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Excessive Pricing in Pharmaceutical Markets – Note by South Africa

28 November 2018

This document reproduces a written contribution from South Africa submitted for Item 9 of the 130th OECD Competition Committee meeting on 27-28 November 2018.

More documents related to this discussion can be found at

www.oecd.org/daf/competition/excessive-pricing-in-pharmaceuticals.htm

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South Africa

1. Introduction

1. The Organisation for Economic Co-operation and Development (OECD) has invited contributions to its round table on "Excessive Pricing in Pharmaceuticals" that will be held in November 2018. This note is prepared to assist in these discussions, which are intended to:

- discuss the economic and legal theories to support competition intervention in the pharmaceuticals markets;
- take stock of experiences in competition cases involving excessive pricing in pharmaceuticals
- identify enforcement challenges that competition authorities face in pharmaceutical cases particularly those assessing excessive pricing; and
- understand price regulation and the extent to which there exists cooperation between sectoral regulators and competition authorities in pharmaceutical markets.

2. In this note, the Competition Commission of South Africa ("CCSA") shares its experiences in assessing and prosecuting excessive pricing in the pharmaceutical market.

2. Background to the pharmaceutical market in South Africa

3. South Africa has a two-tiered healthcare system, comprising a public and private sector which have disparate resources, and access medicines via different channels. The private healthcare sector caters to an estimated 16% of the population (7 million people) that have access to medical insurance via Medical Aid Schemes[1], and who can therefore afford high-quality private healthcare.[2] The private healthcare sector accounts for R33.2 billion of pharmaceutical expenditure which equates to 84% of total pharmaceutical spend in the country.[3] The private market is supplied by medicines from 130 manufacturers and importers supplying 5 000 product lines.[4]

[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?

4. 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)[6] of the total pharmaceuticals expenditure in the country and has access to 2 400 product lines.[7] Public sector medicines are procured through tenders that are administered by the National Department of Health (DoH).[8] Public hospitals can also initiate procurement of medicines from manufacturers and importers through tenders or quotation systems in order to cater for their own needs. Public healthcare is financed by the government, primarily through taxes.

5. Prior to the advent of democracy in South Africa in 1994, the pricing of medicine 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. This is believed to have led to doctors often prescribing more expensive medicines.[9] In addition, pharmaceutical companies were able to discriminate amongst clients on the basis of volume purchases and other considerations.[10]

6. Furthermore, due to pharmaceutical companies' ability to discriminate between customers, patients in poor and marginalised areas ended up paying more for medicines than patients in more affluent areas that were more likely to benefit from price and volume discounts.[11] In 1994, the new democratic government undertook to reform the healthcare system. The drafting of the National Drug Policy (1996)[12] 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.[13]

7. 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

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

[6] ibid

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

[8] ibid

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

[10] Ibid.

[11] Ibid.

[12] National Drug Policy for South Africa (1996)

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

schemes, and made the generic substitution of products mandatory.[14] 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 substances[15] sold in the country.[16]

8. 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 volume sold. Manufacturers are obliged to supply medicines to wholesalers at the SEP plus logistic fees, and pharmacists have to dispense all products to patients at SEPs plus dispensing fees. [17] The objectives of SEP are to ensure price transparency and that manufacturers sell medicine at one price to all customers in the price sector regardless of order size, consumption levels or customer profile. Only scheduled medicines are subject to SEP (Schedule 1 –7).

9. The Minister of Health (through the Pricing Committee) determines an annual percentage increase of SEP that is uniformly applied to all products. In exceptional circumstances (e.g. raw material cost increase), the Minister of Health may permit ad hoc price increases under Regulation 9 of the Medicines Act[18].

10. The ongoing Market Inquiry into the Private Healthcare Sector conducted by an independent panel appointed by the CCSA has revealed that though 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 health care has declined slightly over the same period. Figure 1, below, shows the composition of claims expenditure for members of private medical schemes from 1980. The contribution of medicines increased steadily to 2004, when the introduction of SEP legislation led to a notable decline.

11. The introduction of the SEP and capped annual increases are estimated to have led to a 22% decrease in medicine prices in the first year after the introduction of SEP, showing the importance of effective regulation in ensuring access to affordable medicines.[19]

[14] 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?

