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Foreign Direct Investment in Africa

Steven Adjei, Kwaku Obeng-Appiah and Les Funtleyder outline the healthcare sector in Africa and look at the factors affecting foreign direct investment.

Africa's economic output has almost tripled in the last ten years; more wealth has been created in this period than at any other time in its history...

Marina Zlochin/Thinkstock Images

Even though Africa boasts a fifth of the world's population, it only accounts for 3% of the world's Foreign direct investment (FDI). Corrupt governments, the legacies of colonization, coup d'états, civil wars, bad governance and unfortunate natural disasters have all conspired to hinder Africa's growth, whilst the rest of the world marched on.

But in the last decade, things suddenly began to change. Improved governance, better market-friendly policies, the decline of civil wars, as well as the establishment of

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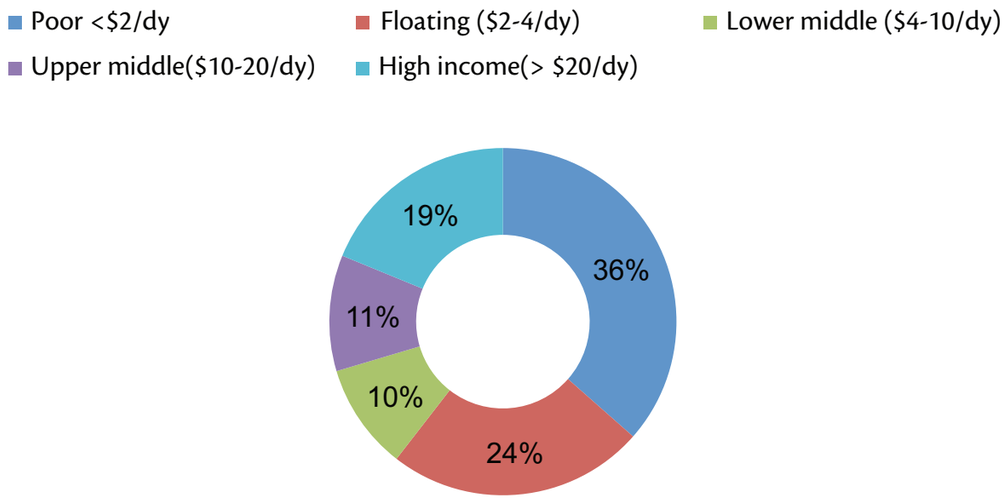
Figure 1: Distribution of the African population by income (including remittances)



democracy began to yield accelerating economic stability and growth.

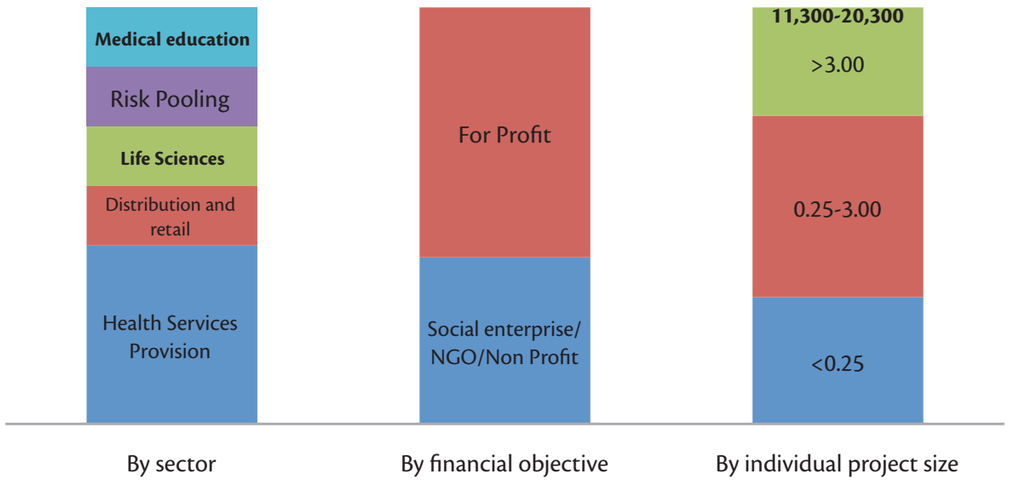
In telecommunications, Africa has more people connected to a mobile network than the whole of Europe, and economic growth, though not quite the 7% needed to achieve the Millennium Development Goals (MDGs) set by the World Health Organization in 2000, was relatively close at 5–6% in the last decade, according to a report by the Commission for Africa in 2010.

According to the World Bank, 60 million Africans earn over $3000 per year, set to reach 100 million by 2015. The consumption of Africa's households has grown by $275 billion in the last decade, similar to Brazil, and higher than India (see Figure 1).

The February 2013 edition of the African Business newsmagazine stated that if current growth continues, by 2050 roughly 300 million Nigerians will enjoy an average income of $10,000 with a GDP of $3 trillion, similar to Germany today.

Africa's economic output has almost tripled in the last ten

Figure 2: Breakdown of private health investment opportunities in sub-Saharan Africa, 2007-2016
%, $ million (11,300-20,300)



Source: The Fastest Billion (2012) Mckinsey reports, Ministries of Health Files

years; more wealth has been created in Africa in the last decade than any other time in its history, writes Evelyn Mhango, an economist in the 'Fastest Billion'

The reasons for this explosive growth are manifold:

1. Improved government policies have increased the scope for the private sector to grow, and have created the low-debt, low-inflation, much improved macro-conditions that have enabled this growth.

2. According to Ernst & Young's African Attractiveness Survey, the strengthening of regulatory and legal systems, privatization of public enterprises and the opening up of economies to international trade have led to the quintupling of exports, record inflows of FDI and a doubling of per Capital GDP.

3. Increased democracy and the sharp decline of civil wars.

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Table 1: FTSE sector performances, the six worst performers in 2012.

Sector	Performance change in 2012(%)
Healthcare	-6.1
Pharma and biotechnology	-6.9
Oil and gas	-11.8
Food and drug retailers	-12.0
Mobile telecoms	-12.6
Industrial metals and mining	-30.1

Adapted Sept 2013 from 'Your guide to the FTSE 350' from the Investors Chronicle News magazine app.

Table 2: The Potential of Africa's elite, middle class, and poor.

Segment	% Of Market	Estimated African Population
Africa One (elite class)	5% - 15%	50-150 million
Africa Two (middle class)	35%- 50%	350-500 million
Africa Three (poor)	50%-60%	500-600 million

Source Mahajan (2009)

4. David Mataen's book, Africa, the Ultimate Frontier Market, lists eight megatrends that have driven Africa's current and future economic realities: population growth and demographic shifts; cultural revolutions; rapid urbanization; commercialisation of essential services such as healthcare,; deregulation and liberalization; growth of credit, capital market development; and consolidation and evolution of intra-African markets.

5. The recent debt relief through the IMF/World Bank Highly Indebted Poor Countries Initiative (HIPC) have enabled African countries to divert much needed funds earmarked for debt repayments into health, education and infrastructure.

According to the TIME magazine (December 3, 2012), business increasingly dominates foreign interest in Africa. Investment first outpaced aid in 2006, and now doubles it. This growth was, contrary to popular belief, spread across various sectors.

Healthcare problems

Healthcare outcomes in Sub-Saharan Africa remain the worst in the world. Even though its population is around 11% of the world's total, it bears a quarter of the global disease burden; less than 1% of the global health expenditure is spent here, and it has just 3% of the worlds health professionals.

