PRICE FORMATION IN THE SOUTH AFRICAN PHARMACEUTICAL MARKET

Russian Competition Week: Roundtable on Pharmaceuticals
21 September 2017

Hardin Ratshisusu, Deputy Commissioner
Competition Commission South Africa
STRUCTURE OF PRESENTATION

- **Background**
  - Structure of healthcare sector in South Africa
  - Pharmaceutical industry in South Africa

- **Price determination of pharmaceuticals**
  - History of price formulation
  - Single Exit Price methodology

- **Price comparison tools**
  - Scoping study analysis in the pharmaceutical sector

- **Competition Cases in the Pharmaceutical Sector**
  - Cases initiated against:
    - Pfizer:
    - Roche:
    - Aspen:

- **International Developments**

- **Concluding remarks**
STRUCTURE OF HEALTHCARE SECTOR AND PHARMACEUTICAL INDUSTRY
BACKGROUND

STRUCTURE OF HEALTHCARE SECTOR IN SOUTH AFRICA

• Two-tiered healthcare system:
  • Private sector:
    – Serves 16% of the population (7 million people)
    – Access to medical insurance
    – Higher-priced than public sector
  • Public sector
    – Serves 84% of the population (44 million people)
    – Financed by government through taxes
    – Importance of access to affordable essential medicines
BACKGROUND – PHARMACEUTICAL LANDSCAPE

• TRADE IMBALANCE
  • 65% of domestic demand is met by imports; medical products 5th largest contributor of SA’s trade deficit
  • Local generic manufacturers: largest are Aspen and Adcock Ingram
  • All originator drugs imported from abroad

• TOTAL SPEND ON PHARMACEUTICALS
  • **Trend:** larger volume of *generic* prescription drugs are sold, but a larger value (i.e. a larger amount of money) is spent on *originator* prescription drugs
  • Prescription drugs comprise 88% of the SA pharmaceutical market
    – Of **total value:** 63% are patented products, and 37% are generic products
    – Of **total volume:** 36% are originator drugs and 64% are generic drugs
BACKGROUND

PHARMACEUTICAL INDUSTRY IN SOUTH AFRICA

• Public and Private Procurement

• **Public sector:** Tender (bidding) process
  – Maximise competition between bidders (especially between originator and generic products)
  – Translates into lower prices for the public sector

• **Private sector:** Directly from manufacturers, or via wholesalers/distributors
  – Pricing regulated in terms of **Single Exit Price methodology**
REGULATORY ENVIRONMENT: PRICE DETERMINATION
SINGLE EXIT PRICE METHODOLOGY (DoH)

- SEP = only price at which a manufacturer can sell medicines to the private sector *irrespective of volumes purchased*

- **Pricing of medicines to be controlled** throughout the value chain:

```
Manufacturer

Ex-manufacturer price

Wholesaler/ Distributor

Ex-manufacturer price + Logistics fee + VAT = SEP

Pharmacies / Dispensing doctors/ Hospital clinics

SEP + dispensing fees

Patient
```
SINGLE EXIT PRICE METHODOLOGY (DoH)

SEP = Ex-manufacturer price (excl. VAT) + Logistics fee + 14% VAT

Final price to end-user = SEP + Dispensing fee (excl. VAT)

- **Ex-manufacturer price**: price that a manufacturer sets to produce a medicine before distribution
- **Logistics fee**: Determined through negotiations between manufacturer/importer and logistics service provider
- **Dispensing fee**: fee charged by pharmacists to dispense medicine

- SEP ensures price transparency
- Only Scheduled medicines are subject to SEP (i.e. Schedule 1 to 7)
- No price differentiations to different private sector customers
SINGLE EXIT PRICE METHODOLOGY (DoH)

- Wholesaler/distributor logistics fee and dispensing fee **fixed on tiered scale**
  - **Example of logistics fee**: If R100 < ex-manufacturer < R500, logistics fee cannot exceed 6% of the ex-manufacturer price plus R4.
    - As ex-manufacturer price gets higher, the logistics fee proportion earned on that product decreases
  - **Example of dispensing fee**: If R100 < SEP < R250, dispensing fee cannot exceed R20.55 plus 33% of the SEP
    - As SEP increases, the dispensing fee proportion earned on that product decreases

- **Price changes regulated**:
  - DoH uniformly applies a pre-determined annual percentage increase on SEP on all products
  - Manufacturer may decrease SEP through notification to DoH
PRICE ANALYSIS BY COMPETITION COMMISSION
COMMISSION STUDY: PRICE BENCHMARKING

