

**BRICS- AN EMERGING NATIONS AND ITS RECENT  
PHARMACEUTICAL OUTLOOK (2015)****Dr. R. Suthakaran\***

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Article Received on  
22 Oct 2015,

Revised on 12 Nov 2015,  
Accepted on 02 Dec 2015

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**ABSTRACT**

BRICS is the acronym for an association of five major emerging national economies: Brazil, Russia, India, China and South Africa. The grouping was originally known as "BRIC" before the inclusion of South Africa in 2010. The BRICS members are all developing or newly industrialised countries, but they are distinguished by their large, fast-growing economies and significant influence on regional and global affairs. All the BRICS countries holding the potential market and expect to grow in steady rate, the details are, Brazil's pharmaceutical market = \$26.4 billion in 2013, Growth rate = 6.4 percent annually in 2014-2018. Russia's pharmaceutical market = \$17 billion in 2013, Growth rate = 10 percent annually in 2014-2018. India's pharmaceutical market = \$18.3 billion in 2013, Growth rate = 10.3 percent (in local currency terms) annually in 2014-2018. China's

pharmaceutical market = \$83.3 billion in 2013 Growth rate = 6.4 percent annually in 2014-2018. South Africa's pharmaceutical market = \$3.9 billion in 2013, Growth rate = 6 percent annually in 2014-2018.

**KEYWORDS:** BRICS is the acronym for an association of five major emerging national economies: Brazil, Russia, India, China and South Africa.

**INTRODUCTION****BRICS countries**

BRICS is the acronym for an association of five major emerging national economies: Brazil, Russia, India, China and South Africa. The grouping was originally known as "BRIC" before the inclusion of South Africa in 2010. The BRICS members are all developing or newly

industrialized countries, but they are distinguished by their large, fast-growing economies and significant influence on regional and global affairs; all five are G-20 members. Since 2009, the BRICS nations have met annually at formal summits. Russia currently holds the chair of the BRICS group, and hosted the group's seventh summit in July 2015.

As of 2015, the five BRICS countries represent over 3 billion people, or 42% of the world population; as all five members are in the top 25 of the world by population, and four are in the top 10. The five nations have a combined nominal GDP of US\$16.039 trillion, equivalent to approximately 20% of the gross world product, and an estimated US\$4 trillion in combined foreign reserves. The BRICS have received both praise and criticism from numerous commentators. Bilateral relations among BRICS nations have mainly been conducted on the basis of non-interference, equality and mutual benefit (win-win). It is estimated that the combined GDP (PPP) of BRICS would reach US\$50 trillion mark by 2020.

### **History**

The term "BRIC" was coined in 2001 by then-chairman of Goldman Sachs Asset Management, Jim O'Neill, in his publication *Building Better Global Economic BRICs*. The foreign ministers of the initial four BRIC states (Brazil, Russia, India and China) met in New York City in September 2006 at the margins of the General Debate of the UN General Assembly, beginning a series of high-level meetings. A full-scale diplomatic meeting was held in Yekaterinburg, Russia, on 16 June 2009.

### **First BRIC summit**

The BRIC grouping's first formal summit, also held in Yekaterinburg, commenced on 16 June 2009, with Luiz Inácio Lula da Silva, Dmitry Medvedev, Manmohan Singh and Hu Jintao, the respective leaders of Brazil, Russia, India and China, all attending. The summit's focus was on means of improving the global economic situation and reforming financial institutions and discussed how the four countries could better co-operate in the future. There was further discussion of ways that developing countries, such as the BRIC members, could become more involved in global affairs.

In the aftermath of the Yekaterinburg summit, the BRIC nations announced the need for a new global reserve currency, which would have to be "diversified, stable and predictable". Although the statement that was released did not directly criticise the perceived

"dominance" of the US dollar – something that Russia had criticised in the past – it did spark a fall in the value of the dollar against other major currencies.

### **Entry of South Africa**

In 2010, South Africa began efforts to join the BRIC grouping, and the process for its formal admission began in August of that year. South Africa officially became a member nation on 24 December 2010, after being formally invited by the BRIC countries to join the group. The group was renamed BRICS – with the "S" standing for South Africa – to reflect the group's expanded membership. In April 2011, the President of South Africa, Jacob Zuma, attended the 2011 BRICS summit in Sanya, China, as a full member.