Infectious and parasitic diseases form the bulk (42.4%) of the disease burden in Africa, but this is rapidly being compounded by the sharp rise of NCDs, particularly diabetes, chronic respiratory diseases, cancers and cardiovascular diseases.

A major problem is the sorry state of the majority of Africa's public health systems. Billions of aid spent on improving Africa's health systems has yielded poor results. Health systems are grossly understaffed, have crumbling and decaying infrastructure and are short on medical supplies. In addition, being built, equipped and trained to handle mainly parasitic and infectious diseases, Africa's health systems are ill prepared for this extra epidemic of NCDs.

Dr Mark Swai, former Hospital director of the Kilimanjaro Christian Medical

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Healthcare outcomes in Sub-Saharan Africa remain the worst in the world.

Centre, talking to Pharm Exec in 2003, said "the beds of our new HIV/AIDS were filled with HIV patients whose diseases were not under control. Since the introduction of affordable anti-retroviral drugs that decreased the disease burden, those beds are now filled with diabetes' patients".

Due to these chronic problems, most Africans flock to the private sector, not through choice but because in most cases, it remains the only option.

But the private sector is also bedevilled with its own serious issues; poor managerial competency and regulatory oversight mean that prices for essential drugs cost hundreds more than the trade costs, services are poor, staff are badly trained with questionable ethics, and the sector is plagued with excessive fragmentation, and medicines are either poor quality, expired or counterfeited. This is especially the case in the pharmaceutical sector.

Opportunities for growth

The problems listed above, though huge issues, point to a low-hanging-fruit market that is ripe for disruption and presents huge opportunities.

The economic growth detailed above signal that the healthcare market is sure to grow; the International Finance Corporation estimates that the pharmaceutical market will expand to $35 billion by 2016, and $40 billion in 2020, surpassing the UK. Spending on healthcare has increased by a Compound Annual Growth Rate of 9.6% since 2000. This demand for better healthcare throws up several different bankable opportunities (Figure 2).

The IFC estimates that $25-30 billion in new

The issue of 'brain drain' has been one of the most problematic areas in healthcare in Africa.

investments will be needed to meet the demand for medical care between now and 2016, of which up to 40% is expected to come from the private sector; Robertson, writing in the 'fastest billion' expects a real increase of 72% in health expenditure through 2020.

Investing in healthcare also makes financial sense; in stark contrast to the 9.6% CAGR in the African healthcare sector from 2000, the healthcare, drug retailing and pharmaceutical market growth were all in the six worst performing sectors in the FTSE 350 in 2012 (Table 1).

However, private investment into the healthcare sector in Africa has been strikingly low.

- Ernst & Young's (E&Y) African Attractiveness survey revealed that, of the $587 billion of FDI that Africa attracted in 2011, only 1% went to healthcare projects.

- In one of McKinsey's often-quoted studies on Africa, 'Lions of the move' (2010), healthcare is not in the top 12 sectors for attracting investment.

- According to an E&Y study of private equity in Africa, healthcare accounted for only 5% of exits by sector; even though 70% of FDI was in the services sector, healthcare did not even make the top ten.

- In the three best selling books 'Africa Rising' (2008), 'Africa, the ultimate frontier market' (2012) and 'The Fastest Billion (2012), healthcare does not feature in the listings of the sectors most attractive for investment.

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The five determinants of FDI in healthcare in Sub-Saharan Africa

1. The question of affordability.
According to Vijay Mahajan's 'Africa Rising' (2009), the low-hanging fruit — or the elite (Africa One) — is the target of most private for-profit healthcare investments in Sub-Saharan Africa. These models tend to be fragmented with minimal capitalization and are non-scalable, putting them beyond the reach of the middle class (Africa Two),where the real per capita growth is taking place (Table 2).

Lack of proper developed affordable health insurance schemes also compounds the affordability problem, further worsening the ability of Africans to pay for healthcare treatment.

2. The question of tangibility.
The issue of tangibility as a determinant of FDI into healthcare can be divided into three areas:

a. Lack of data: African Healthcare data is at best fragmented, unreliable and vertical, hence increasing risk and therefore unappealing to investors.

b. Healthcare infrastructure and uncertainty of demand: Healthcare investing involves huge sunk costs; the issue of affordability leads to uncertainty of demand, which in turn discourages high-level investment.

c. Lack of tangibility. Healthcare is an intangible asset, which cannot be measured, unlike a mobile phone or FMCGs.

3. The question of intellectual capital.
The issue of 'brain drain' has been one of the most problematic areas in healthcare in Africa. As a result, partly at least, Sub-Saharan Africa has the lowest availability of qualified medical resources in the world.

4. The question of uncertainty and risk.
Dr Ernest Darkoh, founding partner of Broadreach Healthcare, an African-based healthcare consultancy, bemoans the "perception of risk putting many investors off making major investments in healthcare in Africa despite the good opportunities available".

Aside from the general perceived and actual risks in investing in Africa, political risks and instability also tend to affect the healthcare sector more disproportionately compared to other sectors due to healthcare provision being perceived as a right, not an option by most African countries.

Linked to political risks are regulatory risks — government resistance to reforms, an inadequate and discriminatory regulatory

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structure, continued threats of strike action by healthcare professionals, and the reluctance to privatize public systems. The availability of cheap money in the form of aid is also a massive put off for potential for-profit investors.

5. The question of competitive strategy. Governments and host countries may need to promote and market healthcare more vigorously to attract increased FDI into the sector. However any marketing strategy must be backed up by advantageous location-specific advantages on the ground (see under 'uncertainty and risk' above). The most critical factors facilitating healthcare FDI in Africa are market openness, good quality government institutions, regulation harmonization and a good regulatory environment.

Many first time investors into healthcare in Africa have had bad experiences, and thus have now become very tentative. To enter an African market, it is vital to choose the right country ,the right risk profile, and the right model. This neccessitates a lot of research work and market analysis. Alliances with domestic African healthcare businesses may increase penetration efficiency and decrease risk.

Linking the five determinants: systems thinking and scalability

The five determinants can be represented as interdependent points on a star with strategy as the head. These determinants should be in constant alignment with each other to attract optimal FDI.

For instance a lack of human capital in a particular FDI target instantly increases affordability (more expensive due to increased demand) increases risk (increased risk of strikes, political instability, etc) and decreases tangibility. Hence the determinants are to be thought of as related to each other much like an ecosystem, rather than focusing on one detail at the expense of the other, the so-called 'systems thinking'.

Related to this idea is the issue of scalability. Successful large scale investments into healthcare in Africa should be affordable to the elite and the middle classes, should have an easily reproducible, standardized scalable model, should take into consideration the lack of highly skilled personnel and should tackle NCDs as at least part of its healthcare strategy. Standardization helps to ensure quality and uniformity and hence reduce clinical and operating risk.

Examples of successful models using the above principles are the franchising model used by the Healthstore Foundation in Kenya; the organic reproducible model used by Vine Pharmaceuticals in Uganda, or World Health partners creating market efficiencies by using telemedicine to connect rural patients and semi-skilled health officials to skilled care professionals.

Standardization helps to ensure quality and uniformity and hence reduce clinical and operating risk.

Healthcare investors who look for these simple principles in addition to their normal due diligence are more likely to see more large scale investments being bankable and profitable, as well as having maximum impact, as Andrew Kuper, head of Leapfrog Investments calls "profits with purpose".

About the authors

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Diabetes in China: Is Pharma Listening?

