Summer Training at
Blueberry Pharma Advisory, Mumbai

Opportunities for Generics in South Africa for HIV and Tuberculosis

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CERTIFICATE

This is to certify that **Mr. Siddarth vasisth** has undergone his summer training in **BLUE BERRY PHARMA ADVISORY, Mumbai** from 3rd April, 2014 to 4th June , 2014.

The candidate has successfully carried out the project "Opportunities for generics in south Africa for HIV and Tuberculosis" assigned to him during summer training and his approach to the study has been scientific and analytical

The summer training is partial fulfilment of the course requirement

I wish him success in all his future endeavours.

Mr.Abhishek Dadhich
Assistant Professor
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Col. (Dr.) Ashok Kaushik
Dean (Academic & Student Affairs)
IIHMR Jaipur

Blue Berry Pharma Advisory

To whomsoever it may concern

This is to certify that Mr. Siddarth Vasisth student of IIHMR has undergone summer internship for the period April 4 to June 4, 2014.

During the period Siddarth has taken keen interest in the project assigned to him, worked very sincerely and demonstrated positive attitude and keen interest to learn.

I wish Siddarth good luck in future endeavor.

Subhash Seth
CEO
Blue Berry Pharma Advisory

June 4, 2014

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INTRODUCTION

1.0 About South Africa

South Africa, officially the **Republic of South Africa**, is a country located at the southern tip of Africa. It has 2,798 kilometres (1,739 mi) of coastline that stretches along the South Atlantic and Indian oceans.

To the north lie the neighbouring countries of Namibia, Botswana and Zimbabwe; to the east are Mozambique and Swaziland; and within it lies Lesotho, an enclave surrounded by South African territory. South Africa is the 25th-largest country in the world by land area, and with close to 53 million people, is the world's 24th-most populous nation.

South Africa is a multiethnic society encompassing a wide variety of cultures, languages, and religions. Its pluralistic makeup is reflected in the constitution's recognition of 11 official languages, which is among the highest number of any country in the world.Two of these languages are of European origin: English and Afrikaans, the latter originating from Dutch and serving as the first language of most white and coloured South Africans. Though English is commonly used in public and commercial life, it is only the fourth most-spoken first language.

About 80 percent of South Africans are of black African ancestry, divided among a variety of ethnic groups speaking different Bantu languages, nine of which have official status. The remaining population consists of Africa's largest communities of European, Asian, and multiracial ancestry. All ethnic and linguistic groups have political representation in the country's constitutional democracy, which comprises a parliamentary republic and nine provinces. Since the end of apartheid, South Africa's unique multicultural character has become integral to its national identity, as signified by the Rainbow Nation concept.

South Africa is ranked as an upper-middle income economy by the World Bank, and is considered to be a newly industrialised country. Its economy is the second largest in Africa, and the 28th-largest in the world .In terms of purchasing power parity,

South Africa has the seventh-highest per capita income in Africa, although poverty and inequality remain widespread, with about a quarter of the population unemployed and living on less than US$1.25 a day. Nevertheless, South Africa has been identified as a middle power in international affairs, and maintains significant regional influence.

1.1 Economic Environment

The average drug developed by a major pharmaceutical company costs at least $4 billion, and it can be as much as $11 billion to bring to market (Forbes, February 2012).

The pharmaceutical industry contributed about 58% to the South African GDP in the 2008/2009 financial year. The sector‘s revenue was R36, 1-billion of which exports were R2,5-billion. The industry employed an estimated 9 625 full-time staff (Deloitte report, February 2010).

As a percentage of gross domestic product (GDP), healthcare expenditure amounts to approximately 8%, which is among the highest in the continent. The South African consumer spends approximately 1,9% of total household expenditure on medical and pharmaceutical products (Macquarie Research, May 2011).

It is expected there will be a significant increase in the total number of people on chronic medication by 2025: from 6, 6-million using ASSA 2003 to 8, 6-million people using ASSA 2008 (131% of the earlier estimate). This is made up of a 10% increase in those being treated for the 25 CDL chronic diseases and a doubling of those needing ARVs.

The period between 2010 and 2015 will be the toughest for innovator companies. Many global blockbusters will lose their patent protection during this period. In 2010 products with an annual market value of R50-million lost their patent protection .This trend continued in 2011 where a further R40-million of branded products lost their protection and now face generic competition (IMS Health).

1.2 Legal and political environment

As with recent country studies of the legal and regulatory environment in India and in China,undertaken in 2010 and 2013 respectively, this study of national legislation in South Africaoffers concrete suggestions on how intellectual property, competition and medicines legislation can be tailored to improve public health outcomes while complying with international obligations, with a particular focus on the World Trade Organization‘s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

TRIPS requires WTO members, with the exception of least developed countries, to adoptminimum standards of intellectual property protection, including at least 20 years of patentprotection in all fi elds of technology. However, it also establishes specific measures that may be used to limit exclusive patent rights. These public health related TRIPS flexibilities allow countries to balance the minimum standards of intellectual property with public health needs .If the benefits of TRIPS fl exibilities are to be more fully realized in South Africa, the fl exibilities must be incorporated in national law—including patent, competition and medicinesregulation laws. For example, the study found that a stricter patentability standard, where theoverwhelming majority of patent applications are from foreigners, would result in a declinein the number of patents, which in turn could increase competition and result in price reductions of essential medicines. Yet implementation in law of a stricter patentability standard is only the first step, and complimentary practices, such as substantive examination and patent opposition processes, are also needed.

This study comes at an opportune time. It offers a number of policy options that from a publichealth perspective could contribute to strengthening South Africa‘s legal and regulatoryenvironment in ways that make a tangible difference to the health of millions and to sustainable development in South Africa.[An analysis ofpatent, competitionand medicines law; Chan Park, AchalPrabhala and Jonathan BergerUnited Nations Development Programme, October 2013][4].

Intellectual property (IP) protection has become a fl ashpoint within the WTO and increasingly, a source of dispute among its Members. The WTO was established in

an era of increased attention to access to medicines; a focus on HIV and AIDS in the developing world led to a focus on access to health care in general. Stakeholders have repeatedly cited IP rules at the WTO, encapsulated in TRIPS, as an underlying and fundamental barrier to increasing access to HIV and other essential medicines. Over the nearly two decades since the introduction of TRIPS, a process of clarifying its contents has occurred at the WTO, under pressure from (mainly) developing countries. This has led to a better understanding of the boundaries of TRIPS flexibilities, as illustrated perhaps most clearly in Indian patent law.

In the last decade, several developing countries took decisive action with respect to IP withintheir jurisdictions, usually intended to benefit patients and local industry. This, in turn, oftenled to long, drawn-out contestations in courts, in trade relations, and in international tradingforums.However, over the last decade, explicitly implementing TRIPS flexibilities into domestic lawand policy has started to become a more widely accepted practice; using TRIPS flexibilitiesis now considered a more realistic possibility. Indeed, given many countries‘ obligationsunder international human rights treaties such as the International Covenant on Economic, Social and Cultural Rights, which recognizes the right to the —highest attainable standardof physical and mental health”,[5] as well as domestic constitutional obligations of similar effect,[6] taking steps to use such flexibilities to improve access to medicines can be seen as an affirmative obligation.

In addition to a lack of a definitive correlation between prevailing norms of IP protectionand innovation, there have been instances in which significant innovation has occurred in the absence of patent protection. Indeed, the existence of patent protection has, on occasion, posed an obstacle to innovation. For instance, Indian generic companies, unhindered by product patent protection in India during that time, were able to develop a single fixed-dose combination of stavudine, lamivudine and nevirapine that dramatically simplifi ed the HIV treatment regimen and allowed for the scale-up of treatment in many resource-limited settings.[7] Because three different companies owned the patents on these drugs, there was little incentive for the patent-holding companies in the developed countries to enter into complicated cross-licensing arrangements in order to produce a single product that drastically reduced pill burden and improved patient compliance.[8]

The lack of innovation around neglected diseases also calls into question the relationshipbetween IP protection and innovation. In 2008, the World Health Assembly adopted theGlobal Strategy and Plan of Action on Public Health, Innovation and Intellectual Property(Global Strategy), recognizing that intellectual property as an incentive —alone does not meetthe need for the development of new products to fi ght diseases where the potential payingmarket is small or uncertain".[9]Multinational pharmaceutical companies have invested limited resources in research and development on diseases predominantly affecting developing countries – such as tuberculosis (TB), malaria, leishmaniasis and kala azar. This has resulted in a push for alternative mechanisms such as prize funds and partnerships like the Drugs for Neglected Diseases Initiative, and government-led initiatives such as the Indian government's open Source TB Drug Discovery project.

