

# PRICE FORMATION IN THE SOUTH AFRICAN PHARMACEUTICAL MARKET

Russian Competition Week: Roundtable on Pharmaceuticals

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*competition regulation for a growing and inclusive economy*



**competition commission**  
south africa

- **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



## 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**

- **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

## PHARMACEUTICAL INDUSTRY IN SOUTH AFRICA

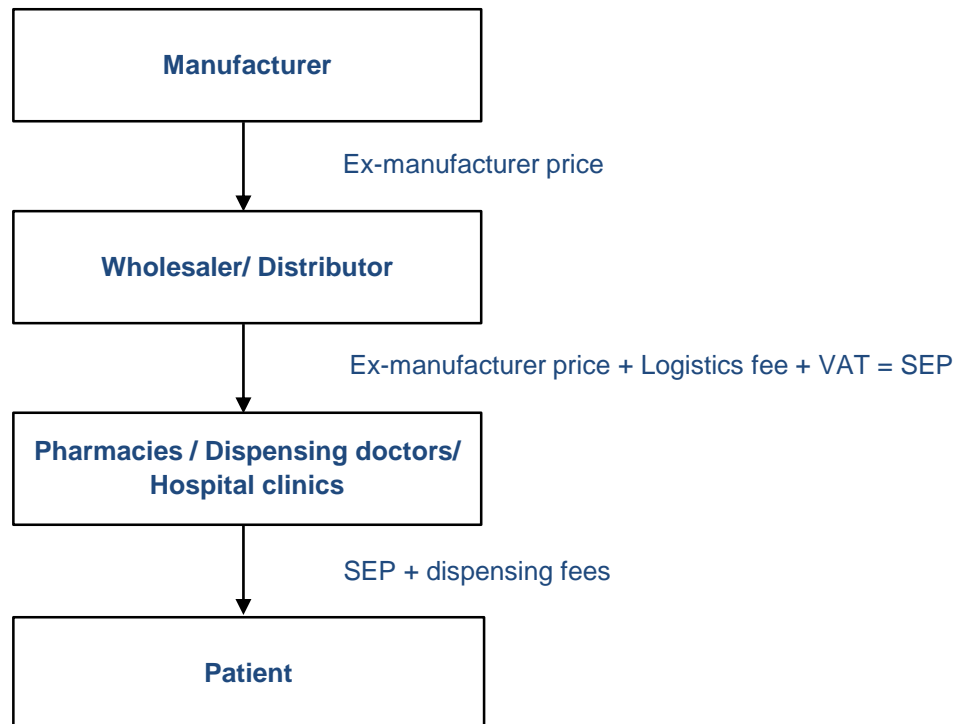
- **Public and Private Procurement**
  - **Public sector:** Tender (bidding) process
    - Maximise competition between bidders (especially between originator and generic products)
    - Translates into lower prices for the public sector
  - **Private sector:** Directly from manufacturers, or via wholesalers/distributors
    - 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:





## 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  $R100 < \text{ex-manufacturer} < R500$ , 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  $R100 < \text{SEP} < R250$ , dispensing fee cannot exceed R20.55 plus 33% of the SEP
    - As SEP increases, the dispensing fee proportion earned on that product decrease
- **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

