapeutic reference pricing which they rely on.

The medical aid has not experienced anti-competitive practices within the pharmaceutical industry as a whole.

Others

Dispensing Doctors – DD

Dispensing doctor – DD1

Dispensing doctor DD1 stated that he dispenses medication depending on the condition of the patient. He does not keep the medicines with him but writes a script and then sends the patient to the pharmacy which is situated on the same premises. He does not have a preference over generics to originator medication that he prescribes, and if the pharmacy does not have it, then they will substitute what he prescribes. Regarding anti-competitive behaviour, he states that there are procurement issues between suppliers and people do not get the medication in time which results in people not necessarily using effective medication.

Dispensing doctor – DD2

Regarding medication dispensed, dispensing doctor DD2 stated that it is dispensed based on quality, affordability, clinical trials, and medical aid considerations. Dispensing doctor DD2 further stated that the criteria used to decide which generics are used are the same as that for how medication is dispensed. Regarding prescriptions obtained from other places, DD2 stated that all chronic medication is obtained from medical aid specified pharmacies accompanied by the relevant script. This is usually two scripts daily. Representatives usually call the offices daily and offer product information and product sales. The representatives are usually helpful in providing new generic medicines on generic releases. DD2 stated that, regarding anti-competitive behaviour, the pricing and mark-ups are fixed by government for dispensing doctors. Dispensing is not profitable as it is an altruistic act toward patients not on medical aids.

Corporate Retailers – CR

Corporate retailer – CR1

Corporate retailer CR1 has relationships with manufacturers, distributors and wholesalers. Regarding dispensing fees it was stated that the demise of a mark-up has also led to the demise of small business ownership.

Monopolisation has led to mixed bag of results, in that it created better working conditions and working opportunities, while on the other hand, it has caused small businesses to fall away as a result of increased competition stemming from SEPs and dispensing fees.

Corporate Retailer – CR2

Medicines for corporate retailer CR2 are supplied by IHD, UPD, Kemco, Transpharm and Questmed. Regarding relationships with other manufacturers, wholesalers and distributors, they stated that they are required to firstly order from a certain supplier and if their supplier does not have stock then they have to use an alternative. Regarding dispensing fees the pharmacist interviewed stated that it keeps smaller privately owned business open as the fees are reasonable for the customer and the pharmacy. Regarding anti-competitive behaviour it was stated that after legislation was passed to regulate incentives on bulk sales of medications all stakeholders are afforded a more equal opportunity.

Individual Retailers – IR

Individual retailer – IR1

Regarding the medication and quantities, individual retailer IR1 stated that there are no legal or prescribed limitations on quantities but the supply and demand, import pressures, time delays on active ingredients, and changes in prescribing habits or seasonal habits often lead to stock shortages from the supplier.

As for the dispensing fee it was stated that it is a workable solution that identifies medication as a separate group of the retail sector and not an ordinary trade or retail item. However, it does not go far enough to encompass the costs and complexities of doing business, holding stock, return on investment, and payment to highly qualified personnel etc. Issues with the SEP are that it should be open for review more often – especially with respect to decreases in pricing.

Concerning the issue of agreements with medical aids, it was stated that in its view they are unlawful, unethical and not in the best interests of the patient's overall healthcare. These agreements look after only medical aids and shareholders' profits. This should be stopped immediately. Regarding the corporate retailers, it was stated that they have their place in the corporate sector.

As for the licensing of pharmacies, it was stated that there should exist enforced controls around where pharmacies are opened and that objections by existing pharmacies need to be heard. There exists no pressure from malls as they do not trade in a mall. They are supplied medication by Wholesalers 70%, Distributors 20%, Manufacturers 5% and Importers 5%. Their policy on providing expensive or rarely demanded medicines is that they provide what the patient needs.

Manufacturers – M

Manufacturer – M1

Manufacturer M1 deals only with originator medicines. All manufacturing takes place in Europe. They usually place orders with wholesalers and these orders go to UTI & UPD who then distribute to the pharmacies and doctors. The promotion of medicines happens only with the doctors and pharmacists.

Regarding anti-competitive behaviour it was stated that the marketing industry is very tightly controlled, and that to their knowledge no anti-competitive behaviour exists. It was stated that the codes are very stringent and many of them do not want to pay the fines as they are hefty amounts.

Looking at problems with the SEP, it was stated that they do not experience any problems as manufacturers were recently granted a price increase.

Regarding the draft regulations dealing with reference pricing it was stated that they will keep the product prices down, even if they fall below the external price reference. Low prices will increase volumes, and increase tenders accepted by the state.

They do not think that distributors will take over entirely from wholesalers in the near future but they do state that distributors will take over eventually as multinationals enter the market.

It was stated that other corporate retailers have their different products, and marketing codes cannot be more than a general guideline.

Manufacturer – M2

Manufacturer M2 stated that the usage of generics in private markets is roughly 60% in volume and 30% by value. Regarding links with Distributors, Wholesalers and Retail pharmacists, it was stated that most manufacturers contract distribution out to Imperial Health Services, UTI and UPD.

Regarding anti-competitive behaviour it was stated that there are formularies devised by medical aids and pharmacy chains.

Looking at issues with single exit pricing it was stated that they personally do not have a problem, but there is some uncertainty relating to pricing and its components.

It was stated that the draft regulations dealing with reference pricing would have very little impact, because international companies have international pricing and therefore such a policy would not make much of a difference to SEPs. It was also stated that applying reference pricing to generics would be impractical, as there exist no central data for generics.

It was stated that manufacturers are price takers, as medical aids are dominant. People prefer to go for medication where there is no co-payment. Companies do not want to trade with South Africa because the registration process for medicines with the MCC is an extremely long process.

Distributors/Wholesalers – DW

Distributor – DW1

Distributor DW1 state that the percentages of originator medicines are 40%, generics accounting for 60%. Looking at the links with manufacturers, importers or retail pharmacies, it was stated that manufacturers supply products to UPD retail Pharmacies which buy from UPD i.e. they are UPD customers. There are also telesales campaigns which collaborate with manufacturer sales reps.

Looking at anti-competitive behaviour it was stated that there has been evidence in the past stating that the competitors offer discounts on scheduled medicine to selected customers on a basket of products.

It was stated that they are not experiencing any problems with singe exit pricing, and that it does regulate the price of medicines.

Regarding the draft regulations on reference pricing it was stated that this policy is long overdue and will bring much needed relief to patients as it will decrease the cost of healthcare and thereby increasing the access.

Looking at the question of wholesalers having a future or distributors dominating, it was stated that wholesalers do have a future in the market but the number of wholesalers in SA is an issue. It was stated that they foresee a consolidation of wholesalers which is driven by logistic fee reductions, energy price increases and tough economic conditions. After this consolidation they foresee a fewer number of wholesalers competing side by side with distributors.

Distributor – DW2

Distributor DW2 noted that the percentage of originator medicines, with 30% originator and 70% generics. They distribute to the private sector, retail pharmacies and dispensing doctors. They also distribute to para-statals such as Transnet. They usually deal with UPD, Imperial and UTI. It was stated that they are totally independent from those entities and they do not hold interests in them.

Regarding competitors competing in an anti-competitive way it was stated that in the past wholesalers engaged in litigation by IHD and in this matter the manufacturers favoured wholesalers. This occurred whereby some manufacturers supplied directly to the retailers and bypassed wholesalers. It was usually that distributors owned the retailers and thereby they made profits such as Clicks and MediRite. It was also stated that many of the manufacturers dictate the logistics fees: for example, Pfizer dictates the logistic fees and then sells their products at a premium. When companies such as theirs distribute the products then they have to charge a smaller fee which is usually between 2% and 3 %.

Looking at problems with the SEP it was stated that manufacturers dictate the logistics fees and this does not benefit DW2. In theory it is a good system but in practice it is not working well as manufacturers do not benefit from it. It was stated that the SEP does eliminate a lot of the perversities from the market.

Looking at the draft regulations on reference pricing it was stated that it is difficult as one needs to establish the similarities and differences between South Africa and other countries. It was stated that it has occurred before where manufacturers were forced to reduce their pricing but that there is enough being done on pricing at the moment and that the focus should be on the cost of healthcare as people should not be priced out of business.

Looking at the future of wholesalers it was stated that they will always have a future, as they do what distributors require. As long as pharmacies and dispensing doctors are available they will survive. There do exist threats to wholesalers whom rely on the ability to negotiate with manufacturers. Flexibility is the issue here as one needs to try and be as flexible as possible to supply medication. If independence is reduced then wholesalers suffer. It was stated that one needs volume to cost subsidies for the service delivery.

Other comments made were that at malls only corporate pharmacies are opening such as Clicks, Medi-Rite and Dischem and no individual pharmacists are opening up due to the regulations favouring some over others.

CHAPTER 8:

CORPORATE AND INDIVIDUALLY OWNED PHARMACIES

Introduction

Of considerable interest is the impact that the extension of the ownership of pharmacies to people and organisations who are not pharmacists has had on the industry. In order to assess impact, it would have been desirable to:

- compile a complete list of pharmacies at the time the legislation became effective;
- draw up a list of pharmacy openings and closures in each year from that date; and
- trace the development of open pharmacies up to the present.

Unfortunately, not all the data needed to establish a complete and reliable account is available to us. On the stock of pharmacies at any one time, we have three sources of information: the South African Pharmacy Council list of registered and active pharmacies, and lists from Scriptnet and Medikredit setting out which pharmacies they deal with. We have regarded a pharmacy as open if it appears on any of the three lists. The data we have put into our data base reflects the position in early 2015.

An attempt to obtain a list of openings and closings from the South African Pharmacy Council met with no response. What we do have are lists of closings reported by the ICPA, and these have been consolidated by us. We also have a list of dates on which licenses were granted by the South African Pharmacy Council for pharmacies on their list in early 2015. These data will be presented below.

Two related issues arise with opening and closing. The first is the issue of pharmacies that were recorded as closed by the ICPA, but were found to be open in 2015. We have deleted pharmacies falling into this category from the closings list. The second issue is the interpretation of the date on which a license was granted by the South African Pharmaceutical Council. Do all these licensing dates refer to the actual opening of a pharmacy, or are they sometimes a response to some other event?

Applications from pharmacies to the South African Pharmacy Council fall into the following categories:

1. Change of address without relocation
2. Re-recording of a pharmacy change of name or trading title
3. Satellite pharmacy in a public institutional facility
4. PHC clinics
5. Approval of premises: internal changes
6. Another business or practice in a pharmacy
7. Automated dispensing unit
8. Duplicate certificate for registered facilities
9. Recording of a pharmacy and its responsible pharmacist.

We think it unlikely that applications under categories 1, 5, 6, 7 and 8 will result in the issuing of a new license. Category 3 is irrelevant to our analysis of the opening and closing of pharmacies, since our attention is confined to corporate and individually owned pharmacies outside private and public hospitals and other public institutions. Insofar as private public PHC clinics are registered, these are picked up in our data base.

This leaves categories 2 and 9. Category 2 applications may result in the issue of a new license (with the recording of a new licensing date) and category 9 applications are likely to have that result. The question is: to what extent do these license dates reflect a genuinely new opening? All genuinely new openings will be recorded, but some licensing dates may reflect only a change of pharmacy name or trading title, or a change in responsible pharmacist. For convenience of reference, 'openings' here will refer to the dates on which licenses are recorded as having been granted, but as they are estimates of genuinely new openings they may be upwardly biased to an unknown extent.

In combining data from sources, one has to consider in some cases whether two pharmacies with a similar name in the same place are in fact two pharmacies or not. Although every care has been taken to make the correct judgement, there remains the possibility of some error.

In line with ICPA practice, we shall regard pharmacies owned by the following as COPs. All other privately owned pharmacies outside private and public hospitals and other public institutions will be regarded as IOP. The corporates are:

- Clicks
- Dis-Chem
- Medirite
- Netcare/Medicross
- Pick N Pay
- Medirite
- Spar

Findings

Corporate pharmacies

In October 2015, the ICPA sent us the following information on the number of corporate pharmacies:

Table 1 – ICPA estimates of the number of corporate pharmacies

Corporate Pharmacy totals	
Clicks	386
Dis-Chem	98
Medicross Pharmacies	66
Pick n Pay	31
MediRite	151
Spar	45
Total	**777**

We have compared the numbers of corporate pharmacies in our early 2015 data base with lists of corporate pharmacies as published by the corporations on the Internet at the end of November 2015. The table below sets out our findings.

Table 2 – HSF and corporate list estimates of the number of corporate pharmacies

Corporate Pharmacy totals	Early 2015	November 2015
Clicks	353	360
Dis-Chem	88	94
Medicross Pharmacies	46	24
Pick n Pay	39	28
MediRite	152	141
Spar	32	48
Total	**710**	**695**

Not reported in Table 2 are our findings that:

- we are unable to find 139 of our early 2015 COPs on the November 2015 corporate lists as published on the Internet
- 124 of the pharmacies on the November 2015 corporate lists were not on our early 2015 data base.

Possible reasons for discrepancies:

1. The ICPA supplied us with the summary statistics in Table 1 only. The total is considerably higher than either of the totals in Table 2, but we have no ICPA list against which we can check the others.
2. We have excluded pharmacies in private hospitals from our lists in Table 2, but ICPA may have included them in theirs. This may be the reason why the worst discrepancy is with the Netcare/Medicross pharmacies.
3. On the other hand, the published corporate pharmacy lists may be incomplete, as well as our early 2015 data base.
4. The measured churn of corporate pharmacies between early 2015 and November 2015 is implausibly high. This may be partly a result of name changes of pharmacies in the intervening period, with the relevant pharmacies operating throughout.