This combination is no longer a preferred regimen. Nonetheless, it is still widely used in many resource-limited settings.

1.3 Cultural environment

South Africa is one of the most multicultural countries in the world. In urban areas many different ethnic groups will make up the population .In addition to the indigenous black peoples of South Africa colonialism and immigration have brought in white Europeans, Indians, Indo-Malays, Chinese and many more.

The basic unit of South African society is the family, which includes the nuclear family and the extended family or tribe.

In traditional African society, the tribe is the most important community as it is the equivalent of a nation. The tribe provides both emotional and financial security in much the same way the nuclear family does to white or coloured South Africans.

The coloured and more traditional Afrikaans cultures consider their extended family to be almost as important as their nuclear family, while the English-speaking white community places more emphasis on the nuclear family.

The nuclear family is the ultimate basis of the tribe. The tribal and family units are being disrupted by changes in the economic reorganization of the country.

Most businessmen are looking for long-term business relationships. Although the country leans towards egalitarianism, businesspeople respect senior executives and those who have attained their position through hard work and perseverance. There are major differences in communication styles depending upon the individual's cultural heritage. For the most part, South Africans want to maintain harmonious working relationships, so they avoid confrontations. They often use metaphors and sports analogies to demonstrate a point. Most South Africans, regardless of ethnicity, prefer face-to-face meetings to more impersonal communication mediums such as email, letter, or telephone.

As more people move into the urban areas, they attempt to maintain familial ties, including providing financial support to family members who have remained in the village.

1.4.0 Business Environment:

1.4.1 Business Meeting Etiquette

Appointments are necessary and should be made as far in advance as possible.
It may be difficult to arrange meetings with senior level managers on short notice, although you may be able to do so with lower-level managers.

It is often difficult to schedule meetings from mid December to mid January or the two weeks surrounding Easter, as these are prime vacation times.

Personal relationships are important. The initial meeting is often used to establish a personal rapport and to determine if you are trustworthy.

After a meeting, send a letter summarizing what was decided and the next steps.

1.4.2 Business Negotiations

It is imperative to develop mutual trust before negotiating. Women have yet to attain senior level positions. If you send a woman, she must expect to encounter some condescending behaviour and to be tested in ways that a male colleague would not. Do not interrupt a South African while they are speaking. South Africans strive for consensus and win-win situations. Include delivery dates in contracts. Deadlines are often viewed as fluid rather than firm commitments. Start negotiating with a realistic figure. South Africans do not like haggling over price. Decision-making may be concentrated at the top of the company and decisions are often made after consultation with subordinates, so the process can be slow and protracted.

In 1994, WTO members signed the TRIPS agreement which came into effect on 1 January 1995.South Africa became a member of the WTO on the same day. TRIPS set out the standards of intellectual property protection that all countries would be required to uphold. South Africaamended its national laws to comply with these requirements in 1997, extending periods ofmonopoly protection from 16 years to 20 years, despite the fact that South Africa was notobliged to comply with TRIPS until 2000 in accordance with the TRIPS transitional period.When negotiating the agreement, developed countries promised developing countries that the implementation and expansion of intellectual property protection would result in greater foreign direct investment which would stimulate economic growth. Yet since expanding patent protection, the opposite has been observed in South Africa.

Following the adoption of TRIPS, South Africa witnessed a massive decline in pharmaceutical production and investment by R&D MNCs. Between 1994 and 2007, 35 pharmaceutical manufacturing plants in South Africa, belonging mainly to R&D MNCs, were shut down (Maloney & Segal, 2007). Rather than expanding investment in countries with strengthened intellectual property protection, R&D MNCs consolidated their operations in regions with skilled labour, low costs of labour and production and other economic incentives (Naude &Luiz, 2013). In the past decade, investment by companies producing generic medicines in South Africa‘s

pharmaceutical market has massively outpaced that of R&D MNCs (DTI, 2011), yet our laws have limited the growth of this industry.

Furthermore, empirical evidence to support the claim that strengthening intellectual property willresult in increased investment is limited. Academic studies have found conflicting results: ‗Proof of a correlation between strong intellectual property rights and foreign direct investment remains elusive' (Musungu, 2005). For example, India's pharmaceutical industry realised foreign direct investment of US$1 billion from April-June 2013, despite India's proactive adoption of legal TRIPS flexibilities to limit intellectual property protection specifically in order to protect health and local industry (The Economic Times, 2013). Conversely, South Africa has attracted far less foreign direct investment than other countries with weaker intellectual property protection (Kaplan, 2009).

A recently published study that investigated the relationship between intellectual propertyprotection and foreign direct investment in 103 countries between 1970 and 2009 found thatstrict intellectual property protection can actually negatively impact on growth associated with foreign investment. The study found that countries that are able to attract foreign investment, while simultaneously retaining ‗lax' levels of intellectual property protection were able to achieve a higher growth rate (Kascheeva, 2013).

2.0 LITERATURE REVIEW

2.1 SOUTH AFRICA'S PHARMACEUTICAL MARKET

South Africa's pharmaceutical market is expected to increase at a compound annual growth rate (CAGR) of 5.8% from 2011 to 2020, when its value will have risen from US$2.5 billion to $4.2 billion, according to new forecasts.

This expected fast growth will be driven by the government's healthcare reforms, which include improving access to healthcare services by expanding National Health Insurance (NIH) coverage to the entire South African population, and overhauling the

nation‘s drug regulatory processes to be faster and more transparent. These moves, together with the introduction of a new regulatory agency and efforts to augment economic growth, will positively contribute to growing the country‘s pharmaceutical sector and boost foreign investment, according to the report, which is produced by market intelligence provider Global data.

The study points out that there are major concerns impeding the growth of the South African healthcare market, including poor infrastructure in rural areas and no universal system to keep healthcare costs in check. However, the government‘s adoption of NHI should significantly reduce the direct healthcare costs for low-income families and households, especially those living in rural areas who bear the highest burden in terms of disease and poverty, Global Data forecasts. The NHI system will expand health insurance coverage and create an opportunity for lower-income households to be included in the South African healthcare system, regardless of income, as access to preventive services such as immunisation against influenza and tuberculosis will contribute to the growth of the country‘s healthcare market, the study says.

South Africa is also modernising its regulatory structure to speed up drug approvals and increase foreign investment in the country. Under the old regulatory regime, drug approvals took a long time and the process was not transparent, and this led many pharma multinationals to consider investing in other markets where there was greater clarity, more streamlined processes and less risk.

To this end, the government is establishing the South African Health Products Regulatory Agency (SAHPRA), to replace the Medicines Control Council (MCC). The new body will have a wide range of responsibilities, including helping to remove the backlog of drug applications and speed up the registration process from five years at present to one year.

SAHPRA will be a key contributor for incentivising foreign investment into South Africa‘s pharmaceutical sector global Data forecasts.

The report also points out that South Africa has taken positive steps to augment macroeconomic growth, including pushing for the country‘s official designation as a BRICS (Brazil, Russia, India, China and South Africa) nation. This will not only

benefit the macro-economy but will also spur investment and drive the couture‘s healthcare sector as well, it says.

The BRICS designation will create additional opportunities for South African pharmaceutical companies to develop new business relationships and strategic partnerships with fellow BRICS nations, along with other rapidly-developing economies, GlobalData forecasts.