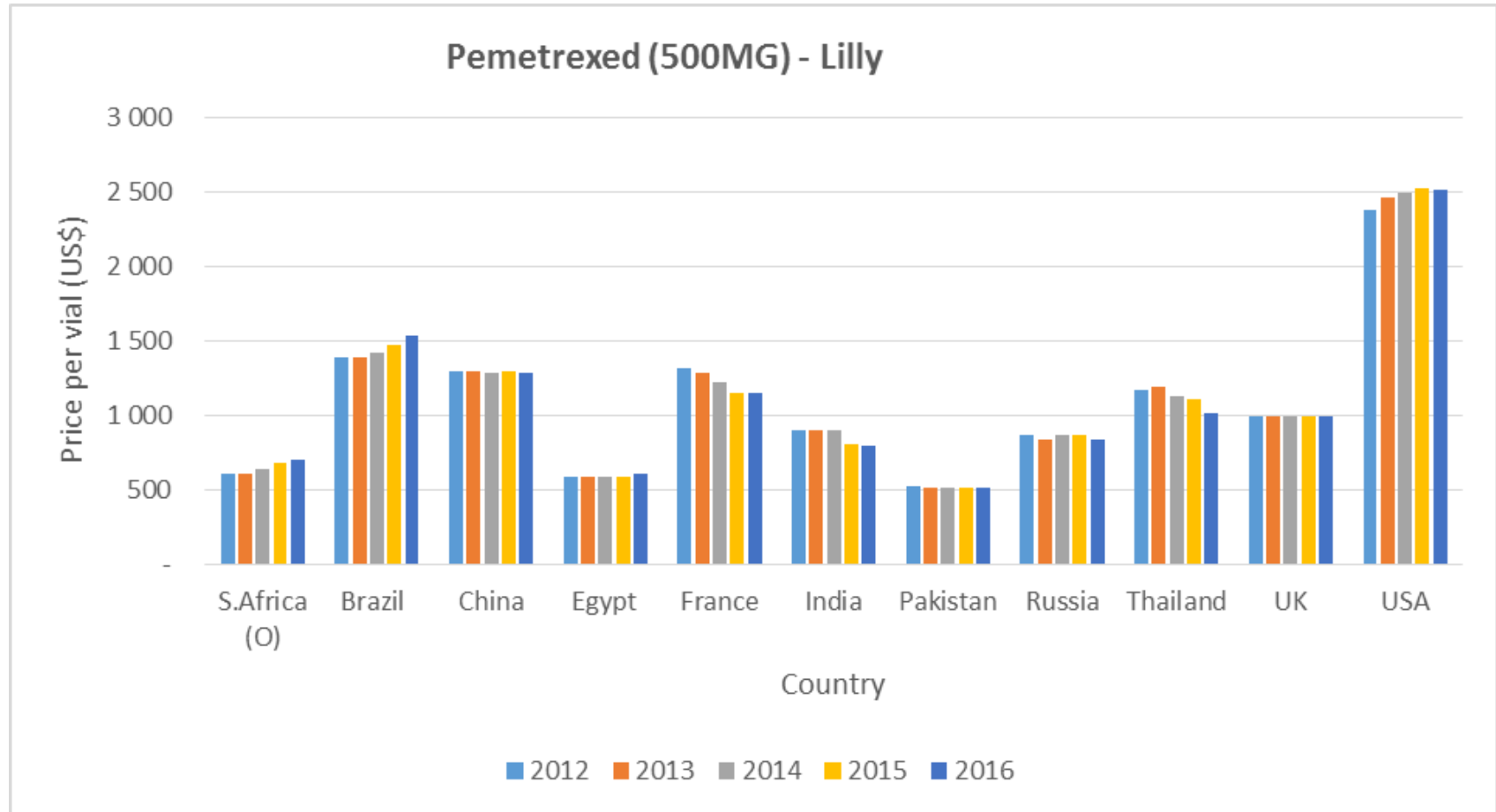
# PRICE ANALYSIS BY COMPETITION COMMISSION