[15] Including generic and originator products across Schedules 1 to 7

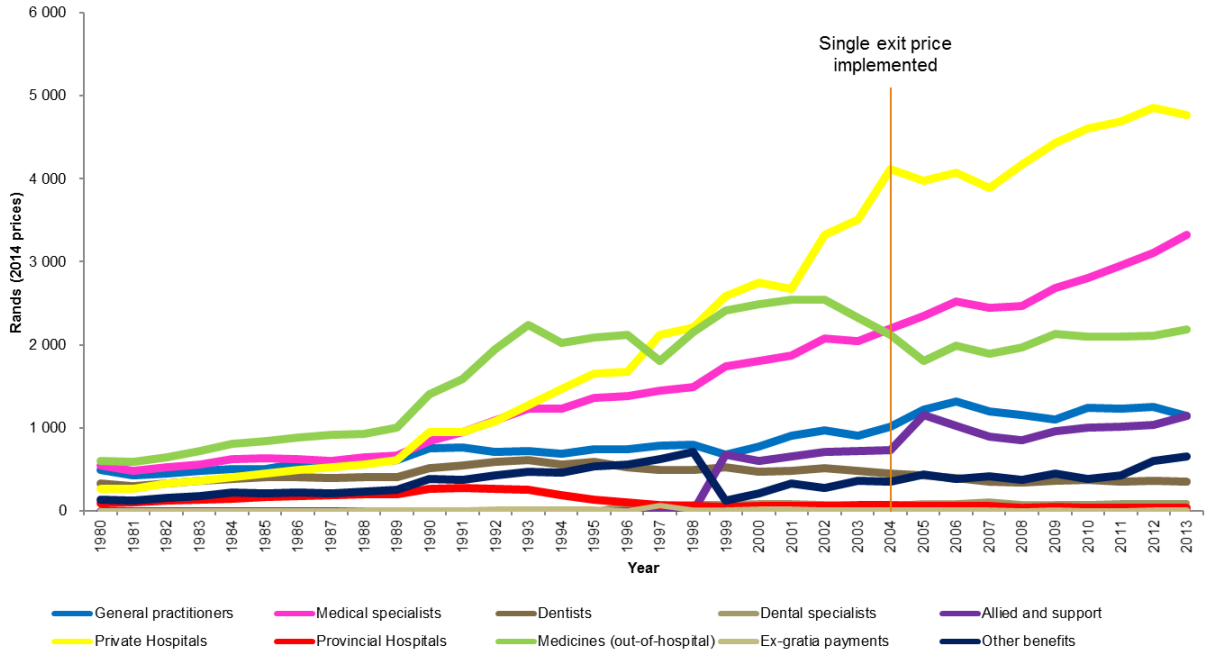
[16] Ngozwana, S. (2016). Policies to Control Prices of Medicines: Does the South African Experience Have Lessons for Other African Countries?

[17] 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.*

[18] Regulation 9 of the Medicines and Related Substances Act, 1965 (Act no. 101 of 1965):

[19] Chowles, T. How medicine prices are regulated in South Africa. 6 November 2017. Available here.

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

2.1. Total spend on pharmaceutical products in South Africa

12. Pharmaceutical products are classified into Schedules 0 to 7 according to their medical properties (e.g. side effects and chemical ingredients). The marketing and dispensing restrictions become tighter the higher the product schedule. Unscheduled and Schedule 0 medicines may be bought without any restriction from shelves in retail outlets and the buyer may buy as much as she requires. Schedule 1 and 2 products are issued over-the-counter by a pharmacist, and do not require a prescription. Medicines which fall into the Scheduled 3 to 7 category can only be dispensed with a prescription from a licensed medical practitioner.

13. Prescription drugs represent approximately 88% of the total pharmaceutical market in value terms. In 2014, the South African prescription drug market was worth R35 billion (US$3.2 billion).[20]

14. In terms of value sales, BMI has estimated that spending on patented drugs totalled R22.12 billion in South Africa in 2014, which is equivalent to 55.60% of total pharmaceutical sales and 63.25% of prescription drug sales. Expenditure on patented drugs is largely driven by the private healthcare market. Patients that rely on public health often

[20] Business Monitor International. (November 2015). South Africa Pharmaceuticals & Healthcare Report Q1 2016.

cannot afford patented drugs, and will either opt for a generic (if available) or forego treatment.[21]

15. Spending on generic drugs totalled R12.85 billion in 2014, accounting for 32.3% of total pharmaceutical sales and 36.7% of prescription drug sales. The SEP regulations are constructed such that pharmacists are able to add larger mark-ups to lower-priced products, thereby incentivising the dispensing of cheaper generic medicines rather than patented products.[22] With respect to volume sales, it is estimated that of the prescription drugs sold in the market, 36% are for originator drugs and 64% for generic products.