[A. Fatti and A.S.A. du Toit;Competitive intelligence in the South African pharmaceutical industry ;Journal of Intelligence Studies in Business 1 (2013) 5-14][11]

Currently the South African pharmaceutical industry is being affected by legislation, as the government is readjusting the whole healthcare system to make it cost-effective and equitable. The purpose of this article is to establish what the current situation is within the South African pharmaceutical‘s industry‘s competitive intelligence (CI) capacity. Questionnaires were administered electronically to senior managers in the pharmaceutical industry. The majority of the respondents were of the opinion that a culture of information sharing and an environment of collaboration on competitive issues exist in their companies. Respondentsconfirm that CI is used on a continuous basis in strategic decision-making and that company strategies are used to manage competitors. It is recommended that senior management of pharmaceutical companies capitalise and consolidate the CI function which is used on a continuous basis in strategic decision-making.

The South African pharmaceutical industry is undergoing rapid transformation spurred on by the current economic climate, government policy and an evolving local existing customer base. Also within this cauldron of factors is the dominating framework of globalisation. South Africa, like many developing countries, needs to embrace an open-market economy to develop competitiveness which, in turn, will ~~-e~~nhance its competitiveness to improve living standards” (Blanke 2007, 3).

Seemingly the current characteristic of the South African pharmaceutical industry is to encourage multinationals to keep their bases on South African soil, as this iswhere the huge disease burdens occur, for example diabetes, TB, high blood pressure and HIV/Aids. They could expand globally to gain a profitable return on their investments, but keep their options open in the hope that new government regulations, economic

and political agendas will become more favourable. Notably the incidence of clinical trials for HIV/Aids is significantly lower than in other countries (Montague & Oosthuizen 2010, 23), providing further reason for multinationals to continue doing business in South Africa.

3.0 Background

Generic medicines provide a major benefit to you as they ensure that you and your family have access to quality, safe and effective medicines while reducing your medicine costs and ultimately stretching your Medical Aid medicine benefits further. Generic medicines account for a major percentage of all prescriptions dispensed in Britain, according to their Department of Health, likewise in the USA.

In South Africa, all medicines including generics must be approved by the Medicines Control Council, an independent and impartial statutory council that exercises its powers in terms of the Medicines and Related Substances Control Act (101 of 1965).

Generic medicines are less expensive because generic companies spend less money on advertising, Promoting and marketing their medicines. Their development costs are also less and they employ highly efficient economies of scale in their manufacturing plant.

A company that first develops a new medicine is allowed to patent it, typically for up to 20 years. This allows the innovator a period of exclusive supply, enabling it to recover its research and development costs. Once the patent expires, generic companies can then manufacture this product.

3.1 Generic medicines as effective as branded medicines?

Generic medicines are subject to the same stringent controls as branded products. In fact branded and generic medicines are sometimes made by the same company.

Generic medicines contain the same active ingredients, are of the same dosage form and are identical in strength to the original medicine. They work in the same way in the body and are associated with the same benefits of the original medicine.

The Medicines Control Council employs a team of doctors, scientists and pharmacists who check the product to ensure it is safety, quality and efficacy.

While the generic has the same key clinical characteristics as the branded product, it can be of a different shape or colour, or is packaged differently.[2014 NAPM - National Association of Pharmaceutical Manufacturing][12]

[06 OCT 2012 08:54 GARETH COETZEE _MAIL & GUARDIAN][2] Africa is where 11% of the world's population lives and 25% of the world's burden of disease is felt. And because access to healthcare is increasing, there is greater demand for medicine on the continent.

But, according to the Council for Health Research and Development, an international non-governmental organisation based in Switzerland, only 37 countries in Africa have some capacity to produce pharmaceuticals. South Africa is the only country with limited primary production of active pharmaceutical ingredients, mostly for non-speciality drugs.

This means African countries, including South Africa, have no choice but to source drugs from outside their borders. There is an exaggerated dependence on imports of pivotal medicines – especially those needed for HIV/Aids and non-communicable diseases – from the United States, Japan, France, Germany and the United Kingdom.

These countries, according to the council's research, produce two-thirds of the global value of pharmaceutical products. The prices of some of these speciality medicines make most of them unaffordable for the majority of the continent. This renders any attempt at national health initiatives unsustainable.

Speaking at a conference organised by the Independent Clinical Oncology Network in Cape Town in March, Professor Richard Sullivan of King's College in London said the price of technology and drugs drives more than 75% of the escalating costs of healthcare globally.

Generic versions of these drugs may offer the only way to ensure that more people gain access to quality treatment, for example: In oncology. Business Day recently published a comparison on the drug Glivec, which costs R862 for 400mg in South Africa. The same dosage of the generic costs R86 in India.

The treatment of cancers is particularly vulnerable to the high cost of medicine. Emile Stipp, chief health actuary for Discovery, South Africa's largest medical scheme, said at the conference that oncology treatment in South Africa was 17 times more expensive than any other treatment for non-communicable diseases.

According to his figures, the cost of oncology in South Africa has grown 11% year on year since 2008 and the increase was mainly because of speciality drugs. In 2008, Discovery paid R188-million for these drugs and R265-million in 2010.

There is a recognition that the cost of speciality drugs, in particular new cancer medicine, is just far too high and completely out of reach for the majority of cancer patients.

"This is of great concern to us," said Dr David Eedes, clinical executive of the Independent Clinical Oncology Network, a countrywide organisation of private oncologists set up to ensure a more equitable and sustainable solution to quality cancer care.

The network has developed treatment protocols that strive to include drugs and treatments that have proven efficacy and are appropriate, cost-effective and affordable. The aim is to reserve the more expensive forms of treatment for where and when it will have the most benefit.

"As we try to address the ever- increasing cost of cancer treatment in the country, taking into account the roll-out of National Health Insurance, we believe that generic substitution will play a major role," he said.

Eedes added that, in addition to cheaper drugs, there needs to be an emphasis on the promotion of cancer awareness and screening that will lead to earlier diagnosis of cancer. The hope is that this will result in better outcomes. The downside is that, with more people needing treatment, the overall cost of treating this disease will increase.

The African Union has taken a policy position on increasing local capacity to produce generic medicine and the South African generics market is already growing. Reports suggest that more than 50% of the population now uses generic medicines

There is now tremendous pressure on medical aids and the need to cut costs is greater than ever. This will inevitably lead to a move towards generic alternatives from expensive originator drugs."

IMS Health, a US-based organisation that analyses healthcare dynamics, forecasts that medicine spending in the developing world will double over the next five years. Of those sales, 83% were predicted to be generic and over-the-counter medicine and diagnostic and non-therapeutic products.

Of course, it is not all plain sailing and drug companies are fighting back. Pharmaceutical giant Novartis is challenging an Indian patent law that prevents originator drug companies from extending their monopolies on patented drugs. It is only when a drug's patent has expired – in most countries a company holds a patent for 20 years – that generics manufacturers may replicate the drug. Because South African patent laws follow the precedent that Indian patent laws set, local oncologists will watch how this drama plays out.

4.0 Problem Statement

Problem of colliding epidemics: 15 years after its first democratic election and liberation from apartheid, South Africa faces colliding epidemics – explosive HIV and TB epidemics, a high burden of chronic illness, mental health disorders, injury and violence-related deaths as well as a silent epidemic of maternal, neonatal, and child mortality.

South Africa‘s per capita health burden is the highest of any middle-income country in the world. The brunt of all these disease burdens is still carried by the poorest families.

The main and fatal disease is found to be HIV and Tuberculosis (TB) and the cost of their treatment is almost unaffordable to these poor families.

Number of people living with HIV: 6,100,000 | Adult HIV prevalence: 17.9 % while South Africa is estimated to have the highest absolute number of people living with HIV of any country in the world.

Many of the families are inaccessible to the medicines for treating these diseases & some are not aware of the treatment as well.

