



OPPORTUNITY

Paulo Jorge Rodrigues Franco Mendes

Colombia: An Opportunity for the Pharmaceutical Industry and the Young Portuguese Pharmacist

Monografia realizada no âmbito da unidade de Estágio Curricular do Mestrado Integrado em Ciências Farmacêuticas, orientada pelo Professor António Augusto Miranda Lemos Romão Donato e apresentada à Faculdade de Farmácia da Universidade de Coimbra

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List of abbreviations

ANDI – Asociación Nacional de Empresarios de Colombia

CAGR – Compound Annual Growth Rate

CIA – Central Intelligence Agency

DANE – Departamento Administrativo Nacional de Estadística

EIU – Economic Intelligence Unit

EPS – *Entidades Promotoras de Salud*

FDI – Foreign Direct Investment

FTA – Free Trade Agreement

GDP – Gross Domestic Product

GES – *Gestores de Servicios de Salud*

GMP – Good Manufacture Practices

GMT – Greenwich Mean Time

INN – International Non-proprietary Name

INVIMA – *Instituto Nacional de Vigilancia de Medicamentos y Alimentos*

IPS – *Instituciones Prestadoras de Salud*

MSPS – *Ministerio de Salud y la Protección Social*

OECD – Organisation for Economic Co-operation and Development

PhRMA – Pharmaceutical Researchers and Manufacturers of America

POS – *Plan Obligatorio de Salud*

SGSSS – *Sistema General de Seguridad Social en Salud*

TRIPS – Trade-Related Aspects of Intellectual Property Rights

UNCTAD – United Nations Conference on Trade and Development

USD – United States dollars

WHO – World Health Organization

WTO – World Trade Organization

Abstract

Colombia is one of the new Pharmaceutical hot markets. Such rising economies may be emerging opportunities for Pharmaceutical companies that aim to succeed in new foreign countries, as well as an opportunity for Young Pharmacists to work and help develop these new markets.

This dissertation intends to summarize this Pharmaceutical market and its recent changes, to provide economic and regulatory data about it and to highlight potential Pharmaceutical opportunities.

Keywords: Colombia; Emerging markets; Health; Opportunity; Pharmaceutical Industry; Pharmaceuticals; Young Pharmacist.

Resumo

A Colômbia é um dos novos mercados Farmacêuticos de grande movimentação. Tais economias crescentes poderão ser oportunidades emergentes para empresas Farmacêuticas que alvejam ter sucesso em novos países estrangeiros, assim como uma oportunidade para Jovens Farmacêuticos de trabalharem e ajudarem a desenvolver estes novos mercados.

Esta monografia pretende sumariar este mercado Farmacêutico e as suas mudanças recentes, disponibilizar dados económicos e regulamentares sobre o mesmo e destacar potenciais oportunidades na área Farmacêutica.

Palavras-chave: Colômbia; Mercados Emergentes; Saúde; Oportunidades, Indústria Farmacêutica; Setor Farmacêutico; Jovem Farmacêutico.

Introduction

We live in an era where thinking locally isn't enough to have success, and yet thinking globally doesn't make us competitive enough to prosper in new markets. Henceforth the term "Glocal" emerged from this necessity to combine the strengths and opportunities of a worldwide mentality, with the experience and success of a local strategy.

Such mentality obliges us to study and to assess thoroughly new markets with favourable characteristics, or those that can be predicted to have similar characteristics in a near future. If these characteristics turn out to be a developed country's characteristics, and if the market is evolving towards that, it can be called an emerging market. Early market positioning in emerging markets can be interesting for a company, so that it can harvest the results of the market growth to its fullest.

In the Pharmaceutical market, an emerging market it's also called a pharmerging market. Such markets have been luring the attention of Pharmaceutical Industries, due to their rising pharmaceuticals usage. One of these markets that have been catching the eye of several international players is Colombia.

So the questions are: Why are these players so interested in Colombia? What makes Colombia so attractive to the Pharmaceutical Sector that leads foreign companies to invest a significant amount of resources in that country? Should Portuguese Pharmaceutical companies and the Portuguese Pharmacists access Colombia's opportunities and invest in them? Before we can answer any of these questions, it's essential to summarize and understand the Colombian Pharmaceutical market, its stakeholders and how Pharmaceutical companies may interact with them.