16. These statistics suggest that, in South Africa, a larger volume of generic prescription drugs are sold as opposed to originator prescription drugs, but in terms of monetary value, a larger amount is spent on originator prescription drugs than generic prescription drugs.[23]

3. Excessive pricing in South Africa – legal and economic framework

3.1. Legal and economic framework

17. South African competition authorities have thus far mainly dealt with exploitative abuses outside of the pharmaceutical sphere.

18. Section 8(a) of the Competition Act. 89 of 1998 ("the Act") empowers to the CCSA to investigate exploitative price abuses in any sector of the South African economy. Section 8(a) prohibits a dominant firm from charging an excessive price to the detriment of consumers. An "*excessive price*" is defined in the Competition Act as a price that bears no reasonable relation to the economic value of that good or service, and is higher than the economic value.

19. The Competition Act does not have a definition of economic value nor measures to assess it. Instead, the legislature has left it to the Courts to define this terminology and to determine ways of measuring it. To date, there have been two notable cases[24] before the Courts which dealt with exploitative price abuses: *Harmony vs Mittal* ("Mittal case")[25] and

[21] Business Monitor International. (November 2015). South Africa Pharmaceuticals & Healthcare Report Q1 2016.

[22] Business Monitor International. (November 2015). South Africa Pharmaceuticals & Healthcare Report Q1 2016.

[23] For instance 1 month's supply of generic Gleevec, a cancer treatment drug, cost US$166 in India but US$2913 as the original drug in South Africa.

[24] Harmony vs Mittal, Competition Tribunal Case no. 13/CR/Feb04: and Sasol Chemical Industries vs Competition Commission, Competition Tribunal Case no: 2011Nov0347; Competition Appeal Court Case no: 131/CAC/Jun14

[25] Competition Tribunal case no. 13/CR/Feb04, Harmony Gold Mining co ltd, Durban Roodepoort Deep limited and Iscor Ltd, Mac Steel International BV

Sasol Chemical Industries ("SCI") vs Competition Commission ("Sasol case")[26]. The Sasol case provides the most recent guidance on excessive pricing assessment in South Africa.[27]

20. The Sasol case recommended the price-cost methodology as the primary excessive pricing methodology.[28] Price-cost methodology involves amongst others, comparing the price charged with the economic value (defined as costs incurred) and determining whether there is a reasonable relation between price and economic value. If the actual price is reasonably higher than economic value, the authorities must determine whether the alleged excessive price is to the detriment of consumers. Other tests of excessive pricing recommended in the Sasol Case include price comparators and profitability analysis.

3.2. Complaints of excessive pricing in pharmaceutical markets

21. The 2002 case of Hazel Tau & others v. GlaxoSmithKline ("GSK") & Boehringer Ingelheim ("BI") ("Hazel Tau Case") remains the landmark excessive pricing case in the pharmaceutical industry in South Africa.

3.2.1. The case of Hazel Tau and others against GlaxoSmithKline ("GSK") and Boehringer Ingelheim ("BI")

22. In 2001, there were approximately 4.74 million people living with HIV/AIDS in South Africa.[29] 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. Non-governmental organisations such as the Treatment Action Campaign (TAC) submitted that most of the people who died were those without access to drugs that could have prolonged and improved their quality of life.[30]

23. The nature and extent of the HIV/AIDS burden on South Africa had the potential to weaken existing health infrastructure and health service delivery. The Department of Health recognised that "*HIV/AIDS represents the greatest threat to public health in our country*"[31] and the Constitutional Court emphasised that "*it is essential that there be a concerted national effort to combat the HIV/AIDS pandemic and that it is important that all sectors of the community…should co-operate in the steps taken to achieve this goal*"[32].

[26] See Commission Case number 2011Nov0347; CAC Case number 131/CAC/Jun14

[27] The Judgement was handed on 17 June 2017.