5.0 Rationale

5.1 South Africa and treatment for HIV infection

Number of people living with HIV: 6,100,000 | Adult HIV prevalence: 17.9%
While South Africa is estimated to have the highest absolute number of people living withHIV of any country in the world,[10] it is also home to the world's largest public sector antiretroviral (ARV) treatment programme.[11]In 2003, a South African government publication recognized that:

> Two years ago, this programme for comprehensive care and treatment would have been impossible, amongst other things due to the cost of the medicines and laboratory tests required.[12]

More recently, South Africa's *National Strategic Plan on HIV, STIs and TB 2012–2016*(NSP) counts among past successes, —the reduction in prices for key commodities, includingantiretroviral (ARV) drugs and TB drugs, which enabled the further expansion of access totreatment".[13] A key intervention for the NSP is —ensuring access to affordable, high-quality drugs to treat HIV, sexually transmitted infections (STI) and TB".
Globally, in 2010, 3.4 million children aged <15 years were HIV-positive, 90% of whom were living in sub-Saharan Africa.[1] In 2011, UNAIDS estimated that in South Africa (SA) alone there were about 460 000 children aged 0 - 14 years living with HIV. Health-facility-based HIV counselling and testing (HCT) does not capture all children and adolescents who are at risk of HIV infection.[2-5] The large number of children not treated suggests that there are still relatively low rates of testing among children.[6] Children are either being missed by the prevention of mother-to-child transmission of HIV (PMTCT) services, are surviving past two years of age without being tested, or are infected after birth through child abuse or health-service-acquired infection. In addition, children aged >12 years may be at increased risk because of their own sexual activity.[7-9] Similarly, rates of testing among adolescents

are particularly low, especially among young males,despite this being an at-risk population.[9] This highlights the need for new, targeted, innovative, age-appropriate counselling and testing services for children and adolescents[10]

6.0 **Research question:**

What are the opportunities for generics in South Africa for HIV and Tuberculosis?

7.0 **Objective(s)**

- To explore the opportunities for generics in South Africa for HIV and TB.
- To enlist the major players in South African pharmaceutical market.

8.0 Methodology:

8.1 Study Design:

This is a descriptive study regarding the opportunities for generics in South African market.

Regarding the study for the above problem secondary data is collected by the help of web, journals ,magazines and Literature reviews .The study is moreover an exploratory study and slightly descriptive to have a knowledge of South African pharmaceutical market.

The study helps in designing the strategies for responding the opportunities for generics in South Africa for HIV and TB.

8.2 Timeline: The project work was done in 2 months.

9.0 Analysis and results approach:

According to the study and literature review the analysis approach was to do the SWOT analysis for South African pharmaceutical market.

STRENGTHS	WEAKNESSES
• Heightened political interest (and will) to support the local production of medicines. • Demonstrated that high quality production of essential medicines is feasible across the continent. •Strengthening of legal/regulatory framework (off a weak base). •Existence of scientific and technical institutions with the relevant skills in a number of countries (as yet underutilized). • Increasing political stability and rapid economic development provide a strong basis for development of the industry. • Developments in health insurance schemes and health systems with increasing investment in public health. • Some countries have well established pharmaceutical sectors and regulatory	• Level of regulatory oversight varies but in general it is insufficient to protect our citizens and to allow fair competition in our pharmaceutical markets. • Currently heavily dependent on imports which often benefit from export incentives as well as favorable duties and tariffs when compared to domestically manufactured products. • Policy incoherence and absent sector development strategies lead to an environment that is not conducive for the industry to flourish. • High utility costs and unreliable supply. • Limited availability of affordable finance of sufficient magnitude and duration constrains the sector‘s ability to invest in necessary upgrades to achieve established quality standards. • Small domestic markets and fragmented regional markets hamper companies‘ ability to manufacture efficiently. • Situation varies dramatically, but in fo

institutions that are relatively strong. • Comparatively low labour costs, especially as Indian labour costs begin to escalate. •Some countries already exporting to industrialized markets.	r many companies the systems, processes, premises and equipment at plant level are insufficient to assure quality of production. • Limited supporting industries including local production of inputs such as APIs, packaging and excipients, as well as availability of services to maintain and repair equipment and to conduct necessary trials to attest to suitability of products. • WHO prequalification scheme covers only a limited range of products whilst the quality assurance for most medicines is under the authority of our highly resource constrained NMRAs.
OPPORTUNITIES	**THREATS**
• Evidence suggests given a conducive environment our manufacturers can compete with imports and produce high quality products. • Time limited support to industry coupled with requirements (and regulatory oversight) to develop provides viable route for building an international standard industry. • Creating more favourable market conditions will encourage investment in the sector.	• Without a holistic and robust approach to developing the sector efforts from committed manufacturers will be undermined by on-going penetration of sub-standard and counterfeit medicines. • An on-going lack of evidence as to the prevalence and impact of substandard and counterfeit medications could undermine the long term political will required to develop the industry. • Development of the sector requires coordination across public health and

• Development of the sector (and requisite national and regional level legislation) will enable TRIPS flexibilities to be utilized for improved access to key medications. • Increased prevalence of lifestyle diseases can be more comprehensively addressed through enhanced local production and they represent a growing market opportunity. • Training programmes and institutions exist but need to be expanded and scaled up. • More advanced countries can look to export drugs to international markets. • On-going work under the African Medicines Regulatory Harmonization initiative could lead to defragmented markets at the sub-regional level. • Strong interest from international generic industry and therefore the possibility for local companies to form alliances with international players.	industrial development components otherwise objectives on both fronts will not be achieved. • Without concerted action reliance on Asian imports may increase and quality of products may be increasingly suspect. • If donor assistance plateaus a possible increase in sub-standard products for the pandemic diseases could jeopardize the health of patients and lead to accelerated resistance generation against critical products. • Donor initiatives that can inadvertently have detrimental consequences for the African pharmaceutical industry.

10.0 **Findings**

The following graph is showing the total sales of three years from 2011 to 2013 in 1000 $ which further shows that sanofi was having the highest sales followed by Astra Zaneca and abbvie respectively.

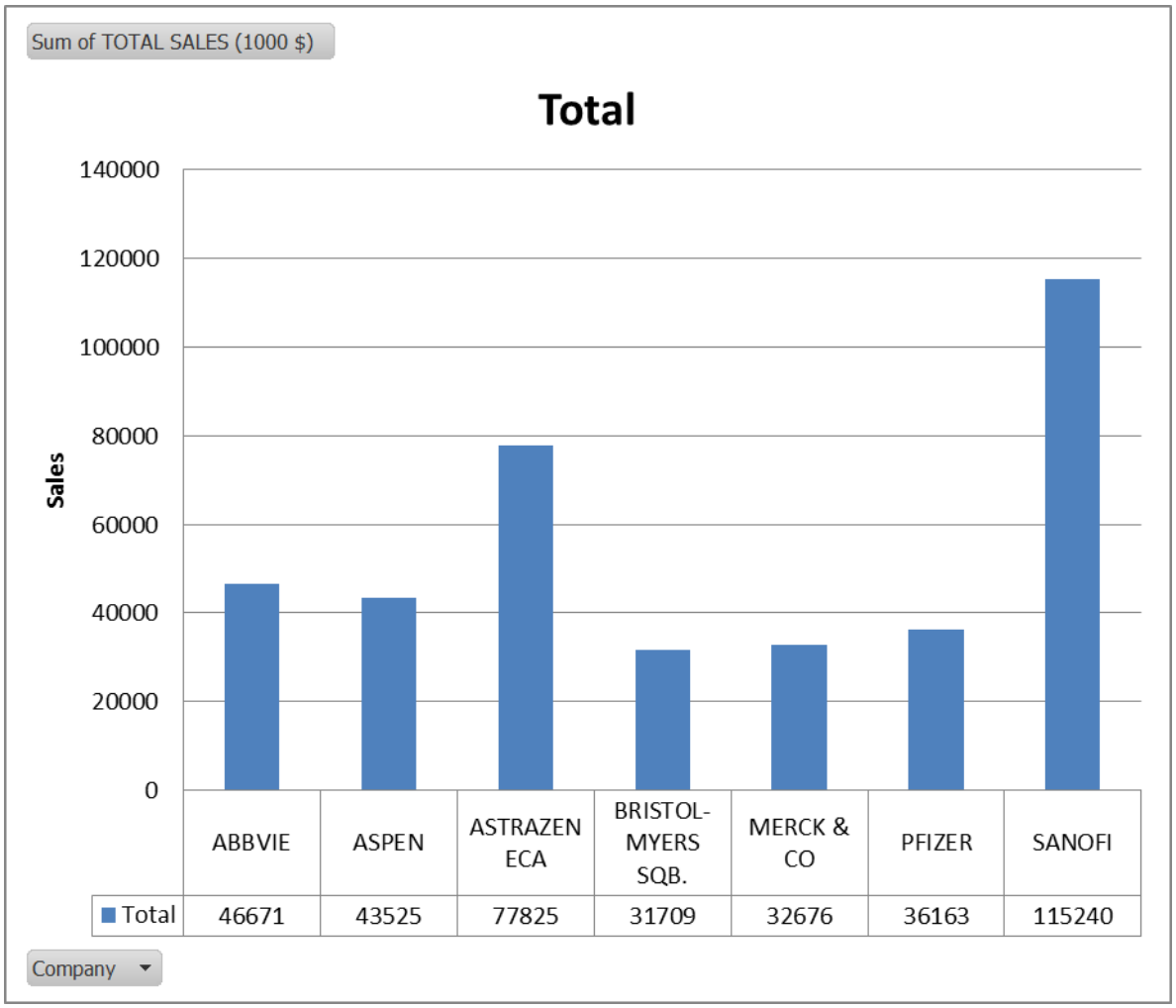

Figure 1.0 Sum of total sales (three years) in 1000 $ of Companies

Sanofi and Astra Zeneca being an innovator of highly demanding drug is having highest sales.