### **Developments**

The BRICS Forum, an independent international organisation encouraging commercial, political and cultural cooperation between the BRICS nations, was formed in 2011. In June 2012, the BRICS nations pledged \$75 billion to boost the lending power of the International Monetary Fund (IMF). However, this loan was conditional on IMF voting reforms. In late March 2013, during the fifth BRICS summit in Durban, South Africa, the member countries agreed to create a global financial institution which they intended to rival the western-dominated IMF and World Bank. After the summit, the BRICS stated that they planned to finalise the arrangements for this New Development Bank by 2014. However, disputes relating to burden sharing and location slowed down the agreements.

At the BRICS leaders meeting in St Petersburg in September 2013, China committed \$41 billion towards the pool; Brazil, India and Russia \$18 billion each; and South Africa \$5 billion. China, holder of the world's largest foreign exchange reserves and who is to contribute the bulk of the currency pool, wants a greater managing role, said one BRICS official. China also wants to be the location of the reserve. "Brazil and India want the initial capital to be shared equally. We know that China wants more," said a Brazilian official. "However, we are still negotiating, there are no tensions arising yet." On 11 October 2013, Russia's Finance Minister Anton Siluanov said that a decision on creating a \$100 billion fund designated to steady currency markets would be taken in early 2014. The Brazilian finance minister, Guido Mantega stated that the fund would be created by March 2014. However, by April 2014, the currency reserve pool and development bank had yet to be set up and the date was rescheduled to 2015. One driver for the BRICS development bank is that the existing institutions primarily benefit extra-BRICS corporations and the political significance is

notable because it allows BRICS member states "to promote their interests abroad and can highlight the strengthening positions of countries whose opinion is frequently ignored by their developed American and European colleagues."

In March 2014, at a meeting on the margins of the Nuclear Security Summit in The Hague, the BRICS Foreign Ministers issued a communique that "noted with concern, the recent media statement on the forthcoming G20 Summit to be held in Brisbane in November 2014. The custodianship of the G20 belongs to all Member States equally and no one Member State can unilaterally determine its nature and character." In light of the tensions surrounding the 2014 Crimean crisis, the Ministers remarked that "The escalation of hostile language, sanctions and counter-sanctions and force does not contribute to a sustainable and peaceful solution, according to international law, including the principles and purposes of the United Nations Charter."<sup>1</sup> This was in response to the statement of Australian Foreign Minister Julie Bishop, who had said earlier that Putin might be barred from attending the G20 Summit in Brisbane.

In July 2014, the Governor of the Russian Central Bank, Elvira Nabiullina, claimed that the "BRICS partners the establishment of a system of multilateral swaps that will allow to transfer resources to one or another country, if needed" in an article which concluded that "If the current trend continues, soon the dollar will be abandoned by most of the significant global economies and it will be kicked out of the global trade finance."

Over the weekend of 13 July 2014 when the final game of the World Cup was held, and in advance of the BRICS Fortaleza summit, Putin met his homologue Dilma Rouseff to discuss the BRICS development bank, and sign some other bilateral accords on air defence, gas and education. Rouseff said that the BRICS countries "are among the largest in the world and cannot content themselves in the middle of the 21<sup>st</sup> century with any kind of dependency." The Fortaleza summit was followed by a BRICS meeting with the UNASUR president's in Brasilia, where the development bank and the monetary fund were introduced. The development bank will have capital of US\$50 billion with each country contributing US\$10 billion, while the monetary fund will have US\$100 billion at its disposal. On 15 July, the first day of the BRICS 6th summit in Fortaleza, Brazil, the group of emerging economies signed the long-anticipated document to create the US\$100 billion New Development Bank (formerly known as the "BRICS Development Bank") and a reserve currency pool worth over another US\$100 billion. Documents on cooperation between

BRICS export credit agencies and an agreement of cooperation on innovation were also inked.

At the end of October 2014, Brazil trimmed down its US government holdings to US\$261.7 billion; India, US\$77.5 billion; China, US\$1.25 trillion; South Africa, US\$10.3 billion.

