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Roundtable on:

***Role of Competition in the Pharmaceutical Sector  
and its Benefits for Consumers***

**Contribution**

**By**

**South Africa**

The views expressed are those of the author and do not necessarily reflect the views of  
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## **South Africa's experience in the Pharmaceuticals Industry**

*Prepared for the 2015 UNCTAD Round Table on*

*"The role of competition in the Pharmaceutical sector and its benefits for consumers"*

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### **1. Introduction**

The UNCTAD has invited members to participate in the roundtable discussions relating to "The role of competition in the Pharmaceutical sector and its benefits for consumers". This note is prepared to assist in the discussions.

We begin this submission by providing an overview of the pharmaceutical industry in South Africa and how the industry fits into broader government policy discussions. The South African pharmaceutical industry is an important component of the Industrial Policy Action Plan (IPAP) and National Industrial Policy Framework<sup>1</sup>. There are at least 8 local South African generic players in this sector including Adcock Ingram, Ranbaxy, BioTech, Cipla and Feza, and at least 25 foreign originators selling drugs in the South African market. The sector is characterised by a large trade imbalance and limited capacity to manufacture active pharmaceutical ingredients. There is no local manufacturer of antiretroviral (ARV) active pharmaceutical ingredients (API). This is in sharp contrast to comparable countries such as Brazil and India. According to the National Association of Pharmaceutical Manufacturers (NAPM)<sup>2</sup>, the total sale in the South African private market for pharmaceuticals is about R20bn-R30bn (US\$2bn-US\$3bn). Local pharmaceutical manufacturers in South Africa produce mostly generics with almost all originator companies coming from abroad. The NAPM represents 24 members involved in the production and distribution of generic drugs.<sup>3</sup>

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<sup>1</sup> 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.

<sup>2</sup> National Association of Pharmaceutical Manufacturers, 2014. The challenges facing generic medicines in South Africa, available: <http://www.slideshare.net/fullscreen/napmSA/market-access-conference-napm-presentation/2>, viewed 13 May 2014.

<sup>3</sup> National Association of Pharmaceutical Manufacturers, 2014. About us, available: <http://napm.co.za/#/about-us-2/>, viewed 14 May 2014.

This excludes other local generic manufacturers such as Aspen, Adcock Ingram, Biotech and Feza. The Innovative Pharmaceutical Association of South Africa (IPASA) represents 25 companies of which most are originator pharmaceutical producers<sup>4</sup>. Almost all of these companies operate at international level and include, Boehringer Ingelheim, Novartis, Eli Lilly, Pfizer, Merck, AstraZeneca, Sanofi.

Prescription drugs represent 70% of the South African pharmaceutical market and the rest is over the counter (OTC) medicines. Of the prescription drugs sold in the private pharmaceutical sector, 61% of its total value related to originator drugs and 36% of its total value related to generic drugs<sup>5</sup>. In terms of volume, 36% of sales are with respect to originator drugs and 63% related to generic drugs<sup>6</sup>. The statistics suggest that, in South Africa, more generic prescription drugs are sold (in volume) as opposed to originator prescription drugs, but more (in monetary value) is spent on originator prescription drugs than generic prescription drugs. This clearly indicates that originator drugs are more expensive than generics in general<sup>7</sup>.

The local manufacture of drugs is declining, with 37 plants closing and 6 500 jobs lost between 1995 and 2010<sup>8</sup>. Both generics and originator drugs are being imported making the pharmaceutical industry the fifth largest contributor to South Africa's import deficit. Imports increased from R6.2bn in 2002 to R16bn in 2011. This reliance on imports is problematic, particularly in the market for ARVs and Active Pharmaceutical Ingredients (APIs), where South Africa is the world's largest consumer of ARV's yet imports all of its ARV's and 95% of its APIs. South Africa is a major centre of the HIV/AIDS epidemic and accounts for about 5.4 million of the total global infections of 33 million.<sup>9</sup> The treatment of such large numbers of patients with ARV is a major public health challenge.