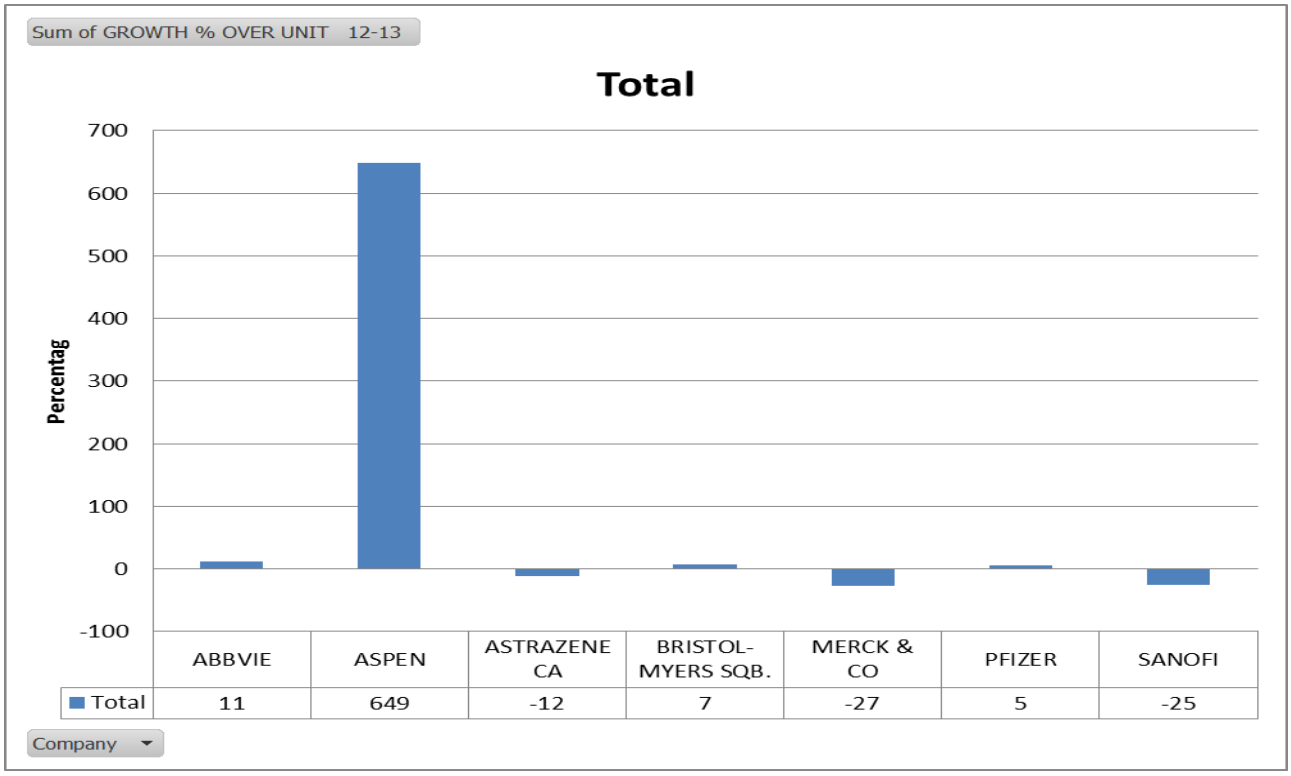

Figure 1.1 Growth in terms of unit of 2013 over 2012 of companies

Aspen is a leading generics manufacturer in the Southern hemisphere and is Africa‘s largest pharmaceutical manufacturer.

Company	Molecule	Therapeutic area
ASPEN	EFAVIRENZ#EMTRICITABINE#TENOFOVIR DISOPROXIL	HIV
ASPEN	TENOFOVIR DISOPROXIL	HIV
ASPEN	OMEPRAZOLE	Anti Ulcer
ASPEN	EFAVIRENZ	HIV
ASPEN	LAMIVUDINE#ZIDOVUDINE	HIV

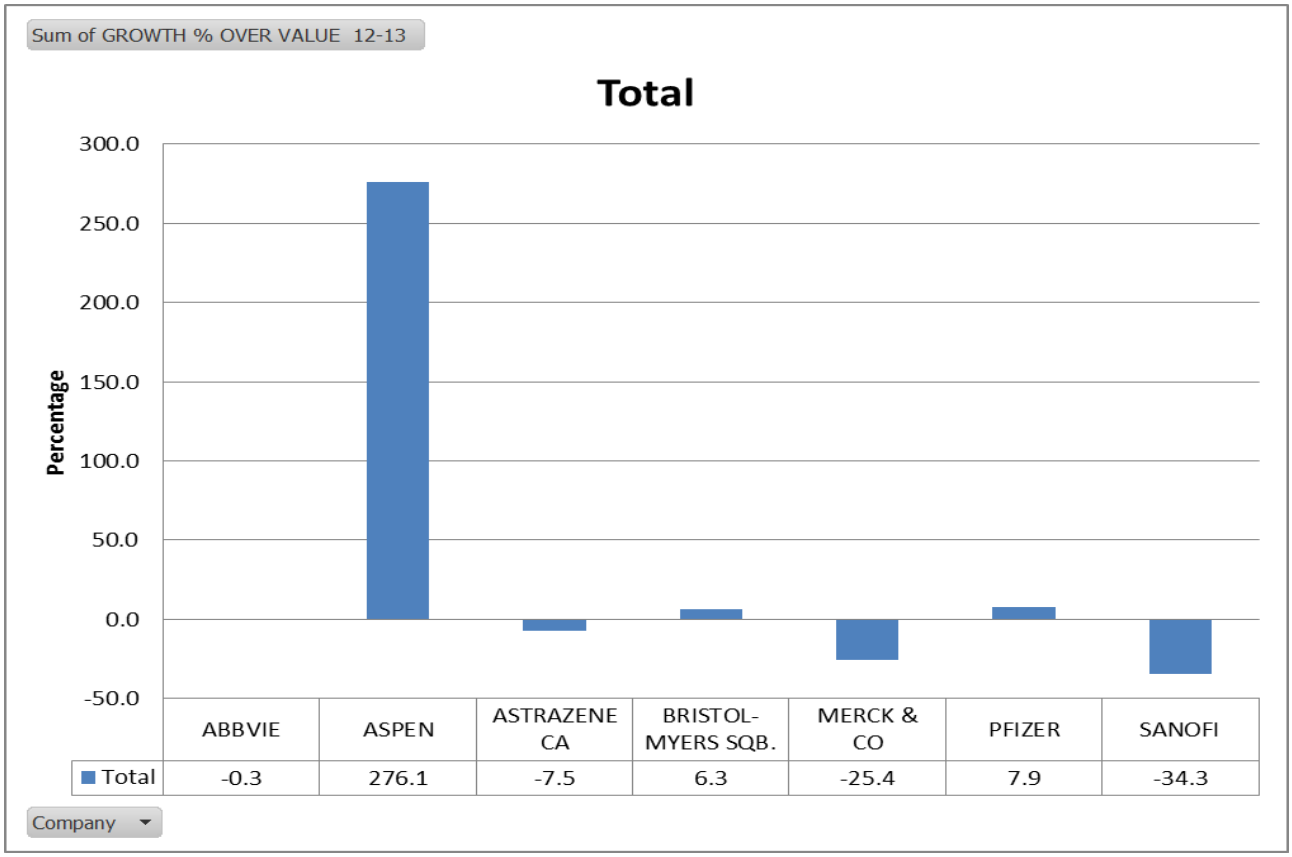

Fig.1.2 Growth in terms of Value of 2013 over 2012 of company

As the number of units increases the value increases. Aspen is having the highest number of generic drugs for the treatment of HIV.

