
Intergovernmental Group of Experts on Competition Law and Policy

18th SESSION

10-12 July 2019

Room XVII, Palais des Nations, Geneva

Friday, 12 July, 2019

Competition in Healthcare Markets: Access and Affordability

Contribution by The Competition Commission – South Africa

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**Prepared for the United Nations Conference on Trade and Development
Intergovernmental Group of Experts on Competition Law and Policy
Eighteenth Session**

**Discussion: "Competition in healthcare markets: access and affordability"
Geneva, Switzerland
Friday, 12 July 2019
Room XVII**

Contribution by the Competition Commission of South Africa

A. Introduction

1. The Republic of South Africa has a two-tiered healthcare system, comprising a public and private sector. The private healthcare sector caters for an estimated 16% of the population (7 million people) that have access to medical insurance via Medical Aid Schemes¹ and access to high-quality private healthcare.² The private healthcare sector accounts for R33.2 billion (approximately USD2.3 billion) of pharmaceutical expenditure which equates to 84% of total pharmaceutical spend in the country.³ The private healthcare market is supplied by medicines from 130 manufacturers and importers supplying 5 000 product lines.⁴
2. The public healthcare sector serves the healthcare needs of 84% of the population (42 million people)⁵ but only accounts for 16% (or R6.1 billion approximately USD400 million)⁶ of the total

¹ Some Medical Aid Scheme contributions are financed by employees and others joint contributions from employees and employers

² IMS Health Company presentation (November 2016): A review of the South African Pharmaceutical landscape.

³ *ibid*

⁴ Ngozwana, S. (2016). Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries?

⁵ IMS Health Company presentation (November 2016): A review of the South African Pharmaceutical landscape.

⁶ *ibid*

pharmaceuticals expenditure in the country and has access to 2 400 product lines.⁷ Public sector medicines are procured through a tender system which is administered by the National Department of Health (**DoH**).⁸ Public healthcare is financed by the government, primarily through taxes.

3. Prior to the advent of democracy in 1994, the pricing of medicine in South Africa was largely subject to market forces, with the result that multinational pharmaceutical companies were free to determine the price at which they sold their products in the country. Innovator brands dominated the market while generics held limited market share. Pharmaceutical companies promoted their products directly to doctors and pharmacists, and would offer samples, bonuses, discounts, rebates and other incentives to encourage the prescription or dispensing of a particular product. In 1994, the new democratic government undertook to reform the healthcare system. The drafting of the National Drug Policy (1996)⁹ sought to increase access to safe, affordable and quality medicines for all South Africans and laid the foundation for subsequent revisions to legislation and regulations to reduce prices and improve access to pharmaceutical products.¹⁰

4. Amendments to legislation in 1997 saw significant changes to the manner in which pharmaceutical products were supplied and marketed in South Africa. In particular, the amendments made provision for the importation of medicines by companies other than the patent holder, prohibited sampling medicines, bonuses, rebates and any other incentive schemes, and made the generic substitution of products mandatory.¹¹ The amended legislation further called for the establishment of a Pricing Committee, which was tasked with correcting the pricing distortions in the market by developing a transparent pricing system for all medicines and scheduled substances¹² sold in South Africa.¹³ This led to the introduction of a Single Exit Price (**SEP**) regulatory framework in 2004. Under the SEP regime, the price at which manufacturers sell to pharmacies is regulated and cannot be varied according to volumes sold.

⁷ Ngozwana, S. (2016). Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries?

⁸ *ibid*

⁹ National Drug Policy for South Africa (1996)

¹⁰ Ngozwana, S. (2016). Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries?

¹¹ Amendments made to the Medicines and Related Substances Act (No. 101 of 1965) ("MRSA"). Refer to discussion by Ngozwana, S. (2016). Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries?