[28] CAC decision on Sasol case [para 70]

[29] http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKevidenceAndLegalSubmissions.pdf [accessed 30 October 2018]

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

[31] Minister of Health and Others v Treatment Action Campaign and Others, CCT 8/02 (5 July 2002), para 1 and 93.

[32] Minister of Health and Others v Treatment Action Campaign and Others, CCT 8/02 (5 July 2002), para 125-126.

24. It is in this dire context that the CCSA received a complaint on the exorbitant prices of Anti-RetroViral ("ARV") treatment in South Africa. This complaint was laid by individuals affected with HIV/AIDS, health care professionals, trade unions and several NGOs. The complainants alleged that GSK and BI violated section 8 (a) of the Competition Act by charging excessive prices for their patented ARV medicines.

25. The CCSA expanded the investigation to include allegations that GSK and BI had further violated sections 8(b) and (c) of the Act by refusing to give competitors access to an essential facility or engaging in a general exclusionary act where the anti-competitive effect outweighed any efficiency gains. These arguments were based on allegations that pharmaceutical firms were not willing to licence their patents to other manufacturers on reasonable commercial terms.

26. In its investigation, the CCSA found that GSK and BI had abused their dominant positions in the market for their respective ARVs by charging excessive prices for ARV drugs under patent and for excluding generic manufacturers from the market by not issuing licences to these generic manufacturers to supply ARV drugs to the market. 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 BI and GSK allow generic manufacturers to use their patents to produce ARV treatment.[33]

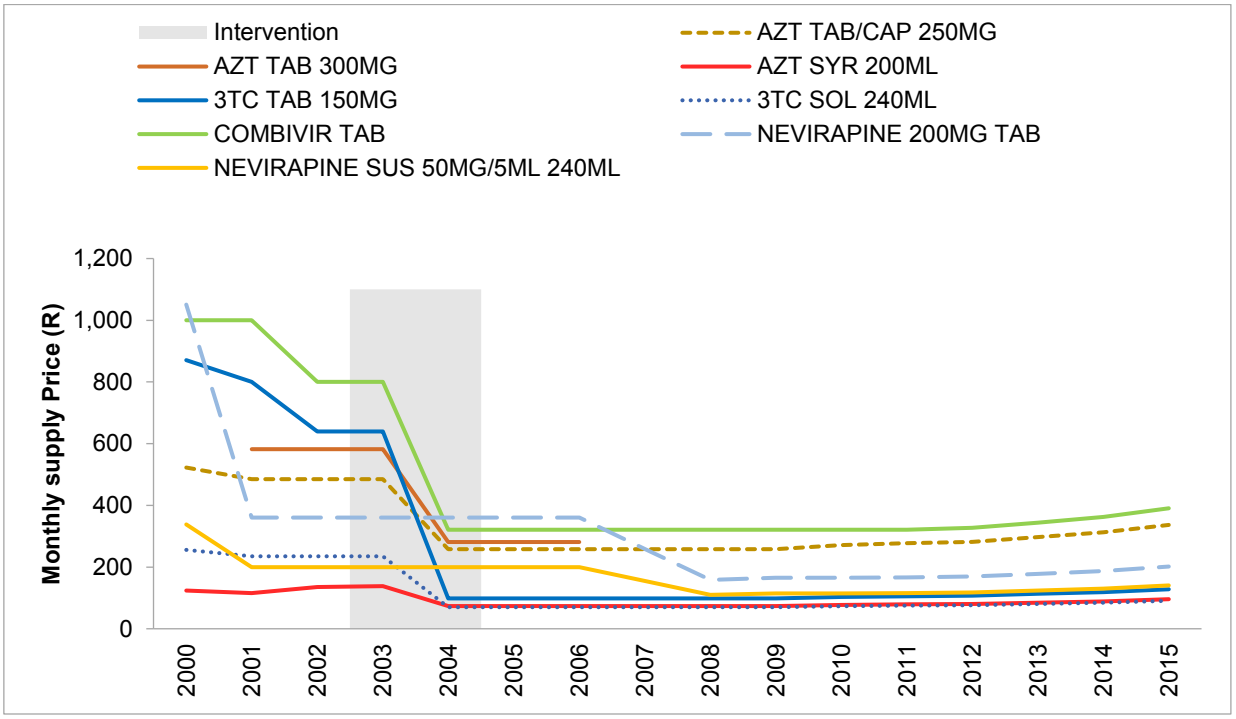
3.3. Impact of the settlement agreement

3.3.1. Pricing of ARV drugs

27. In 2016, the CCSA completed a study on the impact that the Hazel Tau settlement had on the provision of ARVs. The study was 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 state.