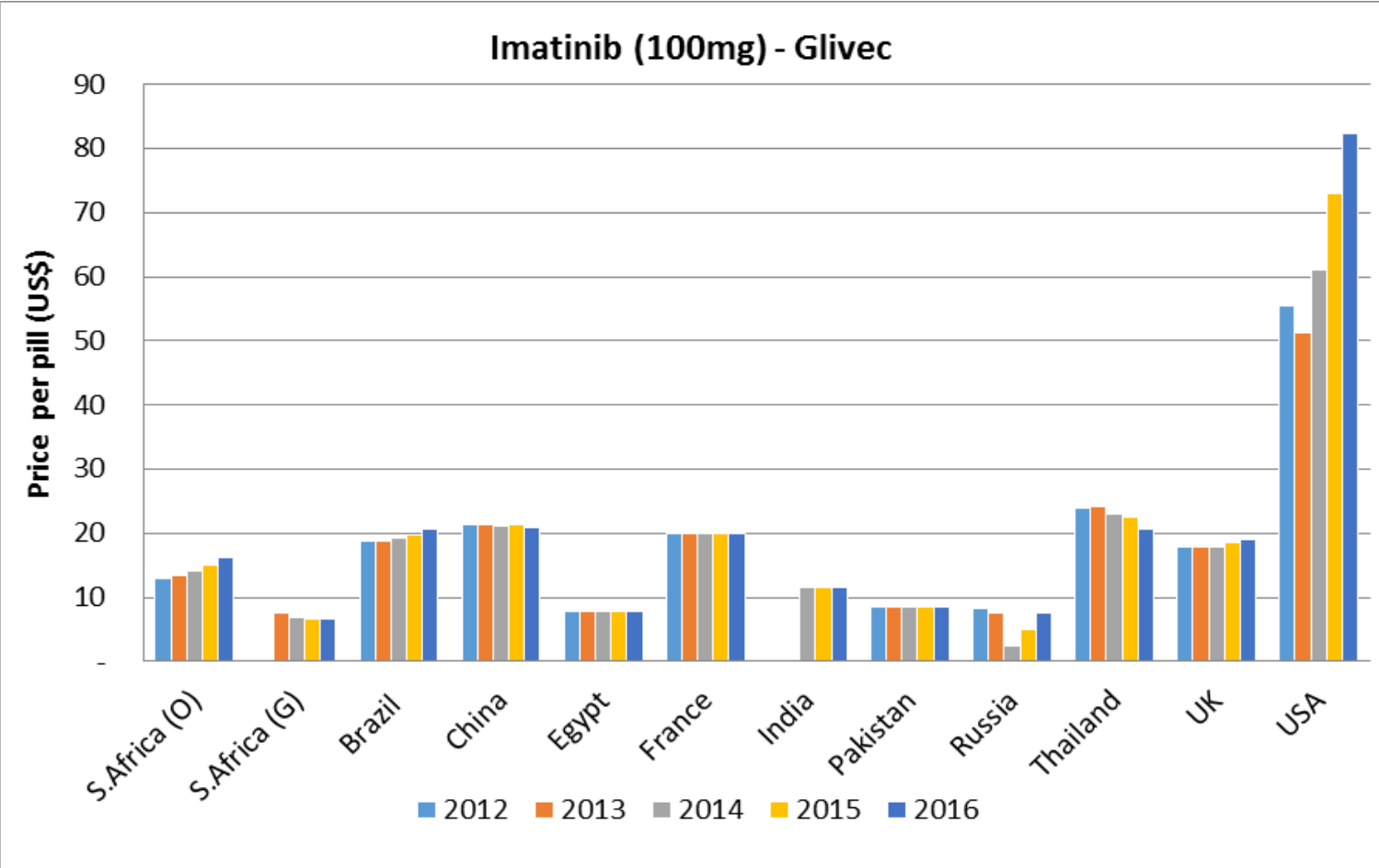
## METHODOLOGY

- **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

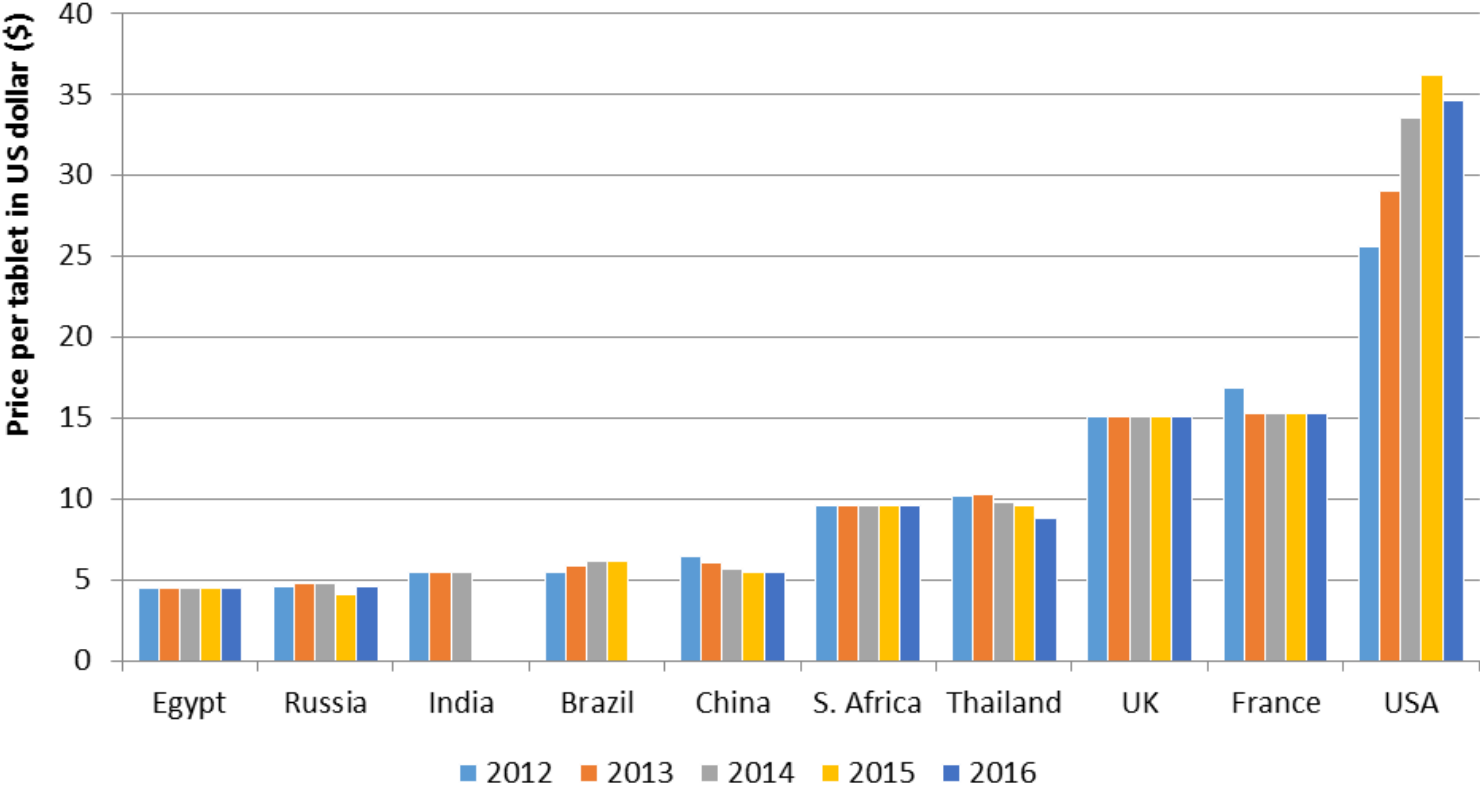