-Characterization of the Colombian Market

-COLOMBIA GENERALITIES AND DEMOGRAPHY

The Republic of Colombia is a South American Country with a double sea front (facing both the Caribe Sea and the Pacific Ocean), and shares its borders with Panamá, Ecuador, Peru, Venezuela and Brazil. It's the third most populated country in Latin America.(1)

As far as Colombia's GDP is concerned, in terms of Purchasing Power Parity, and based on the estimated value for 2015, it occupied the 4th position when compared with the other Latin American Countries, and the 32nd in comparison to the world (Data from CIA's The World Factbook).(2)

Colombia's time zone is GMT – 05:00, which has some advantages because it's the same time zone as the United States East Coast, and it facilitates call centre activities and Business Process Outsourcing from Colombia.(1)

According to the forecasts of the International Data Base of the United States Census Bureau, the Colombian population will have a tendency both to grow and to age throughout the next years, as shown by the Chart that follows:

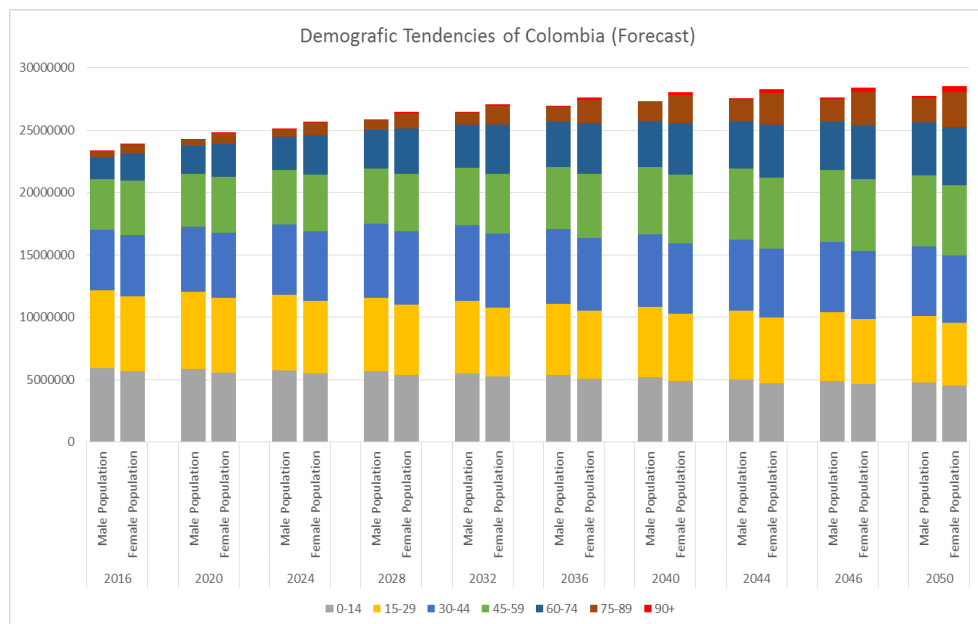


Chart I. Data from the United States Census Bureau International Data Base (June 2016). (3)

This data tells us that there will be an increase of about 11 and a half million Colombian citizens who have 50 or more years, from 2016 until 2050, which is a very relevant data for the Pharmaceutical Industry.(3)

Colombia's current President is Juan Manuel Santos, whose administration has been conducting macroeconomic stabilizing policies, searching to promote growth and job creation, as well as building programs for the high poverty rate, unemployment and overall inequalities and focusing on seeking FDI.(1)