In China, diabetes patients are hungry for information about their condition, and are taking to social media to discuss it. But, asks Simon Li, is pharma paying attention?

By 2030, China, together with India, will make up nearly half of the worldwide diabetes population. But diabetes awareness is low in China...

Diabetes is a rapidly growing global health issue. More than 380 million people had diabetes in 2013, and the International Diabetes Federation (IDF) estimates this population will rise to 592 million by 2035, and the World Health Organization predicts that diabetes will be the seventh leading cause of death in 2030.

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While diabetes is sometimes thought of a as a "western" disease, the prevalence is highest in China, which has an estimated 98 million patients with diabetes, according to the IDF, and has become known as the "diabetes capital of the world." In fact, by 2030 China, together with India, will make up nearly half of the worldwide diabetes population.

However, awareness of diabetes is low in China, so the rate of diagnosis is much lower

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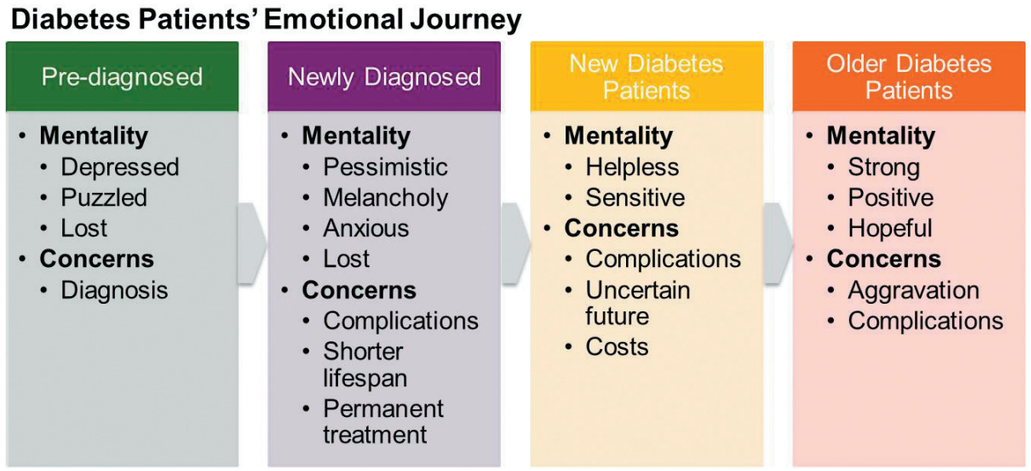
Figure 1



than the actual prevalence of the disease. Even when patients are diagnosed, they may not be properly treated due to a variety of reasons.

According to data from Kantar Health's National Health and Wellness Survey (NHWS), nearly half of Chinese diabetes patients stop taking medication if they feel better rather than complete the treatment as advised by their doctors.

With low awareness of diabetes and a large, diverse population, getting insights into these patients can be a difficult proposition.

A sharing culture

Social media can be a good way to connect and educate patients, especially for diseases that people are not well informed about.

Through a social media listening platform, it has been possible to monitor online conversations between large, robust samples of diabetes patients. (Kantar collected more than 275,000 posts covering six healthcare discussion sites in China, including two specialist diabetes communities, over three months.)

With an online population of over 450 million, it is no surprise that China's patient forums are vibrant.

Tapping into online postings and conversations reveals unique, unforced and summarized insights into these patients' day-to-day behavior patterns and needs.

With an online population of over 450 million, 75% of whom are using social media, it is no surprise that China's patient forums are vibrant.

The Chinese culture of "Shai" (sharing or "showing off" personal details online) means that many patients keep public online diaries, openly detailing their disease challenges. Internet-savvy patients are much more culturally inclined to bare their souls online than they would be in a traditional research setting.

What are diabetes patients in China talking about online?

Diabetes patients in China connect online with not only fellow patients but doctors as well. These patients are hungry for information about their condition and post on a wide variety of topics related to it, which can be broken into three main categories:

- diabetes information: types of diabetes, glycemic index and complications;
- diabetes products: oral antidiabetics, insulin, glucose meters;
- daily life experiences: psychology, diets, exercise, emotional impact.

The majority of patients with diabetes talk about type 1 or type 2 diabetes; 9% are discussing gestational diabetes, with just 3% talking about pre-diabetes.

However, when discussing the features of diabetes, three of four discussions centered around the hallmarks of pre-

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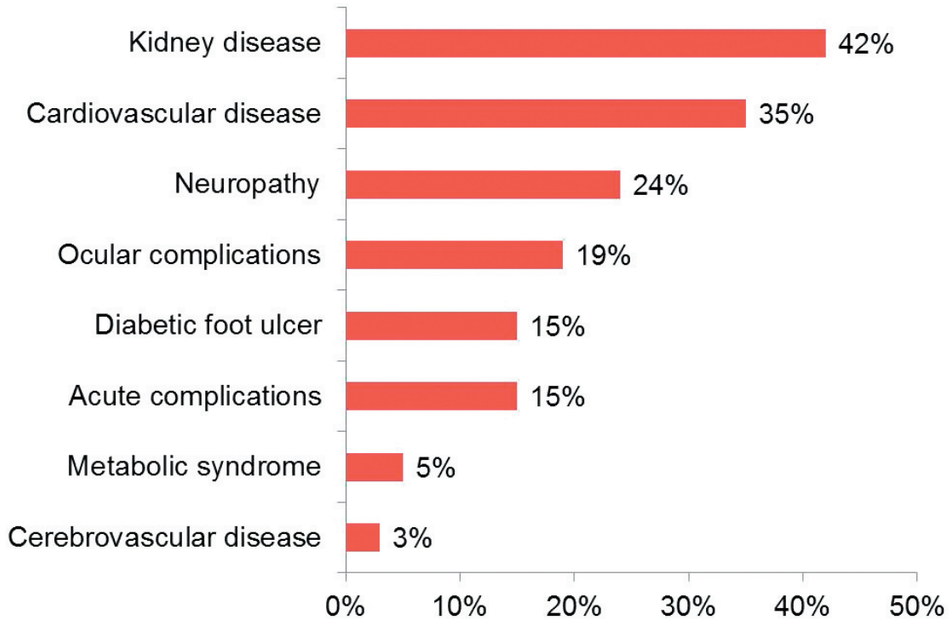
Table 1

Complications That Diabetes Patients Discuss Most Often



diabetes: insulin resistance, impaired fasting glucose and impaired glucose tolerance.

Diabetes control is also a big topic for discussion. HbA1C tests are conducted every three months to monitor how well controlled a diabetic's blood sugar levels are, with less than 7% considered normal among diabetics. Of those patients discussing HbA1C, more than two-thirds have levels of less than 7%, indicating that patients who discuss their condition online are likely to control their condition to stable levels.

Lack of control over blood sugar levels can lead to serious long-term complications, including heart problems, kidney problems, blindness and nerve damage.

Of the online discussions centered on these complications, kidney disease seems to be cause for the most concern, with 42% of discussions addressing kidney diseases such as renal insufficiency, nephritis and kidney failure.

Thirty-five percent are seeking more information about cardiovascular complications, such as hypertension and congestive heart failure, with another 24% are concerned about neuropathy, including numb hands and feet.

Diabetes treatments also feature prominently in these patients' online discussions, with oral anti-diabetics discussed most frequently, followed by insulin and glucose meters.