METHODOLOGY

• **Rationale**: conduct a comparative analysis of the pricing of pharmaceuticals in South Africa and internationally

• **Products considered**: Top 15 brands prescribed in South Africa (according to volume sales) in the treatment of cancer, hepatitis, HIV/AIDS and diabetes

• **Comparator countries**: BRIC, USA, UK, France, Pakistan, Egypt and Thailand

• **Indicators**: Ex-manufacturer price in USD

• **Comparator products** identified based on:
  • Molecule (Active Pharmaceutical Ingredient)
  • Dosage (e.g. per milligram)
  • Price per counting unit (e.g. price per dosage)
Cancer treatment: Pemetrexed

![Pemetrexed Price Benchmarking Chart](image-url)
Cancer treatment: Imatinib
Hepatitis treatment: Entecavir

![Bar graph showing the price per tablet in US dollars for Entecavir/Barackude 1MG across different countries and years. The x-axis represents countries: Egypt, Russia, India, Brazil, China, S. Africa, Thailand, UK, France, USA. The y-axis represents the price per tablet in US dollars. Each country has five bars representing different years: 2012, 2013, 2014, 2015, 2016.]
Hepatitis treatment: Peginterferon

![Bar chart showing the price of Peginterferon Alfa-2b 80y per 0.5ml in US dollars across different countries and years (2012-2016). The countries compared are S. Africa, Russia, China, UK, Brazil, and Thailand. The prices vary significantly across countries and years.]
ARV treatment: Lopinavir
COMMISSION STUDY: PRICE BENCHMARKING

ARV treatment: Raltegravir

![Graph showing the price per unit (US$) of Raltegravir (TABS 400MG 60) in different countries and years.]
COMMISSION STUDY: PRICE BENCHMARKING

Diabetes treatment: Metformin - Sitagliptin

Metformin - Sitagliptin (500MG)

Price per MG (US$)

S. Africa India Egypt Pakistan Russia China Thailand France Brazil UK USA


competition regulation for a growing and inclusive economy
COMMISSION STUDY: PRICE BENCHMARKING

Diabetes treatment: Liraglutide

![Graph showing the price per ML (US$) of Liraglutide (3ml) across different countries and years (2012, 2013, 2014, 2015, 2016) for S. Africa, Brazil, Russia, India, UK, France, Thailand, China, and USA. The graph indicates a notable increase in the price in the USA compared to other countries.]
ENFORCEMENT CASES
ENFORCEMENT CASES

CASES UNDER INVESTIGATION

• In June 2017, CC initiated separate investigations against three global pharmaceutical companies for abuse of dominance in relation to the supply of various cancer medicines in SA

• Companies are:
  • Roche Holding AG and Genentech;
  • Pfizer Inc;
  • Aspen Pharmacare Holdings LTD
INVESTIGATION AGAINST ROCHE AND GENENTECH

- Investigation relates to the supply of *Trastuzumab*
  - Drug is used for the treatment of breast cancer and some types of stomach cancer
  - *Trastuzumab* products branded by Roche are:
    - Herceptin
    - Herclon
  - Roche holds patent for Herceptin in SA – will expire in 2020
  - Genentech provides exclusive marketing rights to Roche for Trastuzumab.
- Currently being investigated for
  - Excessive pricing;
  - Exclusionary conduct; and
  - Price discrimination
INVESTIGATION AGAINST ROCHE AND GENENTECH

- Excessive pricing
- Breast cancer treatment is unaffordable in South Africa and many medical aid schemes/service providers refuse to pay for the treatment based on cost
- *For example*: 12-month course of Herceptin costs approximately R500 000 or more, if a higher dosage is required

- Exclusionary conduct
- Potential abuse of the patent system (by filing multiple patent applications on a particular medicine) through the ever-greening of patents rights which may prevent entry of generic alternatives beyond the original patent period
- *For example*: Roche patent for Herceptin expires in 2020 in SA; Genentech holds patent covering combinations of Herceptin and other drugs expiring in 2033
- Beyond 2020, no generic alternatives will enter the market
ENFORCEMENT CASES

INVESTIGATION AGAINST ASPEN

- Investigation relates to the supply of:

  (i) **Leukeran (Chlorambucil)** (Chemotherapy medication)