## 2. Competition cases

To put context to the discussion above of the competition policy framework, we highlight some of the cases that the Competition Commission of South Africa (CCSA) has dealt with in the pharmaceutical industry. Some of the cases have brought much change in terms of costs and access to drugs especially ARVs. The

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<sup>4</sup> Innovative Pharmaceutical Association of South Africa (IPASA), 2014. IPASA members, available: [http://ipasa.co.za/ipasa\\_members/](http://ipasa.co.za/ipasa_members/), viewed 14 May 2014.

<sup>5</sup> 3% of the value of drugs sold was not categorised.

<sup>6</sup> 1% of the volumes of drugs sold was not categorised.

<sup>7</sup> 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.

<sup>8</sup> 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](http://www.hst.org.za/sites/default/files/SAHR2012_13_lowres_1.pdf), viewed 13 May 2014.

<sup>9</sup> Walwyn, D., (2008). Briefing note for the pharmaceutical industry: proposed support for the local manufacture of active pharmaceutical ingredients.

Competition Act provisions apply to all economic activity that has an effect in South Africa, including intellectual property rights and the exercise thereof<sup>10</sup>.

### **2.1. *The Hazel Tau & others v. GlaxoSmithKline (“GSK”) & Boehringer Ingelheim (“BI”) (“Hazel Tau Case”)***

One of the most notable cases raising intellectual property issues in South Africa was the Hazel Tau case.<sup>11</sup> The complaint was filed by individuals infected with HIV/AIDS, health care professionals, trade unions, and several non-governmental organisations. In particular, 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 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 when it was economically feasible to do so, and by engaging in exclusionary conduct. These complaints were based on allegations of the failure by the pharmaceutical firms to licence their patents on reasonable commercial terms.

At the conclusion of the investigation, the Commission announced that it was referring the matter to the Competition Tribunal for adjudication. The Commission found that GSK and BI had abused their dominant positions in their respective ART markets.<sup>12</sup> They had charged excessive prices, refused to give competitors access to essential facilities and engaged in exclusionary behaviour in which the anti-competitive effect outweighed technological, efficiency or other pro-competitive gains.

Before the referral and prosecution of the case, GSK and BI negotiated a settlement agreement in terms of which they admitted no liability. GSK and BI agreed to:

- grant licences to generic manufacturers;
- permit 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.

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<sup>10</sup> The exemption provisions of the Act refer to the fact that an intellectual property right holder may apply for an exemption as a result of the application of Chapter 2 of the Act. Whether or not the exemption is granted will depend on the merit of each case despite the fact that the exemption application flows from intellectual property rights.