Among oral anti-diabetics, Glucobay (acarbose, Bayer) has the highest share of voice, followed by NovoNorm (repaglinide, Novo Nordisk)

Insulin is another hot topic of conversation, with many patients discussing the rapid-acting brands such as NovoRapid (insulin aspart, Novo Nordisk) and Humalog (insulin lispro, Lilly).

The brand discussed most often, however, is the long-acting insulin Lantus (insulin glargine, Sanofi-Aventis).

Finally, patients have many discussions around glucose meters—or the medical device that allows them to test their blood glucose.

The brand discussed most often is Sanofi's long-acting insulin Lantus.

From depression to optimism: patients' emotional journey

Discussions among diabetes patients via social media also reveal how a diagnosis affects them psychologically.

When patients are in the pre-diagnosis stage, many are depressed or confused, and their main concern is receiving a diagnosis of being diabetic. "I keep thinking there is a chance my glycemic level will become normal again," one patient said pre-diagnosis. Another admitted, "I am very afraid of being diagnosed as diabetic."

When patients are newly

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diagnosed with diabetes, they are not only depressed but also anxious and pessimistic; they are concerned about the complications they may experience, having a shortened lifespan or having to take their medication for the rest of their life. "I am afraid complications have already occurred and feel depressed. Does anyone know how long a diabetic can live if well-controlled?" one newly diagnosed patient asked. Another said, "I am really depressed and lost. I will have no future!"

Acceptance of a diabetes diagnosis comes several years after the diagnosis, but patients remain sensitive about their condition. Having taken their medication for a while, they are concerned about the economic costs of diabetes and still fear for the future.

With time, patients who have been lived with diabetes for many years become optimistic and strong. Complications remain the main concern for these patients. "The depression period is gone, and the most important thing for now is to prevent disease deterioration," said patient with long-term diabetes. Another advised, "Keep a good attitude and always have confidence."

According to diabetes patients' online conversations, the one thing that most affects patients' attitudes toward their condition is their treatment's efficacy, and they are willing to recommend that treatment to other patients online:

- "At 11 pm I could not fall asleep so I checked my glycemic level — 5.9. Such a good result without an added injection."
- "I have tested many times after meals, and most are below 6. It is a little unbelievable that it's even lower than for healthy people."

However, taking a less efficacious product will make patients feel panicky and helpless and makes them doubt their product. As one patient said, "If I test too often, my fingers will hurt and I'll use too many test strips. If I test less often, I feel anxious and suspicious. If my glycemic level increases I feel bad. If it decreases I worry about the accuracy of the glucose meter."

What will you do now that you know what patients are talking about?

Traditionally, pharmas are focused on marketing their products to physicians. Patients are largely ignored in the treatment decision, especially in China.

However, as patients become increasingly empowered by social media and technology, they will start to have more of a say in deciding whether to get treated, where and how. Online voices of diabetes patients are an invaluable source to develop patient insights and to bring the best treatment to them.

These online conversations promote patient education and raise disease awareness, so that patients can better manage their condition and this, in turn, can improve compliance.

Inuit co-founder Scott Cook once said, "A brand is no longer what we tell the consumers it is — it is what the consumers tell each other it is," which underlines the importance of social conversations in making or breaking brands.

Plugging into current trends and conversations helps pharma companies communicate their brands to target audiences

Likewise, if patients feel a brand's message resonates, they are more likely to seek out that brand and listen closely to what the company has to say.

About the author

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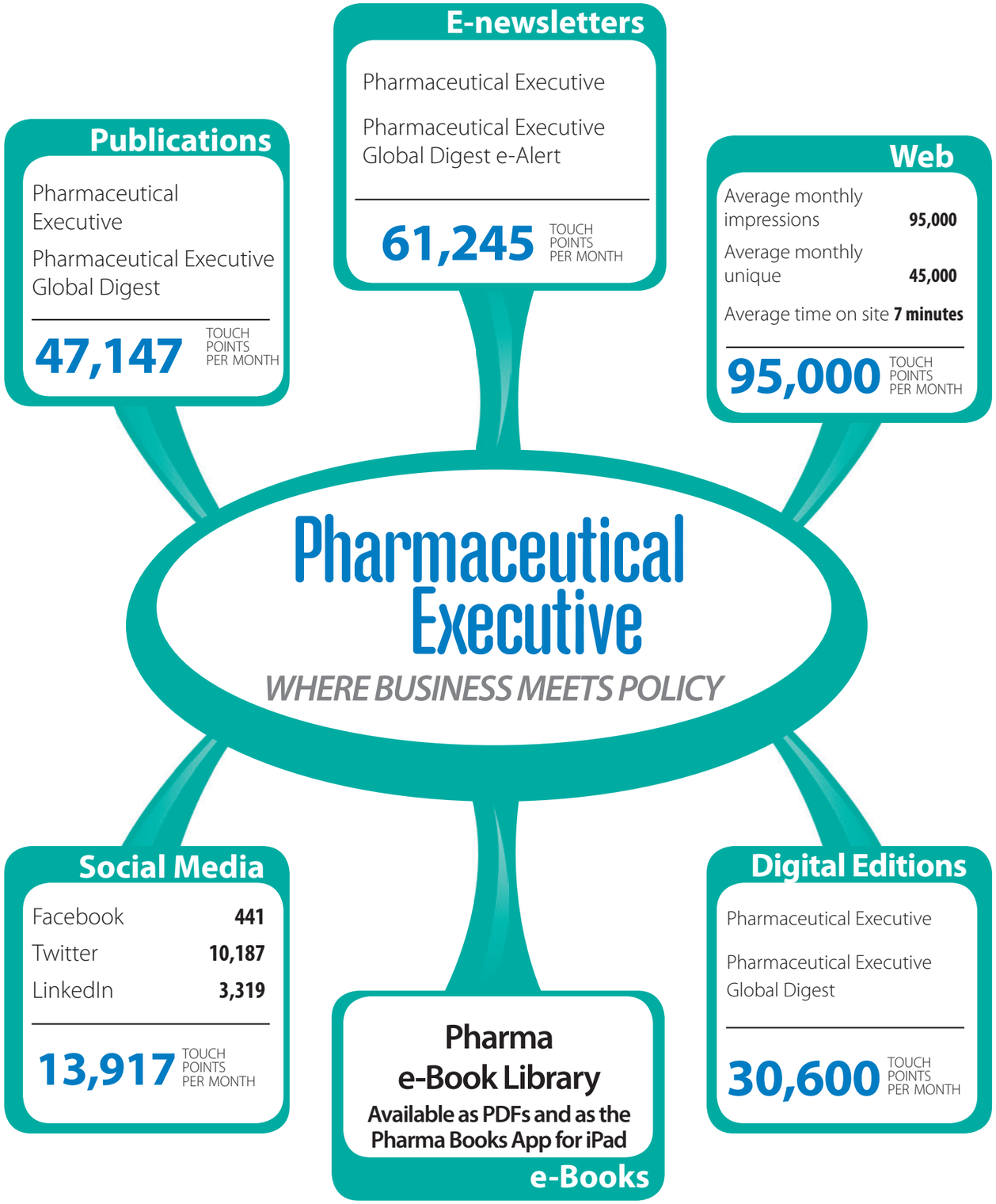

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HIV in Russia: Dynamics, Challenges, Recommendations

Samantha Fernando and Victoria Allan offer some recommendations that could allow for a greater number of HIV+ patients to be successfully treated in Russia.

Russia has one of the most rapidly growing HIV populations in the world.