These findings illustrate the difficulties of providing a reliable data base of pharmacies, even in 2015. The problems will present themselves again when considering IOPs. Even careful combining of data sets from different sources is a risky procedure and will inevitably include some error in the results.

We shall standardise our results on our early 2015 data base. Table 3 sets out the 710 COPs by date on which the license was granted:

Table 3 – Corporate pharmacies by date of registration, early 2015

Year	Number
Pre-2003	82
2003	6
2004	18
2005	76
2006	69
2007	71
2008	88
2009	73
2010	84
2011	32
2012	44
2013	22
2014	30
Unknown	31
Total	**710**

Table 4 – Corporate pharmacies by province, early 2015

Province	Number
Eastern Cape	46
Free State	24
Gauteng	312
KwaZulu-Natal	91
Limpopo	22
Mpumalanga	26
North West	24
Northern Cape	12
Western Cape	153
Total	**710**

Individually owned pharmacies

In October 2015, the ICPA informed us that it estimated the number of independent pharmacies at 2 222, of which 1 054 were ICPA members. Our data base yields a higher estimate of 2 475 independent pharmacies in early 2015, distributed across dates of license and province as follows:

Table 5 – Individually owned pharmacies by date of registration, early 2015

Date	Number
Pre 2003	1202
2003	44
2004	68
2005	49
2006	65
2007	102
2008	227
2009	129
2010	182
2011	83
2012	48
2013	95
2014	25
Unknown	156
Total	**2475**

Table 6 – Individually owned pharmacies by province, early 2015

Province	Number
Eastern Cape	179
Free State	126
Gauteng	906
KwaZulu-Natal	427
Limpopo	165
Mpumalanga	167
North West	137
Northern Cape	43
Western Cape	325
Total	**2475**

On the basis of lists supplied to us by the ICPA, with:

- duplicates excluded;
- attention confined to independently owned pharmacies outside private hospitals;
- deletion of pharmacies found to be open; and
- deletion of pharmacies closed before 2003.

We find 602 independent pharmacy closures between 2003 and 2014, distributed across years of closure and provinces as follows:

Table 7 – Closures of individually owned pharmacies by date of closure, 2003-2014

Date	Number
2003	25
2004	72
2005	74
2006	35
2007	3
2008	168
2009	6
2010	11
2011	11
2012	18
2013	31
2014	5
Unknown	143
Total	**602**

Table 8 – Closures of individually owned pharmacies by province, 2003-2014

Province	Number
Eastern Cape	47
Free State	22
Gauteng	210
KwaZulu-Natal	72
Limpopo	23
Mpumalanga	22
North West	26
Northern Cape	10
Western Cape	121
Unknown	49
Total	**602**

602 closures over 12 years represents an annual closure rate of 50 – or just under 2.5% of pharmacies each year.

What can we conclude about the relation of independent pharmacy openings compared with independent pharmacy closures?

Two difficulties beset conclusions. The first is that the list of closures may be incomplete. The second is that the date of registration may not always indicate the opening of a new pharmacy. We thus present our results in the form of a contingency table. Along the top, there will be three categories: closures as found, closures 10% higher than found, and closures 20% higher than found. Down the side will be five categories: all registrations representing new openings, 90% of registrations representing new openings, and 80%, 70% and 60%. The entry in each cell of the table will take the form of:

A – B = C,

where A represents genuine openings, B represents closures, and C represents net addition to the stock of independent pharmacies. The table will deal with all openings and closures between 2003 and 2014, including those on unknown date.

Table 9 – Contingency table for net addition to pharmacy stock, 2003-2014

	Closures as estimated	Closures plus 10%	Closures plus 20%
All registrations openings	1 276 - 602 = 674	1 276 - 662 = 614	1 276 - 722 = 554
90% of registrations openings	1 148 - 602 = 546	1 148 - 662 = 486	1 148 - 722 = 426
80% of registrations openings	1 020 - 602 = 418	1 020 - 662 = 358	1 020 - 722 = 298
70% of registrations openings	893 - 602 = 291	893 - 662 = 231	893 - 722 = 171
60% of registrations openings	765 - 602 = 163	765 - 662 = 103	765 - 722 = 43

Within the bounds of the table, independent pharmacy openings exceed pharmacy closings over the period. But the extent to which they may have is very uncertain. On the one hand, the entry in the top left cell indicates that openings have exceeded closures by a margin of more than 2:1. On the other, the entry in the bottom right cell indicates that openings barely exceed closings. The data leave a wide margin for interpretation.

A prospective measurement system would yield much more precise and reliable estimates in the future. Such a system could be designed as follows:

1. Twice or three times a year, a complete list of registrations with the South African Pharmacy Council should be downloaded.
2. Each list should be compared with the list before it, to establish:
   (a) deregistrations in the intervening interval;
   (b) new registrations in the intervening interval, divided into:
      (i) those for pharmacies which existed before, and
      (ii) those which introduce new pharmacies entirely.

The division between (b)(i) and (b)(ii) would not be entirely accurate, since it is possible that a pharmacy may change its name and re-register, while remaining open. But it would be the best one can do, short of more information being supplied by the Pharmacy Council.

A complete list of corporate pharmacies, independent pharmacies, hospitals and clinics in early 2015

Finally, we can present a complete list of:

- corporate pharmacies outside hospitals;
- independent pharmacies outside hospitals;
- general hospitals (i.e. excluding specialist hospitals, for example, TB hospitals); and
- general clinics (i.e. excluding specialist clinics, for example, dental clinics).

Table 10 – Existing pharmaceutical distribution sites and clinics, early 2015

	Existing sites			
Province	**Corporate Pharmacies**	**Independent pharmacies**	**General hospitals**	**General clinics**
Eastern Cape	46	179	126	786
Buffalo City	11	30	6	79
Nelson Mandela Bay	22	72	14	55
Elsewhere	13	77	106	652
Free State	24	126	44	300
Mangaung	11	33	10	48
Elsewhere	13	93	34	252
Gauteng	312	906	106	438
Ekurhuleni	76	222	24	25
Johannesburg	101	304	30	143
Tshwane	92	254	32	90
Elsewhere	43	126	20	180
KwaZulu-Natal	91	427	109	179
Ethekwini	51	249	29	65
Elsewhere	40	178	80	114
Limpopo	22	165	46	460
Mpumulanga	26	167	34	283
Northern Cape	12	43	34	190
North West	24	137	30	260
Western Cape	153	325	81	420
Cape Town	117	216	42	189
Elsewhere	36	109	39	231
SOUTH AFRICA	710	2 475	610	3 316
Metro	481	1 380	267	694
Elsewhere	229	1 095	343	2 622

68% of corporate pharmacies are located in the metropolitan areas of Buffalo City (East London), Cape Town, Ekuruhleni (East Rand), Ethekwini (Durban), Johannesburg, Mangaung (Bloemfontein), Nelson Mandela Bay (Port Elizabeth) and Tshwane (Pretoria). The corresponding figure for individually owned pharmacies is 56%.

In South Africa, it is appropriate to distinguish metropolitan areas, platteland towns and rural areas, subdivided into generally low population density commercial farms and higher density tribal areas. It is rare for either a corporate or an individually owned pharmacy (IOP) to penetrate beyond metros and platteland towns. People in rural areas rely either on dispensing clinics, hospitals or courier pharmacies for their medicine.

How concentrated is the manufacture/import and wholesale/distribution of pharmaceuticals?

Table 11 sets out the distribution of manufacturers/importers and wholesalers/ distributors by province:

Table 11 – Manufacturers/importers and wholesalers/distributors, early 2015

	Manufacturers/importers	**Wholesalers/distributors**
Eastern Cape	3	17
Free State	0	8
Gauteng	47	145
KwaZulu-Natal	6	12
Limpopo	0	6
Mpumalanga	0	1
Northern Cape	0	2
North West	5	6
Western Cape	13	24
Total	**74**	**221**

That manufacturers and importers are concentrated in Provinces with a high proportion of metropolitan areas is inevitable. There is a case for regulation of them, especially when there is no generic substitute for the pharmaceuticals they supply. The best way is through external reference pricing, a subject of draft regulations by the DoH – as yet not finalised.

Distribution is another matter. In five provinces, the number of distributors/wholesalers is below ten, and the situation is made worse by exclusive dealing arrangements. The result is that individually owned pharmacies are unable to procure certain pharmaceuticals. The remedy would be a regulation which requires distributors to make medicines available to any pharmacist wishing to order them.

CHAPTER 9:

A PHARMACEUTICAL DISTRIBUTION NETWORK FOR THE FUTURE

Pharmaceuticals are made available to the general public through:

- Corporate or other retail pharmacies not in hospitals
- General public or private hospitals
- Some government clinics
- Dispensing doctors

A Geographical Information System data base has been complied for corporate or other retail pharmacies not in hospitals, general public or private hospitals, and all government clinics other than specialist or mobile clinics. There is no systematic information on dispensing doctors. Nor do we know which clinics dispense medicine, or the range of medicines available within them.

No-one keeps full and accurate registers of retail pharmacies, so the list used here has been compiled from several sources including the Pharmacy Council, the ICPA, MediCredit and ScriptNet. The list of public and private hospitals has been compiled from information supplied by ICPA and the government health clinics site. The government clinics list has been compiled from the government health clinics site, with our classification of clinics into general, specialist and mobile clinics.

The existing network of retail pharmacies and hospitals is not adequate for the provision of pharmaceuticals to the public. Accordingly, we have identified new sites for distribution. These sites should provide the full governmental formulary, except those pharmaceuticals which can be provided only in hospitals. The following criteria have been used in the identification of these sites:

1. The country is divided up into the 4 277 wards used in the 2011 local government elections. These wards are divided into the following mutually exclusive and collectively exhaustive classes:

- Wards in metropolitan authorities
- Wards in predominantly urban areas outside the metros. This class is subdivided into wards with populations of 10 000 (large wards) or more and wards with smaller populations
- Wards in predominantly rural areas with population densities of more than ten people per square kilometre
- Wards in predominantly rural areas with a population density of more than five but fewer than ten people per square kilometre (low density wards)
- Wards in predominantly rural areas with a population density of five or fewer people per square kilometre (very low density wards).

2. There should be one site (existing or new) for every 10 000 people. The population is taken as that enumerated in the 2011 population census. An expanding population will mean an expanding need for new sites.

3. The distance between sites should depend on population density. If one imagines a map divided into interlocking hexagons with a site at the centre of each, a distance between sites of 71 kilometres will create hexagons containing 10 000 people in very low density areas. In low density areas, the distance drops to 39 kilometres. There should be a site in each large and metropolitan ward.

4. Where possible, new sites have been located at existing clinics. Where this has not been possible, a new site has been placed at the centre of large and metropolitan wards, and of collections of wards in other categories.

5. These criteria have been used as guidelines rather than inflexible rules in identifying new sites.

The results of the analysis are presented in a table and an atlas of maps. The atlas contains, for each province, a provincial map of existing and new sites, a provincial map of general government clinics, and a map of existing and new sites in each metropolitan area.

We have identified 710 corporate pharmacies, 2 475 other pharmacies and 610 hospitals in South Africa as a whole. We have identified 919 sites for new distribution: Of these:

- 182 are in metro areas
- 375 are in large wards
- 230 are in medium density rural wards
- 69 are in low density wards
- 63 are in very low density wards

Provincial figures are indicated in the table.

These sites represent a considerable opportunity for retail pharmacists. As incomes rise, new pharmacies will open at some sites, or nearby them. However, a great many poor people are in need of better pharmaceutical distribution, either to be handled by the government alone, or the private sector and government together is some form of co-operative scheme. Retail pharmacists wishing to expand their activities should work towards reaching agreements with government on a framework for co-operation.

Existing and future pharmaceutical distribution sites

	Existing sites				Future sites					
Province	**Corporate pharmacies**	**Independent pharmacies**	**General hospitals**	**General clinics**	**Very low density**	**Low density**	**Medium density**	**Large wards**	**Metro wards**	**Total new**
Eastern Cape	46	179	126	786	11	9	75	78	42	215
Buffalo City	11	30	6	79	–	–	–	–	15	15
Nelson Mandela Bay	22	72	14	55	–	–	–	–	27	27
Elsewhere	13	77	106	652	11	9	75	78	–	173
Free State	24	126	44	300	12	6	4	7	10	39
Mangaung	11	33	10	48	–	–	–	–	10	10
Elsewhere	13	93	34	252	12	6	4	7	–	29
Gauteng	312	906	106	438	–	–	56	–	50	106
Ekurhuleni	76	222	24	25	–	–	–	–	2	2
Johahnnesburg	101	304	30	143	–	–	–	–	17	17
Tshwane	92	254	32	90	–	–	–	–	31	31
Elsewhere	43	126	20	180	–	–	56	–	–	56
KwaZulu-Natal	91	427	109	179	–	–	41	134	52	227
Ethekwini	51	249	29	65	–	–	–	–	52	52
Elsewhere	40	178	80	114	–	–	41	134	–	175
Limpopo	22	165	46	460	6	23	20	94	–	143
Mpumulanga	26	167	34	283	–	–	9	35	–	44
Northern Cape	12	43	34	190	20	3	–	–	–	23
North West	24	137	30	260	7	14	22	27	–	70
Western Cape	153	325	81	420	7	14	3	–	28	52
Cape Town	117	216	42	189	–	–	–	–	28	28
Elsewhere	36	109	39	231	7	14	3	–	–	24
SOUTH AFRICA	710	2 475	610	3 316	63	69	230	375	182	919
Metro	481	1 380	267	694	–	–	–	–	182	182
Elsewhere	229	1 095	343	2 622	63	69	230	375	–	737

ATLAS

The following pages present maps of each province, and of each metropolitan authority.