In March 2015, Morgan Stanley stated that India and Indonesia had escaped from the 'fragile five' (the five major emerging markets with the most fragile currencies) by instituting economic reforms. Previously, in August 2013, Morgan Stanley rated India and Indonesia, together with Brazil, Turkey and South Africa, as the 'fragile five' due to their vulnerable currencies. But since then, India and Indonesia have reformed their economies, completing 85% and 65% of the necessary adjustments respectively, while Brazil had only achieved 15%, Turkey only 10%, and South Africa even less.

After the 2015 summit, the respective communications ministers, under a Russian proposal, had a first summit for their ministries in Moscow in October where the host minister, Nikolai Nikiforov, proposed an initiative to further tighten their information technology sectors and challenge the monopoly of the United States in the sector.

Since 2012, the BRICS group of countries have been planning an optical fibre submarine communications cable system to carry telecommunications between the BRICS countries, known as the BRICS Cable. Part of the motivation for the project was the spying of the National Security Agency on all telecommunications that flowed across the US.

### **Summit**

The grouping has held annual summits since 2009, with member countries taking turns to host. Prior to South Africa's admission, two BRIC summits were held, in 2009 and 2010. The first five-member BRICS summit was held in 2011. The most recent BRICS summit took place in Ufa, Russia, from 8 to 9 July 2015.

### **MEMBER COUNTRIES**

Economic data is sourced from the International Monetary Fund, current as of April 2015, and is given in US dollars.

## POTENTIAL MEMBERS

Argentina, Indonesia and Turkey have expressed strong interest in full membership of the BRICS, while Egypt, Iran, Nigeria, Sudan, Syria and most recently Bangladesh and Greece have also expressed interest in joining BRICS.

**Table 1: BRICS summit.**

Date(s)	Host country	Host leader	Location	Notes
16 June 2009	 Russia	Dmitry Medvedev	Yekaterinburg (Sevastianov's House)	
15 April 2010	 Brazil	Luiz Inácio Lula da Silva	Brasília	Guests: Jacob Zuma (President of South Africa) and Riyad al-Maliki (Foreign Minister of the Palestinian National Authority)
14 April 2011	 China	Hu Jintao	Sanya (Sheraton Sanya Resort)	First summit to include South Africa alongside the original BRIC countries.
29 March 2012	 India	Manmohan Singh	New Delhi (Taj Mahal Hotel)	
26–27 March 2013	 South Africa	Jacob Zuma	Durban (Durban ICC)	
14–16 July 2014	 Brazil	Dilma Rousseff	Fortaleza (Centro de Eventos do Ceará) <sup>[44]</sup> Brasília	BRICS New Development Bank and reserve currency pool agreements signed. Guest: Leaders of Union of South American Nations (UNASUR) <sup>[45][46]</sup>
8–9 July 2015	 Russia	Vladimir Putin	Ufa <sup>[47]</sup>	Joint summit with SCO-EEU
2016	 India	Narendra Modi	New Delhi	

## RECEPTION

In 2012, Hu Jintao, who at the time was President of China, described the BRICS countries as defenders and promoters of developing countries and a force for world peace. Western analysts have highlighted potential divisions and weaknesses in the grouping, including significant economic instabilities is agreements between the members over UN Security Council reform and India and China's disputes over territorial issues.

In June 2015, Jim Rogers said that he does not see any current alternative to US dollar and that “The world needs something to compete with the US-dominated institutions, some of

them - the World Bank and the IMF. So, if BRICS offer any new structures that can compete with these long-standing institutions, it will be very good”.

## **PHARMACEUTICAL EXPANSION AND GROWTH RATE OF BRICS COUNTRIES**

### **1) Brazil**

Sales of pharmaceuticals in Brazil have expanded strongly in recent years, with a compound annual growth rate (CAGR) of 7.7% in local currency terms between 2008 and 2013. The high growth rate highlights the sector's strong potential and resilience to fluctuations in economic activity. In 2013, pharmaceutical sales in Brazil reached a value of BRL57.0bn (US\$26.4bn), making Brazil the eighth-largest market globally.