[33] 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.

Figure 2. Price movements of ARV's following intervention to promote the entry of generics



Source: MedPrax (Pty) Ltd

3.3.2. Access to ARV treatment

28. It is submitted that the CCSA's intervention through the Hazel Tau case also 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 3 407 336 people, the largest number in the world.[34] 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 in 2015 – and the antiretroviral therapy programme is partly credited for this.[35]

29. In addition, before January 2015, HIV+ people were started on antiretroviral therapy when their CD4 count[36] fell below 350 cells per cubic millimetre of blood. Treatment is now started when it falls below 500.[37]

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

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

[36] A measure of how well a person's immune system is working.

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

30. 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.

3.3.3. Generic competition

31. The settlements achieved through the Hazel Tau case contributed to dismantling the duopoly in the supply of ARV drugs in South Africa at the time. Through the settlements, more than 14 new drugs were able to enter including the introduction of generic drugs which were not sold in the past. As a result of the voluntary licensing regime, there are now 32 producers of commercial ARVs in South Africa.

32. 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 generics to Sub-Saharan Africa due to the Hazel Tau case[38]. We briefly consider its experience below.

33. The table shows key points in Aspen's evolution in growing its manufacturing of generic ARV drugs and its distribution of the drug across other Sub-Saharan African countries including South Africa.

Table 1. Aspen's entry into generic manufacturing of ARVs

Year	Description
2003	Aspen entered into a twelve (12) year agreement with GSK South Africa to distribute and market a range of 40 branded products to the private health sector in South Africa.[39]
2004	Aspen commenced operations at their manufacturing facility based in Port Elizabeth which produces a range of generic ARV drugs amongst others.[40]
2005	Aspen's Port Elizabeth facility became the only facility to be approved by the United States Food and Drug Administration ("FDA") for the manufacture of certain generic ARVs.[41]

[38] 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).

[39] Aspen Pharmacare reviewed preliminary Group financial results, June 2009. Available at: https://www.aspenpharma.com/wp-content/uploads/2017/02/Aspen-reviewed-preliminary-Group-Financial-results-booklet-30-June-2009.pdf. Aspen Pharmacare Holdings Limited – Integrated report 2013. Available at: http://www.financialresults.co.za/2013/aspen_ir2013/downloads/Aspen_IR_2013.pdf

[40] Aspen Pharmacare reviewed preliminary Group financial results, June 2009. Available at: https://www.aspenpharma.com/wp-content/uploads/2017/02/Aspen-reviewed-preliminary-Group-Financial-results-booklet-30-June-2009.pdf. Aspen Pharmacare Holdings Limited – Integrated report 2013. Available at: http://www.financialresults.co.za/2013/aspen_ir2013/downloads/Aspen_IR_2013.pdf

[41] Aspen Pharmacare reviewed preliminary Group financial results, June 2009. Available at: https://www.aspenpharma.com/wp-content/uploads/2017/02/Aspen-reviewed-preliminary-Group-Financial-results-booklet-30-June-2009.pdf. Aspen Pharmacare Holdings Limited – Integrated

2005	Aspen had further strengthened its representation in the ARV market by signing a deal with Merck Sharp and Dohme in September 2005. The deal included a voluntary licence for the generic, Efavirenz which is a product that was under technical development at the time. In addition, an agreement had been concluded with Bristol-Myers Squibb for the transfer of technology and manufacture of a generic of the new generation of ARV drug named, Atazanavir. This agreement was set to be implemented late 2006.[42]
2006	Aspen was awarded distribution rights for ARVs from MSD, Bristol-Myers Squibb, Roche and Tibotec. This resulted in Aspen being the biggest supplier of ARVs in Africa.[43]
2009	The CCSA approves the proposed transaction of 16% stake in Aspen by GSK. This is however on condition that GSK grant licences to generic manufacturers to produce their patented drug Abacavir, an ARV treatment for children.[44]

34. Other firms have also benefited from greater generic competition. In March 2016, the Department of Health requested Abbvie (the HIV division of pharmaceutical company Abbot) to license other pharmaceutical companies 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 request[45] and issued licenses to other drug companies to manufacture Aluvia.