## Cancer treatment: Imatinib



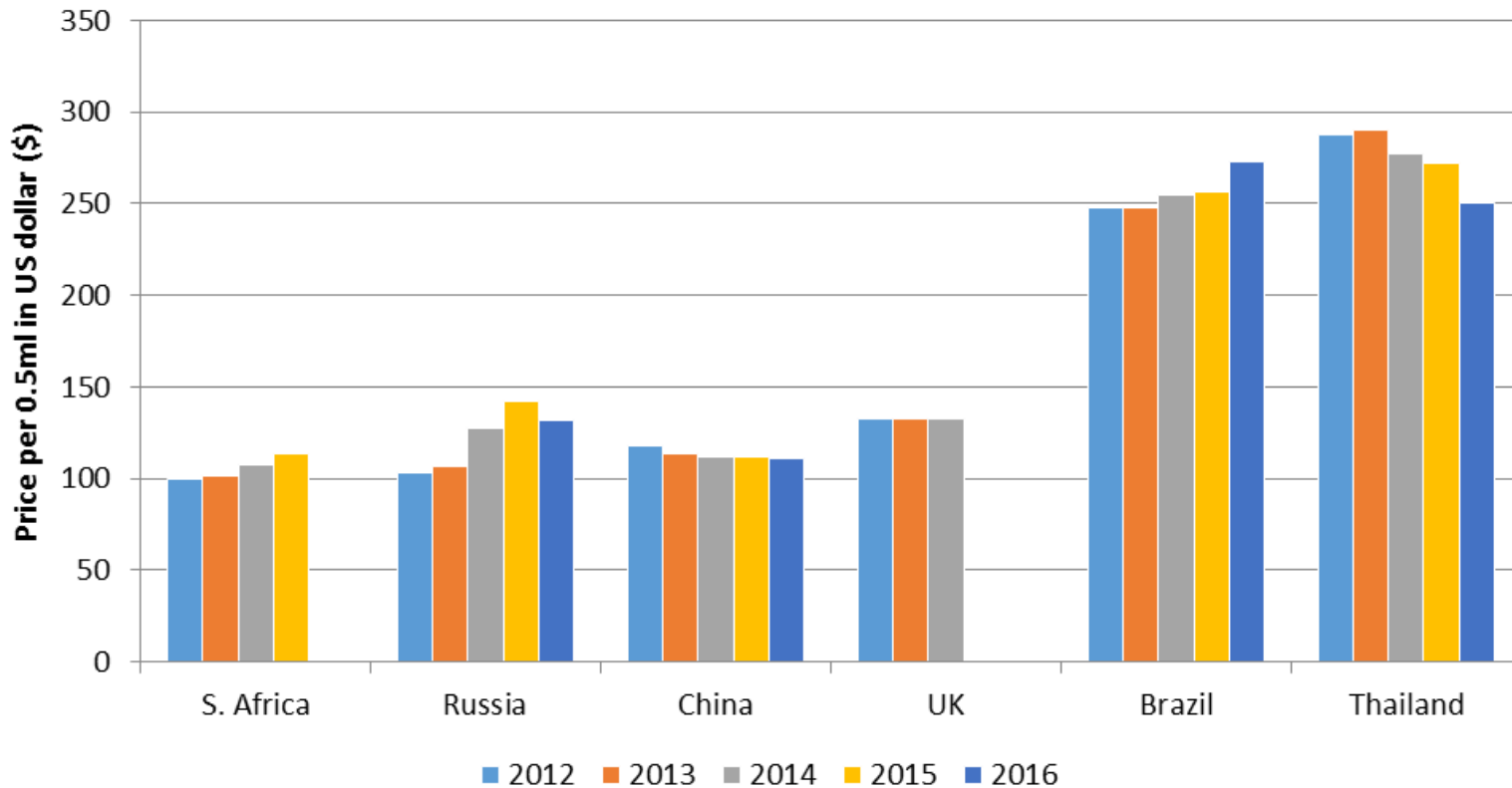
## Hepatitis treatment: Entecavir

Entecavir/Barackude 1MG



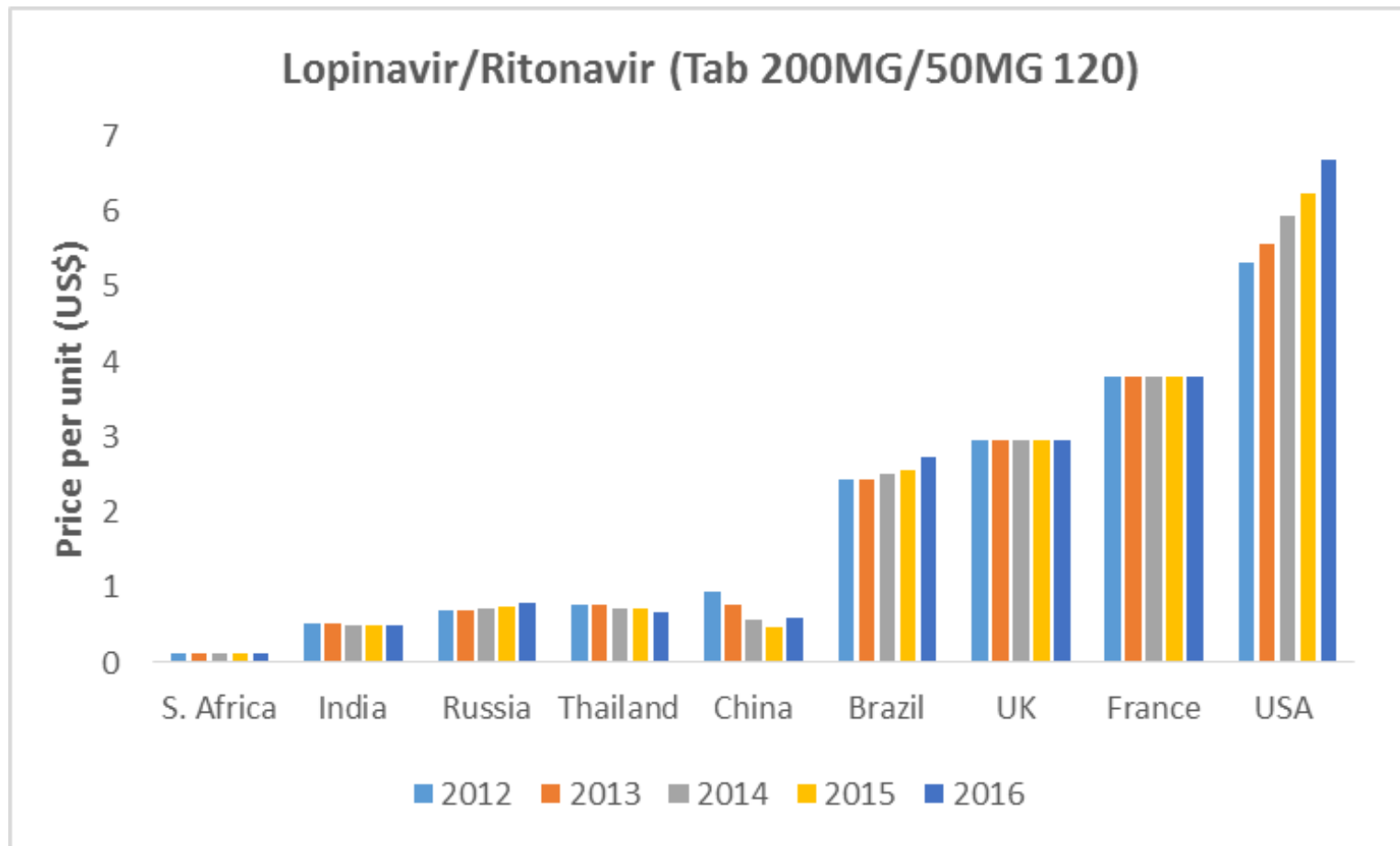
