



competition commission
south africa

The Pharmaceutical Industry and its Competitive Dynamics: South Africa

BRICS Working Group:

Roundtable Discussion

12 March 2015

Moscow, Russia



Outline of Presentation

- Background on the Regulatory framework
- Cost of Healthcare
- Patent applications and grants
- Market structure
- CCSA interventions in the market
 - ▶ Enforcement cases
 - ▶ Merger cases
- Market inquiry into the Healthcare sector
- Policy Developments
- Conclusions



Regulatory Framework

- Medicines and Related Substances Amendment Act of 2002
 - To make drugs more affordable and provide for transparency in the pricing of medicines.
- Pharmacy Amendment Act of 2000 - effective since 2003
 - To allow non-pharmacists to own pharmacies, with the aim of improving access to medicines.
- Medical Schemes Act 1998
 - To regulate the medical schemes industry to prevent it from discriminating against "high risk" individuals like the aged and sick.

Regulatory Framework (cont,)

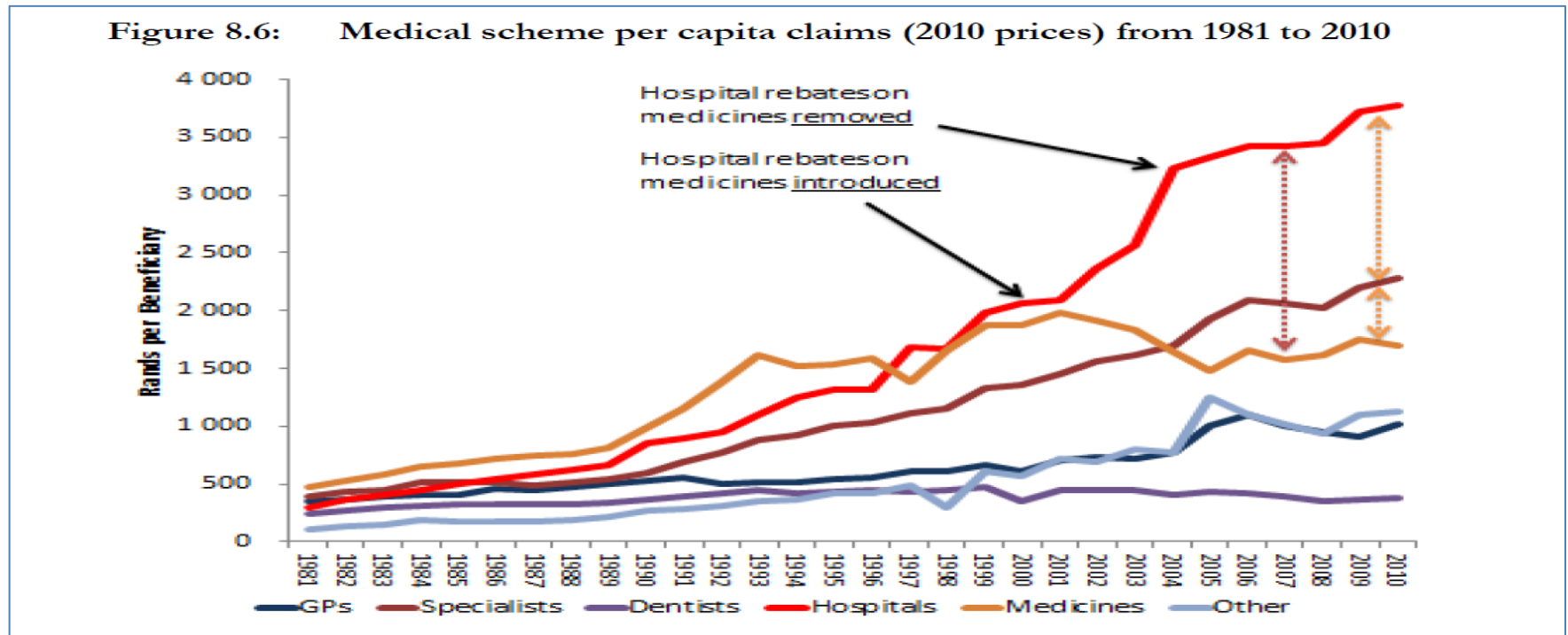


competitioncommission
south africa

- Price regulation implemented since May 2004
- All pharmaceutical products supplied to the private sector is subject to single exit price (SEP) regulations i.e.,
 - ▶ manufacturer is obliged to supply medicines to wholesalers at SEPs plus logistic fees.
 - ▶ Pharmacists have to dispense all products at SEPs plus dispensing fees.
- The objectives of SEP are to ensure price transparency and no price differentiations to different private sector customers.

Cost of HealthCare in South Africa

The relative high costs of healthcare services and the above inflations price increases amongst other factors informed the inquiry into healthcare sector.



Source: Medical schemes claims data from the Council for Medical Schemes annual reports for 1993 to 2011; GDP and CPI data from Statistics South Africa.

Patent applications and grants



competitioncommission
south africa

- RSA largely a depository patent application system
 - ▶ Check-lists that is adhered to.
 - ▶ Large numbers of approvals confirm depository system
 - For South Africa possible every-greening take place i.e. protecting market positions and monopoly rents.