3.3.4. Ongoing enforcement cases relating to excessive pricing in pharmaceutical products

35. In 2017, the CCSA initiated complaints of excessive pricing against two pharmaceutical manufacturers, Roche Holding AG ("Roche") and Genentech Inc ("Genentech"). The CCSA alleged that Roche and its wholly-owned subsidiary Genentech[46] contravened the Competition Act by engaging in excessive pricing,

report 2013. Available at: http://www.financialresults.co.za/2013/aspen_ir2013/downloads/Aspen_IR_2013.pdf

[42] Aspen Annual Report 2006. Available at: https://www.issuu.com/aspenaustralia/docs/aspen_annual_report_-_2006

[43] Aspen Pharmacare reviewed preliminary Group financial results, June 2009. Available at: https://www.aspenpharma.com/wp-content/uploads/2017/02/Aspen-reviewed-preliminary-Group-Financial-results-booklet-30-June-2009.pdf. Aspen Pharmacare Holdings Limited – Integrated report 2013. Available at: http://www.financialresults.co.za/2013/aspen_ir2013/downloads/Aspen_IR_2013.pdf

[44] Competition Commission of South Africa Press Release dated 02 September 2009. Available at: http://www.compcom.co.za/wp-content/uploads/2014/09/02-Sept-09-Competition-Commission-approves-pharma-merger-on-condition-that-Abacavir-is.pdf

[45] 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).

[46] A Biotechnology company based in the United States.

exclusionary conduct and price discrimination with regard to the sale and supply of a drug named Trastuzumab, sold under Roche's brand names, Herceptin and Herclon for the treatment of breast cancer.

36. The information obtained by the CCSA prior to the initiation of the complaint indicated that:

- 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 ($35 000)[47] or more if a high dosage is required and as such most patients are unable to afford the treatment;
- 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
- 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.

37. The investigation of this complaint is still ongoing.

4. Pharmaceutical markets, pharmaceutical regulation and price regulation

4.1. Work conducted on the pricing of pharmaceutical drugs

38. Below, we provide detail on the recent internal work conducted by the CCSA in assessing pricing of pharmaceutical products in South Africa.

4.1.1. Scoping study into life-saving drugs

39. The CCSA conducted an internal scoping study in May 2017 following widespread complaints about the price of pharmaceutical products, in particular of "life-saving" drugs, and increased pressure from non-Government Organisations ("NGOs") for the South African government to institute reforms on patent laws to make life-saving drugs more affordable. The scoping study considered the pricing dynamics as well as identified any potential issues associated with 'life saving' drugs used in the treatment of HIV/AIDS, cancer, hepatitis B and C, and diabetes.

40. The main findings emanating from this study include: (1) South Africa is amongst the cheapest for certain drug treatments; (2) the single-exit price ("SEP") regulatory framework has been successful in constraining the prices charged by manufacturers and retailers of pharmaceutical products; (3) the depository patent system currently implemented in South Africa has been found to have contributed to the pharmaceutical industry becoming susceptible to potential abuse by multinational pharmaceutical companies. This study led to the initiation of a case against Roche and Genentech as discussed above.

41. It is also worth noting that following the 2017 scoping study, the CCSA has decided to broaden its scope of assessment and consider all pharmaceutical drugs whose prices are potentially excessive in South Africa with priority focus on drugs that have high impact in

[47] Converted at current exchange rate (16 November 2018).

the society (i.e. drugs that are used to treat prevalent diseases in South Africa). The project is still in the early stages.

4.2. Generic medicines entry and consumption

42. The South African pharmaceutical industry is a focus of its growth and industrial policy framework[48]. The country has a mix of locally- and foreign-owned firms, joint ventures, large firms and small firms.[49] There are at least eight local South African generic players in this sector including Adcock Ingram, Aspen, Ranbaxy, BioTech, Cipla and Feza, and at least 25 foreign originators selling drugs in the South African market.