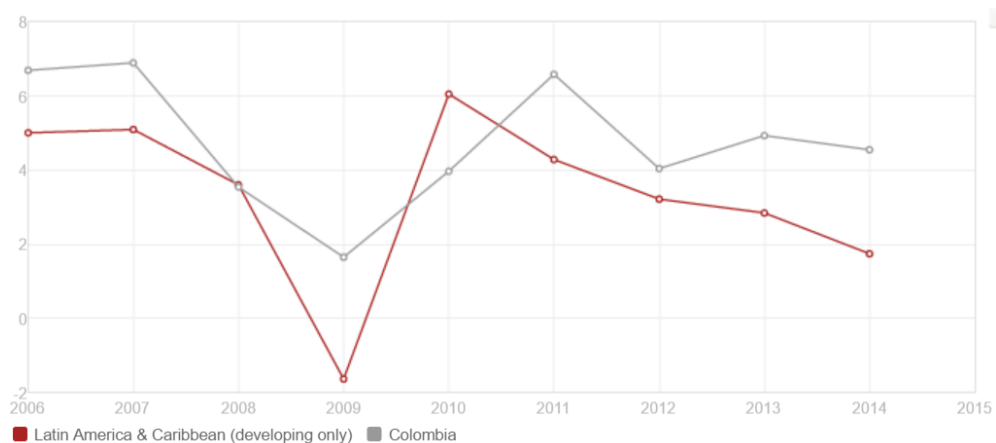
The decree 2080 of 2000 consecrates the equality of treatment of foreign and national capital investment, and foreign free access to almost all activities.(1) However, in

order to develop permanent economic activities in Colombia, foreign investors need to make their presence official in the country by opening a Branch Office.(4)

With the signing of several FTAs with numerous countries since 2011, macroeconomic stability, increased security level, increased ratings from international credit companies and a favourable regime to foreign investment, Colombia's FDI has broken new records. (1,5) The World Investment Report 2015 of UNCTAD shows that the FDI value has doubled from 2009 to 2014.(6)

The Country's GDP has been growing for the past years, this growth has usually surpassed the Latin America and Caribbean average, even staying positive when the average growth went to negative values, as we can see in the following graph:

Colombia's GDP growth vs Latin America & Caribbean average (Annual %)



Graph I. Data from The World Bank (Growth based on constant U.S. dollars).(7)

The EIU predicted an GDP's annual growth rate of 4,5% between 2015 and 2019.(1)

The investment grade status, the long term interest rates, which are below 5%, and a macroeconomic landscape with a contained inflation and a sustained reduction of unemployment, has made it possible to make plans in the mid and long terms.(8)

As for the business environment, Colombia is now in position n° 54 of the *Doing Business' 2016*.(4)

The Colombian government offers several aids to foreign investors such as fiscal benefits (like a payment exemption of the "*impuesto sobre la renta*" in many sectors, like the Health sector) as well as fiscal and tax benefits in free trade zones.(4)

Another measure that reassures foreign investors is its request to join OECD, from which we can infer a commitment to market economics standards and economic opening.(9)

The transport infrastructures still have a big deficit, its interconnection is poor and most companies assume a regional dimension.(8)

The purchasing power *per capita* of Latin America population has been increasing due to improvements in human development standards such as job opportunities, food security and hygiene. In return, they're starting to demand for a better quality in services and goods.(10)

The rise of the middle class in Colombia can be witness with data of the population that doesn't consider itself poor: 57,6%, 59,4%, 63,3% and 64,3% (in the years 2012,2013,2014 and 2015, respectively).(11-13)

- THE COLOMBIAN PHARMACEUTICAL MARKET

The Pharmaceutical Industry in Colombia has also been increasing its revenues. Although this growth is happening at a slow pace, Colombia has a lot of potential due to the economic improvement of the Country.(5) This market has been through some changes over the past years, essentially due to the launch of new products, increasing competition at price level, new players in the market, and with shifts in the Colombians needs and demands, which for existing companies means change,(14) but for others it could be seen as opportunities.

Although Colombia is below the average of Latin America's *per capita* health care spending, it ranks at number 4 in total health care spending, predicting that the expenditure *per capita* will tend to rise over the next years.(15)

However, some of the multinational Pharmaceutical companies in Colombia have been trading their factories in Colombia, leaving for Countries with better fiscal incentives and less quality and process regulation. These events have left an opening in the market that national Pharmaceuticals ended up fulfilling, elevating the Pharmaceutical sector's final product exportation and raw materials importation.(14)

Michael Himmel, General Manager Andean Region of Takeda considered in the Focus reports' "Colombia: Confidence in Uncertainty" that "The difference between Colombia and other Latin American markets basically lies in the comparative de-centralization of key customers over the country. Being successful in Colombia means being able to adapt to this structural and geographical reality". One can infer this decentralization by noticing the presence of big Pharmaceuticals outside of Colombia's capital, Bogotá. Such as