KEY

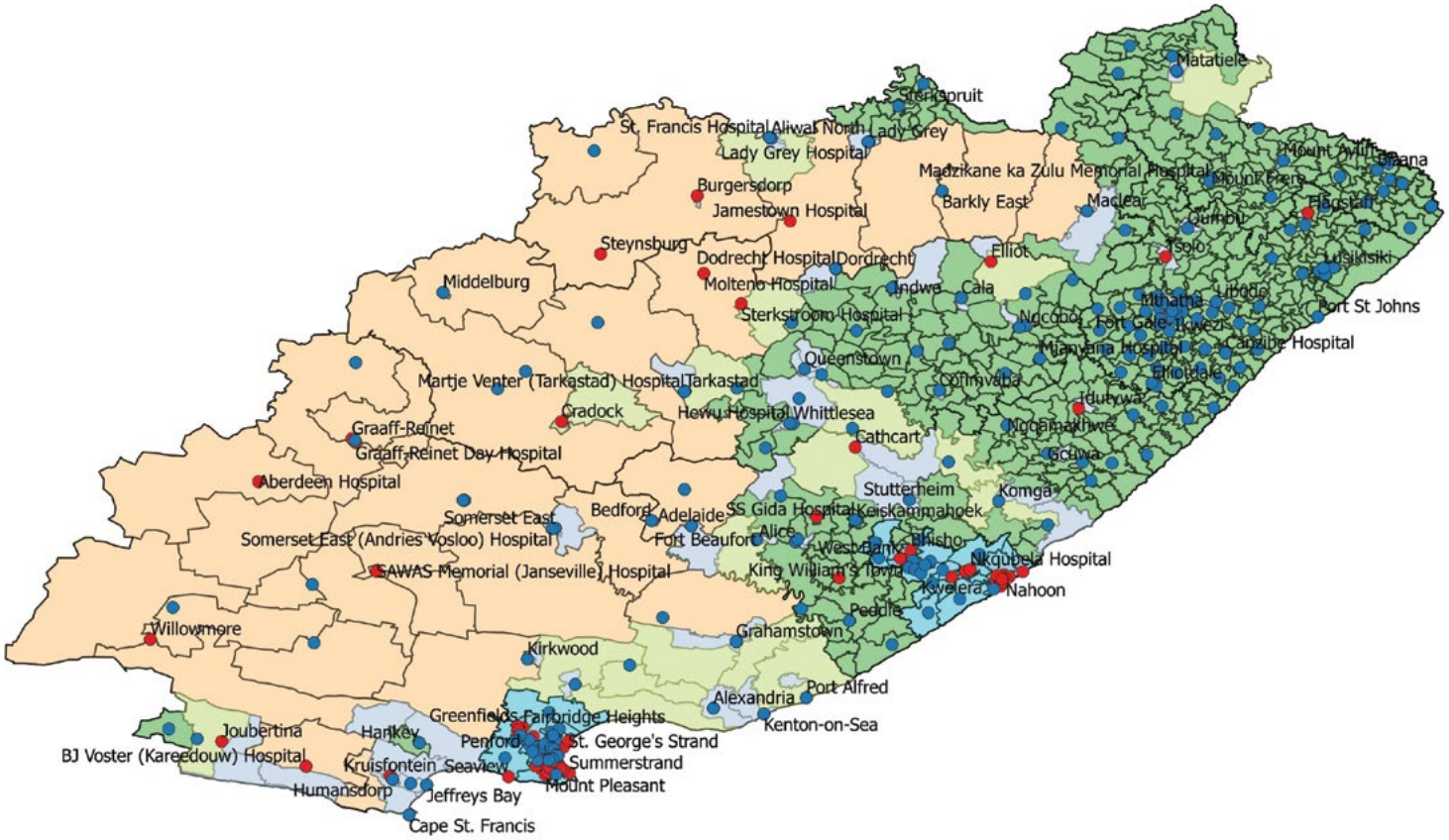
Background colour by local government electoral ward (2011 elections)

- Metropolitan areas
- Wards where half or more of the population lives in urban areas
- Wards where more than half of the population lives outside urban areas and where the population density is greater than ten people per square kilometer
- Wards where the population density is at least five but less than ten people per square kilometer
- Wards where the population density is less than five people per square kilometer

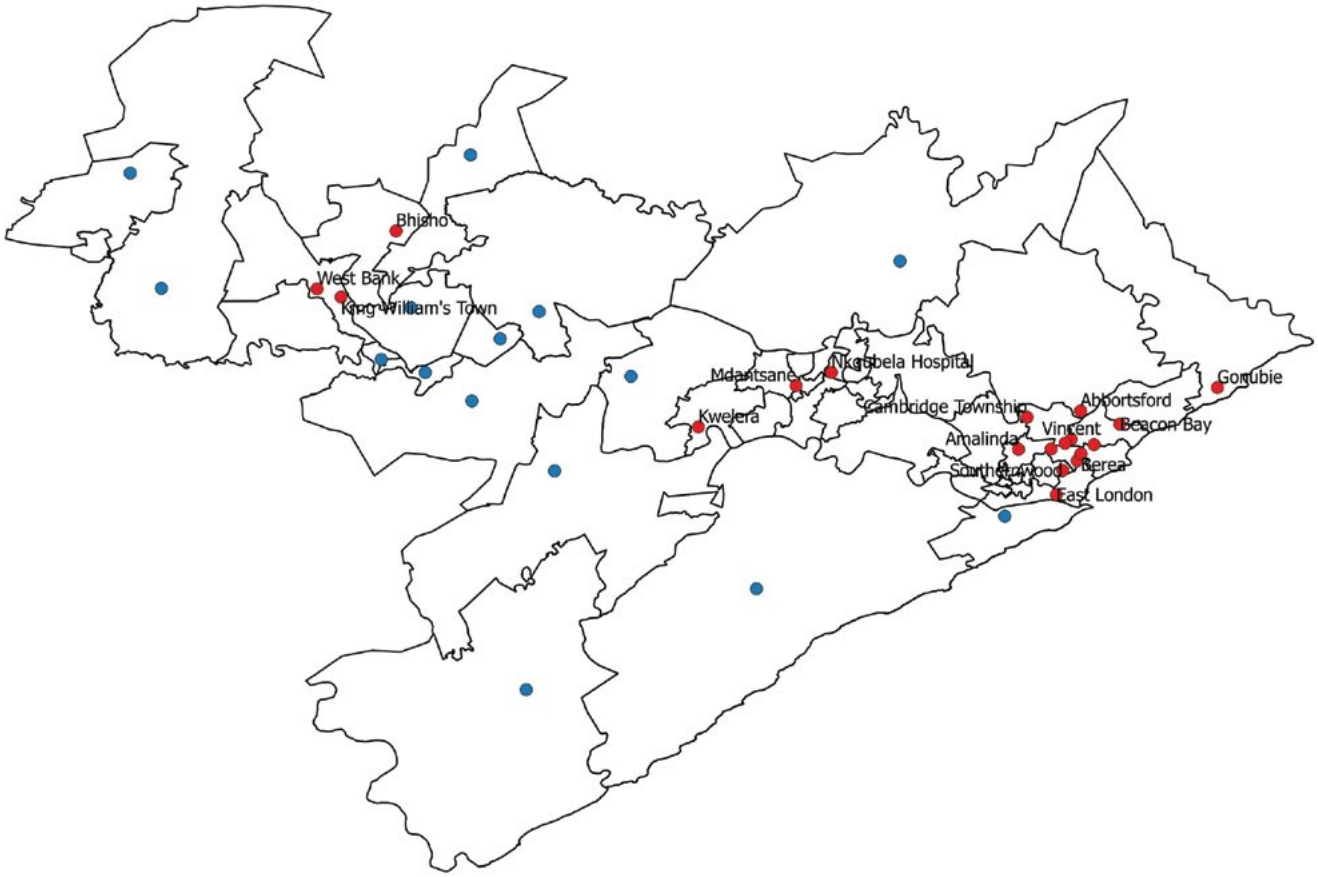
Location of facilities

- Towns in which retail pharmacies open to the general public are located or places where general hospitals are located.
- Sites of government clinics, excluding specialist clinics and mobile clinics
- Sites having the potential for distribution of at least the full government formulary, excluding medicines which have to be administered in hospitals

Figure EC 1 Eastern Cape



EC 2 Buffalo City Metro



ATLAS (CONTINUED)

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Background colour by local government electoral ward (2011 elections)

- Metropolitan areas
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Figure EC 4 Eastern Cape General Clinics

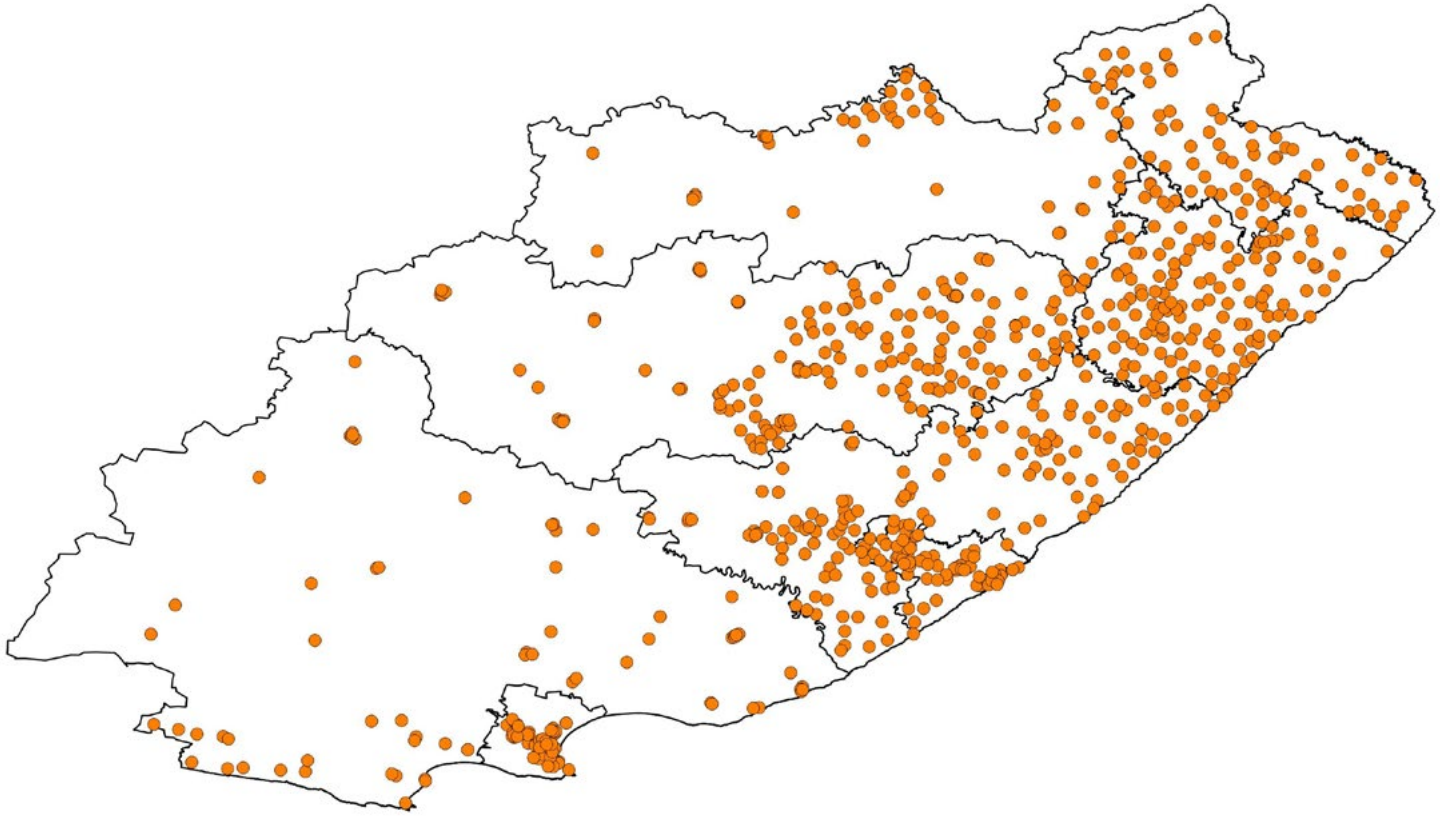
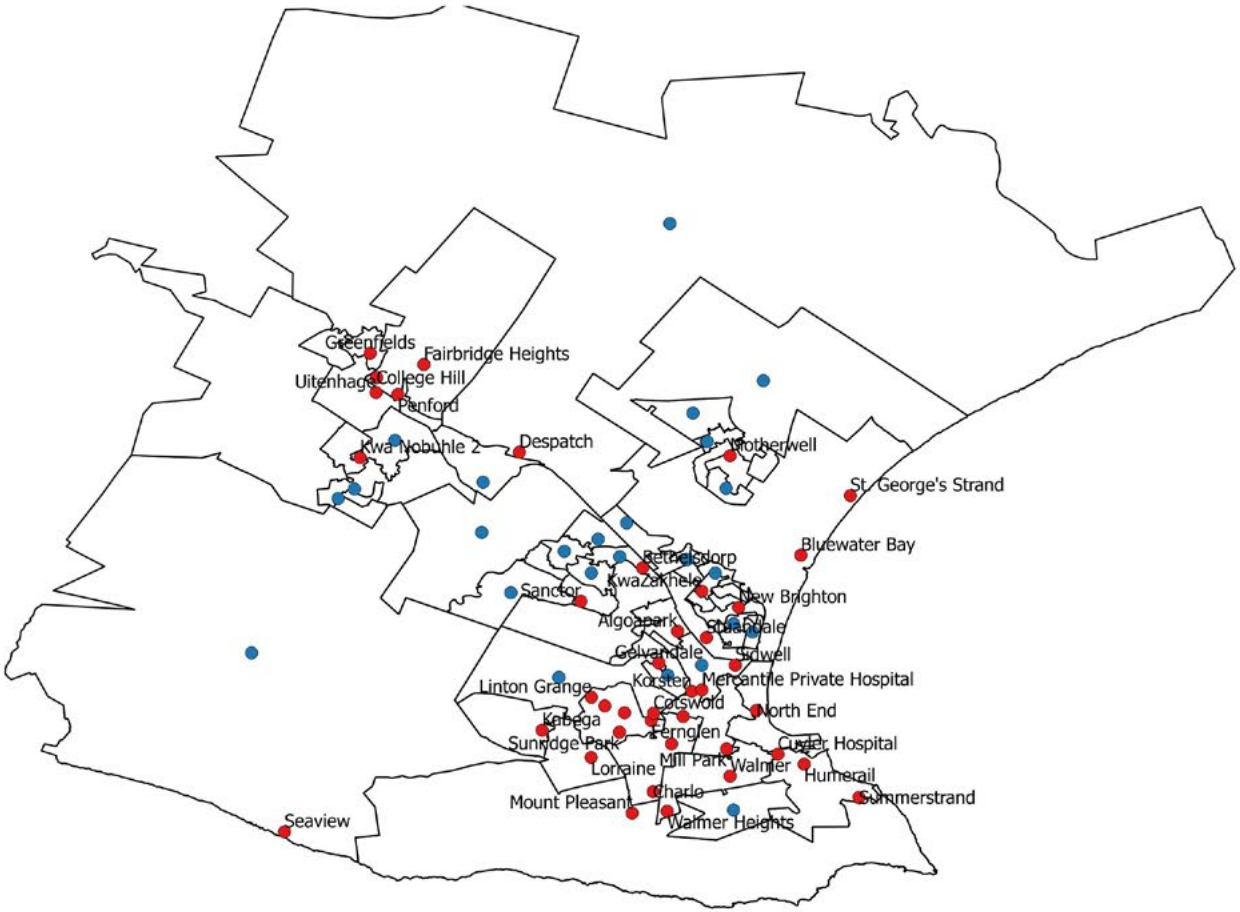