43. While there is some local pharmaceutical production capacity for generic products, the market is declining with 37 plants closing between 1995 and 2010.[50] Imports of pharmaceutical products have become an important source of supply of medicines to South Africa. This is particularly relevant in that the country's unique disease burden (particularly with HIV/AIDS) necessitates drugs formulated using specific active pharmaceutical ingredients (APIs) of which global supply is limited.[51]

44. The South African government is, however, in the process of establishing a state-owned pharmaceutical company through *Project Ketlaphela*. The company's focus will be on the manufacture of APIs, particularly for the treatment of ARVs. APIs account for between 50% and 75% of production of generic ARVs. It is expected that this domestic manufacturing capacity will benefit local pharmaceutical product manufacturers provided that the products are of the appropriate price and quality to compete with international South Africa has been a member of the World Trade Organisation (WTO) since its establishment in 1995 and is signatory to all WTO multilateral agreements, including the Trade-Related Aspects of Intellectual Property ("TRIPs") agreement to which it became voluntarily compliant in 1997. TRIPs establishes minimum standards of intellectual property protection that each member state is expected to implement. Amongst these requirements are that members provide copyright and patent protection of pharmaceutical goods for 20 years.

45. Pre-TRIPS many developing countries did not recognise patents for pharmaceuticals, or only for processes and not for products. This allowed copies of new

[48] The IPAP is an industrial action plan compiled by the Department of Trade and Industry. It aims to promote diversification in the economy, promote a labour-absorbing industrialisation path, contribute to industrial development in other African countries, and facilitate a movement towards a knowledge economy. The National Industrial Policy Framework is the policy framework for the IPAP.

[49] See the Genesis Analytics Report entitled *"The Growth Potential of the Pharmaceuticals Sector in South Africa: Background Working Paper"*, dated 16 May 2007.

[50] The Health Systems Trust, 2013. The South African Health Review 2012/2013, available: http://www.hst.org.za/sites/default/files/SAHR2012_13_lowres_1.pdf. Accessed 27 September 2018.

[51] For example, Emtricitabine is frequently used in South Africa whereas globally lamivudine is more prevalent.

drugs to be made through reverse engineering.[52] The case for South Africa is slightly different. Prior to the country becoming a signatory to TRIPS in 1997, South Africa provided 16 years of monopoly protection on patents.[53]

46. In 2016 South Africa accepted the 2005 TRIPS amendment which allows any member country to export pharmaceutical products made under a compulsory license to countries that do not have the capacity to manufacture the product locally. This protocol improves ease of access to affordable medicines by the WTOs poorest members.

47. The TRIPs Agreement also incorporates *flexibilities* – a broad term used to describe a set of norms, rules and standards that allow variations in the implementation of the TRIPS Agreement obligations, including limits on the exercise of intellectual property rights. These flexibilities enable developing and least-developed countries to remain TRIPS compliant whilst allowing them to pursue public policy objectives, either in specific fields such as access to pharmaceutical products, or more generally in establishing macroeconomic and institutional conditions that support economic development. Some of the flexibilities accommodated by TRIPS – namely voluntary licenses, parallel importation and the Bolar provision have been incorporated in South Africa's Patent Act. Voluntary licensing has been conducted by South African authorities as a means to promote the entry of generic medicines.

4.3. Promotion of generic medicines entry – CCSAs involvement through antitrust enforcement

48. While pharmaceutical companies have been prosecuted for anti-competitive conduct on patent law abuse internationally, South Africa is yet to encounter a case in the pharmaceutical sector in which a firm has employed deterrent strategies to delay entry of competing generic products.

49. he CCSA's current investigation against Roche includes an allegation wherein Roche is alleged to be using strategies such as evergreening and patent thicketing as a way to delay or prevent entry of generic alternatives of breast cancer drugs in South Africa. The investigation is still on-going. If referred, this would be the seminal case in which the deterrence of generic entry would be formally assessed by competition authorities.

5. Likely challenges in pursuing antitrust enforcement in pharmaceutical market

50. One particular challenge noted with regard to the pursuit of competition enforcement in pharmaceutical markets is access to information required to conduct a thorough analysis. For example, 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 or not the secondary patent was granted based on a negligible technological advancement. Similarly, uncovering patent

[52] Lowenson, R. Essential Drugs in Southern Africa Need Protection from Public Health Safeguards under TRIPs. BRIDGES, 4:7 September 2000.

