

COLOMBIA

Emerges as an Attractive Pharma Market

With a growing interest in attracting R&D and continual economic growth, Colombia is seen as an attractive market for pharmaceutical companies.

The Republic of Colombia is evolving from an emerging economy, having enjoyed an economic turnaround since 2000, when it was perceived by economists and political experts as a failed state. Fueled by improvements to the business environment, sound macroeconomic management, and continued investment growth, GDP growth is expected to reach 5% in 2014 and remain robust between 2015 and 2018, according to The Economist.

The economy has experienced improvement and growth since 2010, including the pharmaceutical industry, showing increased product sales every year, says Paul Toralva, director, Peru and Colombia, clinical site monitoring, Quintiles.

Colombia is experiencing increasing demand for pharmaceutical products as a result of the country's positive economic landscape, booming population and government policies to broaden access to medicines through the expansion in health insurance and affordable drug coverage, according to a Decision Resources report.

"The country's political and economic stability, higher education levels within Latin America, and national safety conditions reached over the last decade create a favorable and friendly business environment, which is why several companies use Colombia as a platform for their Andean Community business expansion and/or distribution," says JeanMarie Markham, CEO and founder of Clinlogix.

According to Ash Kuchel, global group president, Publicis Healthcare Communications Group, the Colombian market is very much emerging.

"Healthcare reforms over the past two

decades have led to an increase in access to care, and have paved the way for a more robust economic climate to support pharmaceutical investment," Mr. Kuchel says.

Pharmaceutical Status

The country touts itself as being a center for innovation. In fact, in 2012 Medellin was named the "Innovative City of The Year" in a Wall Street Journal and Citi Global competition, Ms. Markham says.

"There is an increasing awareness and interest in attracting research and development," Ms. Markham says.

Colombian production of pharmaceutical products, medical devices, and equipment is conducted by national and multinational companies, such as Johnson & Johnson and Boston Scientific, supplying the local and the Andean region, including the surrounding countries, she says.

"Multinational companies are using Colombia as a regional platform for the access to the surrounding regions of Argentina, Peru, Chile, and Ecuador," Ms. Markham says.

Mr. Kuchel says global pharmaceutical companies, including Bayer and Merck, have facilities in the country, and there are also a growing number of local pharmaceutical manufacturers.

"The country boasts a good market for medical device manufacturing and generic medication market, but continues to rely heavily on imported drugs," Mr. Kuchel says.

The pharmaceutical industry sector in Colombia covers a broad range of product types and includes the production of active ingredients, medicinal and pharmaceutical products, antibiotics, vitamins and pro-vita-

Colombia at a Glance

Total population (2012)	47,704,000
Gross national income per capita (PPP international \$ 2012)	\$9,990
Life expectancy at birth m/f (years, 2012)	76/83
Probability of dying under 5 (per 1,000 live births, 2012)	18
Probability of dying between 15 and 60 years m/f (per 1,000 population, 2012)	147/74
Total expenditure on health per capita (Intl \$ 2012)	\$723
Total expenditure on health as % of GDP (2012)	6.8

Source: Global Health Observatory

mins, biological products, and veterinary medications. Ms. Markham adds that there is generally good access to new products and technologies.

Drug pricing has been a focus of the current government, which is focusing on correcting the poor enforcement of drug pricing controls that previously existed, by taking direct control of a more centralized pricing strategy, Decision Resource analysts note.

Government cost-containment efforts have helped to create a thriving generic sector in the country, according to Decision Resources. The Colombian pharmaceutical market was valued at 8.126 trillion Colombia peso (U.S. \$4.35 billion) in 2013 and is expected to grow at a CAGR of 7.3% to reach COP 10.032 trillion (U.S. \$5.37 billion) by 2016.



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Publicis Healthcare Communications Group

The government has been working to strengthen vigilance on sanitary regulation for pharmaceuticals, emphasized through changes issued to the health system in February 2014, the new organization and norms approved for INVIMA in 2012, an increase of human resources, and a three-fold increase of the budget from 2009 to 2012, Mr. Toralva says.