Figure EC 3 Nelson Mandela Metro



ATLAS (CONTINUED)

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Background colour by local government electoral ward (2011 elections)

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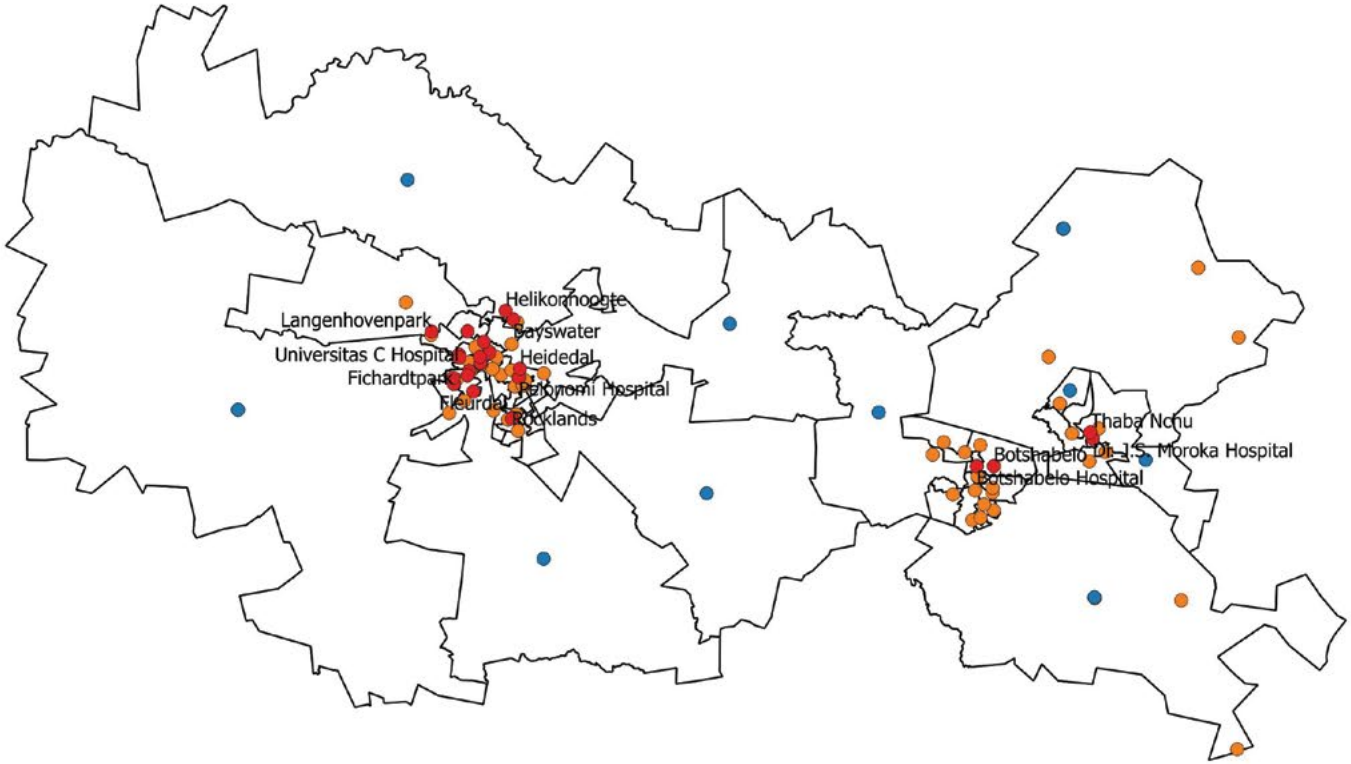
Figure FS 1 Free State

Figure FS 2 Manganung Metro



ATLAS (CONTINUED)

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Figure FS 3 Free State General Clinics

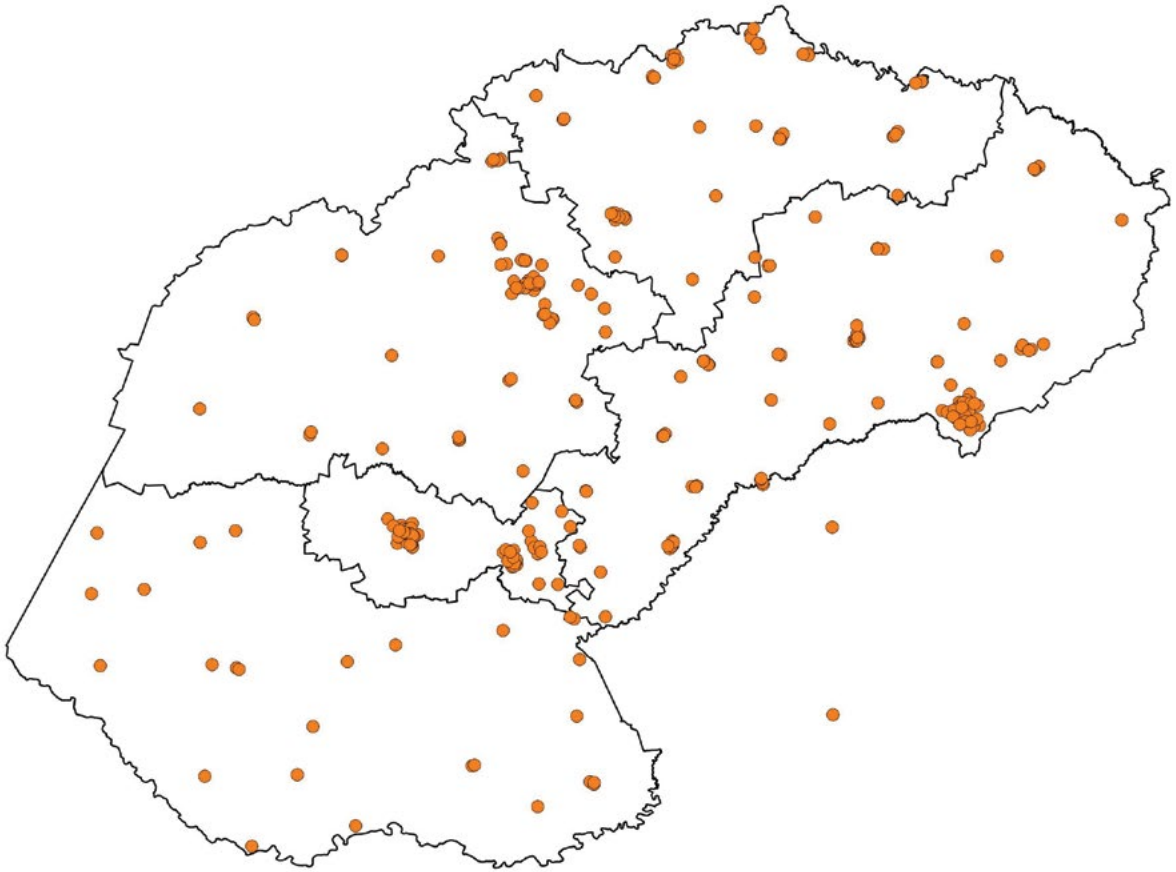
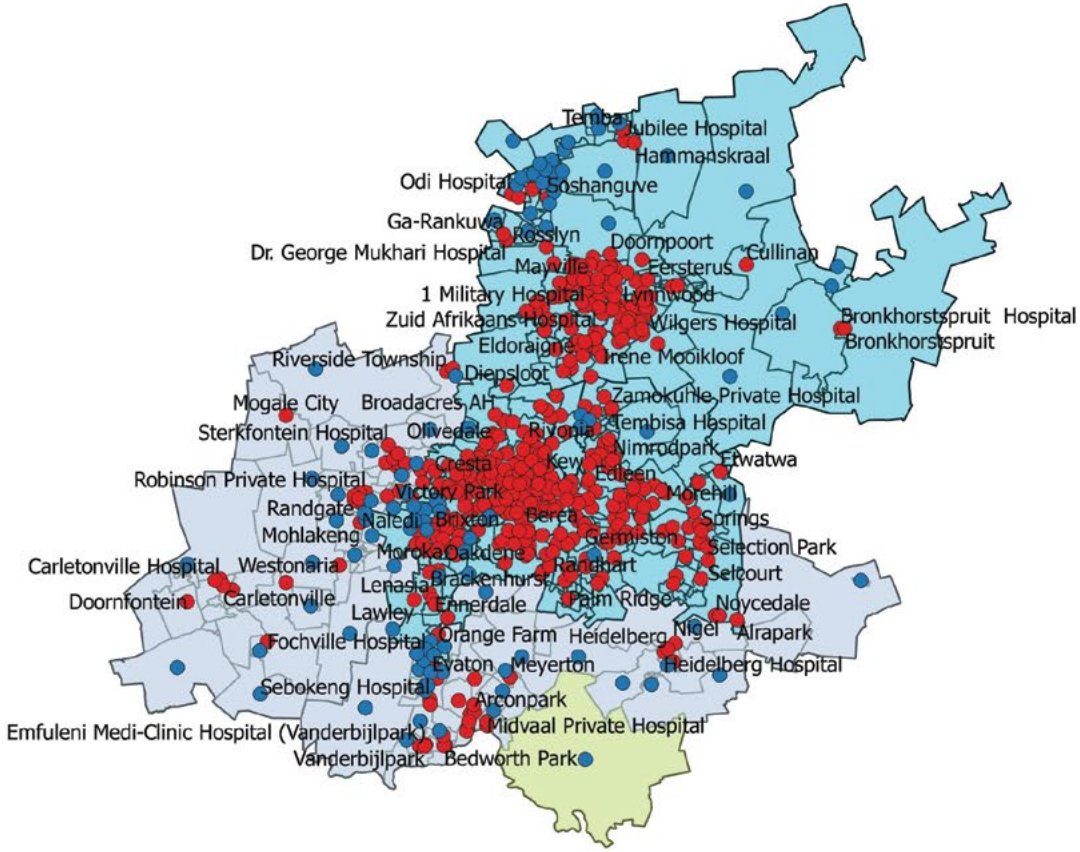


Figure GT 1 Gauteng



ATLAS (CONTINUED)

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Figure GT 2 Ekurhuleni Metro