Brazil will remain high on the list of emerging markets being targeted by multinational patented-drug companies and international generic manufacturers, although both segments will face tough challenges; among them, complex fiscal and regulatory frameworks, restrictive pricing policies, and a strong local industry.

The Brazilian government is heavily involved in regulating drug development, pricing and distribution (wholesale and retail). Price controls are the responsibility of the Agência Nacional de Vigilância Sanitária (ANVISA), which operates mainly through the Câmara de Regulação do Mercado de Medicamentos (CMED). The potential approval of a new regulation allowing interchangeability of similars at the point of sale may mean stiffer competition for market share and the possible introduction of compulsory price discounts for similars in relation to the originator product. In positive news, ANVISA aims to speed up drug registration with a new electronic system under which drugs can be approved within six months (rather than up to two years).

Demand for medicines will continue to rise in 2015, but Brazilian patients and payors alike remain very price-sensitive. Significant increases in government spending on free and heavily-subsidized drugs — through initiatives such as the Programa Farmácia Popular (PFP) — will decelerate post-election year (2014) as the government shifts its focus to cost-containment. Spending cuts, along with continued patent expiries, may limit sales of original branded products and enable generics and branded similars to continue dominating the market in volume terms. According to Associação Brasileira das Indústrias de Medicamentos Genéricos (Pró Genéricos), a Brazilian industry group for generics manufacturers, more than 20 best-selling pharmaceuticals lost patent protection in Brazil in 2012-13; this boosted the



generics market by over \$400 million. By 2018, the volume market share for generics is expected to exceed 33 percent.

Brazil has a strong local generics industry (the largest in Latin America), supported by government policies aimed at extending the availability of medicines to low-income consumers. In fact, domestic manufacturers have essentially cornered Brazil's retail generics market. While Medley was acquired by Sanofi in 2009, it continues to operate as a largely autonomous business and Sandoz — currently ranked sixth among generic companies — is the most prominent foreign player in the segment.

Leading players in Brazil's life sciences sector have built comprehensive portfolios of both branded and unbranded products, and use scale as a means to repel advances from manufacturers offering deep discounts in a bid to grow market share. The result is a market that is increasingly concentrated. The combined share held by the five leading players is in excess of 48 percent, while aggregate sales of the top ten companies are equivalent to almost two-thirds of total retail generic market value.

Brazil's pharmaceutical market = \$26.4 billion in 2013.

Growth rate = 6.4 percent annually in 2014-2018.

## 2) Russia

Russia has the largest pharmaceutical market in Central and Eastern Europe, although consumption per head remains far below that of Western European countries.<sup>1</sup>

Russia's pharma market has undergone major expansion since 2011, stoked by increasing consumer affluence, government health programs and strong investment by foreign firms. 2014 saw a slowdown in the Russian market's growth rate; even so, when compared to European countries, it is developing quite dynamically.<sup>2</sup> While the unstable political situation may put long-term growth forecasts into question, the Russian market still provides significant opportunities for drug makers.<sup>3</sup> Revenues are forecast to continue grow at rates similar to other emerging markets and could potentially total around \$25.7 billion by 2018.<sup>4</sup> The government's plans to implement universal pharmaceutical coverage will likely be a major contribute to sales growth.

Russia's pharmaceutical market is dominated by generic products and foreign imports. The country has around 400 pharmaceutical companies but most local manufacturers are small



and uneconomical, relying on outdated equipment to produce mainly older drugs. Under a program titled “Development of the Pharmaceutical and Medical Industry for 2013-2020,” the government aims to raise the share of domestically produced pharmaceuticals in the market from around 20 percent to 50 percent by 2020, while the share of domestically produced medical equipment is intended to rise to 40 percent. State procurement is one of the main instruments of government support for domestic pharmaceutical manufacturers and the new Law on State Procurement is expected to provide a more accurate and transparent approach to its drug purchases, although the law currently serves only as a basis for the development of bylaws. The list of medicines that may be purchased by brand names has yet to be drawn up and the criteria used for including or excluding medicines from this list are open to interpretation. Government restrictions on the access of imported drugs for state purchases are also being discussed in cases where there are at least two drugs locally produced with the same INN. Currently the government provides a 15% benefit in state purchasing of locally produced drugs (those produced in Russia, Belarus and Kazakhstan). Even as the government boosts its efforts to support local drug production, foreign companies continue to invest in Russia’s life sciences industry by entering into alliances, making acquisitions, expanding sales efforts and launching new drugs. Global companies are also building manufacturing plants to leverage favorable domestic production policies—and they do not appear to be changing their strategies based on the current political climate; indeed, having positively assessed the potential of the market, they are working to increase their presence in the country.