Tecnoquímicas (big national player), Johnson & Johnson and Reckitt Benckiser in Cali and Procaps (another one of the biggest Industries in the Colombian market) in Barranquilla.(5)

The national legislation states that any Pharmaceutical Company present in the Colombian market, national or multinational, needs to be habilitated with WHO's GMP certification. This legislation has also recently been adapted to apply WTO's TRIPS, strengthening intellectual property rights legislation, which is a major concern for Industries that rely on Innovation to thrive. However, as it will be mentioned ahead, the new health reform has stirred the waters on this matter.(16)

The contraband of medicines is still a concern, however great results have been achieved in fighting this phenomenon.(14)

-IMPORTS AND EXPORTS

In the Colombian pharmaceutical commercial scale, the exports have a much larger weight than the imports due to the sector's imports from raw materials to finished products (although the exports of raw materials have been increasing since 2005). Colombian companies most times must import raw materials, among others, in order to stay competitive against foreign companies.(14)

The article *Escandón Barbosa, D.M., et al. Sector Farmacéutico colombiano: factores que afectan la exportación* has concluded that even with the high logistic cost, it's still more rentable to import raw materials than to produce them internally, in the Pharmaceutical Sector. This article also states that the Colombian market focuses on low complexity medicines and it's very dependent on importation, and, therefore, from external markets.(17)

Most of these imports are usually free of taxes, however they're not free from regulation. Some imports are restricted or banned, and they require a previous licensing, authorization and record by the competent authorities, which, in the Pharmaceutical case, would be INVIMA.(18)

These tax exemptions, most of them due to FTAs signed from several parts of the World, are a sign of Colombia's opening to external commercialization and to foreign investment.

-MARKET NUMBERS

As of the 31st of March of 2014, Colombia had 484 Pharmaceutical product Manufacturers with GMP certificate.(16)

In 2014, 67% of the Colombian Pharmaceutical market was owned by national companies, whereas international companies held the remaining 33%.(14) Overall, these companies amount to about 2,5% of the Colombian economy.(5)

Colombia minor sales represented 2 Billion USD in 2014, a value 4,2% superior to the one in 2013 (CAGR 2014vs2010= 7,6%) (Considering constant dollar value).(19)

-MARKET MOVEMENTS

Some multinational players have started to acquire local companies, not only due to the strong positioning and know-how some already have in the market, but also because some regulatory Framework tend to benefit local companies.(10)

Colombian market acquisitions: Genfar (local generics company) by Sanofi, raising it to market leader. Recalcine (from Chile) has bought Lefrancol (Colombian) in order to stay competitive in the Colombia market.(5)