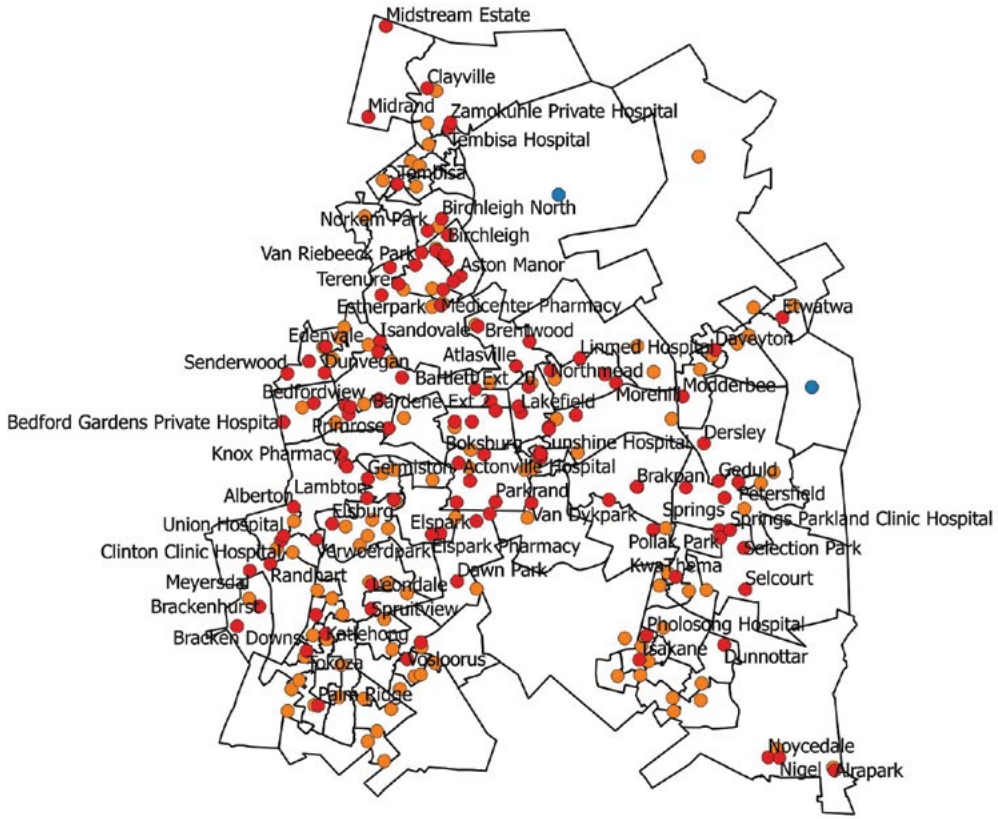
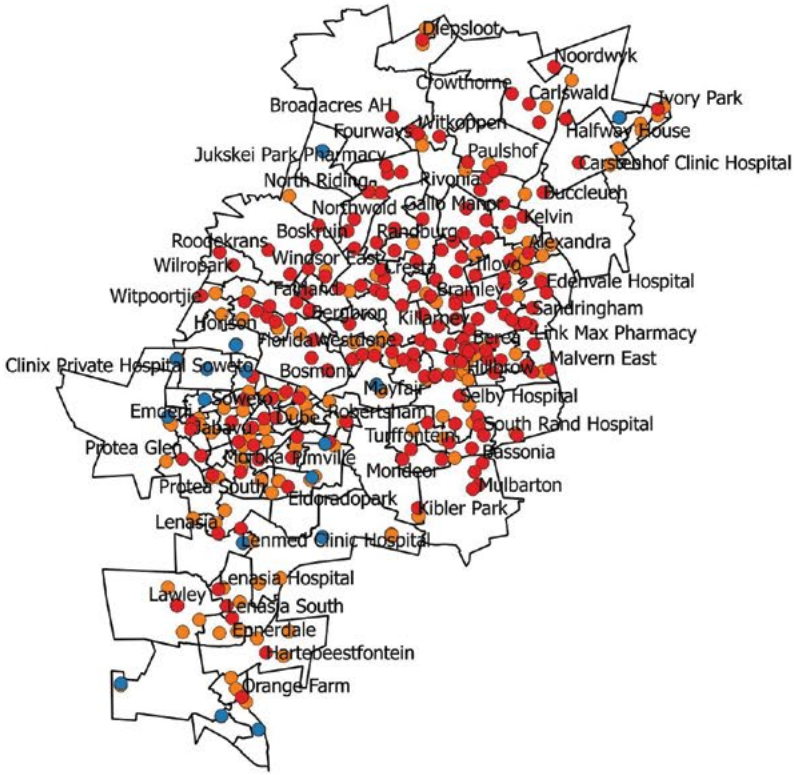


Figure GT 3 Johannesburg Metro



ATLAS (CONTINUED)

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Figure GT 4 Tshwane Metro

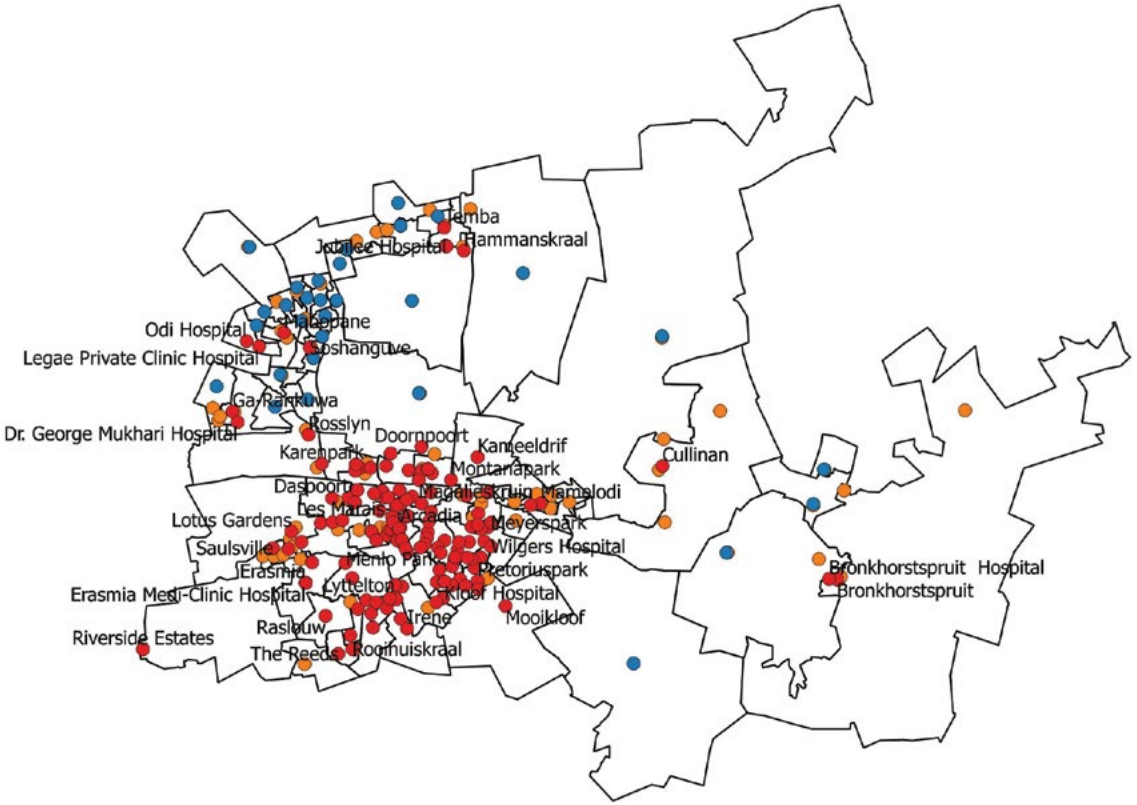
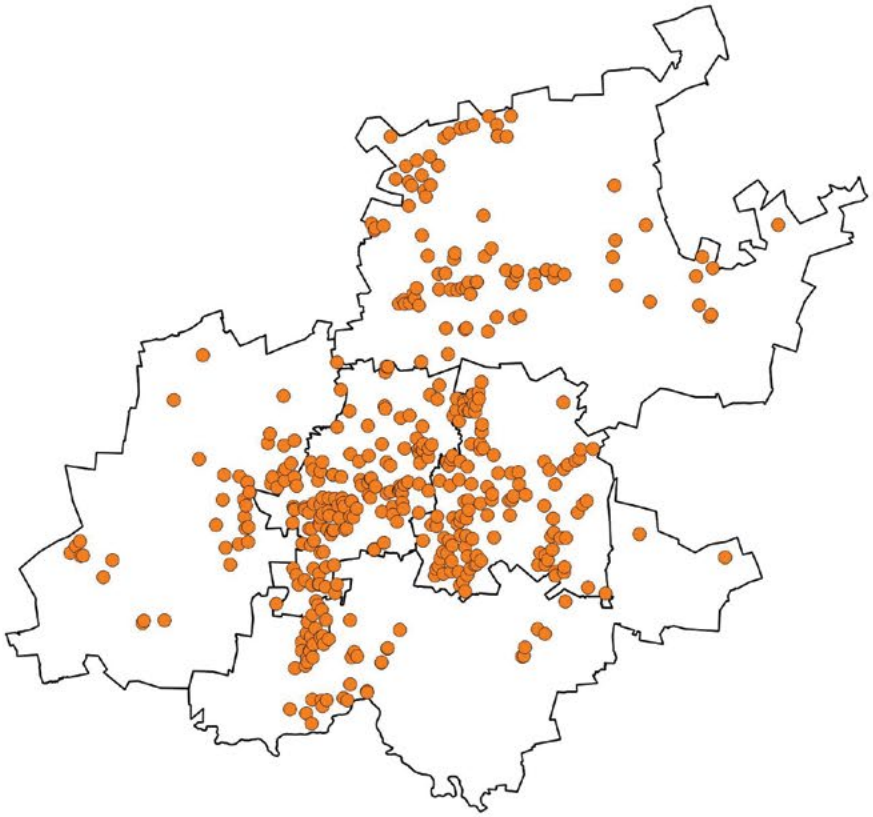


Figure GT 5 Gauteng Metro General Clinics



ATLAS (CONTINUED)

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Background colour by local government electoral ward (2011 elections)

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Figure KZ 1 KwaZulu-Natal

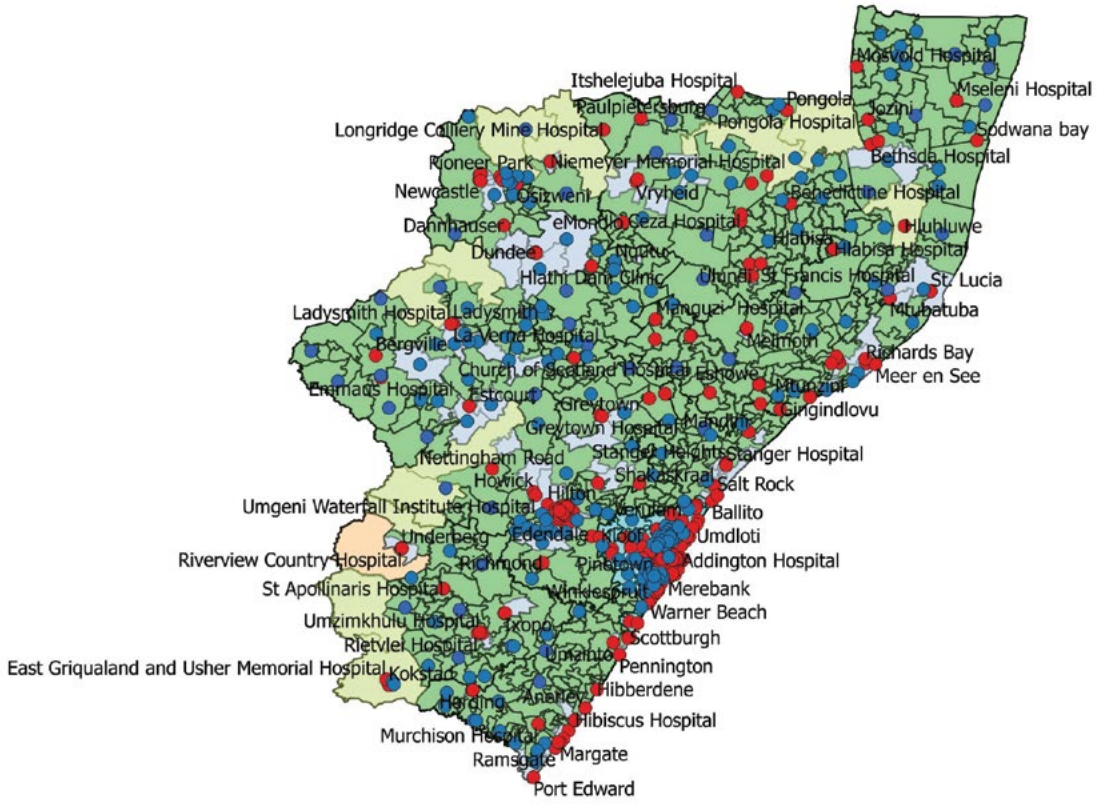
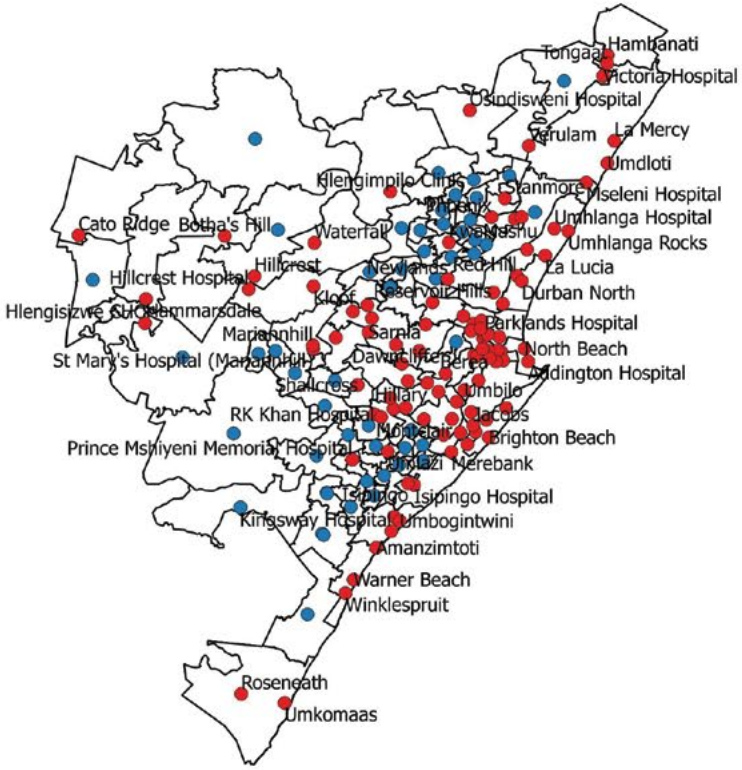


Figure KZ 2 Ethekwini Metro



ATLAS (CONTINUED)

KEY

Background colour by local government electoral ward (2011 elections)

- Metropolitan areas
- Wards where half or more of the population lives in urban areas
- Wards where more than half of the population lives outside urban areas and where the population density is greater than ten people per square kilometer
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Figure KZ 3 KwaZulu-Natal