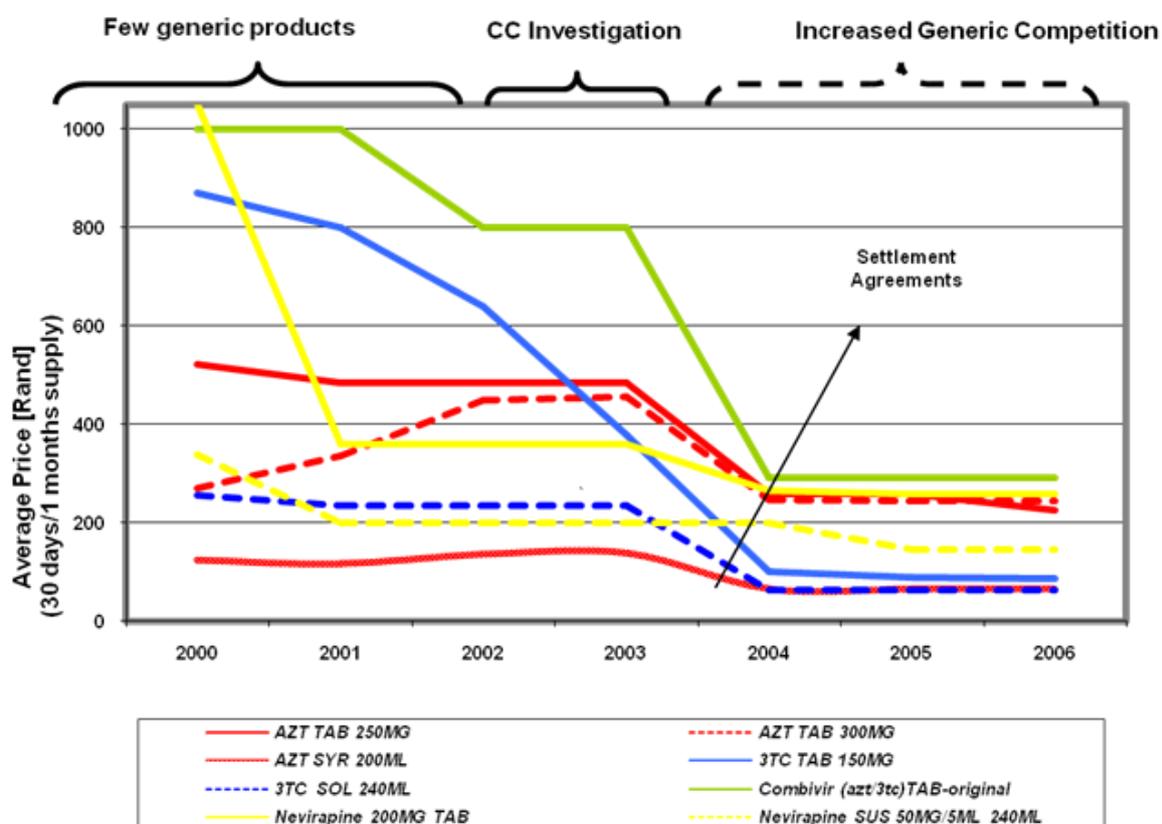
<sup>11</sup> Competition Commission Case Number: 2002Sep226.

<sup>12</sup> Competition Commission, Media release No. 29 of 2003, 16 October 2003: *Competition Commission finds pharmaceutical firms in contravention with the Competition Act.*

An assessment of the impact of the decision revealed the following:

- Decrease in prices of the ARVs that were the subject of the complaint as shown in figure 1 below
- The figure also shows a general movement of the combined prices of both patent and generic ARVs, from 2000 to mid-2006 i.e. pre and post the settlement agreements.
- From 2000 to 2003/4 ARV prices were on a slight downward trend although substantially high. During the Commission's investigation, the prices continued to drastically decrease and after the investigation (from 2004 to date) they have stabilized at a significantly lower rate with the introduction of competition from the generics.