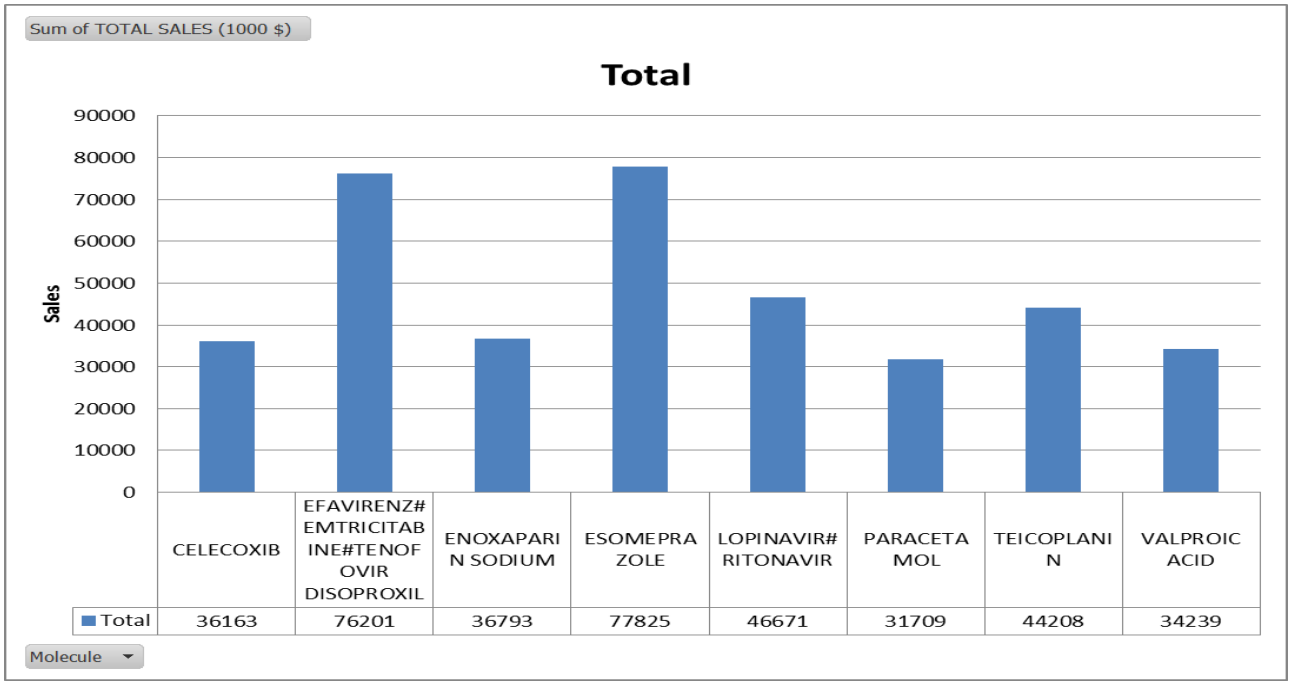

Fig 1.3 Sum of total sales (three years) in 1000 $ of molecules

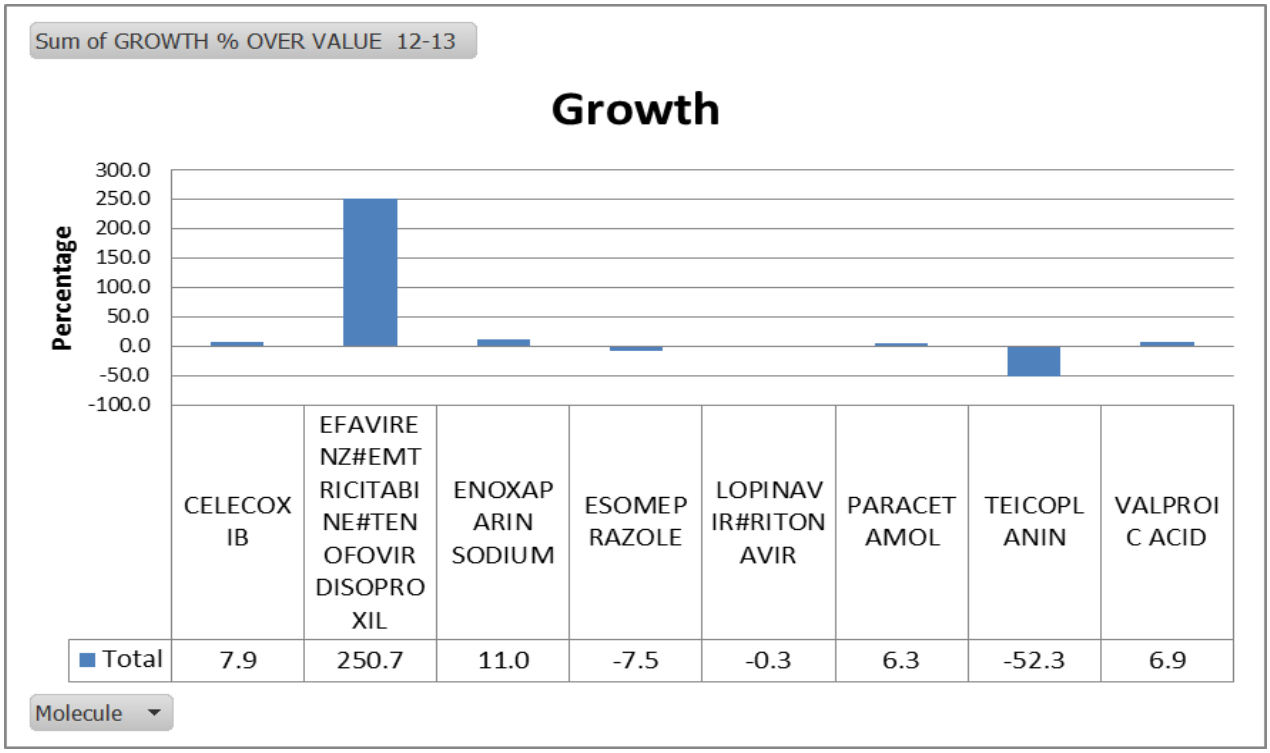

Fig.1.4 Growth in terms of Value of 2013 over 2012 of molecules

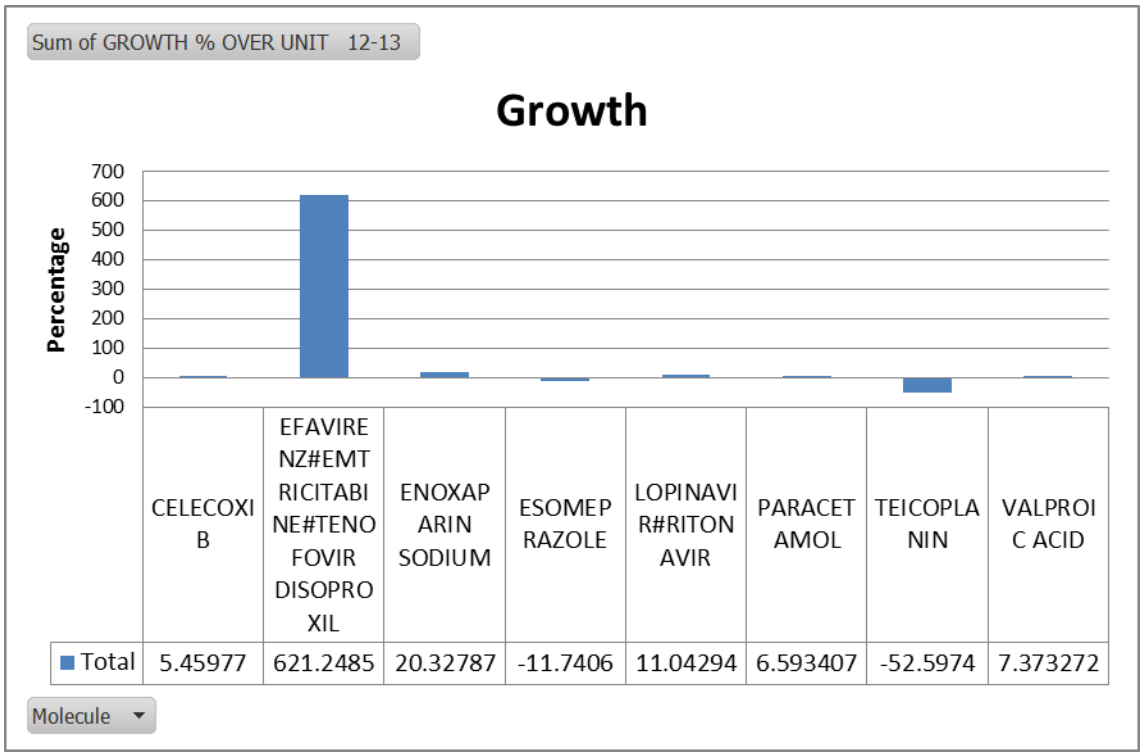

Fig 1.5 Growth in terms of units of 2013 over 2012 of molecules

11.0 Analysis:

According to the above findings-

The growth of drugs for HIV is very high and the drugs which are patented now will be losing their patents in coming one or two years.