## Hepatitis treatment: Peginterferon

Peginterferon Alfa-2b 80y

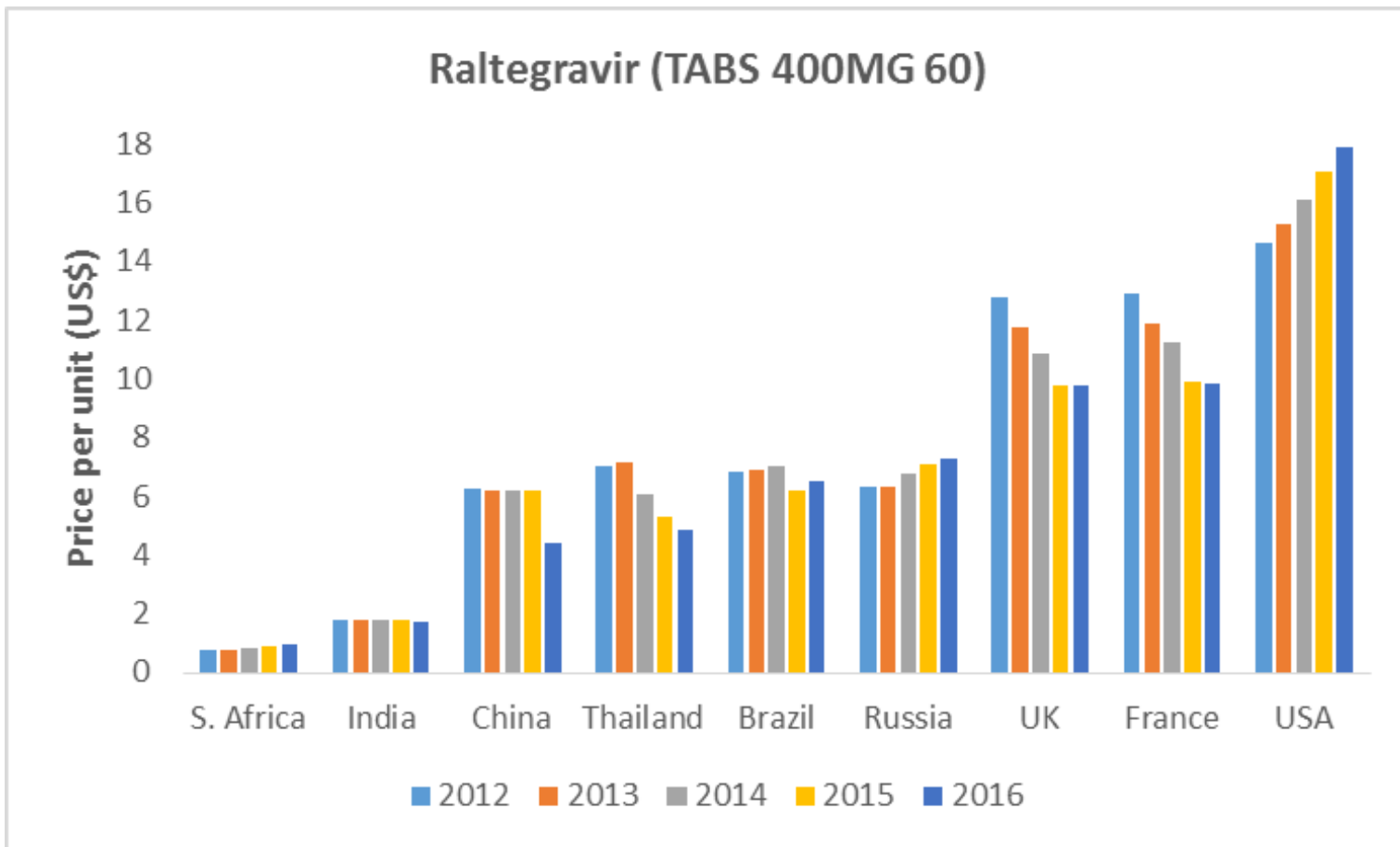




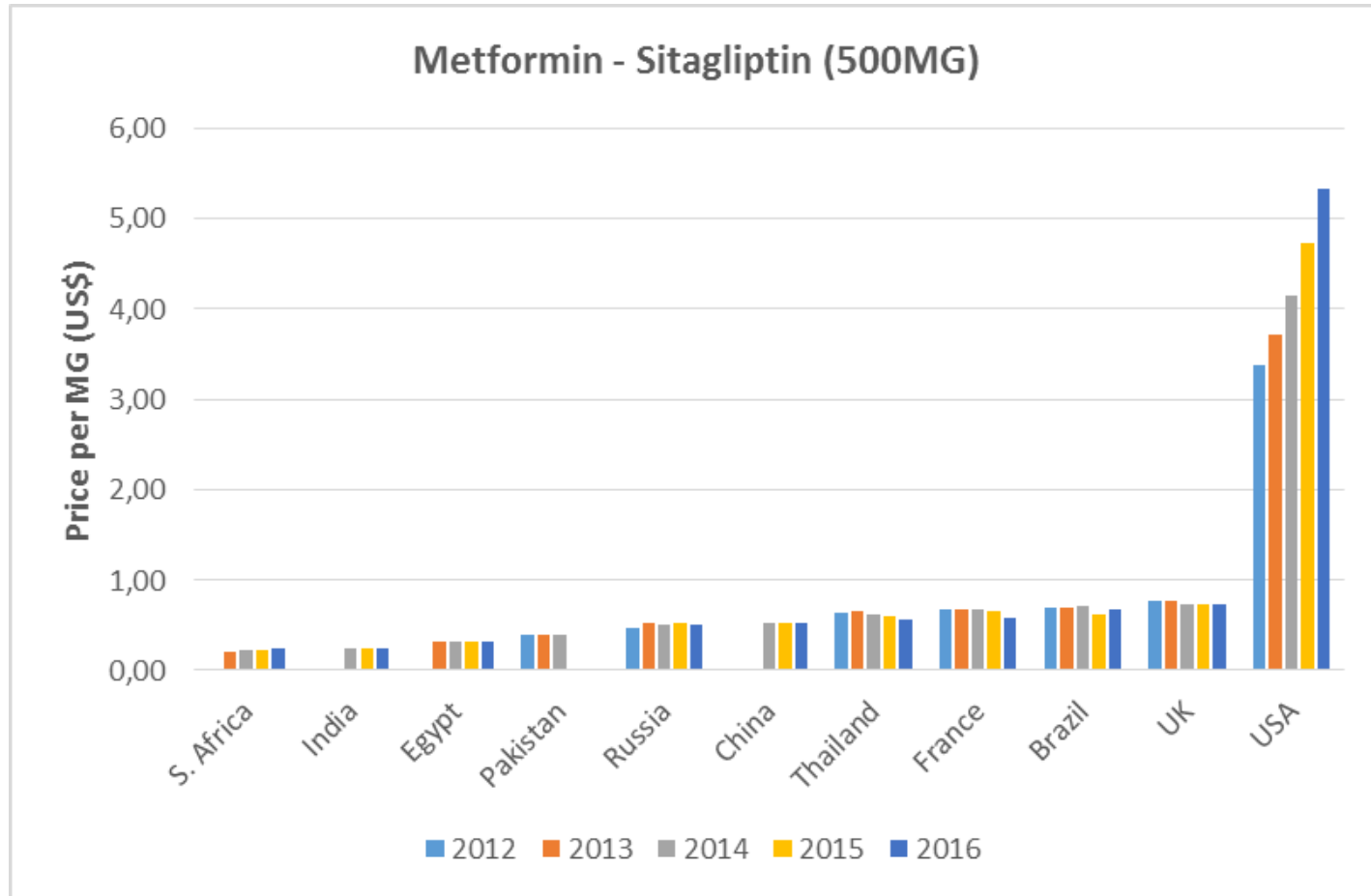
## ARV treatment: Lopinavir



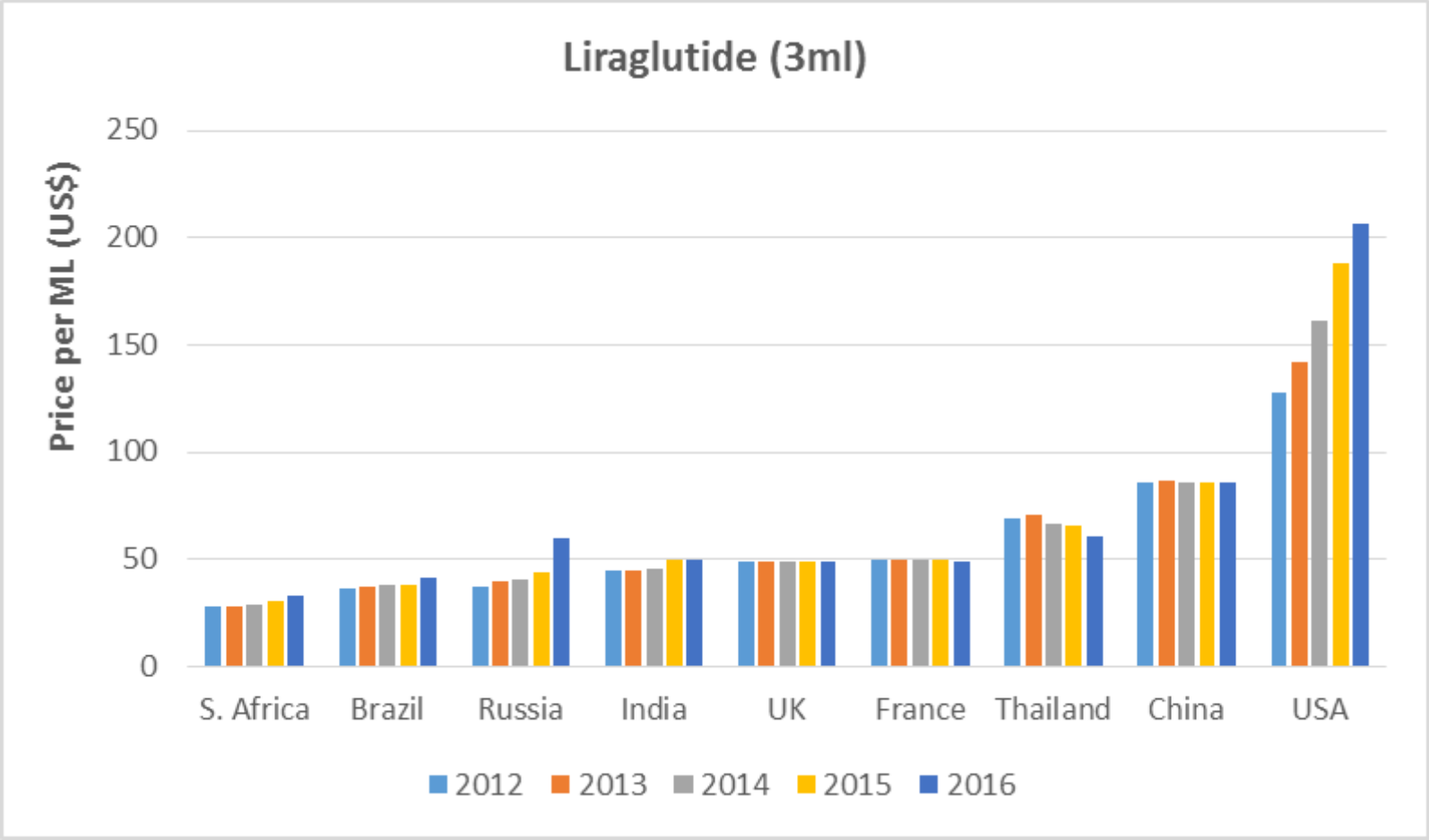