**Figure 1: Impact of the Hazel Tau case on ARV prices (2000-2006)**



Source: MedPrax (Pty) Ltd 2006

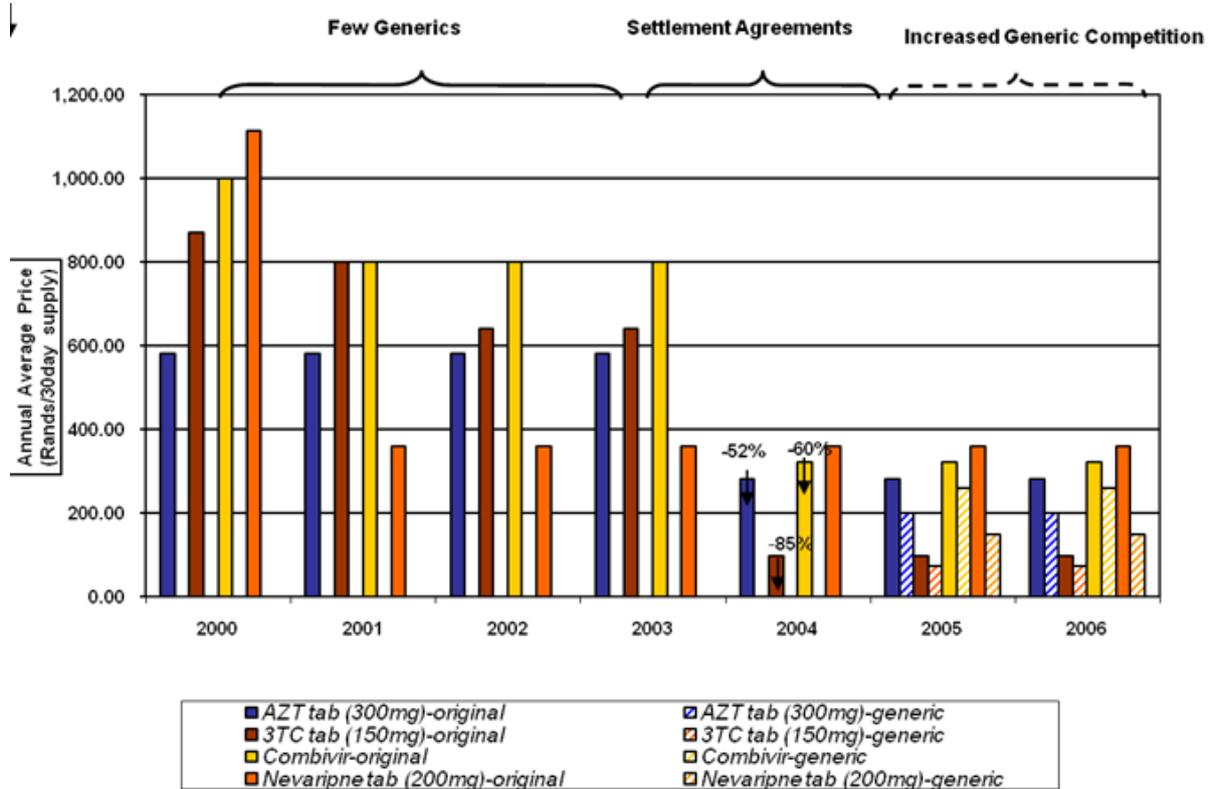
It is evident from the figure above, that, over the five-year period, prices of the relevant ARVs dropped on a regular basis. The prices were significantly high, during the period 2000 to 2003, though on a downward trend, as there were very few generic drugs. During the period 2003-2004, which are the periods in which the settlement agreements and the consequent voluntary licences were concluded, the prices decreased significantly. **Figure 2** below also reflects the same point and in

addition to prices, there was broad access to the ARVs from 4 drugs in 2000 to 8 drugs in 2006.

In terms of prices, for instance, between 2000 and 2003 AZT fell by 52% from ZAR582 to ZAR281 per annum. 3TC tab sold at ZAR870.67 in 2000, then decreased to ZAR640.00 in 2002/3, and ultimately plunged down by approximately 85% to ZAR98.40 in 2006. The Combivir tab, sold at ZAR1000 in 2000, decreased to ZAR800 in 2002, and then stabilised at ZAR321 in 2004. The only drug that seems to have remained at a fairly high price is nevirapine. However, its original price fell by approximately 68% from ZAR1113.42 to ZAR360.00. The generic versions of these are also significantly lower.

A further significant achievement is the trend towards minimal or royalty free licence agreements. These observations correspond with international experiences (Uganda) which similarly observe that introduction of generic drugs competition brings about substantial decreases in prices of ARVs. This intervention broadened access of ARVs – in 2002, there were no ARVs supplied to patients in public sector healthcare and only 20 000 had access in the private sector. This has since increased to millions in public sector clinics and hospitals.

**Figure 2: Impact of the Hazel Tau case on ARV prices and number of generics licenced (2000-2006)**



In 2007, the Commission received another complaint<sup>13</sup> relating to HIV/AIDS medicine from the non-governmental organisation the Treatment Action Campaign (TAC) alleging that Merck (and its South African subsidiary, MSD) had abused their dominant positions in the markets for the ARV medicine efavirenz (EFV) by refusing to license other firms to import and/or manufacture generic versions of this medicine on reasonable and non-discriminatory terms.<sup>14</sup> MSD holds a twenty-year patent on efavirenz that expired in 2013. The TAC case resulted directly in MSD and Merck reaching agreement with multiple licensees on reasonable terms to bring a wide range of generic products containing EFV (an essential drug used as part of first-line ARV treatment in South Africa) to market.<sup>15</sup> While the Hazel Tau case was settled only after the Commission had taken a decision to refer the matter to the Tribunal for adjudication, the TAC case was resolved before the Commission completed its investigation on the matter.