Country	Patent applications	Patent grants	% granted 2012	% granted 2011
Brazil	30 116	2 830	9%	14%
Russian Federation	44 211	32 880	74%	72%
India	43 955	4 328	10%	12%
China	652 777	217 105	33%	33%
South Africa	7 444	6 205	83%	73%

Source: World Intellectual Property Organisation (WIPO) Indicators, 2013.

Market Structure



competitioncommission
south africa

- Approximately 8 local manufacturers
 - ▶ Produce mainly generics.
 - ▶ No local manufacturer of antiretroviral (ARV) active pharmaceutical ingredients (API).
- Approximately 25 foreign pharmaceutical companies selling medicine into South Africa market (e.g. *Boehringer Ingelheim, Novartis, Eli Lilly, Merck, AstraZeneca, Pfizer*).
- Local manufacture declining
 - ▶ 37 plants closed and 65 000 jobs lost between 1995 and 2010
 - ▶ Imports increased from R6.2 billion in 2002 to R16 billion in 2011



Market Structure (cont,)

- Total market estimated at US\$2bn approximately 1% of GDP
 - ▶ 70% is prescription medicines
 - ▶ 61% in value is originator medicines
 - ▶ 63% in volume is generic medicines

Enforcement Cases



competitioncommission
south africa

■ *Aspen Mylan case*

- ▶ Complaint received in 2012 from Medesins Sans Frontieres (MSF).
- ▶ Allegation that Aspen and Mylan entered into vertical arrangements for the supply of API (Active Pharmaceutical Ingredient) that prevents Mylan from entering South Africa to supply fixed dose combination of ARVs (antiretroviral).
- ▶ Mylan leading international supplier of APIs.
- ▶ Complaint also alleged that Mylan is prohibited from selling the same API it sells to Aspen to any other firm in South Africa.
- ▶ South Africa the biggest customers internationally for ARVs.



Enforcement Cases (cont,)

■ Aspen Mylan case

- ▶ Agreement allegedly in place until 2016.
 - ▶ APIs are used to manufacture ARVs used to treat HIV/AIDS
 - ▶ CCSA initiated further complaint against Aspen and Mylan for engaging in possible market allocation because the supply agreement may have the effect of dividing markets in contravention of 4(1)(b)(ii).
-
- Two complaints are being investigated simultaneously and are on-going.