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Russia has one of the most rapidly growing HIV populations in the world. A primary route of infection — intravenous drug use — is increasingly hard to control, and often goes hand in hand with rates of HCV co-infection.

Compounding this issue are the many obstacles limiting the uptake of antiretroviral (ARV) therapy, from the compliance levels of the affected population to the limitations of the healthcare infrastructure to the barriers of social stigma.

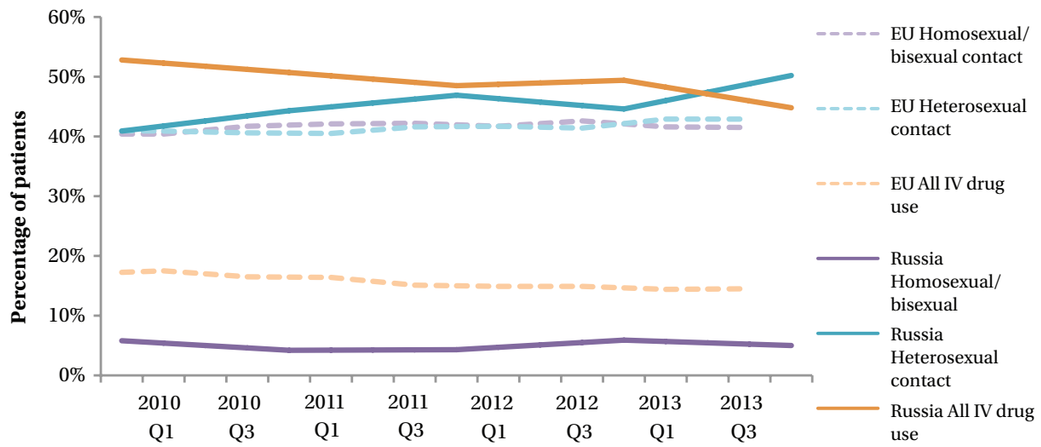
The rise of IVDU

HIV infection via intravenous drug use (IVDU) accounts for over 42% of the total infected HIV population in Russia. This is compared to just 14% in the EU5.(1)

Recent trends in the Russian IVDU community are thought to be exacerbating the problem.

Although the availability of heroin has declined since the 2000s, the use of 'krokodil' (desomorphine) has increased.

Figure 1: Trends of HIV patients by route of infection in Russia and the EU5



Source: Ipsos' HIV Monitor study, Russia and EU. Base: all patients excluding unknowns

Alongside the high population of HIV patients infected via IVDU, Ipsos' Therapy Monitor also reveals a sharp increase in the number of cases attributed to heterosexual transmission — above levels seen in Europe.

Overlapping of these patient groups is attributed to the longstanding stigmas associated with HIV, which may deter some at-risk individuals risk from being tested. As such, many infected patients remain undiagnosed.

The compliance issue

The unconventional behavior of injecting drug users means that compliance is a major obstacle to effective disease management.

As demonstrated in data from across the EU5, increased compliance leads to an increased likelihood of treatment success and viral load reduction. Recent results from a recent PARTNER study have reiterated that individuals diagnosed with HIV with an undetectable viral load are highly unlikely to pass on the infection.

> As a result of the social stigma of HIV, it is likely that infection is underreported and the necessary treatment often unsought.

Patients with poor compliance, meanwhile, are at a higher risk of experiencing virologic failure and building resistance to their ARV therapy.

In view of the compliance issues associated with these patients, trended data shows that physicians in Russia now indicate that convenience — compared to tolerability and efficacy, previously — now underpins their prescribing choice for injecting drug users.

The social dimension

The social stigma associated with HIV is well known, and a number of initiatives to address these issues are ongoing in the EU.

However, prejudices towards HIV patients in Russia are ever-present, with the disease often associated with immoral behavior.(2)

For example, medication-assisted therapies and needle exchange programs, vital to the successful rehabilitation of injecting drug users (and recommended by the WHO and the UN), have long been adopted in the EU but are non-existent in Russia.

Currently, patients seeking government-funded HIV treatment are required to add their names to a government register.

This enables the federal HIV center responsible for monitoring and carrying out statistical research to collect and accumulate accurate information on the epidemic.

However, it also prevents patients from keeping their HIV diagnosis discreet.

Our interviews with HIV patients in Russia have

indicated that the requirement to join a federal register in order to receive ARV treatment does in fact act as a deterrent to seeking treatment. Many patients prefer their HIV diagnosis to remain anonymous, even amongst close family members, and will not seek medical advice if the anonymity of their diagnosis is at risk.

Treatment programs in Russia can also be strict on injecting drug users. Patients who inject drugs during an HIV treatment program within a facility are often removed from that program.

As a result of the social stigma of both HIV and a main route of infection, IVDU, it is likely that infection is underreported and the necessary treatment often unsought.

By contrast, support for this affected population, along with measures to address the underlying drug dependency, could potentially aid uptake of, and compliance to, HIV anti-retroviral medication and increase the probability of long term treatment success.

A struggling infrastructure

For those patients who are receiving therapy, the infrastructure of the Russian healthcare system presents further complications. Funding is limited, physician caseloads are high, the administration process is long and specialist centers are few in number.

Although government funding for ARV treatment and HIV research is increasing over time, the system is still under-funded.

The federal government guarantees free therapy for those living with HIV, but it is evident that the federal healthcare budget is unable to cover ARV treatment for all patients, and additional support from international charitable donors is not enough to bridge the gap.

Despite the number of HIV testing clinics across Russia, there are a limited number of both HIV clinics and physicians actually treating HIV.

Ipsos data reveals that physician caseloads are high and, on average, patients wait up to three years between diagnosis and treatment initiation. This is a deterrent to seeking initial treatment advice or linkage to care.

Moreover, multiple stakeholders and specialists are included in the decision-making process on whether patients can receive government-funded treatments, creating delays in the decision making.

Treatment centers themselves are typically located in larger metropolitan cities and many HIV patients living outside of these cities find it too difficult — financially and geographically — to access them.

Finally, there is an absence of auxiliary support specialities within patient clinics (such as physiologists, TB specialists and counsellors), making infectious disease specialists the key managers of HIV patients at present. Support with the demands of taking ARVs could potentially enhance treatment success rates.

> Physicians should be educated about how to treat these patient groups, and could be supported in this by the pharma manufacturers.

A limited treatment algorithm

Treatment options in Russia and the EU differ significantly.

Russia currently represents a less established market, given the absence of newer antiretrovirals that are now well ingrained in the European treatment algorithm.

Patients in Russia are typically prescribed multiple pill therapy (two NRTIs and a third

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agent) and many experience unpleasant side-effects (23% of patients reporting gastrointestinal issues). Kaletra use is high, representing a 36% share in all patients, with Combivir + Kaletra currently the top regimen.

In Europe, however, treatment has shifted towards well-tolerated alternatives, with a focus on simplification to aid compliance. The first single tablet regimen (STR) was launched in Europe in 2008, followed by new STRs over the past two years. With another STR launch imminent, the future of treatment in Europe looks to be set around STR use.

Conclusions

Given the high prevalence of injecting drug users in Russia's HIV population, achieving good compliance — especially with multiple pill regimens — is challenging. Monitoring these patients, alongside continued communication reinforced by a support network, is imperative. These patient groups should have access to support groups and education programs that promote the benefits of antiretroviral therapy and the importance of compliance.

Physicians should also be educated about how to treat these patient groups, and could be supported in this by the pharmaceutical manufacturers.