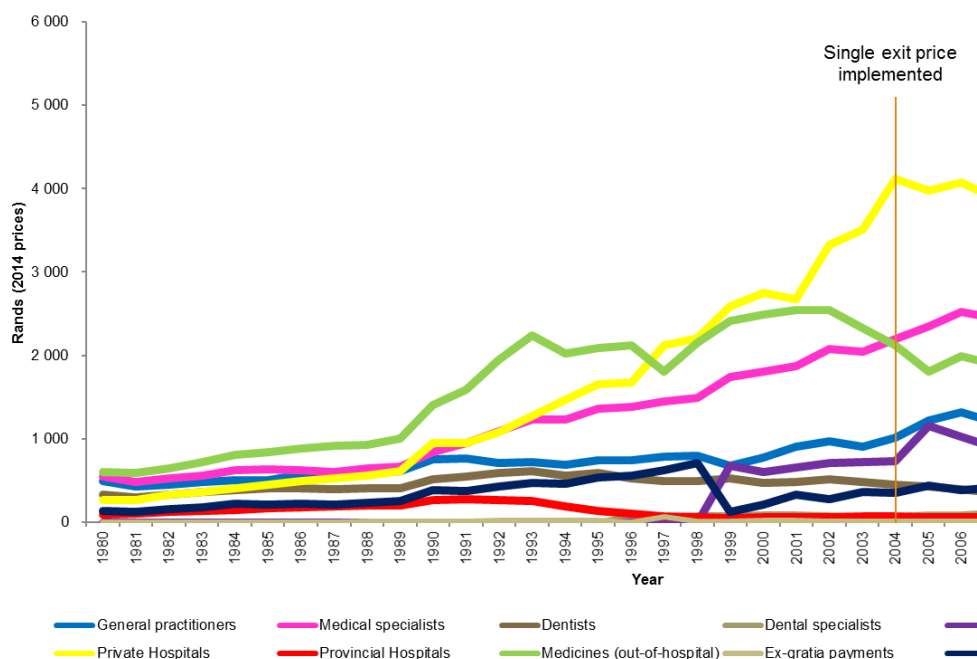
¹² Including generic and originator products across Schedules 1 to 7

¹³ Ngozwana, S. (2016). Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries?

Manufacturers are obliged to supply medicines to wholesalers at the SEP plus logistic fees and pharmacists have to dispense all products to patients at SEP plus dispensing fees.¹⁴ The objectives of SEP is to ensure price transparency and that manufacturers sell medicines at one price to all customers in the private sector regardless of order size, consumption levels or customer profile. Only scheduled medicines are subject to SEP (Schedule 1 –7).

5. Historical data indicates that although the cost of healthcare (i.e. private hospital claims expenditure per beneficiary per annum) in South Africa has increased by approximately 200% between 1997 and 2013, the contribution of medicines to total cost of healthcare has declined slightly over the same period. Figure 1, below, shows the composition of claims expenditure for members of private medical schemes from 1980.

Figure 1: CLAIMS EXPENDITURE, PER BENEFICIARY PER ANNUM FROM 1980 TO 2013 (2014 PRICES)



Source: Health Market Inquiry Analysis using data from Council for Medical Schemes

6. The contribution of medicines increased steadily until 2004 when the introduction of SEP legislation led to a notable decline. The introduction of the SEP and capped annual increases

¹⁴ Medicines and Related Substances Act, 1965 (Act no. 101 of 1965): **Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances (Draft Dispensing Fee for Pharmacists)**. Government Notice 895 in Government Gazette 40188 dated 5 August 2016.

are estimated to have led to a 22% decrease in the price of medicines in the first year after the introduction of SEP, showing the importance of effective regulation in ensuring access to affordable medicines.¹⁵

B. Excessive Pricing Enforcement in South Africa in Pharmaceutical Markets

7. In 2017, the Competition Commission of South Africa (**CCSA**) initiated complaints of excessive pricing against Roche Holding AG (**Roche**) and Genentech Inc (**Genentech**), alleging that the firms have contravened the Competition Act by engaging in excessive pricing, exclusionary conduct and price discrimination with regard to the sale and supply of a drug named Trastuzumab. This drug is sold under Roche's brand names, Herceptin and Herclon for the treatment of breast cancer.
8. The information obtained by the CCSA prior to the initiation of the complaint indicated that:
 - 8.1. Trastuzumab is sold at excessive prices in South Africa by Roche and Genentech. For example, a 12-month course of Herceptin in the private sector costs over R500 000 (approximately USD35 000)¹⁶ or more if a high dosage is required and as such most patients are unable to afford the treatment;
 - 8.2. Roche and Genentech use strategies such as 'ever greening' and 'patent thickening' to delay and/or prevent entry of generic alternative breast cancer drugs in South Africa; and
 - 8.3. Roche and Genentech charge their customers different prices for breast cancer medicines. For example, the private sector is charged approximately double the price paid by the public sector for aforementioned drugs.
9. The investigation of this complaint is still ongoing.
10. A seminal case in excessive pricing was conducted by the CCSA in 2001/02 following the receipt of a complaint in relation to Anti-RetroViral (**ARV**) treatment in South Africa against Boehringer Ingelheim (**BI**) and GlaxoSmithKline (**GSK**) (**referred to as the Hazel Tau case/settlement**).
11. The complaint was laid by individuals affected with HIV/AIDS, health care professionals, trade unions and several NGOs. At the time of the complaints, there were approximately 4.74 million

¹⁵ Chowles, T. How medicine prices are regulated in South Africa. 6 November 2017. Available [here](#).