## **2.2. Adcock Ingram Critical Care (“AICC”) and Fresenius Kabi South Africa (“FKSA”).**

The Department of Health annually invites tenders for the supply of pharmaceutical products to its public hospitals.

During 2005, the Competition Commission initiated an investigation into allegations of a cartel between Adcock Ingram Critical Care (“AICC”), Dismed Criticare (“Dismed”) and Thusanong Health Care (“Thusanong”), as well as Fresenius Kabi South Africa (“FKSA”). AICC, Dismed and Thusanong are competitors who supply pharmaceutical products to the health care market.

The Commission’s investigation found that the parties were engaged in collusive tendering and market allocation, both of which are contraventions of section 4 of the Competition Act. The conduct was designed to avoid competition between the colluding firms and manipulate prices for pharmaceutical and hospital products.

FKSA confessed its involvement in the cartel and agreed to co-operate with the Commission’s investigation. It was therefore granted immunity from prosecutions in terms of the Commission’s Corporate Leniency Policy.

The Commission’s investigation found that the representatives of AICC, FKSA, Dismed and Thusanong held telephone discussions and meetings prior to the submission of their respective responses to the invitations to tender. In these discussions and meetings they collaborated on their responses and discussed and

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<sup>13</sup> Commission case number 2007Nov3328.

<sup>14</sup> The TAC’s full complaint and supporting documents is available at <http://www.tac.org.za/documents/TACvMSDFinalCompCompapersFinalOf041107.zip>

<sup>15</sup> See Section 27 Discussion paper on compulsory licencing available at <http://www.section27.org.za/wp-content/uploads/2010/10/S27submissionToDIPP.pdf>

agreed on prices. This involved the manipulation of prices for the pharmaceutical and hospital products with which the tender was concerned. The colluding firms agreed amongst themselves who would win the tenders and, to give effect to this agreement, the terms of their respective bids. They would also agree that whenever tenders were not awarded as agreed or arranged between them, the winning firms would cede portions of the tender to one of their colluding partners.

The Commission also found that AICC and FKSA were engaged in dividing markets in the supply of pharmaceutical products and services to private hospitals, including Afrox Healthcare Limited (now Life Healthcare Group Holdings), Network Healthcare Holdings, Medi-Clinic Corporation and mine hospitals. This involved them agreeing who would provide which products and to which hospitals.

In February 2008, the Commission referred a case of collusion against the firms to the Tribunal for prosecution. The firms subsequently settled with the Commission. AICC agreed to pay an administrative penalty of R53,5m (US\$4.28m), Dismed R1,3m (US\$104,000) and Thusanong agreed to pay R287 000 (US\$22,000).

### ***2.3. The GlaxoSmithKline (GSK) / Aspen merger***

In February 2009, Aspen notified the Commission of its intention to acquire the Lanoxin brand from GSK South Africa. In its investigation, the Commission noted that GSK had voluntarily licensed three patented antiretroviral medicines, including: Zidovudine where the parties (GSK and Aspen) hold a combined market share of 95.7%; Lamivudine where the parties hold a combined market share of 88.5%; and the combination (Zidovudine Lamivudine) a cocktail including both products where the parties hold a combined market share of 85.3%.

The Commission focused predominantly on the horizontal aspects of the merger since GSK to some degree also competed with its generic licensees. Accordingly, no competition issue was recognized with respect to Zidovudine, Lamivudine and the Zidovudine/Lamivudine cocktail since GSK licenses the production and supply of these medicines to various other generic medicine companies such as Adcock Ingram, Ranbaxy (Sonke), BioTech, Cipla and Feza. The Commission however found that the merger was likely to result in the removal of an effective competitor in these markets comprising of the aforementioned seven competitors. Accordingly, the Commission's conclusion was that the remaining competitors will ensure that the market remains competitive notwithstanding the merging parties' significant market share.