- COLOMBIAN HEALTH SECTOR AND IT'S HEALTH SYSTEM

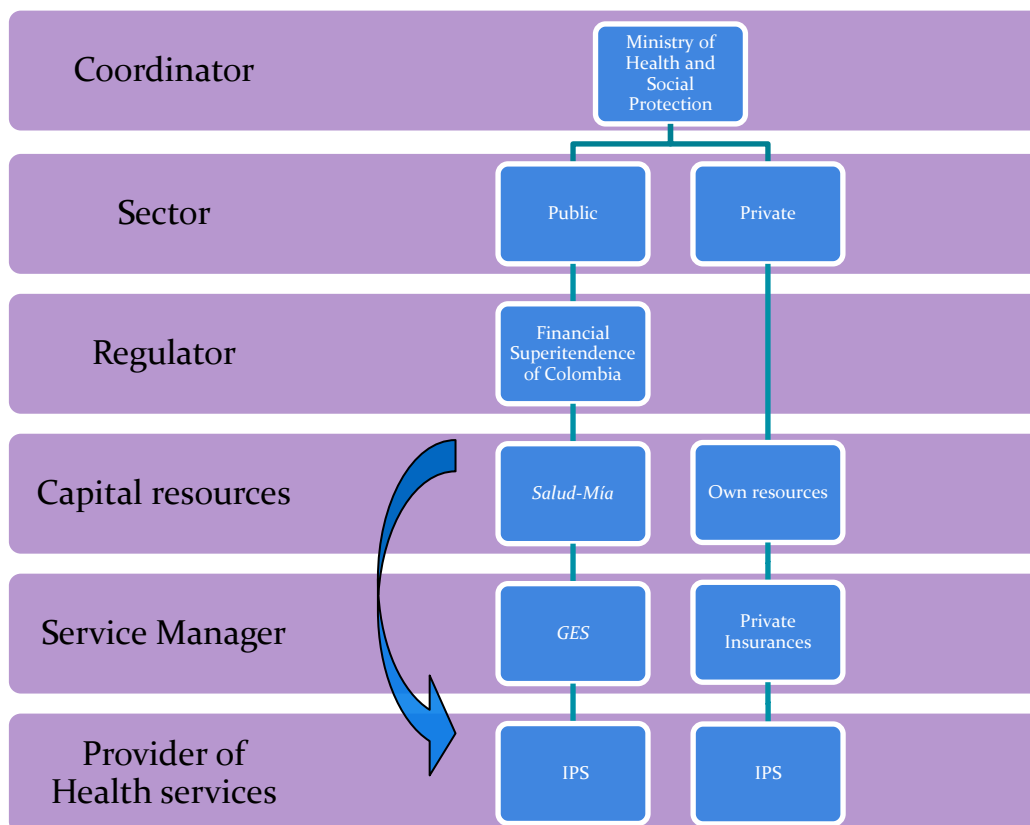


Chart 2. New Healthcare system (SGSSS): (Ley Estatutaria 20 junio 2013).(20)

Salud-Mía is a public fund that's responsible for collecting, managing and distributing public health resources. Its control and surveillance is delegated to the Financial Superintendence of Colombia.(20)

Salud-Mía is in charge of assuring that the GES bring good health results, and of paying directly to the IPS (function which was assumed by the previous EPS).(20)

Mi-Plan is a health plan that ensures a bigger coverage and overall performance than its predecessor, POS, reducing the need for the population to set in motion legal actions in order to have access to some health services. The only health services (which include medicines and treatments) that will be left out will be those who are not approved in Colombia, those whose main function is cosmetic, sumptuary or doesn't have as a goal the diagnosis or treatment of an illness, those that aren't categorized by a competent authority as a health technology or service, or those who don't have technical or scientific proof of clinical relevance.(20)

To help finance this system, and prevent a financial crisis like the one that happened in 2010 with the deregulation of the Health budget (8), the Ministry of Health and Social Protection will have a strict control over the prices of medicines and combine health technology assessment with price regulation upon the entrance of a new health technology in the market.(15)

The GES will manage the health of the affiliated citizens, but won't handle any funds themselves. Instead, they will be regulated by the health of their affiliates, and will be rewarded accordingly. Which will lead these structures to make sure people get less sick, through promotion and prevention activities, and that those that get sick get the most adequate treatment to regain their health. Each GES will have a sanitary management area, with a minimum number of affiliates that guarantees its sustainability, and may operate under the contributive system or the subsidized system, but cannot own any IPS. Its supervision is done by the Financial Superintendence of Colombia.(20)

Territorial structures are in charge for the Public Health actions while individual actions are at the responsibility of the GES (as long as they are contemplated on Mi-Plan). The network of providers is organized accordingly to the location of the user.(20)

In the contributive system of the SGSSS, Colombian citizens have access to drugs by paying a fixed fee called "*quota moderadora*". The amount of this fee is set according to the

salary of the patient, but if he or she belongs to the subsidized system, this fee isn't applied.(16)

The national regulation of medicines is the authority of INVIMA. (16) And, as far as access to these medicines goes, there are two channels from which citizens may be provided: The institutional channel, made by the affiliated of the SGSSS and funded by *Salud-Mía*, in which the use of generic medicines, when available, is mandatory; and the private channel, funded by private insurances or personal funds, and where the user can choose between branded or generic medicines.(21)

Prescription by INN is mandatory in the public sector. This aims to promote cost reduction in this sector and to strengthen the national industry.(16,21)

The population's aging aforementioned creates financial weight on the health system, therefore the Colombian government has been pressuring Pharmaceutical products prices, among other measures to retain costs.(22)