In addition to an unstable political situation, life sciences companies face other challenges when operating in Russia. Government drug price controls are expected to remain strong and could put pressure on margins. A sharp rise in pharmaceutical prices in 2009 led the Russian authorities to introduce price regulations on medicines on the essential drugs list, which account for around one-third of the market. Also, official monitoring of prices through the Federal Anti-Monopoly Service has been stepped up.

Weak patent protection poses threats to branded drug makers. Russia’s IP rights remain weak and improvements will be slow, despite the country’s accession to the World Trade Organization (WTO) on the August 2012. Product quality also remains a concern. More than 10 percent of products on the market, including prescription medicines, over-the-counter drugs, and vitamins, are believed to be counterfeit. As of January 1, 2014 Russian medicine

manufacturers must comply with GMP international quality standards. The Ministry of Industry and Trade must monitor compliance with these standards.

Russia's pharmaceutical market = \$17 billion in 2013.

Growth rate = 10 percent annually in 2014-2018.

### 3) India

India's pharmaceutical sales were an estimated \$18.3 billion in 2013. They are forecast to rise an average of 10.3 percent annually in 2014-18 (in nominal local-currency terms) to reach \$33.8 billion. This growth will be driven by increasing personal incomes and the escalation of chronic diseases.

India's pharmaceutical market is dominated by generic drugs, which account for around 75 percent of the market by volume. Supplied mainly by domestic companies, generics have helped to keep pharmaceutical prices low and the market is expected to continue expanding rapidly. Still, India's growing middle class is increasing demand for more advanced and costly medicines.

Although domestic pharmaceutical companies were established primarily to supply the local market, they have taken advantage of their low labor and research costs to export generic drugs to developed countries, notably the U.S, its largest export market. 4 India is also a major supplier to other emerging markets and has become the biggest supplier to UN health care programs.

Domestic and international pharmaceutical companies operating in India face issues ranging from the new Drug Price Control Order (DPCO), which prescribes a ceiling on the prices of several essential medicines, to drug and clinical trial quality, patent issues and the misclassification of medical devices.

- Drug Price Control Order (DPCO) 2013 — The National Pharmaceutical Pricing Authority (NPPA) announced in July 2014 that it plans to add 50 drugs in the cardiovascular and anti-diabetic segment to the 348 drugs that were brought under price control following the implementation of the new Drug Price Control Order (DPCO) in July 2013.<sup>6</sup> The move could have far-reaching implications for branded pharmaceutical manufacturers with patented products. Drug quality — India is the biggest foreign supplier of medicines to the U.S. and has about 200 U.S. Food and Drug Administration (FDA)-approved drug manufacturing

facilities. India produces nearly 40 per cent of generic drugs and over-the-counter products and accounts for 10 per cent of finished dosages in the U.S.<sup>7</sup> The FDA has highlighted a growing number of quality issues and taken a series of actions against Indian pharmaceutical companies (e.g., for documentation and data maintenance issues), restricting India's shipments to the U.S. Based on these actions and quality concerns raised by other importers of Indian pharmaceutical products, the Indian government is working with the FDA to resolve its issues, as well as with the World Health Organization (WHO) and the Partnership for Safe Medicine (PSM) to put in place initiatives to combat counterfeit drug manufacturing. These include equipping state drug testing laboratories, enforcing serialization, non-clonable packaging and 2-D barcoding, and investing in more drug manufacturer inspectors.