¹⁶ Converted at current exchange rate (16 November 2018).

people living with HIV/AIDS in South Africa.¹⁷ The Medical Research Council (**MRC**) reported that AIDS was considered the leading cause of mortality in South Africa at the time with approximately 200 000 people estimated to have died of AIDS-related illnesses in 2001 alone. The MRC also reported that about 40% of adult deaths for people aged 15 – 49 in 2000 were due to HIV/AIDS and at least 20% of all adult deaths were AIDS-related.

12. The CCSA expanded the investigation to include allegations that GSK and BI had also refused to grant access to an essential facility and were engaging in general exclusionary conduct. These allegations were premised on the fact that pharmaceutical firms were not willing to licence their patents to other manufacturers on reasonable commercial terms.
13. The CCSA concluded its investigation and found that GSK and BI had abused their dominant positions by charging excessive prices for ARV drugs under patent and for excluding generic manufacturers from the market by refusing to issue licences. Before the case could be referred to the Competition Tribunal for adjudication, GSK and BI opted to resolve the matter by negotiating settlement agreements with the CCSA. The eventual settlement agreements required that, *inter alia*, BI and GSK allow generic manufacturers to use their patents to produce ARV treatment.¹⁸
14. In 2016, the CCSA completed an impact assessment study of the Hazel Tau settlement based on pricing data from 2000 to 2015. It found that the prices of ARVs had decreased by more than 11% per annum, on average, and that an estimated cost saving of US\$887m had been realised over the period, much of which accrued directly to the government of South Africa. Further, the Hazel Tau settlement contributed to making access to ARVs easier for South African citizens. In 2004, the year the South African government introduced its ARV treatment program, only 47 500 people received treatment. By 2016, this number had increased to over a million people, the largest number in the world.¹⁹ Since the country's national antiretroviral therapy programme was rolled out in 2004 life expectancy has risen by nearly ten years – from 53.4 in 2004 to 62.5

¹⁷ <http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKEvidenceAndLegalSubmissions.pdf> [accessed 30 October 2018]

¹⁸ As part of the settlement agreement concluded with GSK and BI, they agreed to: (i) grant licenses to generic manufacturers; (ii) permit the licensees to export the relevant ARV medicines to sub-Saharan African countries; (iii) where the licensee did not have manufacturing capability in South Africa, permit the importation of the ARV medicines for distribution in South Africa only (provided all the regulatory approvals were obtained); (iv) permit licensees to combine the relevant ARV's with other ARV's medicines; and (v) not require royalties in excess of 5% of the net sales of the relevant ARVs.

¹⁹ <https://africacheck.org/reports/yes-south-africa-has-the-worlds-largest-antiretroviral-therapy-programme/> [accessed on 30 October 2018]

in 2015 – and the antiretroviral therapy programme is partly credited for this.²⁰ Overall, the intervention of the CCSA in this market has enabled the state to expand treatment of HIV/AIDS at a much more reasonable cost than it would have been, absent the intervention.

15. The Hazel Tau settlement also enabled the entry of generic medicines primarily due to the voluntary licensing regime. This led to the entry of 32 producers of commercial ARVs in South Africa. Aspen Pharmacare Holdings Limited (**Aspen**), the largest pharmaceutical drug company in Africa, was one of the manufacturers who were able to effectively enter into the market and expand their supply of generic medicines to Sub-Saharan Africa as a result of the Hazel Tau settlement²¹. Other firms have also benefited from greater generic competition. In March 2016, the DoH requested Abbvie (the HIV division of pharmaceutical company Abbot) to license other pharmaceutical companies to enable them to manufacture Aluvia, a second-line ARV for HIV patients. This request came in response to Abbvie's inability to meet global demand for the drug, which is provided to approximately 300 000 HIV patients per month in South Africa alone. Abbvie agreed to the request²² and issued licenses to other drug companies to manufacture Aluvia.

C. Challenges to the enforcement of excessive pricing in pharmaceutical and healthcare markets

16. Competition law related pricing enforcement has many challenges, including but not limited to the following:
 - 16.1. **Access to information required to conduct thorough analyses.** By way of example, in South Africa screening for ever-greening is reliant on obtaining patent information from the Companies and Intellectual Property Commission (**CIPC**) which records the application and/or granting of secondary patents. Once identified, each of these applications would have to be scrutinised to establish whether the secondary patent was granted based on a negligible technological advancement. Similarly, uncovering patent thickets requires untangling a web of patents related to a particular product which could include the active pharmaceutical ingredient, process or method of intake, amongst other things. Given South Africa's weak patent system, the CIPC is unable to prevent or