Enforcement Cases (cont,)

■ *Hazel Tau and others vs GSK and Boehringer Ingelheim*

- ▶ Complaint lodged by individuals living with HIV/AIDS, healthcare professionals, trade unions and NGOs.
- ▶ Complaint alleged that GSK and BI charged excessive prices for patented ARV medicines.
- ▶ CCSA expanded the investigation and included allegation of exclusionary conduct and refusal to supply essential facility.
- ▶ CCSA concluded GSK and BI abused their dominant positions by:
 - Charging excessive prices;
 - Refusing access to essential facility; and
 - Engaging in exclusionary conduct.



Enforcement Cases (cont,)

■ Hazel Tau case (cont,)

- ▶ Before prosecution of the case, GSK and BI entered into settlement agreements, and agreed to:
 - grant licences to generic manufacturers;
 - permit the licensee's 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.



Enforcement Cases (cont,)

■ *TAC vs Merck / MSD case*

- ▶ Complaint alleged abuse of dominance in relation to ARVs by refusing license to other firms to import and /or manufacture generic versions.
- ▶ Prior to concluding the investigations, MSD and Merck entered into multiple license agreements on reasonable terms that allowed for the increase of generic products in the market.



Merger Cases

■ *Pfizer /Wyeth*

- ▶ Affected both Human and Animal health products
- ▶ No competition concerns in the human health products
 - Post-merger market share low
 - Numerous alternative players present in the market
- ▶ Competition concerns in 2 of 8 relevant markets identified
 - market shares high in the 2 markets (the one led to monopoly)
 - Ability to unilateral increase prices post-merger
 - No other similarly effective products registered that can be viewed as economical viable alternatives
- ▶ Imposed supply condition for a period of 3 years



Merger Cases (cont,)

■ *GlaxoSmithKline (GSK)/ Aspen*

- ▶ 5 products affected used for the manufacture of antiretroviral medicines (Zidovudine, Lamivudine and combination of the two, Lanoxin and Abacavir).
- ▶ Pre-merger GSK had voluntarily licensed three of the patented these medicines (Zidovudine, Lamivudine and a cocktail of the two).
 - Market shares were over 80% for all three products
- ▶ Numerous alternative suppliers active in the market and the voluntary license practise mitigated against competition concerns.
- ▶ CCSA imposed a condition which required licensing of Abacavir.



Health Inquiry

- ▶ Market inquiry into private healthcare including the pharmaceutical industry.
- ▶ The purpose is to understand cost drivers in the private health care in general.
 - Not focused on any particular conduct and/or firm
- ▶ Phase 1 – Information gathering period
- ▶ Phase 2 – Public hearing to commence in May 2015
- ▶ Phase 3 – Final Report and Recommendation November 2015



Policy developments

- Draft policy on Intellectual Property (2013)
 - ▶ move from a depository patenting system to a substantive patenting system i.e.
 - patent applications will undergo scrutiny to prove that a patentable product is novel and that an inventive step has taken place;
 - allows for pre- and post- patent approval opposition; and
 - advocates for the integration of databases between the patent office and the Medical Control Council (MCC) in order to share information.
 - ▶ Allows South Africa to take advantage of the flexibilities granted to developing countries under the TRIPS agreement e.g.
 - making use of parallel imports;
 - compulsory licensing; and
 - Bolar provision (allows generics to be tested before patents lapse).

Policy developments (cont,)



competitioncommission
south africa

- The New IP policy will deter:
 - ▶ Granting of frivolous patents that render monopoly rents for little or no innovation; and
 - ▶ Reduce anti-competitive conduct of ever greening;
- In the context of competition law, the new policy will:
 - ▶ Encourage production of generics; and
 - ▶ Compulsory licensing will stimulate entry.
- Substantive patenting is however time and resource intensive



Conclusions

- High-cost of health care
- Limited domestic production capacity
- High government spend on health care relative to GDP
- Patent policy review
 - ▶ Potentially lowers barriers to entry



competition commission
south africa

Thank You

Tel: 012 – 394 3200

Fax: 012 – 394 0166

Email: CCSA@compcom.co.za

Website: www.compcom.co.za