- Clinical trial quality — India's clinical trials industry has seen substantial growth in the last decade due to its large pool of patients with diverse treatment needs and access to a large, scientifically skilled, workforce. While the number of clinical trials has increased, the country's capacity to regulate trials has not kept pace, resulting in some unethical practices. The Indian government has enhanced regulatory controls like mandatory trial registration, and is creating committees to oversee trial approval, trial execution and ethical treatment of patients. All of these measures have had a positive impact; however delays in drug approvals following the regulatory controls are prompting multinationals to rethink their strategy of conducting clinical trial activity in India. Even Indian pharmaceutical companies are now conducting some trials outside the country.
- Patent issues — To make health care affordable to all, the Indian government is promoting the use of generics and ensuring that prices of lifesaving drugs are not governed by market forces. As a result, some pharmaceutical multinationals have been entangled in legal battles with the government over patent issues, with several long-running court cases centering on how India's stringent Patents Act defines innovation.
- Misclassification of devices as drugs — Medical devices currently fall under the purview of India's Drugs and Cosmetics Act and foreign direct investment (FDI) in the sector is governed by the same rules as for pharmaceuticals, which is stunting green field medical device projects. The Indian government is actively considering a proposal to have a separate policy for allowing 100 per cent FDI in the manufacture of medical devices, which could help to boost investment and generate interest in the med tech sector.

The Indian pharma sector is at the threshold of exponential growth. However, to be a true player on the world stage, the sector needs to continuously invest in development of global R&D capabilities and its well-established Contract Research and Manufacturing Services (CRAMS) segment. Strong international collaborations and partnership will support India's efforts to deliver more value-added products to the global market.

India's pharmaceutical market = \$18.3 billion in 2013.

Growth rate = 10.3 percent (in local currency terms) annually in 2014-2018.

#### **4) China**

The past 24 months have seen a rapid acceleration in the development of the life sciences and health care market in China. This trend will continue as government support and changing lifestyles combine to increase health care supply and demand. However, with this acceleration comes rising uncertainty about where the market is headed and how it will impact the companies that operate within it, especially as the government experiments with ways to expand health care accessibility, improve quality and control costs.

Pricing pressures will continue to be a major challenge for life sciences companies, although China is backtracking on its policy of mandating maximum retail prices on certain drugs. The policy had inadvertently resulted in drug shortages and patient safety risks because some manufacturers closed production on low-cost drugs while others started to use poorer-quality ingredients to reduce production costs. Government involvement in drug pricing should remain strong in 2014-18, partly through specifying which drugs will be reimbursed under the Essential Drugs List (EDL) and other public health insurance plans. An era of lax regulatory enforcement appears to be over as China's anticorruption campaign targets domestic and foreign life sciences companies. According to Reuters, as of May 2014 more than half of all drug makers operating in China were being investigated in one or more areas. The opportunities for life sciences companies to drive growth in China are less clear in 2015 than in the previous decade—the operating environment is difficult and the risks are considerably higher. Rapid economic growth and expansion has slowed in China and this, combined with the changing health care system, is squeezing margins and forcing life sciences companies — both domestic and multinational — to rethink the way they do business in the country, particularly if they want to continue on a trajectory of rapid growth and expansion. Looking at specific opportunity areas, technology and business innovations such as mobile healthcare (mHealth), eHealth care and new insurance models are driving

horizontal and vertical consolidation. Life sciences manufacturers and distributors are acquiring health care service providers and talking with insurance companies about joint ventures. Additionally, the government released a bio-industries development plan in 2013 that aims to help the segment double its value-add between 2010 and 2015. This strong state support could bolster biotech companies' efforts to grow their presence in China and provides the impetus for large pharmaceutical companies to buy into biotech as their R&D functions struggle to fill the product pipeline.

China's pharmaceutical market = \$83.3 billion in 2013.

Growth rate = 6.4 percent annually in 2014-2018.

### **5) South africa**

South Africa's pharmaceutical market, the largest in Sub-Saharan Africa, is fairly well-developed and totaled an estimated \$3.9 billion in 2013. Revenue growth has been constrained in recent years by government price regulations, slowing economic growth and the subsequent weakened purchasing power of most of the population. Although these trends will continue in 2014-2018, the market is anticipated to grow by an average of six percent a year, to an estimated \$5.1 billion.