The government is also working to bring about price regulation, changes in the patent structure, and improved access to affordable medicines. At the same time, there are efforts to increase competition in the biotechnology industry and create an attractive environment for investors and industry, Mr. Toralva says.

When it comes to bringing products to market, Ms. Markham notes that Colombia is very relationship oriented.

“Face-to-face meetings to negotiate and finalize deals are a requirement for success,” she says. “The import/export and approval process is relatively straight forward, once you understand the requirements. Patience and perseverance are essential, as decisions are contemplated over a period of time and require multiple face-to-face meetings.”

Clinical Research

Colombia is rapidly developing in the area of clinical research, and is overseen by a strong, well-organized regulatory body, INVIMA, which works in conjunction with the Ministry of Health/Social Protection for the safe conduct and oversight of clinical trials, Ms. Markham says.

“Hospital facilities are very well-equipped with the latest technology, and medical staff are well trained,” she says. “Specifically for clinical research, institutions have to undergo

Colombia Healthcare Coverage

Benefits covered by the national healthcare scheme include:

- » Access to healthcare institutions and professional attention in any field
- » Telemedicine
- » Medical diagnosis (RX, laboratory Test, biopsy)
- » Medical treatment (medication, surgery, devices)
- » Rehabilitation
- » Medical support in promotion and prevention programs.

Source: Quintiles

a certification process in order for them to participate as a clinical site for pharmaceutical studies.”

Colombia is ranked sixth in clinical trials within Latin America, with 5.9% of studies, Mr. Toralva says. Between 1995 and 2013, 738 clinical trials took place, of which 90% were sponsored by the pharmaceutical industry.

“Most of them were Phase III (62%), and were comprised of trials focused on chronic illnesses such as cancer, cardiovascular, and degenerative conditions,” Mr. Toralva says.

By the end of 2013, 116 institutions were GCP certified by INVIMA, and of this total 107 (92.2%) are private, 93 (80.2%) are IPS (Health Providers Institutions), and 21 (19.8%) are research sites. These sites are distributed across the country, with the majority in the four most populated cities: Bogotá, 44 (37.9%); Medellín, 17 (14.7%); Barranquilla, 14 (12.1%); and Cali 11 (9.5%), Mr. Toralva says.

According to the information available on INVIMA’s web page, the therapeutic area in which more clinical trials have been conducted is rheumatology (2011- July 2014).

A total of 771 studies have been registered in clinicaltrials.gov, of which 214 are still open, Mr. Toralva says. In addition, there are 63 ethics committees that have been GCP certified by INVIMA.

Patient recruitment and retention are very high, partially due to the culture in the region, Ms. Markham says, adding that there is little competition for patients for research projects.

However, she notes that fewer than 1% of all clinical trials globally are being conducted in the Latin American region.

According to Mr. Toralva, there are two



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JEANMARIE MARKHAM / Clinlogix

types of research institutes in Colombia: public and private hospitals and private exclusive research centers.

“Hospitals and private clinics have research sites inside their facilities and recruit subjects from their own population of patients,” Mr. Toralva says. “With private exclusive research centers, a group of investigators works exclusively to develop clinical trials. They have patient databases from their own clinical practices and from previous clinical trials. Sites also conduct searches through colleagues working at national health institutions and through publicity campaigns.”

Approval timelines in Colombia are among the fastest in South America, taking around 60 days on average to get IRB/IEC approval, 90 days for INVIMA approval, and 30 days to get an import license, adding up to 180 days on average, Mr. Toralva says.

The regulatory body is increasingly focused on the correct execution of clinical trials, and has recently released different guidelines to help sponsors, sites, and ethics committees to harmonize the execution and oversight of clinical trials, Mr. Toralva says.

“As these guidelines have only been recently issued the impact on study approval timelines isn’t yet clear,” Mr. Toralva says. “What is clear from the increased oversight is that INVIMA has been performing more inspections of research sites and ethics committees.”