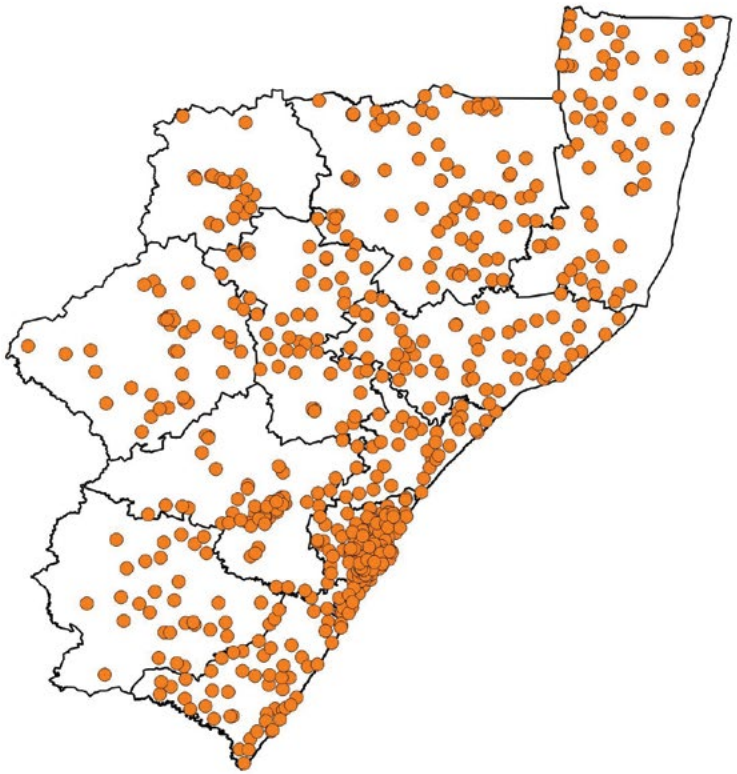
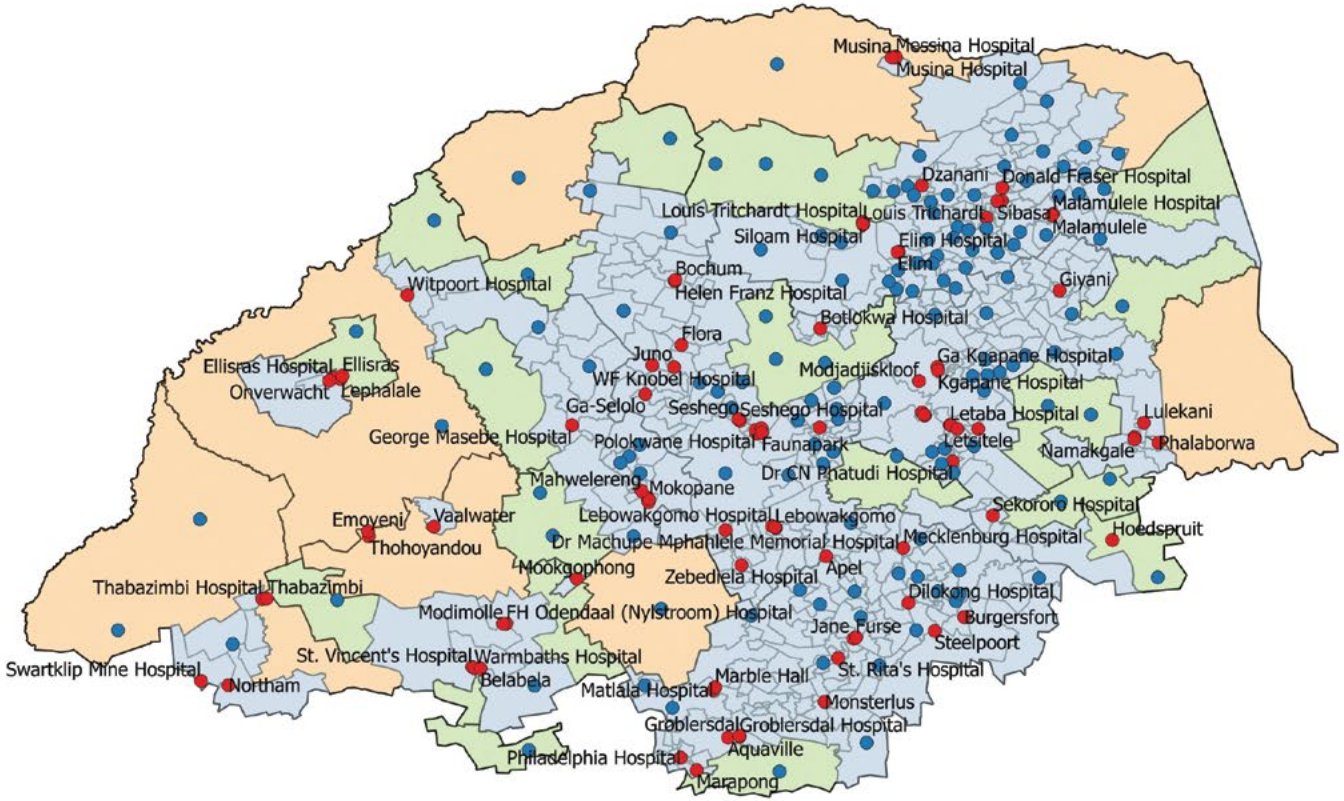


Figure LP 1 Limpopo



ATLAS (CONTINUED)

KEY

Background colour by local government electoral ward (2011 elections)

- Metropolitan areas
- Wards where half or more of the population lives in urban areas
- Wards where more than half of the population lives outside urban areas and where the population density is greater than ten people per square kilometer
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Location of facilities

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- Sites of government clinics, excluding specialist clinics and mobile clinics
- Sites having the potential for distribution of at least the full government formulary, excluding medicines which have to be administered in hospitals

Figure LP 2 Limpopo General Clinics

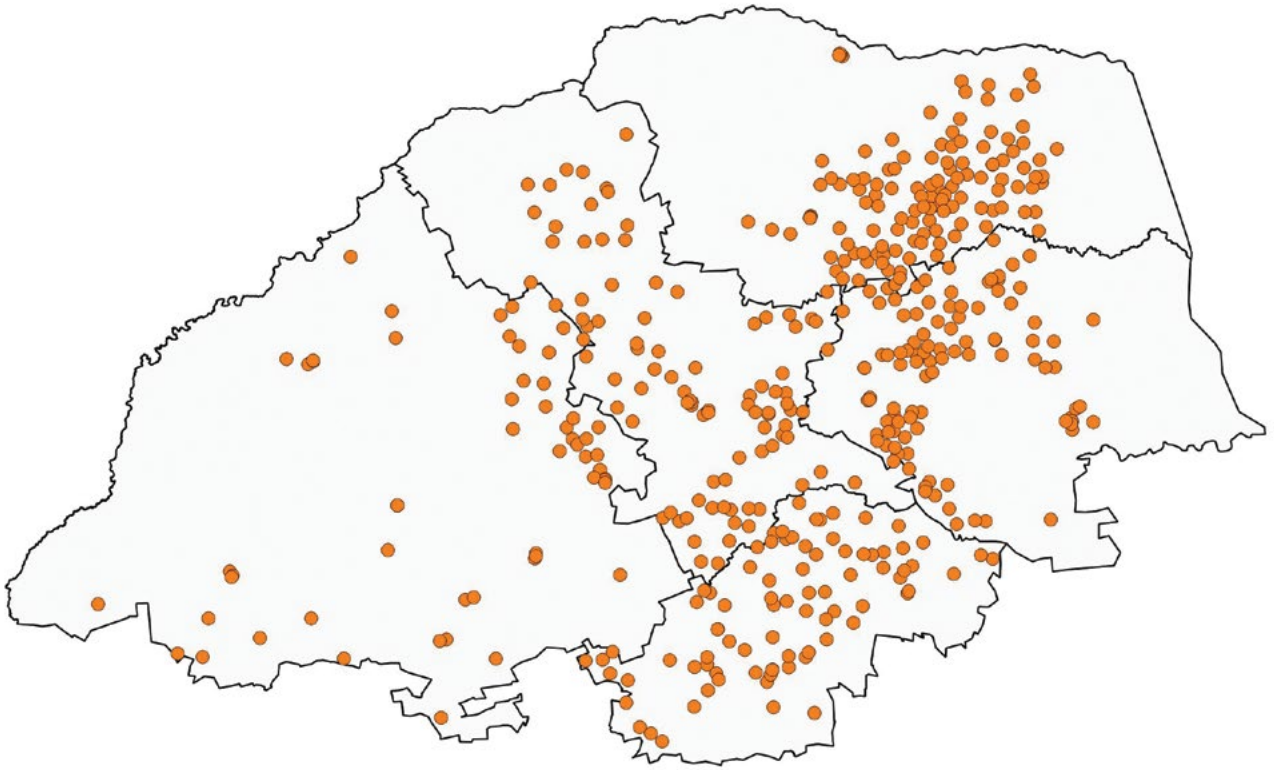
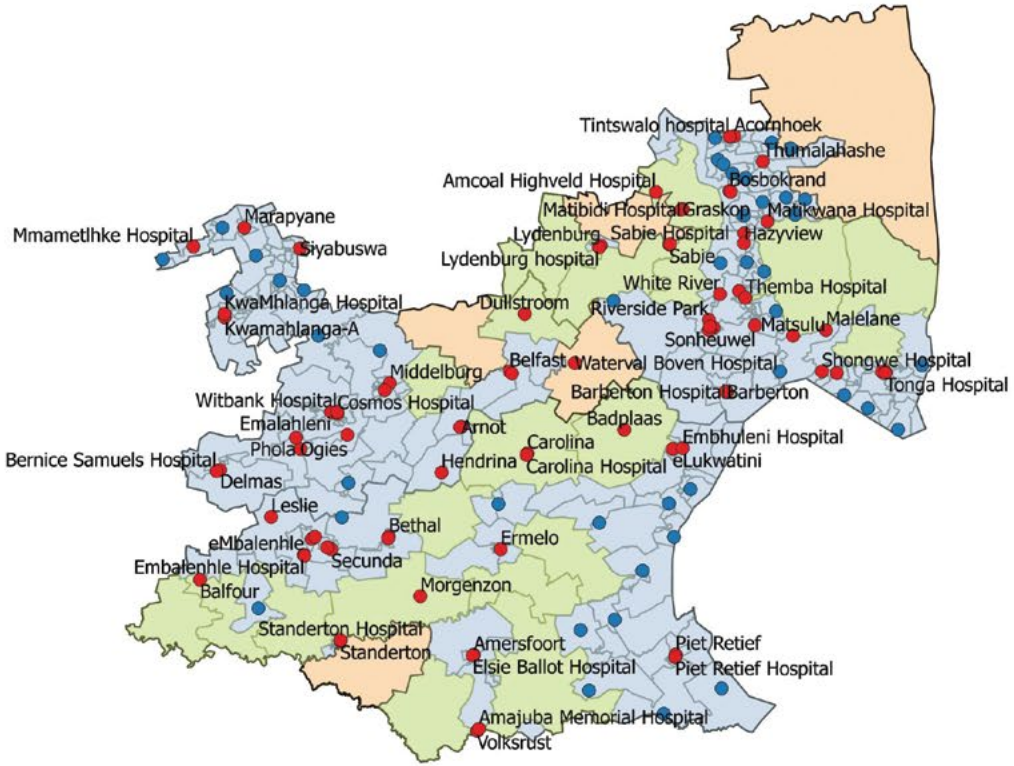


Figure MP 1 Mpumalanga



ATLAS (CONTINUED)

KEY

Background colour by local government electoral ward (2011 elections)

- Metropolitan areas
- Wards where half or more of the population lives in urban areas
- Wards where more than half of the population lives outside urban areas and where the population density is greater than ten people per square kilometer
- Wards where the population density is at least five but less than ten people per square kilometer
- Wards where the population density is less than five people per square kilometer

Location of facilities

- Towns in which retail pharmacies open to the general public are located or places where general hospitals are located.
- Sites of government clinics, excluding specialist clinics and mobile clinics
- Sites having the potential for distribution of at least the full government formulary, excluding medicines which have to be administered in hospitals