Pursuant to its horizontal assessment of the Aspen GSK merger the Commission sought conditions for extension of the license of antiretroviral medicines to include the Abacavir product. Abacavir is a GSK patented product which is used primarily for the treatment of children suffering from HIV. At the time of the merger, GSK was the only supplier of this product in South Africa. The Commission sought and obtained

as a condition for the approval of the merger an undertaking by GSK to not only license the production and/or importation of this product by Aspen but to also extend the license to other generic companies.

#### **2.4. Aspen Pharmacare Holding & Mylan, Mylan Laboratories and Mylan South Africa (“Aspen Mylan Case”)<sup>16</sup>**

In September 2012, the CCSA (the “Commission”) received a complaint from Medesins Sans Frontieres, commonly known as Doctors Without Borders (“MSF”) against Aspen Pharmacare Holdings Limited (“Aspen”) and Mylan Inc. (“Mylan”). MSF is an international humanitarian organisation committed to providing medical assistance to people affected by armed conflict, epidemics, healthcare exclusion, man-made disasters etc.

Aspen is involved in the manufacture, marketing and distribution of branded and generic pharmaceutical products. Mylan is one of the leading generic and speciality pharmaceutical companies in the world. Its product portfolio includes, *inter alia*, the manufacture and supply of active pharmaceutical ingredients used to manufacture generic antiretroviral therapies for the treatment of people living with HIV/AIDS.

The complaint by MSF concerned a vertical supply agreement for the supply of active pharmaceutical ingredients (“API Agreement”) between Aspen and Mylan which, *inter alia*, allegedly precludes Mylan from bringing its fixed dose combination antiretroviral drugs to the South African market. It is alleged that in terms of the API agreement, Mylan sells to Aspen an active pharmaceutical ingredient (“API”) which is necessary for the production of the final fixed dose combination antiretroviral drug (“FDCs”) that is used by HIV/AIDS patients, and further in terms of the Finished Dosage Form ‘(FDF) supply arrangements, Aspen is the exclusive supplier of FDCs in South Africa. Allegedly, the exclusive supply arrangements prohibit Mylan from entering the South African market, directly or indirectly, to supply the FDCs or any other products that Aspen supplies to the South African market as licensed by Mylan. It is alleged that the agreement endures until 2016. In terms of the agreement, Mylan can also not offer APIs purchased by Aspen to any other South African company<sup>17</sup> to manufacture the FDC drug. Furthermore, MSF is concerned about the ongoing negotiations between Aspen and Mylan regarding the price of APIs, alleging the negotiations may influence the price of the FDC drugs that will be available in the market. The complaint is in respect of the introduction of the FDCs in South Africa’s public health sector.

Further to the above allegations, the Commission initiated a further complaint against Aspen and Mylan for engaging in possible market allocation conduct, after concluding that the exclusive supply agreements could possibly constitute a division of markets in contravention of section 4(1)(b)(ii) of the Act.

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<sup>16</sup> This case is still under investigation and a decision will be made in the coming few months.

<sup>17</sup> A company registered or incorporated in South Africa.

The two complaints were non-referred after the investigation.

### **3. Recent developments**

#### **3.1. New IP policy**

On 4 September 2013, the South African government published a draft documenting its new policy stance on IP in South Africa. The final document on IP policy has not been published as yet. The essence of the new IP policy captures a move from a depository patenting system to a substantive patenting system. This means that patent applications would have to undergo intense scrutiny in order to prove that a patentable product is novel and that an inventive step has been taken rather than merely ticking off a set of requirements. Secondly, it allows for pre- and post- patent approval opposition. Thirdly, it advocates the integration of databases between the patent office and the Medical Control Council (MCC)<sup>18</sup> in order to share information. This will limit the granting of some second generation patents. Lastly the new IP policy also allows South Africa to take advantage of the flexibilities granted to developing countries under the TRIPS agreement. These flexibilities include making use of parallel imports, compulsory licensing and the Bolar provision.

