SOUTH AFRICA’S EXPERIENCE IN PHARMACEUTICALS INDUSTRY
- The case of antiretroviral drugs

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competition regulation for a growing and inclusive economy
Outline

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  • Price movements for ARV brands in the Hazel Tau Case
  • Antiretroviral Therapy (“ART”) Programme in South Africa
  • Pricing of originals vs. generics and post-intervention market dynamics
  • Cost saving estimates
  • Increased access to public sector ART scheme
• Conclusion
South Africa at a glance

Key Facts

- GDP (in PPP): $724 billion
- GDP per capita (in PPP): $13,407
- Contribution to GDP of Africa: 19%
- People living with HIV/AIDS: 6,836,500
- Health expenditure: 9% of GDP
Background – Hazel Tau & others v. GlaxoSmithKline (“GSK”) & Boehringer Ingelheim (“BI”) (“Hazel Tau Case”) - 2003

• Complaint filed by individuals infected 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.

• The Competition Commission 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.

• These complaints were based on allegations of the failure by the pharmaceutical firms to licence their patents on reasonable commercial terms.
Background – Hazel Tau & others v. GlaxoSmithKline (“GSK”) & Boehringer Ingelheim (“BI”) (“Hazel Tau Case”) - 2003

• The Commission found that GSK and BI had abused their dominant positions in their respective ARV markets:
  – They had charged excessive prices, refused to give competitors access to essential facilities and engaged in exclusionary behaviour.

• Before the referral and prosecution of the case, GSK and BI negotiated a settlement with the Commission in 2003. GSK and BI agreed to:
  – grant licences to generic manufacturers;
  – permit the licensees to export the relevant ARV medicines to sub-Saharan African countries;
  – 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;
  – permit licensees to combine the relevant ARV’s with other ARV medicines; and
  – not require royalties in excess of 5% of the net sales of the relevant ARV’s.

• This turned out to be a ground-breaking settlement for access to ARVs in South Africa.
Impact of the settlement on pricing by BI and GSK

Month supply Price (R)

Intervention Boehringer Ingelheim Glaxco Smithkline
Price movements for ARV brands implicated in the Hazel Tau Case

- Intervention
- AZT TAB 300MG
- AZT TAB CAP 250MG
- AZT SYR 200ML
- 3TC TAB 150MG
- 3TC SOL 240ML
- 3TC 240ML
- NEVIRAPINE 200MG TAB

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Antiretroviral Therapy (“ART”) Programme in South Africa

- Largest ART programme in the world
- Mainly administered by the public sector, private sector and non-governmental organisations (“NGO’s”)
- Accounts for approximately 81% with the private sector and NGOs accounting for the balance
- Commission’s intervention made access to the ARV’s much easier
Pricing of originals vs. generics

Average price (R) monthly supply

- Intervention
- Generic
- Original

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Impact on prices: generics v originals

- Significant price decrease – certain brands more than 17% p.a.
- Price of ARV’s with active substance available in both original and generic, decreased by significantly more than those available in original only

<table>
<thead>
<tr>
<th>Active substance availability:</th>
<th>Average price decrease (average % p.a.)</th>
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</thead>
<tbody>
<tr>
<td>Generic only</td>
<td>17,2%</td>
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<tr>
<td>Generic and original</td>
<td>11,5%</td>
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- Increased competition – brands of 32 manufacturers sold currently, compared to only 8 (eight) manufacturers pre-intervention (before 2003)
Cost saving estimates: Post Commission’s intervention

• Lower prices reduced cost of ART

• Cumulative cost saving 2004-2015
  - Scenario 1: Price assumed to remain at 2003 level - US$887m
  - Scenario 2: Assumed overcharge of 10% - US$577m
  - Scenario 3: Assumed overcharge of 8% - US$462m

• Also lower tender prices
  - Tender for 1/04/2013 to 31/03/2015 worth R5.9bn ($664m) – Department of Health reported saving of $248m (38%) due to availability of single-dose combination drugs

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Cost saving estimates: Post Commission’s intervention

Scenario 1 (2003 price level)  Scenario 2 (10%)  Scenario 3 (8%)
Increased access to public sector ART scheme

- Under 2002-prices, less people at given budget of 2015
- Estimated 677 317 more individuals can be treated due to Commission intervention
Conclusion

• The Commission (with complementary policies from government) has brought significant changes to the ARV market in South Africa in terms of:

  - Pricing
  - Access
  - Competition

• It is evident that anti-competitive practices in pharmaceuticals do lead to high cost of treatment
Thank you!

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