Figure MP 2 Mpumalanga General Clinics

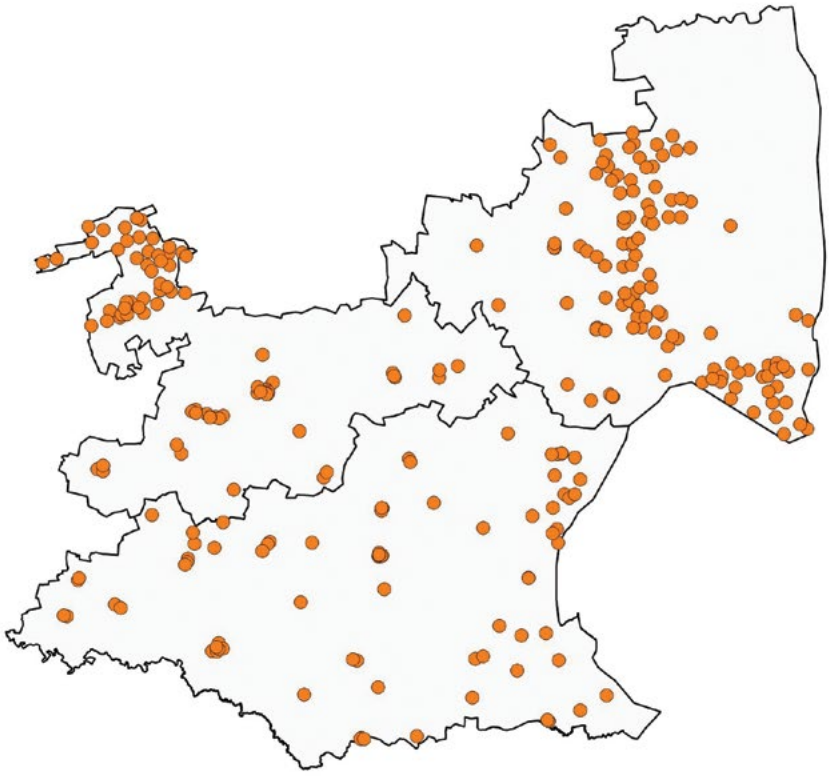
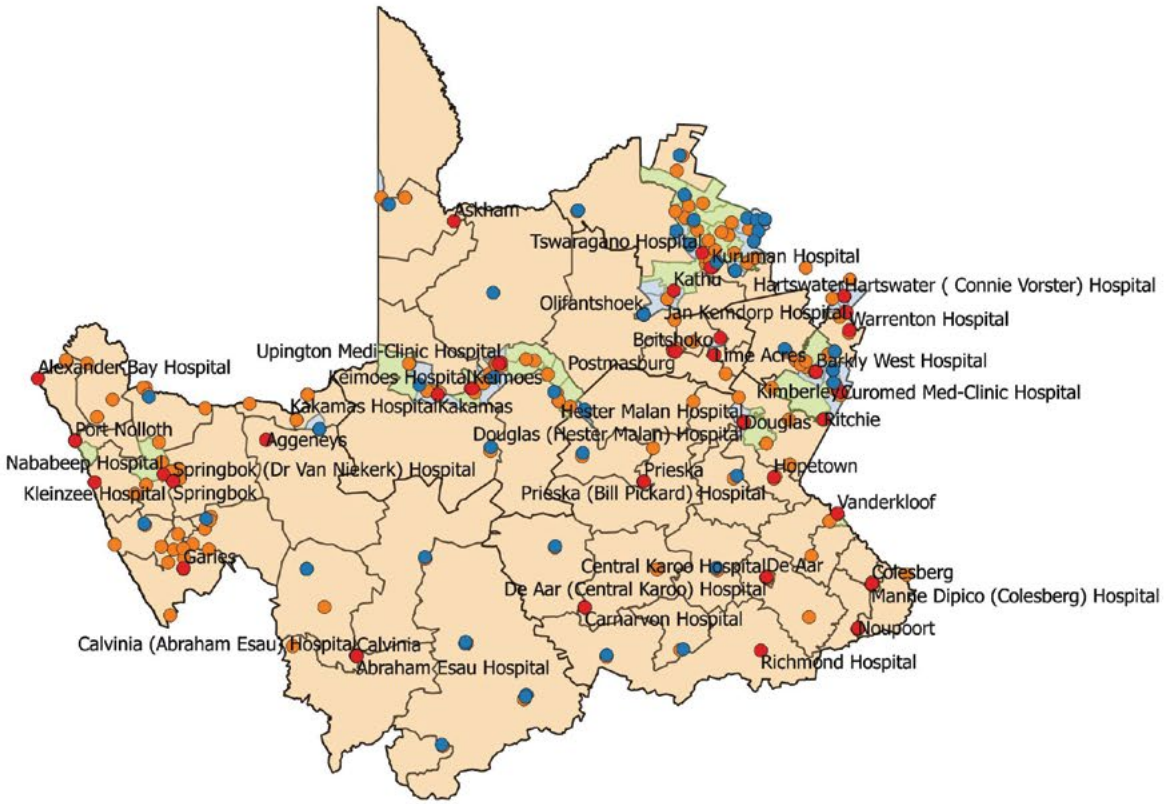


Figure NC 1 Northern Cape



ATLAS (CONTINUED)

KEY

Background colour by local government electoral ward (2011 elections)

- Metropolitan areas
- Wards where half or more of the population lives in urban areas
- Wards where more than half of the population lives outside urban areas and where the population density is greater than ten people per square kilometer
- Wards where the population density is at least five but less than ten people per square kilometer
- Wards where the population density is less than five people per square kilometer

Location of facilities

- Towns in which retail pharmacies open to the general public are located or places where general hospitals are located.
- Sites of government clinics, excluding specialist clinics and mobile clinics
- Sites having the potential for distribution of at least the full government formulary, excluding medicines which have to be administered in hospitals

Figure NC 2 Northern Cape General Clinics

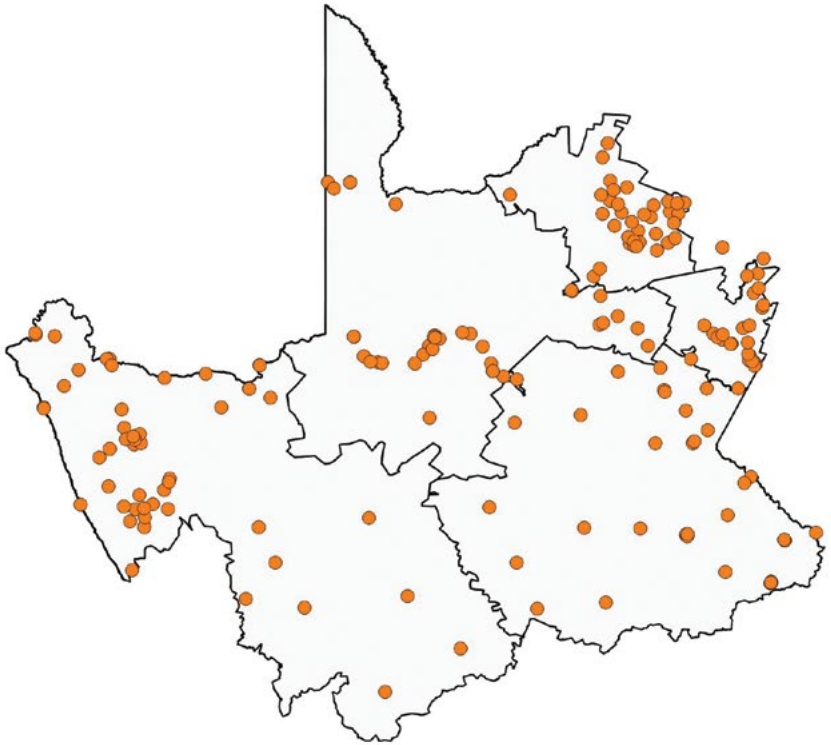
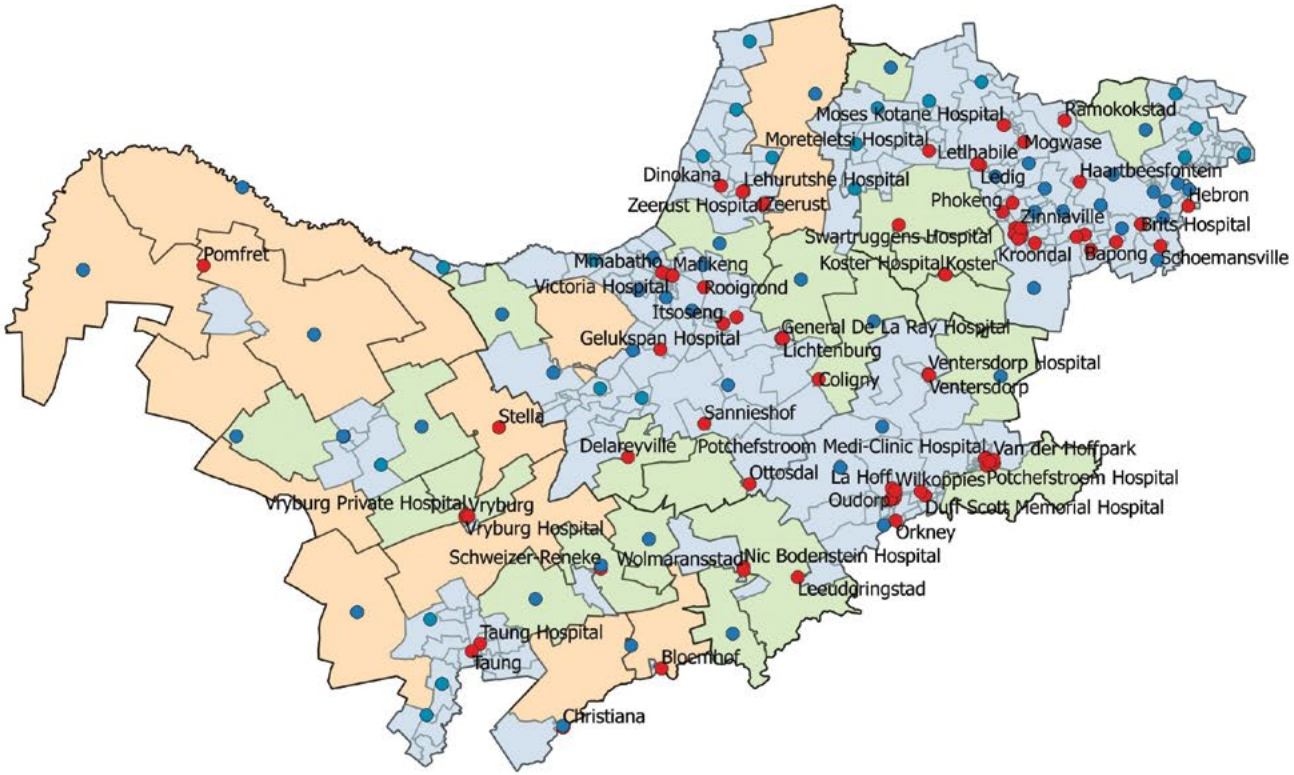


Figure NW 1 North West



ATLAS (CONTINUED)

KEY

Background colour by local government electoral ward (2011 elections)

- Metropolitan areas
- Wards where half or more of the population lives in urban areas
- Wards where more than half of the population lives outside urban areas and where the population density is greater than ten people per square kilometer
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Figure NW 2 North West General Clinics

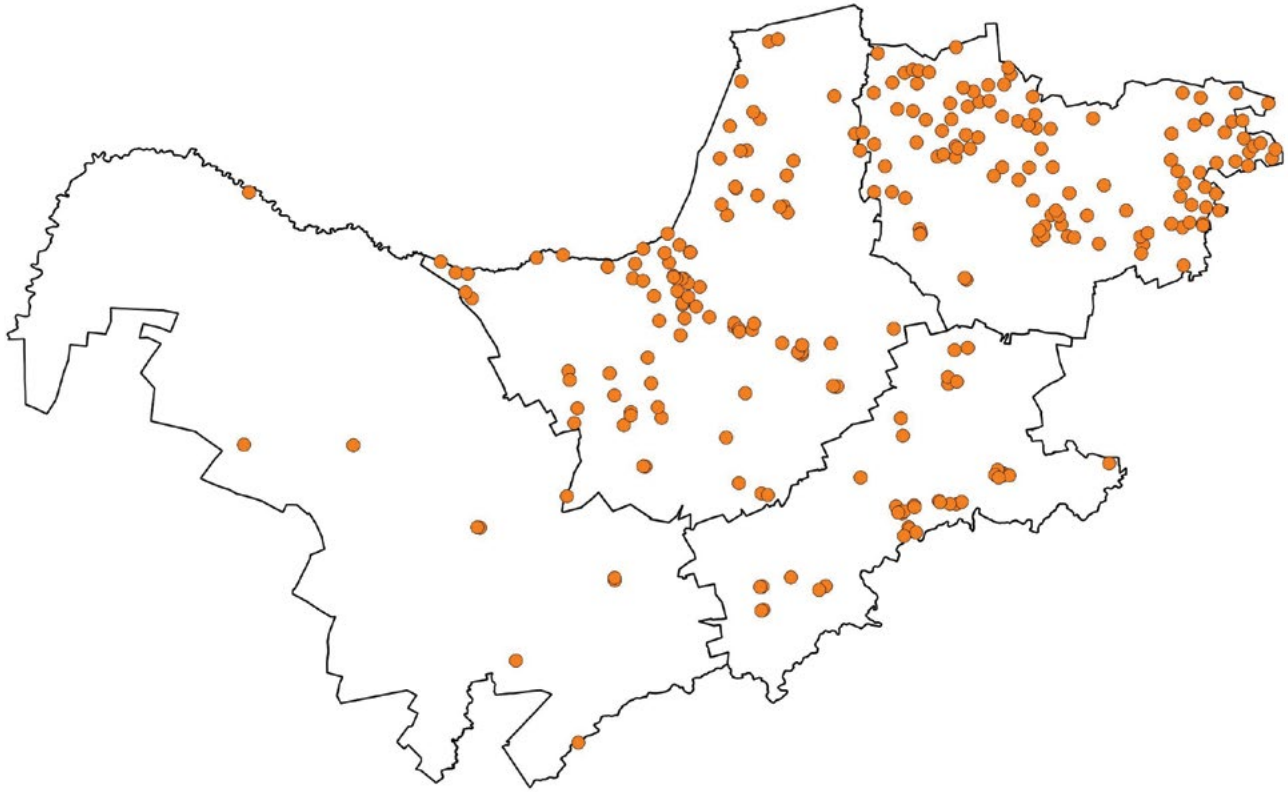
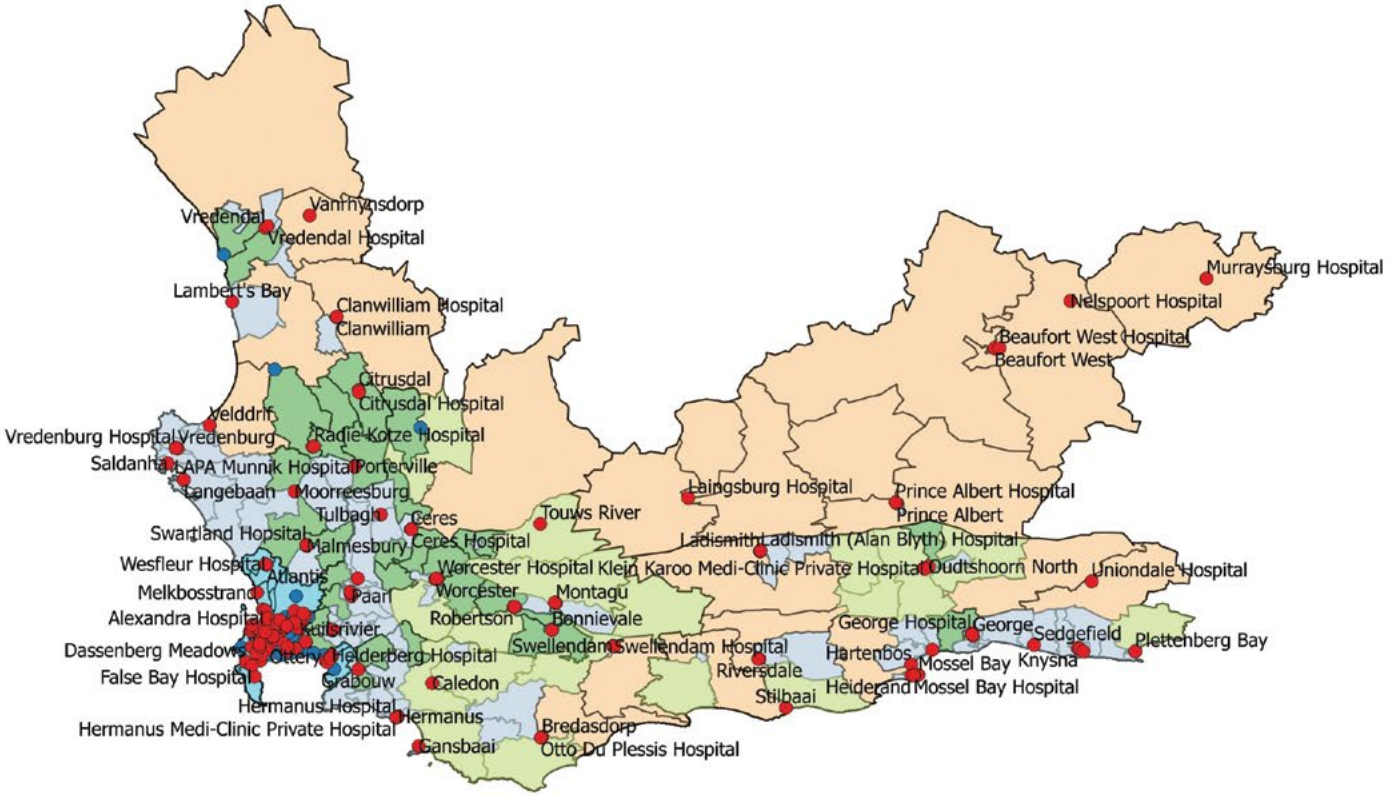