The pharmaceutical sector is the most patented sector in South Africa<sup>19</sup>. A substantive patenting system will deter the granting of frivolous patents which render undue monopoly rents in return for little or no innovation. This means that anti-competitive practises such as patent thickets and ever-greening would be reduced by such a system. This in turn would constrain the patent barriers that originators put up to retard the entry of generics. The flexibilities granted to developing countries under the TRIPS agreement open the market for cheaper life-saving drugs. Parallel imports mean that South Africa can import the same patented drug at a lower price from another country. Compulsory licensing means that the South African Department of Health can order an originator to license its drug in return for royalties. The Bolar provision allows potential generic entrants to conduct research, develop, conduct clinical trials and get market authorisation on drugs before the originator's patent expires. This allows generic drugs to enter the market as soon as the originators patent expires.

The amendment of South Africa's IP policy is a step forward in creating a more competitive pharmaceutical sector. This however has certain drawbacks. Assessing patent applications under a substantive patenting system is both time and resource intensive. Longer assessment times delay the entry of generics and create uncertainty. Everything considered the merits of the new IP policy outweigh the merits of the current system.

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<sup>18</sup>The MCC is a South African statutory body that regulates medicines ensuring that they are safe, therapeutically effective and that they meet certain quality standards.

<sup>19</sup> According to the Treatment Action Campaign, South Africa granted 2442 pharmaceutical patents in 2008 alone. It was also noted that for the same patent applications, 40% more patents were granted in South Africa as opposed to the US and EU.

### **3.2. Exploring establishment of State-owned pharmaceutical company**

In 2015 government resolved to start a state-owned pharmaceutical company that will respond to and intervene in the curbing high medicine prices in SA. Ketlaphela, the new state-owned company, was formed and it is also a shareholder in the Biovac Institute, which imports vaccines directly for the Department of Health's childhood immunisation programme. Ketlaphela is to begin by procuring finished products whilst it builds manufacturing capacity. It is anticipated that manufacturing will commence in 2016.

### **3.3. Cost of healthcare enquiry**

The Commission is conducting a market enquiry into the cost of healthcare in South Africa. The outcomes of this enquiry are expected in 2016.

## **4. Conclusion**

The South African pharmaceutical sector is relatively small, where total sales account for less than 1% of the total GDP. Furthermore the local manufacture of drugs has declined and the majority of pharmaceuticals are increasingly being imported (this includes both originator and generic drugs). More generic drugs are consumed in South Africa than originator drugs yet more money is spent on originator drugs; this is suggestive of the relatively high prices of originator drugs. Originator drugs are typically protected by patents which act as barriers to entry for generics, creating a de facto monopoly for that specific drug. The price that pharmaceutical companies charge for such a drug, however, is constrained by single exit price (SEP) regulation. The SEP acts as ceiling on drug prices, however it does not necessarily mean that drugs are cheaper.

Developments in South Africa's IP policy will promote competition by making earlier entry of generics more viable. A substantive patenting system is likely to reduce the incidence of ever-greening and patent thickets. Parallel imports and compulsory licensing will ensure the availability of cheaper drugs. Competitive entry by generic drug manufacturers into the South African pharmaceutical market has been important in ensuring substantial benefits to consumers and reducing costs of health care to millions of poor persons living with HIV/AIDS.

Yet the benefits of generic competition, the static price reductions and their associated consumer benefits must be balanced against the important dynamic benefits of continued investment in the development of new drugs. The Commission's assessments did not view intellectual property rights as being beyond competition scrutiny. Rather, the exploitation of these rights was assessed against competition principles and the benefits they provide to end-consumers.

Competition policy in pharmaceutical markets should ensure that anticompetitive conduct does not further prevent entry by generic drug manufacturers and where the conduct of manufacturers of innovator drugs results in abuse of patent rights (such as in the Hazel Tau case) or potentially threatens access to treatment (for example in the GSK/Aspen merger).