Healthcare access is improving, the percentage of the Population affiliated to the SGSSS in 2015 was 94,6% (being 94,1%, 91,3% e 90,6% in 2014, 2013 and 2012, respectively).(11-13)

- DRUG DISTRIBUTION

The distribution of Medicines follows, essentially, two pathways: the public pathway and the private pathway. In the public pathway, Pharmaceutical manufacturers supply the IPS and the pharmacies of the SGSSS, which then dispense the Medicines to patients. In the private pathway, Pharmaceutical manufacturers supply supermarkets and pharmacy chains, independent pharmacies or other small supply stores, all of which can be made, through wholesalers or by their own means.(16,21)

-REGULATORY FRAMEWORK

Colombia's regulatory framework is defined by the Decree 677 of 1995 (with some modifications since the publishing of Decree 1505 of 2014), which regulates the registration and licensing regime, as well as the sanitary surveillance regime of Medicines, Pharmaceutical Preparations derived from Natural Products, Cosmetics, among other products.(23,24)

For the products mentioned above, this decree states that their manufacturers must have a sanitary function license, which is granted by INVIMA, or an INVIMA delegated authority. This licensing is obligated to stick to the GMP. In addition, the processes of

importation, exportation, processing, storage, packing, expense and commercialization also need a sanitary license provided by the competent authority.

It divides Medicines into two categories: The ones included in the officially accepted Pharmaceutical norms and the new Medicines.

For the first category, in order to obtain the sanitary registration, a Pharmaceutical evaluation and a legal evaluation are required. In the Pharmaceutical evaluation, certain requirements are confirmed (such as record of the visit regarding the manufacturers GMP compliance) and product related aspects are evaluated (such as its composition, manufacture, stability, among several other aspects). As for the legal evaluation, it comprises the evaluation of the documents required for the product's registration with the law's standards.

The second category mentioned, the new Medicines, in addition to the two requirements stated previously, it needs a third requirement: a pharmacologic evaluation. This evaluation consists in an assessment of the product's utility, convenience and security, throughout a diverse roll of the drug's characteristics.

The Resolution number 1400 of 2001 establishes the bioavailability and bioequivalence guide from Decree 677 of 1995. However, in April 2016, a new resolution (Resolution number 1124 of 2016) was published, containing the criteria and requirements of these studies, which Medicinal products must present them and the mandatory conditions of the institutes performing them. This resolution is established on the follow-up of the *Política Farmacéutica Nacional* of 2012 which has identified some flaws in these registrations and processes.(23,25,26)

Also in April 2016, the Resolution 1160 of 2016 was published. This resolution establishes the GMP manuals and the inspections guidelines for Medicines' Manufacturer Laboratories or Establishments, in order for them to acquire the GMP certificate.(27)

-NICHE MARKETS AND OPPORTUNITIES

The Medical tourism might be an opportunity to consider in Colombia, due to the rise of this event from the USA to this country, encouraged by the quality of the health care and the low prices compared to the one that some population have access in their home Country.

Focus reports “Colombia: Confidence in Uncertainty” states that one of the most profitable Colombian health sector niches are the Medical Devices. 90% of these products are imported, however some national companies have been successful in this area, even exporting to other Countries in the region. Even though there’s a good availability of these devices, access to population is still an issue, however efforts are being made to improve this access, which can be a good indication for a potential market niche.(5)

The article “Quality by design: Principles and opportunities for the pharmaceutical industry” considers that the introduction of the quality by design model would lead the Colombian industries to the vanguard of global tendencies and would increase its competitiveness in the markets. It states that the Colombian industries’ national manufacture value is limited, and that its export rates have been stagnating due to “low innovation capacity correlated to technological problems of various kinds in the quality assurance system, development and innovation area and in the export profile of the laboratories”.(27)

-An Opportunity for the Pharmaceutical Industry

-COLOMBIA AS A GATEWAY TO THE PACIFIC ALLIANCE AND THE REST OF LATIN AMERICA

The Pacific Alliance is a trading bloc composed of four member states: Colombia, Mexico, Peru and Chile. This alliance has around 216 million people with an average GDP *per capita* of USD 9,910, according to the structure itself, and it reinforces Colombia’s commercial attractiveness due to its favourable mid-long term landscape, and because of the business opening for Mexico, Peru and Chile.(8) These countries’ middle class is also growing, a sign not to disregard by an Industry that needs a population with some purchasing power, like the Pharmaceutical Industry.(15)