Curbing the rise in HIV infection in Russia must comprise a multi-faceted approach.

Meanwhile, improving the referral process by streamlining the administrative workload and reducing the number of stakeholders involved in the treatment decision-making process could reduce the time lag between diagnosis and initiation, and so increase treatment rates.

Improvements could also be made for patients living outside of large metropolitan cities to gain easier access to HIV-treating clinics. This could mean setting up new or mobile clinics and/or screening sites in high HIV infection areas, or providing better transport connections which can support patients in travelling to the nearest HIV clinics on a regular basis.

Finally, although barriers exist, the introduction of the single tablet regimen in Russia — versus the prevailing triple pill therapy — could increase compliance and therefore treatment success.

Ultimately, curbing the rise in HIV infection in Russia must comprise a multi-faceted approach, whereby the rehabilitation and support of these patients is a priority. However, the social and political barriers to HIV treatment should not be underestimated.

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About the Authors

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Market Access for Specialty Products in Latin America

Andrea Sobrio and Dr. Sandra Schoenes examine the market access challenges and opportunities specifically for premium, specialty inpatient products in the LatAm region.

Brazil, Mexico, Argentina, Chile, Colombia, Cuba, Peru and Venezuela represented a market retail value of $80bn in 2013, up from $50bn in 2010.

The pharmaceuticals market in the Latin America (LatAm) region is experiencing a period of healthy growth. It is estimated that the region's eight major countries — Brazil, Mexico, Argentina, Chile, Colombia, Cuba, Peru and Venezuela — represented a market retail value of $80bn in 2013, up from $50bn in 2010.

Opportunities exist both within the public and private sectors, but the biggest potential is arguably with private payers — in particular, premium specialty products can provide good returns with the right, tailored approach. But market access environments vary widely across LatAm, and there are specific access challenges for premium products.

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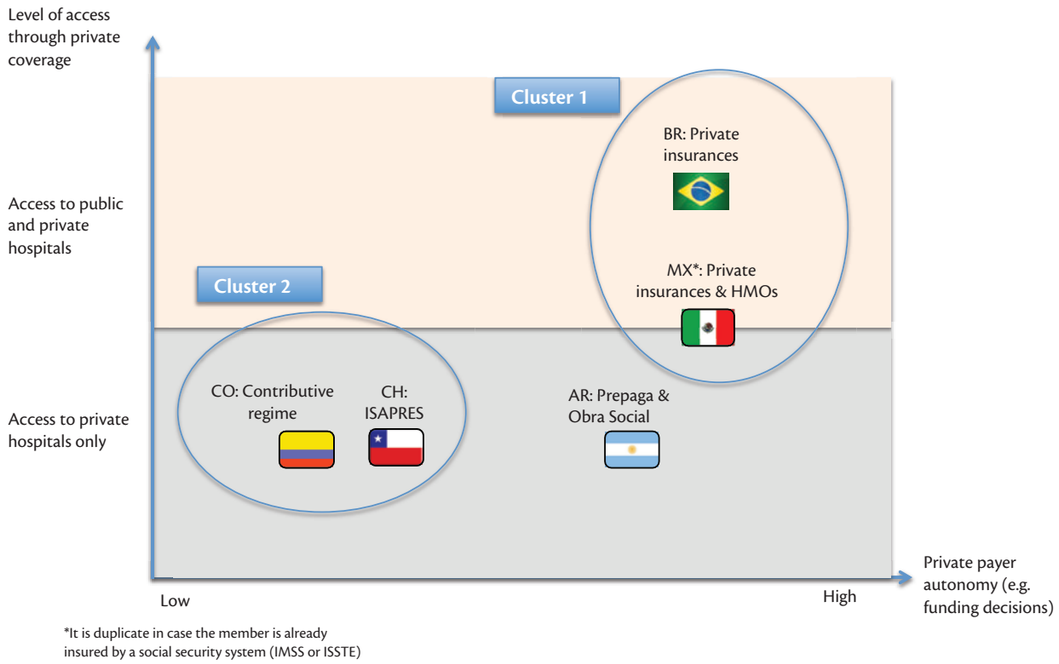
Figure 1: Clustering markets into payer segments



*It is duplicate in case the member is already insured by a social security system (IMSS or ISSTE)

A heterogeneous region

There is no 'one size fits all' approach to market access in Latin America — while it is an attractive region overall for pharma, each country is unique and companies must tailor their approach and be sensitive to national variations.

There are significant differences in pricing and reimbursement across the region. Some countries, such as the region heavyweight Brazil, utilize HTA assessment for pricing, while others such as Mexico use reference prices; others (e.g. Chile and Argentina) leave it to the companies to decide price. However, the landscape is dynamic and needs monitoring, with Colombia as one example transitioning from free pricing to reference pricing.

In terms of reimbursement, there is a wide range of payers — from health plans and insurers, to hospital financial management and health department officials — all trying to find a balance between the need for cost-containment and increased consumer expectations for improved healthcare.

Clustering the LATAM countries to make strategic decisions

To bring their premium products to these markets, pharmaceutical companies need to ensure there is tight alignment between global HQ and local operations. It is important that markets are clustered effectively to sequence and prepare launches — this is something that local operations can also benefit from, sharing learnings across markets within the same cluster.

Figure 1 shows one way of clustering markets into private payer segments, based firstly on their degree of autonomy (e.g. the degree to which funding decisions can be made without influence by national or regional health authorities) and secondly on the level of access through private coverage (e.g. if members of the private sector also have access to a public health sector).

There is no 'one size fits all' approach to market access in Latin America...

Understanding just how quickly and through how many stakeholders (e.g. including national and regional health authorities) listing decisions are made is vital, and dictates where the country is on the degree of autonomy x-axis in the Figure 1 graph.

In countries with high levels of private payer autonomy — e.g. Brazil and Mexico circled here in cluster 1 — private payers are free to decide which drugs they reimburse in any of the multiple health plans they offer. In countries with a low level of private payer

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autonomy — e.g. Colombia and Chile in cluster 2 — the private payers have a reduced level of freedom regarding funding decisions. In Colombia for example, the contributive EPS — the HMO segment, which subcontracts mostly to private providers — needs to reimburse all drugs on the national health formulary (POS). At the moment this national formulary does not include most premium drugs, but with the upcoming healthcare reform, this could change.

The level of access of those with private coverage (the y axis on the graph) is also an important consideration. Firstly, access to both public and private hospitals gives physicians in public institutions access to, and experience with, patients taking premium, innovative medicines. Secondly it usually means that the private sector has more freedom in making coverage decisions as the citizen is already covered by a national health insurance.

Mexico and Colombia — two divergent opportunities

Countries representative of the two clusters we have highlighted include Mexico — the second largest LatAm market behind Brazil — in cluster 1, and Colombia — a complex market due to its dependence of national funding policies — in cluster 2.

Mexico

The private sector in Mexico has a limited patient base — only 3.5% of population — but provides a relevant benchmark in terms of early product adoption and purchasing power.

Private payers can be divided into two segments — "normal" private insurances and HMOs. Unlike "normal" private insurances, HMOs have non-mandatory formularies, where selected premium drugs (over $10,000) can be included. However, since 2012, all private and HMO insurances carry one-time and usually non-renewable policy limits.