²⁰ <https://africacheck.org/reports/yes-south-africa-has-the-worlds-largest-antiretroviral-therapy-programme/> [accessed on 30 October 2018]

²¹ Current key countries identified by Aspen in the Sub-Saharan African region include: Kenya, Namibia, Nigeria, South Africa and Tanzania (Aspen Holdings website, available at: <https://www.aspenpharma.com/sub-saharan-africa/>; accessed on 19 August 2018)

²² Should Abbvie not have extended this license, the DoH had threatened to source the drug from other suppliers (although it is not clear whether this would have been through an outright compulsory license or parallel importing).

identify patent abuses such as ever-greening or patent thickets. This weakness has been acknowledged by the CIPC and the Department of Trade and Industry and being addressed through the redrafting of the National Policy on Intellectual Property.

- 16.2. **Enforcement action against multinational companies.** This is pertinent where the locally-based company is often a subsidiary of a parent company based abroad. For instance, the CCSA is currently facing this challenge in its enforcement action against Roche and Genetech. Often the parent company would have the final say on strategic decisions which may have an impact on the conduct observed in South Africa. If authorities require information which resides with the parent company and not the subsidiary based in South Africa, authorities are likely to struggle to access this information. This therefore requires cooperation between competition authorities across jurisdictions to assist in bridging this gap where possible and within the confines of the law.
- 16.3. **The interplay between competition law enforcement and intellectual property rights.** In such instances, authorities would have to engage with how to measure the innovation protected and rewarded by the patent in existence. Further, competition authorities would also have to outline how to account for this in their competitiveness assessment whilst balancing the legitimate commercial interests of the patent-holder.

D. Healthcare Funding and Facilities: Health Market Inquiry (HMI)

17. In 2013 the CCSA initiated the HMI which broadly sought to ascertain whether there are features in the private healthcare market which harm competition or have the potential to harm competition.
18. In July 2018, the HMI released its preliminary findings and recommendations across the healthcare sector, including the following in relation the funding and facilities:
- 18.1. The facilities market is concentrated at both national and regional levels with three large hospital groups having a substantial share of the national general acute hospital care market based on both admissions and registered beds with HHIs in the range of 2500.
- 18.2. Given that healthcare funders negotiate with hospitals at a national level, the national concentration levels provide a significant strategic advantage in bilateral negotiations to the three largest hospital groups. Nationally operating schemes/administrators cannot avoid contracting with any of the three big hospitals.

- 18.3. The structure of the funders' (insurers) markets is also concentrated. In the open medical scheme market²³, the C3 ratio is 75% of which the largest scheme/insurer alone accounts for approximately 55% of the market. Further, the HHI index in the open scheme market changed from 1510 in 2005 to 3391 in 2016.
19. The preliminary recommendations of the HMI in relation to the above preliminary findings include:
- 19.1. The introduction of a national facilities licensing framework with effective monitoring, inspection and reporting to support the development of a comprehensive and reliable database of healthcare facilities.
- 19.2. Greater transparency and more objective benchmarking along with a standard system should be developed to monitor the quality and outcomes of healthcare services.
- 19.3. Although networks such as Designated Service Providers or Preferred Provider Arrangements are generally positive for consumers, they do raise exclusionary concerns. To ameliorate for this, there should be greater transparency in the selection of 'designated' providers who should be appointed through an open tender process and have limited contracts of no more than two years.

E. Conclusion

20. The increase in competition enforcement in pharmaceutical markets in recent times follows widespread and general complaints about the price of pharmaceutical products and through non-Government Organisations putting pressure on the South African government to institute reforms on patent laws to make life-saving drugs more affordable. The CCSA's previous interventions in the pharmaceuticals market like in the Hazel Tau case has enabled patients to have access to ARV treatment at lower prices. Moreover, the Hazel Tau settlement dismantled the barriers to entry in the production of ARV treatment.
21. However, the challenges for competition authorities in undertaking pricing enforcement such as access to information, enforcement action against multinational companies which necessitates international cooperation and the interplay between competition law enforcement and intellectual property rights remain as hurdles that competition authorities will continue to face.

²³ Open medical schemes are legally required to accept anyone who wants to become a member. Restricted medical schemes are attached to a defined group such as an employer, industry, or union and are open only to the members of the associated group

22. Once the HMI is finalised in September 2019, the CCSA will continue to play a significant role in working together with stakeholders such as the government and the DoH in ensuring that its recommendations are implemented.

23. The CCSA has prioritised healthcare and pharmaceutical markets and is currently looking into the cost of pharmaceuticals, particularly “life-saving” medicines used to treat HIV/AIDS, cancer, hepatitis B and C, and diabetes.