Colombian Market Access Trends

» Expanded access to pharmaceuticals

Recent government policies have successfully expanded access to pharmaceuticals to all strata of the population through increased insurance coverage and an expanded basic drug list from the country's Mandatory Health Plan. Specifically, health insurance coverage has grown to 95% of the population, with President Juan Manuel Santos targeting universal coverage by 2015.

» Regulatory and pricing environment

Colombia offers a stable political and economic environment, although the government has tightened the regulatory and pricing environment for pharmaceuticals in recent years.

» Entry point to region

Colombia has geographic advantages. The country is an entry point into South America for multinational pharmaceutical companies wishing to enter the region.

» Opportunities for international companies

The government does not favor domestic companies in the tendering process or any other form of trade in the country's pharmaceutical sector, creating equal opportunities for international firms operating in the country. Furthermore, the cost of local production is lower than that of most other Latin American countries.

Source: Decision Resources. For more information, visit decisionresources.com



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PAUL TORALVA / Quintiles

Clinical Trials and Area of Therapeutic Focus

Therapeutic Area	2011	2012	2013	2014	Total
Rheumatology	17	12	20	3	52
Endocrinology	13	3	7	2	25
Infectious Disease	6	2	11	2	21
Psychiatry	6	7	5	2	20
Oncology	7	1	7	3	18
Pneumology	4	1	6	4	15
Cardiovascular	3	0	7	4	14
Hemato-oncology	3	0	9	1	13
Ophthalmology	2	1	5	1	9
Neurology	2	0	3	1	6
Others	4	0	2	0	6
Urology	3	0	1	1	5
Dermatology	3	0	0	1	4
Transplant	1	0	1	1	3
Gynecology	0	0	1	1	2
Nephrology	0	0	0	2	2
Gastroenterology	0	0	1	0	1
Immunology	1	0	0	0	1
Radiology	0	0	0	1	1

Source: INVIMA, www.invima.gov.co

Health Coverage

In 1993, Colombia introduced reforms to how it organizes its health funding. It began by unifying the existing social security, public, and private financing institutions under

the umbrella of the General Social Security System for Health (SGSSS). The SGSSS program regulates essential public health services and creates the access to all services to the public in all levels of healthcare.

“Before 1993, only a quarter of the population was insured, but in 1993, the government made it mandatory for all citizens to be insured by a government healthcare system financed through payroll contributions and taxes,” Mr. Kuchel says. “The program helped more people gain access to healthcare, but lacked adequate funding and economic resources.”

The country is also working toward providing healthcare coverage to its entire population, Mr. Toralva says. According to a health department statistic, in the first quarter of 2014, 91.3% of the Colombian population took part in the National Health Plan — 60% subsidized and 30% contributors.

According to Ms. Markham, the healthcare sector in Colombia is, by law, the responsibility of the Ministry of Social Protection (MSP), which in turn partially delegates that responsibility to the private sector.

“It is a general system of integrated social security and includes: pension, health, occupational hazards, and complementary social


services,” she says. “The healthcare subsystem is a social security system focused on insurance, competition among insurance managers and service providers, with a solidarity component to finance citizens with limited access to these services.”

The system is comprised of three bodies: the state, insurers and healthcare providers. Individuals are provided basic coverage in this system in one of the two plans as either a contributor or as being subsidized, Ms. Markham says.

Mr. Toralva says contributors pay 12% of their monthly salaries for healthcare coverage for themselves and their families. There is also an “unaffiliated” category for those who are not legally registered in the health system yet due a variety of reasons.

“There are additional healthcare plans that offer optional benefits or premium plans that may be purchased by individuals,” Ms. Markham says. “The most common services are prepaid medical plans or complementary plans.”

Mr. Kuchel says although most of the population is now insured, access to services remains an ongoing issue.

“Colombia has been playing catch up with its medical system, and access to care is still not equal across the country and in some areas, the medical infrastructure is still being built out,” he says. “Like other emerging countries, there continues to be a difference in access to healthcare providers and clinics between rural, coffee-growing, and urban areas. The healthcare reform is slow, but ongoing, and there’s been increased focus on prevention and diagnosis.” 

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