[53] Fix the Patent Laws. A Timeline of Intellectual Property Reform in South Africa 1994 – 2015. 29 October 2015. Available from http://www.fixthepatentlaws.org/?p=1037. Accessed on 8 March 2017.

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.

51. Given South Africa's weak patent system, the CIPC is unable to prevent or identify patent abuses such as ever-greening or patent thickets. It is possible that pharmaceutical companies have exploited the absence of a thorough search and examination system by employing deterrent strategies such as ever-greening and patent thickets to prolong their exclusivity over a product. These weaknesses have been acknowledged by the CIPC and the Department of Trade and Industry and are being addressed through the redrafting of the National Policy on Intellectual Property.

52. Another potential challenge faced by South African authorities in their pursuit of antitrust enforcement in this sector arises from the fact that the majority of pharmaceutical companies supplying 'life-saving' drugs are multinational companies. This means that the locally-based company is often a subsidiary of a parent company based abroad.

53. 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.

54. Another possible challenge is in relation to enforcement investigation in instances in which the pharmaceutical product of interest may still be under its patent. In such instances, authorities would have to engage with how to measure the innovation protected and rewarded by the patent in existence. Further, authorities would also have to outline how to account for this in their competitiveness assessment.

55. Finally, there has been a degree of legal uncertainty related to how the competition-specific courts (i.e., the Competition Tribunal as well as the Competition Appeal Court) may interpret and apply the law in relation to excessive pricing contraventions. This legal uncertainty has been observed in the relation to the two prior excessive pricing cases, namely, Mittal Steel and Sasol. Specifically, in both cases, the upper court (CAC) revoked the decision of the Tribunal primarily based on differing interpretations of the law. As such, the likely differing interpretations of the law are recognised as potential challenges facing the CCSA in its pursuit of antitrust enforcement in the pharmaceutical market.

6. Cooperation between CCSA and sector-specific regulators in the pharmaceutical sector

56. The pharmaceutical sector is a highly regulated sector in South Africa. To date there are six regulatory bodies in the pharmaceutical sector and they are listed in the table below.

Table 2. Regulatory bodies in the pharmaceutical sector

Regulator	Responsibility
Medicines Control Council (MCC)	Regulates medicines sold in South Africa

South African Pharmacy council (SAPC)	Regulates pharmacists and pharmacy assistants. It provides guidance and regulates the pharmaceutical profession
The South African National Accreditation System (SANAS)	Accredits pharmaceutical laboratories
Department of Health	Regulates the prices of all pharmaceutical products sold in South Africa
National Health Research Ethics Council (NHREC)	Is a custodian of the Department of Health (DoH) regulations when it comes to clinical trials conducted in South Africa
South African Health Products Regulatory Authority (SAHPRA) *(replaces the MCC above)*	Responsible for monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substances, clinical trials, medical devices and related matters in the public interest.

Source: CCSA

57. As indicated in the table above, the Department of Health plays a role in respect of prices of pharmaceutical products sold in South Africa. It is worth noting that the CCSA does not have an official MoU with the Department of Health. Nonetheless, there is cooperation between these two bodies. For instance, the Department of Health is currently assisting the CCSA in respect of the ongoing investigations initiated in 2017 in respect of the oncology drugs. This assistance has occurred through the DOH making submissions to the CCSA and providing data as required by the CCSA.

7. Conclusion

58. 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 ("NGOs") putting pressure on the South African government to institute reforms on patent laws to make life-saving drugs more affordable. The CCSA's previous intervention in the pharmaceuticals market like in the *GSK and BI* matter has enabled patients to have access to ARV at lower prices. Moreover, settlement agreements concluded by the CCSA in the *GSK and BI* matter dismantled the barriers to entry into the production of ARV treatment. Therefore, it is evident that the intervention by the CCSA in this market has been a success.

59. In addition to the above, through its current and future investigations, the CCSA intends to prohibit the potential abuse of dominance by manufacturers of 'lifesaving' drugs. The ongoing scoping study into the pharmaceuticals sector will also assist in identifying other important drugs that require the intervention of the Competition Authorities. Where possible, the CCSA will also consider other avenues such as collaboration with other stakeholders (i.e. DoH) and pursue advocacy to resolve some of the matters in order to make healthcare affordable to ordinary citizens.