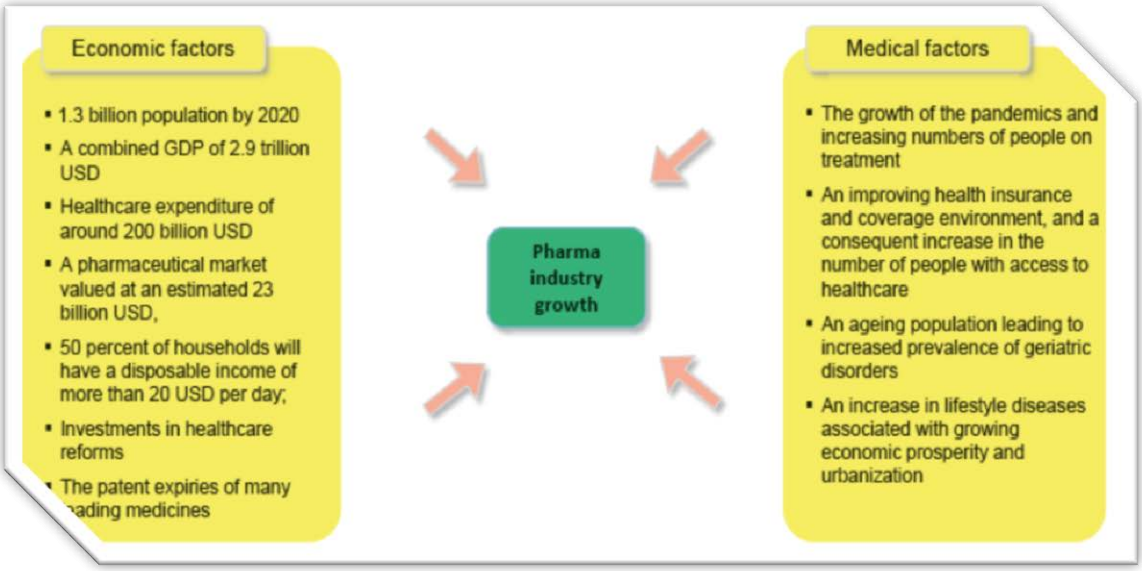

Fig 1.5 Economic and medical factors in pharma industry

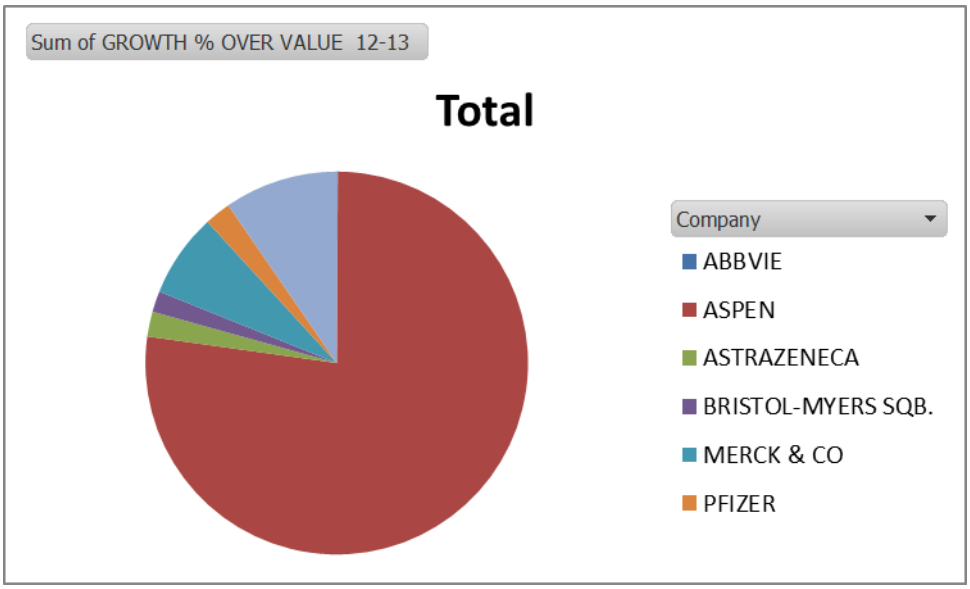

Fig 1.6 Growth in terms of Value of 2013 over 2012 of companies

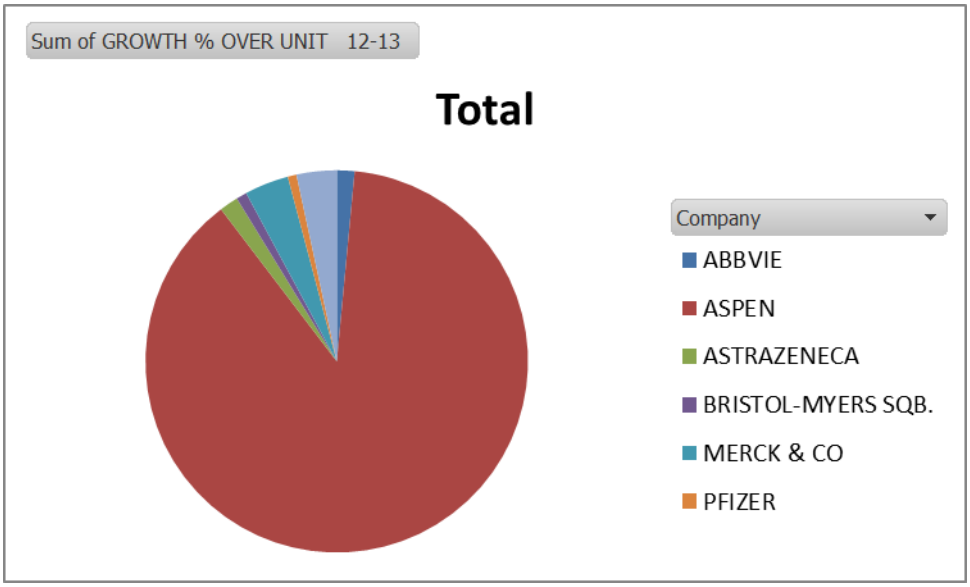

Fig 1.7 Growth in terms of units of 2013 over 2012 of companies

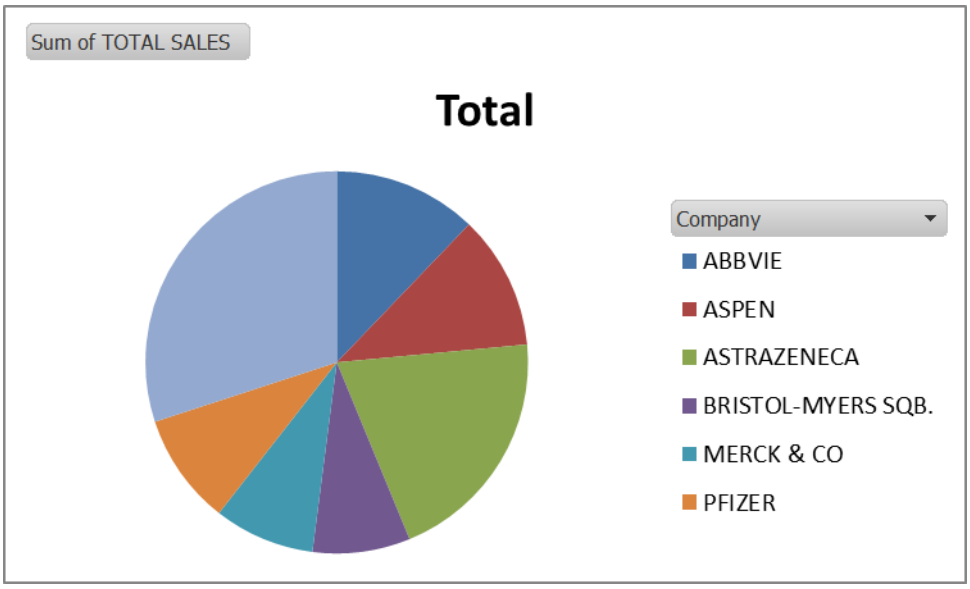

Fig 1.7 Sum of total sales of top South African pharmaceutical companies

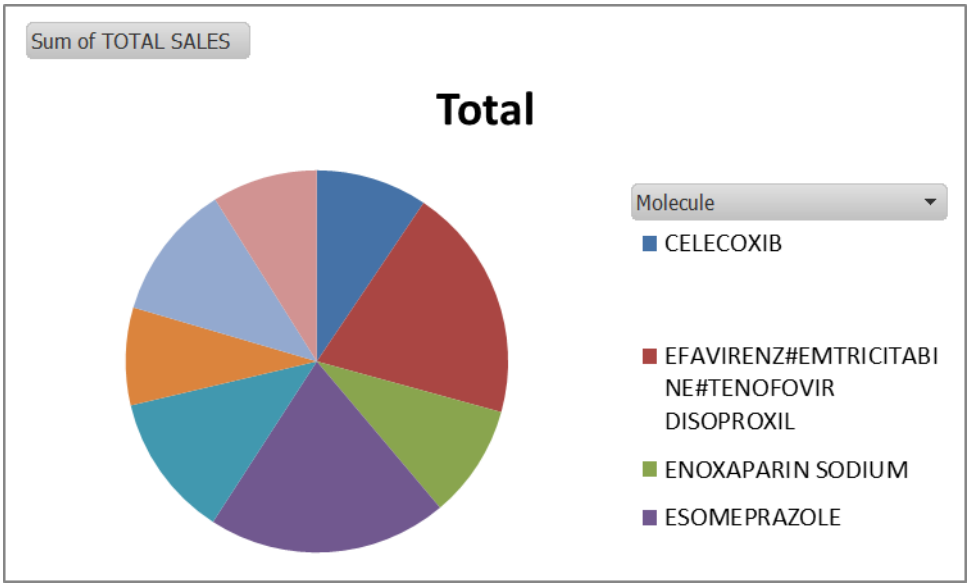

Fig 1.8 Sum of total sales of top molecules in South Africa

12.0 Conclusion:

- Aspen is having highest growth percent over value as it is manufacturing Efavirenz,emtricitabine, & tenofovir disproxil which is an anti retroviral.
- Efavirenz, emtricitabine, & tenofovir disproxil is an antiretroviral drug having the highest growth.
- Aspen is a leading generics manufacturer in the Southern hemisphere and is Africa‘s largest pharmaceutical manufacturer.
- As Antiretroviral is having highest growth percentage over value this shows that opportunities for generics for HIV are existing in South Africa.
- As incidence of HIV are increasing in South Africa so there are possibilities of increase in demands for Anti retrovirals.

13.0 **References:**

1. WHO, UNICEF, UNAIDS. Global HIV/AIDS response. Epidemic update and health sector progress towards universal access. Progress report. Geneva, Switzerland: WHO UNICEF, UNAIDS, 2011.

2. Bwambale F, Ssali S, Byaruhanga S, Kalyango J, Karamagi C. Voluntary HIV counselling and testing among men in rural western Uganda: Implications for HIV prevention. BMC Public Health 2008;8(1):263. [http://dx.doi.org/10.1186/1471-2458-8-263]

3. Hutchinson PL, Mahlalela X. Utilization of voluntary counseling and testing services in the Eastern Cape, South Africa. AIDS Care 2006;18(5):446-455.

4. Chhagan MK, Kauchali S, Arpadi SM, et al. Failure to test children of HIV-infected mothers in South Africa: Implications for HIV testing strategies for preschool children. Trop Med Int Health 2011;16(12):1490-1494. [http://dx.doi.org/10.1111/j.1365-3156.2011.02872.x]

5. Venkatesh KK, Madiba P, de Bruyn G, Lurie MN, Coates TJ, Gray GE. Who gets tested for HIV in a South African urban township? Implications for test and treat and gender-based prevention interventions. J Acquir Immune Defic Syndr 2011;56(2):151-165. [http://dx.doi.org/10.1097/QAI.0b013e318202c82c]