## ARV treatment: Raltegravir



## Diabetes treatment: Metformin - Sitagliptin



## Diabetes treatment: Liraglutide



# 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

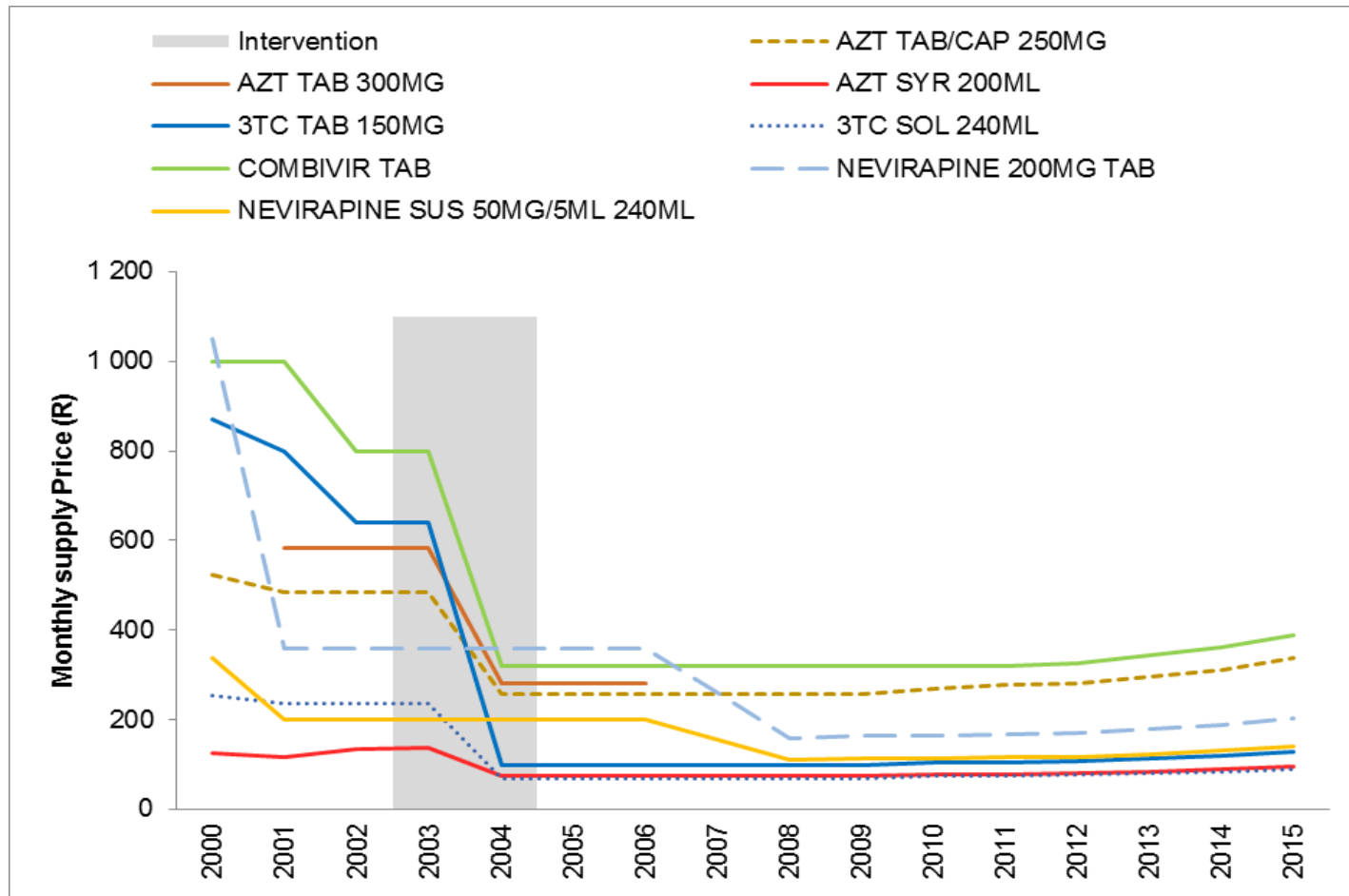


## **Excessive pricing & access to essential facility:** Hazel Tau Case

- 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



**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**).

- **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

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