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Table 1: Key elements to consider when targeting LatAm countries

Have the appropriate **commercial organization** (e.g. right structure, right capabilities) in place
Ensure **supportive evidence** at the country level is in place
Define a **payer targeting sequence** based on stakeholder mapping
Achieve **coverage in key health plans** by target payers (in BR, CH, AR and the HMOs in MX)
Define a **hospital targeting sequence** based on advocacy, tiering, and influence mapping
Support the individual **coverage (and pre-clearance) negotiations** between payers and hospitals
Achieve timely **hospital formulary inclusion**
Support key stakeholders in the **budget allocation process**
Support/facilitate **purchasing process** (e.g. through innovative contracting and financing schemes)
Achieve national **guideline and secure protocol inclusion**

Depending on the policy these limits can be prohibitive for the use of premium innovative drugs.

In addition, there is a smaller segment of patients seen in private hospitals who are very wealthy individuals (often "health tourists") who pay "out-of-pocket" for products prescribed by their treating physician.

On the public sector side, most premium innovative drugs are classified as "clave 5000" and their prescription is rare outside certain specialist hospitals. The few granted access now have to face extra layers of approval before reaching the hands of doctors — the two major public payers (IMSS and ISSTE), have both recently introduced a new prescription control program (called Catálogo II at IMSS), which restricts and delays access to premium innovative drugs by up to three weeks due to a centralized pre-authorization and drug delivery process.

Mexico's private sector provides a relevant benchmark in terms of early product adoption and purchasing power.

Colombia

Colombia currently has near-universal coverage, something rarely seen in Latin America. The financial strain however, has created the need for change, and the country is entering a period of transformation.

Currently, Colombia's health system operates under two schemes; contributory and subsidized. Forty percent of the Colombian population holds formal employment and receives health insurance through the contributory scheme, granting access to private hospitals. The remaining 60% of the population are subsidized by the public health system.

The greatest potential for premium in-patient drugs lies within the contributive EPS. This is because the use of premium drugs is higher in private than in public hospitals due to their increased purchasing power, their strong negotiation power, and the existence of independent funding, if the hospital has the status of a foundation with independent resources.

The contributive market is currently fragmented into 21 players (some of them also offering subsidized insurances). A key factor differentiating Colombia from other Latin American markets

is this de-centralization of key customers over the country. Being successful in Colombia means being able to adapt to this structural and geographical reality.

There are two strategic approaches to market access in Latin America — independent development or partnership.

Premium innovative drugs are usually excluded from the national compulsory health plan (POS). In order to prescribe a non-POS drug, the hospital needs to send a request to the EPS in charge of the patient — this is either authorized and reimbursed, or rejected. Although the cost for the drug is not borne by the EPS, they have incentives not to approve non-POS treatments.

However, two major changes proposed in the healthcare reforms are imminent — firstly the abolition of funding for non-listed treatments, and secondly the creation of a unique national fund for direct hospital financing. The implementation of a unique benefit package (Mi Plan) is expected to represent an additional market access hurdle.

Overcoming the hurdles and achieving access for premium, specialty products in LatAm

There are two overall potential strategic approaches to market access in Latin America — independent development or partnership. The decision on which to implement will depend largely on a) the current company presence within the target country, and b) the level of company experience with in-patient products.

Those without any existing country presence should develop a LatAm market access strategy and then aim to set up an appropriate "critical mass" organization. This can either be achieved by mergers and acquisitions or by partnership with a local distributer or non-competing manufacturer. Alternatively, the company can decide to invest significant resources in building-up an organization with the required capabilities in the target market(s) systematically over the medium-term. Those with a presence in the target market but limited in-patient product experience will essentially need expert consultation to guide them through.

In countries where low private payer autonomy exists, a dual public-private approach should be taken, in order to achieve national product endorsement (e.g. national listing, inclusion into national clinical guidelines) while achieving private payer coverage.

In countries where private payers have a high level of autonomy, the manufacturer can focus on the private sector and market access is generally quicker. It is also worth targeting leading public reference centers, given their influence on private hospitals.

In the long term, pharma companies can shape and develop their markets by aligning with payers to create novel insurance options, particularly if they possess a rich portfolio of high-cost products in a yet underfunded therapeutic area.

Several other essential factors should be considered in each case (see Table 1). But what specific steps could be taken to facilitate hospital access in the two example markets we have highlighted?

Colombia currently has near-universal coverage, something rarely seen in Latin America.

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Access to Mexico
To achieve hospital access in Mexico, try to facilitate the use of your product in reference institutions, which can be both private and public (e.g. tertiary care IMSS hospitals). Doctors who use the product and work across both settings can be powerful advocates.

You can also consider organizing medical education programs in partnership with the reference institutions, and establish preceptorship programs for other doctors to visit reference hospitals.

However, it is important that key account managers are in place on the ground to liaise with individual physicians about the benefits of the product, as protocols are only loosely followed in private hospitals.

Access to Colombia
In Colombia, a discount pricing agreement may be essential to incentivize the hospital to include your product in the formulary, and this may include portfolio agreements and Managed Entry Agreements.

It is critical to perform a market access assessment at country level in the pre-launch phase...

In the case of an acute care drug, it is advisable to avoid pre-clearance and instead facilitate approval post-use by facilitating supportive clinical and health economical evidence for your product and implementing medical education of prescribers to ensure correct and rapid patient identification.

To help achieve formulary inclusion you should build KOL and medical society endorsement and consider investing in local cost-effectiveness and cost-benefit studies.

Make sure you map the budgeting process in the different hospitals in order to identify the key stakeholders, and then support them with a budget forecast tool as well as with a business case for your product.

Conclusions
The LatAm region holds significant potential for pharma, but achieving market access for premium specialty products requires a customized strategy accounting for the high level of heterogeneity of the countries.

Clustering markets by level of private payer autonomy and by level of access to public and private hospitals provides a starting point for an effective market access strategy.

It is critical to perform a market access assessment at country level in the pre-launch phase to develop country launch roadmaps and inform the launch sequencing.

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About the authors


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Dr. Sandra Schoenes is Subject Matter Expert, also at Executive Insight.

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Innovation and Market Growth in Brazil

Brazil is the first Latin American country to emerge as a global biopharmaceutical collaborator, writes Hellen Berger.

Brazil is eying production and innovation, relying on the key support of the government.

The pharmaceutical market in Brazil has been growing steadily and strongly in the past five years. The country is eying production and innovation, relying on the key support of the government. According to industry associations, biopharmaceutical innovation in Brazil will increase in the future as the country starts facing its challenges and participating globally with local and multinational companies.

Abifina, Brazil's Fine Chemicals, Biotechnology, and Specialty Industries Association, says that Latin American countries are still planting seeds to develop and compete in the global biopharmaceutical market. Brazil, however, plays a key role in the sector with a series of universities and

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institutes promoting research and development actions, a public health system capable of sustaining part of the local pharmaceutical industry, and a large consumer population at more than 200 million people.

Market growth in Brazil

"Brazil has definitely been growing steadily over the 10% mark in the past five years and we should continue seeing sales increasing annually by 12-15%," Nelson Mussolini, executive president of Sindusfarma, told Pharmaceutical Technology. Sindusfarma is the São Paulo state pharmaceutical products industry association.

According to Mussolini, citing IMS Health figures for the past five years, Brazil's growth is considered relevant if compared with data for Europe and the U.S., whose growth levels were around 1%. Mussolini says that the increase is especially due to the fact that the local job market has heated in the past five years and has been transforming the lower classes into active consumers of goods and services.