Figure WC 1 Western Cape



ATLAS (CONTINUED)

KEY

Background colour by local government electoral ward (2011 elections)

- Metropolitan areas
- Wards where half or more of the population lives in urban areas
- Wards where more than half of the population lives outside urban areas and where the population density is greater than ten people per square kilometer
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Figure WC 2 Cape Town Metro

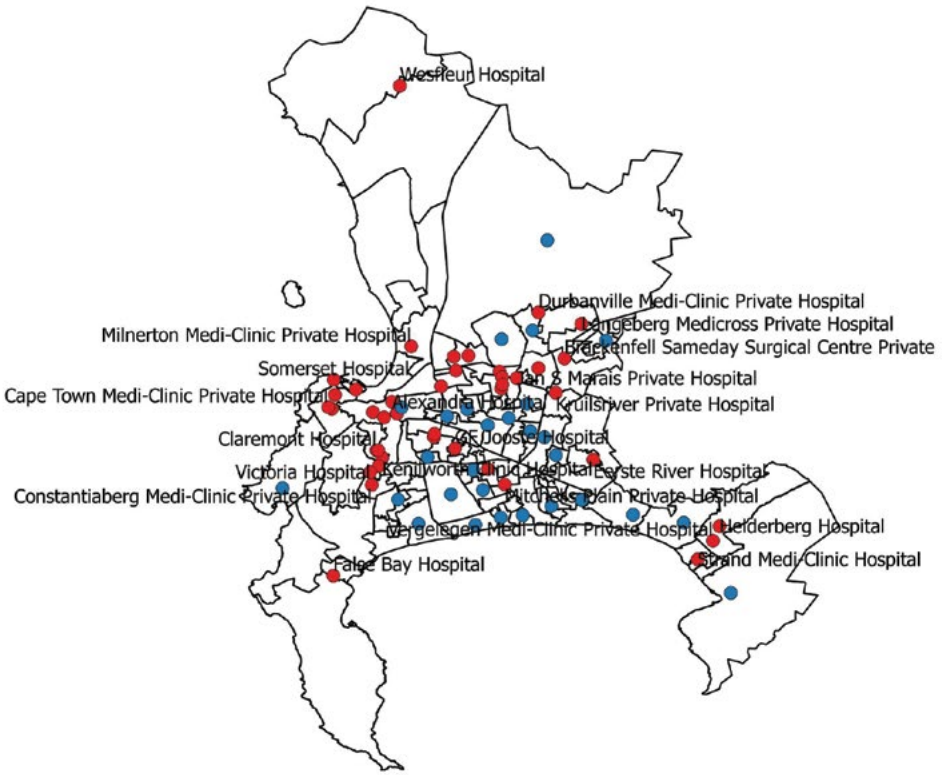
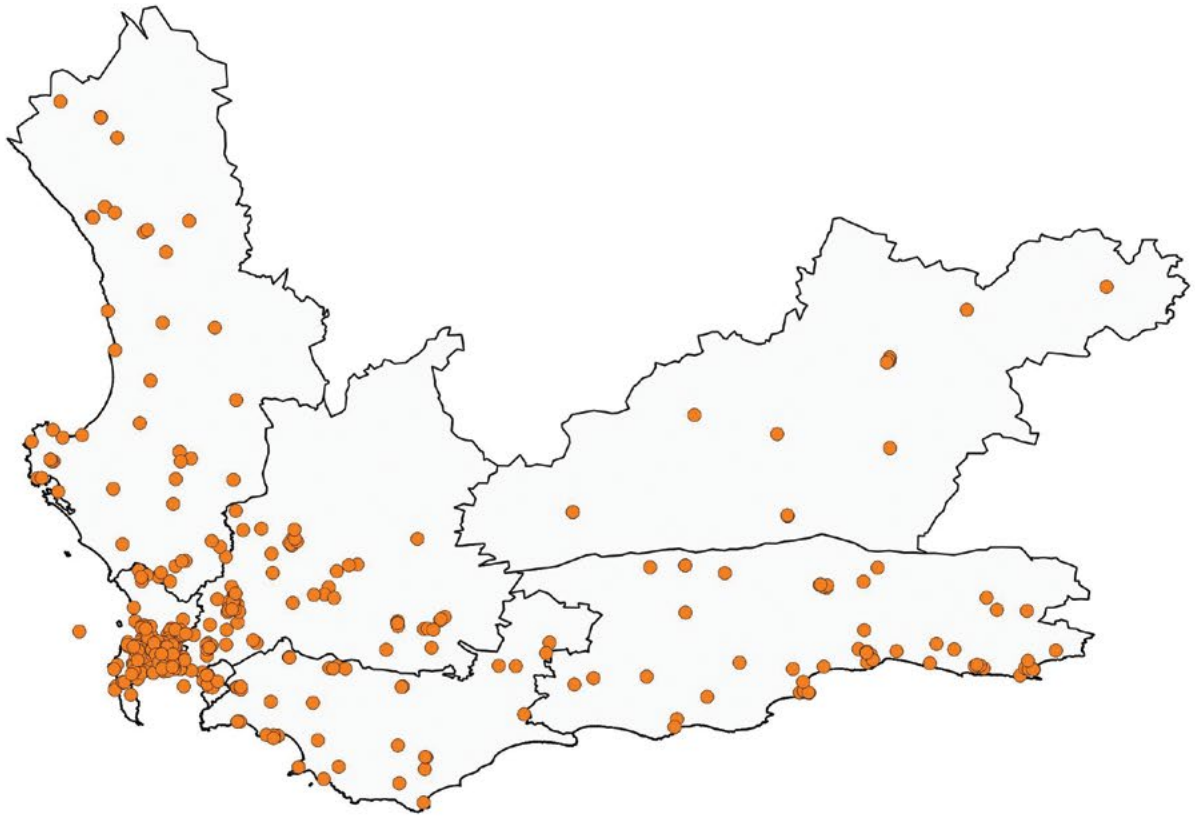


Figure WC 3 Western Cape General Clinics



Conclusions

The world contains a wide variety of pharmacy ownership regimes. At one extreme, there are rules restricting ownership of each pharmacy to a different pharmacist, with a requirement that the pharmacist must be in attendance during trading. At the other, lay ownership is permitted without restriction.

1. Pharmacy ownership regimes are persistent within countries, with little change over the last thirty years. Where there has been change, it has been in a liberalizing direction, but there are many cases where there is no desire for change and some cases, such as North Dakota and Australia, where there has been successful resistance of liberalisation. However, once a system has changed, it is very unlikely to change again. A new set of vested interests arises, which gives a new stability to the altered system.
2. Moreover, change in pharmacy ownership has usually been the result of political change, as in Scandinavia, or Eastern Europe. In South Africa, the party in government which introduced the change is still in power.
3. For these reasons, we believe that a reversion to a policy ownership of pharmacies by pharmacists only is highly unlikely. This is not to say that the concerns of pharmacists are unfounded, but it does mean that these concerns would be pursued more effectively if they were not embedded in a flat opposition to lay ownership.
4. While there are uncertainties about the opening and closing of individual pharmacies, we do not believe that individual pharmacies are in terminal decline. While corporate pharmacies have carved out substantial market share, attrition of individual pharmacies are to be expected, just as in other businesses. Moreover, the rate at which newly licensed pharmacies have opened since 2003 have almost certainly exceeded the closure rate, though the extent of the difference is debateable given the state of the evidence. The individual pharmacy sector is participating in a growing market.
5. The objective of supplying medicine to as many people as possible at the lowest possible cost requires fair competition between pharmacies within the given framework of regulation. We believe that the three most important factors disadvantaging individually owned pharmacies are as follows:
    i. Licensing. The law on licensing requires that the interests of existing pharmacies must be taken into account before new licenses are issued. However, there appears to be no effective or systematic processes of advertising applications for licenses, giving existing pharmacies time to prepare objections, and ensuring that these objections are carefully considered, by making possible appeals against licensing decisions. Pharmacists have complained that the first they know about licensing decisions is when new pharmacies appear.
    ii. Horizontal collusion, particularly between shopping mall owners and managers and corporate pharmacies. There have been cases where corporate pharmacies have exploited their position as large lessees of space in shopping malls to insist that the leases of smaller pharmacies already in the malls are terminated. This adds a twist to inadequately consulted licensing decisions. If the volume of mall custom justifies the presence of more than one pharmacy, the eviction of an existing pharmacy is counterproductive and is an abuse of competitive principles.
    iii. Exclusion of individually owned pharmacies from access to some pharmaceutical products as a result of exclusive dealing arrangements between manufacturers/importers, distributors and corporate pharmacies. This is promoted by vertical integration and is its key adverse outcome. In a regulated environment, one further regulation would be appropriate: a requirement that any pharmacy may require any distributor to supply medicine to it.
6. The present system underservices rural areas. Individual and corporate pharmacies are present in most of the small towns where one would expect to find them outside the metropolitan areas. But it is important to be clear on what the problems are:
    - Sixty nine percent of corporate pharmacies and fifty six percent of individually owned pharmacies are located in the metropolitan areas. Thirty one percent of corporate pharmacies and forty four percent are in smaller towns. People in rural areas proper, particularly the tribal areas, rely mainly on government clinics and hospitals and often have to travel to the nearest town to obtain the medicines they need.
    - There are very large differences in population density across the country. The maps in the atlas shows that much of the land in the western half is very lightly populated, with densities of fewer than five persons per square kilometre and more land with densities between five and ten persons per square kilometre. Substantial distances between pharmacies would exist under any dispensation. Assuming that a pharmacy serves 10 000 people, pharmacies in very low density areas would need to be 71 kilometres apart and in low density areas 39 kilometres apart.
    - In the rest of the country, purchasing power is clearly the issue and is the key limiting factor on the formation of new privately owned pharmacies. At public hospitals and clinics, people obtain medicine at zero or low cost which they could not afford at a private pharmacy. However, they often confront substantial travel costs, congestion, taking the form long queues and waiting times, and frequent stockouts as a result of poor inventory management and logistics. This helps bifurcate the health system into a generally efficient one for the middle class and an inefficient one for everyone else, contrary to the fundamental goal of meeting everyone's needs adequately.
    - What can be done about this at the level of the distribution of pharmaceuticals? There have already been some experiments with the supply of state provided medicine through private pharmacies. These tentative beginnings should be expanded rapidly. New outlets need to be opened at many sites: people's dispensaries, as they might be termed, which would offer the full government formulary, apart from medicines which can only be administered in hospitals. At the least, they could offer people with chronic medicine requirements a better service than having to wait long hours at government clinics and endure stockouts. They would take pressure off clinics to allow more attention to diagnosis, treatment and referral. Considerable thought needs to be given to developing business models, and making proposals to government.

Our general conclusion is this: individual pharmacies have legitimate concerns, and they have considerable unexploited opportunities. The issues and opportunities should be taken up one by one, and not forced into a framework focused only on ownership.

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