  (ii) **Alkeran (Melphalan)** (for bone marrow and epithelial ovarian cancer)

  (iii) **Myleran (Busulfan)** (conditioning agent prior to bone marrow transplantation)

- **Excessive pricing** - Significant price increases have been imposed across all drugs

INVESTIGATION AGAINST PFIZER

- Investigation relates to the supply of **Xalkori Crizotinib** (lung cancer medication)

PRELIMINARY VIEWS ON ASPEN and PFIZER CASES

The products in all three investigations make up a relatively small portion of usage by South African patients.
PREVIOUS CASES
Excessive pricing & access to essential facility: Hazel Tau Case

- Complaint filed against GlaxoSmithKline (“GSK”) and Boehringer Ingelheim (“BI”) on allegations of **excessive pricing** of ARVs
- Commission expanded investigation to include contraventions by refusing to give competitors **access to an essential facility**
  - Related to allegations of the failure of these firms to license their patents for generic manufacture
- **Negotiated settlements** included, amongst other things:
  - Grant licenses to generic manufacturers
  - Permit export of relevant ARVs to sub-Saharan Africa
PREVIOUS COMPETITION CASES

Hazel Tau Case: **Price movements after Commission’s intervention**

![Graph showing price movements after Commission's intervention for various medications.](image)
PREVIOUS COMPETITION CASES

Cartel investigation: Adcock Ingram Critical Care (Pty) Ltd (“AICC”) and Fresenius Kabi South Africa (Pty) Ltd (“FKSA”)

- Parties engaged in collusive tendering and market allocation
  - **Effect**: Avoidance of competition between firms and manipulation of prices of pharmaceutical and hospital products
  - **Administrative penalties** to the value of over R55 million

Merger case: Aspen / GlaxoSmithKline (GSK)

- Involved ARV medication (Zidovudine, Lamivudine and a cocktail thereof)
- GSK had licensed the manufacture of relevant products to various generic manufacturers
- Focus shifted to another ARV medication, Abacavir
  - At the time of the merger, Abacavir was a GSK patented product used in the treatment of children suffering from HIV. GSK was only supplier of product in SA.
  - **Condition to merger**: GSK extend the license for the generic manufacture of Abacavir to other manufacturers
INTERNATIONAL DEVELOPMENTS
There has been a concerted effort by competition authorities globally to combat anticompetitive conduct in pharmaceutical markets.

In October 2016, the **Italian Competition Authority** fined Aspen €5 million for abusing its dominant position during negotiations with Italy’s drug regulator over the price of **four cancer drugs** – Leukeran, Alkeran, Purinethol and Tioguanine.

Aspen is facing similar allegations relating to excessive pricing in the **UK** and **Spain**. The company tried to sell the medicines in Europe for up to **40 times their previous price** (e.g. ubusulfan used to treat leukaemia, rose from £5.20 to £65.22 in England and Wales. Similar price increases were observed for Leukeran (also used by **leukaemia** patients) and Alkeran (used for **skin and ovarian cancers**).
INTERNATIONAL DEVELOPMENTS

• **European Commission** investigation into Aspen Pharma regarding alleged **price-gouging** on **cancer medicines** (May 2017).

• **FTC** investigation against Turing Pharmaceuticals for possible antitrust violations in connection with the company’s decision to **hike the price** of a life-saving drug by **more than 5,000 percent** (2015).

• **Competition Commission of India** published a regulatory notice relating to conducting a study into India’s Healthcare and Pharmaceutical sector (September 2017).

• **FAS** is undertaking a lot of work in pharmaceuticals including an investigation against Novartis Pharma.
Concluding Remarks
Concluding Remarks

- The investigations and enforcement action undertaken by competition authorities globally provides evidence of the existence of exploitative pricing practices in pharmaceutical markets.

- Such exploitative conduct appears to be in respect of critical product lines.

- It is important that competition authorities must step up and increase their enforcement efforts.

- In South Africa:
  - The healthcare sector is a priority focus area for the Commission,
  - While the investigation is at early stages, there are indications of not only exploitative but also discriminatory conduct between the private and public sector, and
  - It appears that the conduct may also extend to vaccines as well.

- There is a great need for enhanced co-operation between competition authorities in order to better deal with these issues.
Thank you

Tel: +27 (0)12 394 3200
Fax: +27 (0)12 394 0166
Email: hardinr@compcom.co.za
Follow us on Twitter @CompComSA or me
@hardinratshi