South Africa has a two-tier pharmaceutical market. The public sector tier is characterized by high demand and low prices caused by low levels of funding. The private sector tier has drug prices similar to those in the developed world. The government sets a single exit price (at ex-factory level) for all prescription medicines, regardless of the channel through which they are purchased. Recently, the annual increases on the single exit price have not been in line with the recommended/published equation to calculate this increase. This has had a negative impact on the sector, which is still heavily reliant on imports – and as such has been negatively affected by the devaluation of the ZAR against the U.S. dollar and Euro.

The government's national health plans are expected to boost demand for lower cost drugs—especially generics—in coming years, as is its commitment to provide greater access to anti-retroviral (ARV) medication within the public health system to combat the HIV/AIDS pandemic. Generics currently account for around 60 percent of the overall market in terms of volume, but because of their low cost, around one-third in terms of value. The government procures mass volumes of generic products via tender. However, the private market for generic drugs is growing; the higher prices paid by the private sector help to subsidize the

low-cost generics made available to the public sector. Currently, innovative pharmaceutical products are not well represented on South Africa's essential drug list, which includes products that are available through the public healthcare system. The opportunity for such products to enter the market exists, as does the opportunity to introduce more innovative pricing models, such as a value-based pricing in which reimbursement is based on a drug's clinical effectiveness.

A significant number of international life sciences manufacturers have a presence in South Africa through direct manufacturing facilities, distribution operations, or licensing agreements. To grow the relatively small scale of local pharmaceutical manufacturing, the government is initiating a number of industrialization policies and programs. Among these are the ambitious Ketlaphela project, which intends to manufacture active pharmaceutical ingredients in South Africa by 2017 and is currently seeking international technology and investment partners. The manufacture of APIs in South Africa via Ketlaphela could potentially add another competitor to the market and increase South Africa's ability to supply increasing domestic and global supply.

The South African medical environment is the most regulated on the African continent. There is pending discussion on further regulating the sector, which some argue will stifle competition and increase prices, while others justify additional regulation as necessary to limit price inflation. Among recent initiatives, the government has drafted new IP regulations in recognition that South Africa lacks a unified, well-coordinated IP policy. The government is also implementing legislation to speed up the drug registration process, make South Africa more attractive as a destination for clinical trials and increase the overall competitiveness of the country's life sciences market as a whole. Currently, the Medicines Control Council (MCC) is South Africa's primary regulatory agency for the manufacture, distribution and marketing of medicines in the country. One of the key challenges it faces is long delays in the regulatory approval process. (MCC employees are qualified professionals who work on a part-time basis, sometimes resulting in significant delays when it comes to approval of medicines.) To address this and other regulatory issues, MCC is set to be replaced by the South African Health Products Regulatory Agency (SAHPRA), which will be tasked with regulatory responsibility across the life sciences sector—pharmaceuticals, biologics, medical devices and in-vitro diagnostics, complementary medicinal products, foods and cosmetics. It is, however, not exactly clear when the transition to SAHPRA will be completed.

South Africa has a well-developed scientific base in terms of existing infrastructure and human capital. Leveraging both of these factors, coupled with the appropriate strategic focus, could potentially unlock significant value on a fast-growing continent. Local companies should seek to forge partnerships with international partners to secure their investment and transfer of knowledge and technical expertise. This applies all across the life sciences value chain.

South Africa's pharmaceutical market = \$3.9 billion in 2013.

Growth rate = 6 percent annually in 2014-2018.

## CONCLUSION

The 7<sup>th</sup> BRICS summit was the seventh annual diplomatic summit of the head of states or government of the BRICS member states. It was held in the Russian city of Ufa in Bashkortostan on 8–9 July 2015. The summit coincided with the entry into force of constituting agreements of the New Development Bank and the BRICS Contingent Reserve Arrangement and during the summit inaugural meetings of the NDB were held and it was announced it would be lending in local currency; and open up membership to non-BRICS countries in the coming months. The expected growth rate for the BRICS countries in pharmaceutical sector is 6.4%, 10%, 10.5%, 10.5%, 6.4% and 6 respectively for the period of 2014-2018. In this India has had highest growth rate of 10.5% among other BRICS countries.

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