6. Shisana O, Rehle T, Simbayi LC, et al. South African National HIV Prevalence, Incidence, Behaviour and Communication Survey, 2008: A Turning Tide Among Teenagers Cape Town: HSRC Press, 2009.

7. Lesch A, Swartz L, Kagee A, et al. Paediatric HIV/AIDS disclosure: Towards a developmental and process-oriented approach. AIDS Care 2007;19(6):811-816.

8. See B. Baker, —U.S.‘s Misguided and Bad-Faith Attack on the WHO‘s 3-by-5 Plan”, Health GAP (2003), available at http://www.healthgap.org/press_releases/03/121803_HGAP_BP_USG_3x5.html

9. World Health Assembly, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHA61.21, 24 May 2008 available at http://apps.who.int/gb/ebwha/pdf_fi les/A61/A61_R21-en.pdf.

10. Rotheram-Borus MJ, Flannery D, Rice E, Lester P. Families living with HIV. AIDS Care 2005;17(8):978-987.

11. Ramirez-Avila L, Nixon K, Noubary F, et al. Routine HIV testing in adolescents and young adults presenting to an outpatient clinic in Durban, South Africa. PLoS One 2012;7(9):e45507. [http://dx.doi.org/10.1371/journal.pone.0045507]
12. Kellerman S, Essajee S. HIV Testing for children in resource-limited settings: What are we waiting for? PLoS Med 2010;7(7):e1000285. [http://dx.doi.org/.1371journal.pmed.1000285]
13. According to UNAIDS figures from 2012 there are 5.6 million people living with HIV in South Africa; see UNAIDS,World AIDS Day Report, 2012 at http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434_WorldAIDSday_results_en.pdf
14. According to UNAIDS, South Africa has scaled up its treatment services to 1.7 million people – an increase of 75 percent over the past two years. See UNAIDS, World AIDS Day Report, 2012 at http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434_WorldAIDSday_results_en.pdf
15. See —Question and Answer: Cabinet's decision on the Operational plan for comprehensive care and treatment of people living with HIV and AIDS, 19 November 2003", available at http://www.info.gov.za/issues/hiv/aidsqa19nov03.pdf
16. National Strategic Plan on HIV, STIs and TB 2012–2016, South African National AIDS Council, Republic of SouthAfrica, available at http://www.doh.gov.za/docs/stratdocs/2012/NSPfull.pdf
17. Based on the presumption that a functioning domestic generic pharmaceutical industry not only provides broad economic Benefits, but to an extent also secures the supply of pharmaceuticals within the country and the continent.
18. UN General Assembly, International Covenant on Economic, Social and Cultural Rights, 16 December 1966.