The country's impact, however, within the biological products market is limited to production and sales and does not necessarily include relevant innovations, according to Reinaldo Guimarães, intellectual property director of Abifina.

> The Brazilian government is seeking less dependence on imports and a stronger local market...

"Our increase of the biopharmaceuticals market share is mainly a result of public investments for the government's health system," Guimarães told Pharmaceutical Technology. The government is acting as a main buyer, currently responsible for as much as 25% to 30%, with an estimated participation reaching as much as 50% in the next few years, according to Guimarães.

The government is establishing key partnerships with local and multinational, private, and public companies, and is funding local production capacity expansions for public and private companies. Brazil is also controlling the efficacy and safety of pharmaceutical products through market regulation.

According to Guimarães, considering government expenditures with health products, biopharmaceuticals correspond to only 5% in terms of units sold and as much as 40% in terms of sales.

"The government is definitely investing on the development of the local biopharmaceutical sector through partnerships and by obtaining technology," says Mussolini.

According to Sindusfarma's executive president, however, companies face challenges to become profitable and still lack large production scales.

It seems that Brazil-based companies are seeking to increase production scales and profitability, while government is seeking less dependence on imports and a stronger local market, establishing a strong pharmaceutical partnership intended for growth.

Hellen Berger is a business writer based in Sao Paulo, Brazil.

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APPOINTMENTS

EUROPE

IMS Health UK (London) named Tim Sheppard as the new general manager for its UK and Ireland business. Mr. Sheppard joins IMS from Unipart Group, where he was Head of healthcare in its consulting practice.

Celgene (Stockley Park, UK) appointed Rob Moore as its new Inflammation and Immunology (I&I) Business Unit Director. Mr. Moore worked in variety of primary care sales and marketing roles at Abbott before progressing to its Immunology division in 2006.

Cardio3 BioSciences (Mont-Saint-Guibert, Belgium) appointed Hanspeter Spek as a Non-Executive Director. Mr. Spek retired after a career at Sanofi in 2013, but he continues to serve on the company's Board in Germany.

Sanofi (Paris, France) has become the first major pharma company to appoint a Chief Patient Officer. Dr. Anne C. Beal joins from the Patient Centered Outcomes Research Institute (PCORI) in the US, where she was Deputy Executive Director and Chief Officer for Engagement.

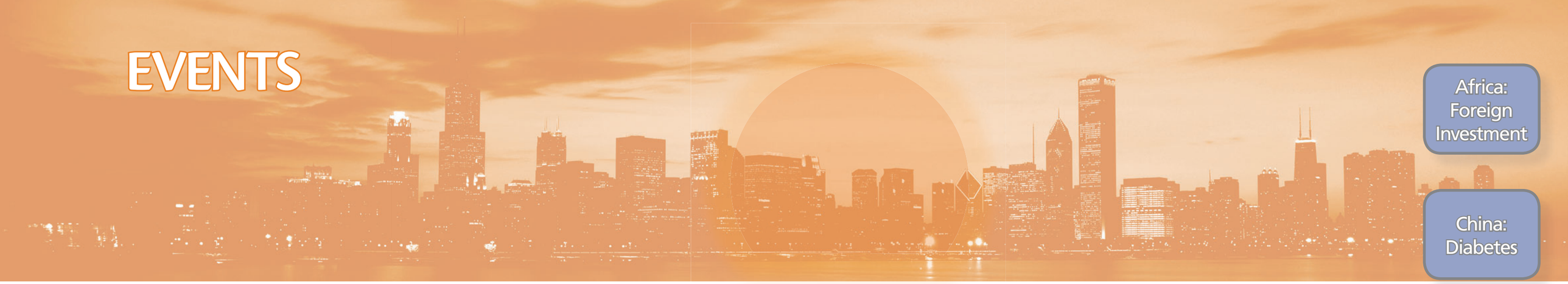
USA

Tonix Pharmaceuticals (New York, NY) appointed Donald J. Kellerman, Pharm.D. as Senior Vice President, Clinical Development and Regulatory Affairs. From 2008 to 2013, Dr. Kellerman served as Senior Vice President, Clinical Development and Medical Affairs at MAP Pharmaceuticals, Inc.

Osiris Therapeutics, Inc. (Columbia, MD) appointed Therésa K. Dixon to General Manager, Market Access and Reimbursement. Ms. Dixon previously served as VP of Government Affairs & Health Economics at Advanced BioHealing, Inc.

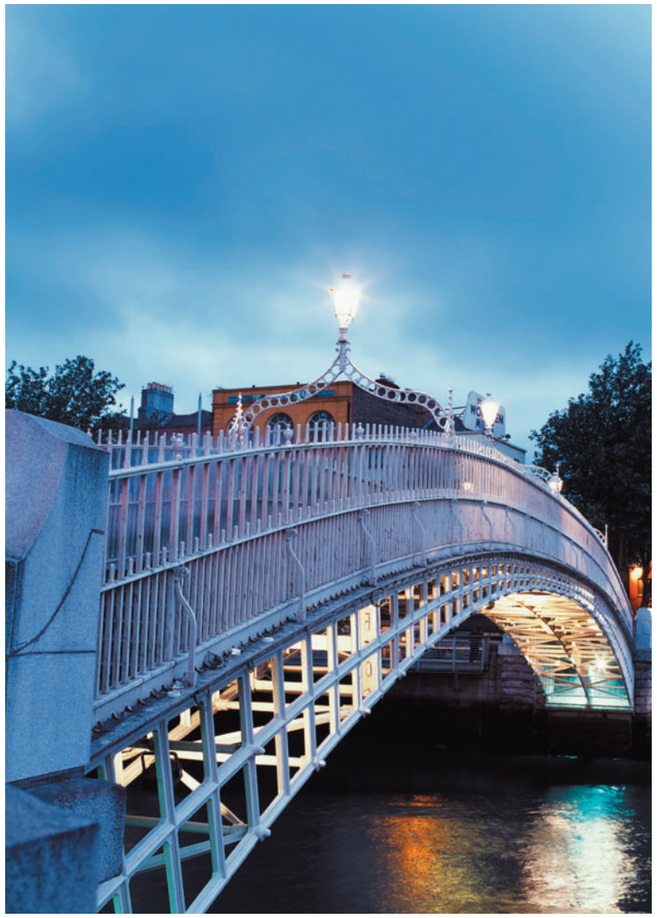
Par Pharmaceutical Companies, Inc. named Terrance J. Coughlin as Chief Operating Officer. Mr. Coughlin joins from Glenmark Generics, Inc., where he most recently served as President and CEO.

Cytomedix, Inc. (Gaithersburg, MD) announced the appointment of Andrew Cohen as Vice President of Marketing.



LATE PHASE RESEARCH/REAL-WORLD DATA

May 22–23: Dublin, Ireland



Real world data is quickly becoming a necessary component of evidence that must be gathered to demonstrate a product's effectiveness to payers, regulatory agencies, physicians and patients. This event will examine the Big Data explosion and the role of new healthcare delivery models, looking at shifting stakeholder demands and understanding how payer motivations are driving requests for value-based outcomes data.

http://www.cbinet.com/conference/pc14011#.Us2AYP15lFw

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PAAS 2014 — PATIENT ADHERENCE AND ACCESS SUMMIT

June 17–18, 2014: Philadelphia, PA, USA

PAAS moves adherence programs from theory into action. This year's event puts on spotlight on programs achieving ROI on adherence.

http://www.cbinet.com/conference/conference/pc14116#.UwzE3f3nffM

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