Colombia is also a great gateway to the rest of Latin America and to Central America, be it by North America, Europe or Asia, with huge importation advantages by having harbours in two different oceans.(5,15) Latin America, in itself, is a major market with 530.8 million people and a GDP at market prices of 4.845 trillion dollars (Data from The World Bank). Projections declare an increase of an average of 4,6% in health care expenditure annually until 2018 in Latin America.(28) An Investor in Colombia Pharmaceutical market needs to be fully aware of the other potentialities that go beyond

Colombia itself, may it be the American continent, or any other opportunity provided by an oceans distance to Asia, Europe, Africa and Australia.

-THE INNOVATIVE COMPANIES' VISION

Clinical trials may be one of Colombia's opportunities that can't be ignored. They represent advantages to both sides of the equation. On one hand the Colombian health system gains free access to new therapies for the trial patients, and their doctors obtain experience with Good Clinical Practices.(5) On the other hand companies get big savings in personnel costs due to the region's conditions (great concentration of population in urban centres, big ethnic diversity and high patient enrolment, compliance and retention rates).(29) (28) Clinical trials require an approval by an ethic committee and an authorization by INVIMA.(16)

Member companies of PhRMA are worried with the Decree 1782 on sanitary evaluation for biologics, published on the 18th of September 2014, that establishes a abbreviated pathway for the approval of biologics, claiming that it's not contemplated in WHO's guidelines or the USA practices (unlike the Full Dossier Route or the Comparability Pathway). This organization considers these politics to be non-transparent and hurtful to innovation.(30)

In addition, the companies that make part of PhRMA have several other concerns:

They claim that the decision not to grant patents for second uses goes against the article number 27.I from WTO's TRIPS. (30) The previously mentioned article can be consulted in Annex I.

PhRMA states that Colombian authorities apply weak patent protection, and that there's not a mechanism to defend patents prior to the launch of follow-up products. PhRMA also argues that the National Development Plan, approved in May 2015, is a regression in some innovation promotion initiatives Colombia had recently implemented, focusing on the article 72 that turns price one of the factors for regulatory approval, and article 70 that establishes a role for the Ministry of Health and Social Security in the process of approval of Pharmaceutical patents (giving non-binding opinions) and may cause unjustified compulsory licensing.(30)

It is also a concern of the organization that the implementation of the reference price methodology might be used to set the same prices in the institutional and private markets. And so, they set Colombia in the Priority Watch List for the 2016 Special Report 2016.(30)

-AN OPPORTUNITY FOR GENERIC COMPANIES

The demand for generics has been on the rise in the Colombian market, for the past decade. They became an excellent tool for the government to provide an almost universal health accessing system, without exhausting all public funds. To deliver basic health care to a larger set of population has been one of the major focuses of the last Colombian health reforms. Their price control measures have ambitioned to control this expenditure, not the use of medicines.(31)

Some of the last regulations and decisions made by the Colombian government can be seen as opportunities for generic companies, like some of the ones mentioned in previous sections, or the National Pharmaceutical Policy from the 30st of August 2012. In which the government sets some goals:(32)

-“Define and lay out the regulator tools that contribute to reduce the pharmaceutical market distortions and to improve the efficiency of the financial resources of the SGSSSS, oriented by health outcomes.”

-“Trustworthy and reliable public information about access, prices, usage and quality of Medicines (...) It will be expected to make accessible to the government, technical and normative institutions and to the users timely and trustworthy information for decision making, through one unique information system”.

-“Adequacy of medicines’ supplies to the needs of national and regional health. This strategy includes activities for the encouragement of research; development and production of strategic drugs; the promotion of competition (generic) drugs and; national availability of medicines for diseases prioritized by the MSPS.”

Each one of these strategies can be used to align the company’s focuses and priorities, in order for them to meet the needs of one of the Colombia’s greatest stakeholders, the government.

Espicom Business Intelligence sets the following SWOT analysis for the generics landscape in Latin America:(31)

Strengths: Generic competition encouraged; Weak reimbursement systems;

Weaknesses: Regulatory differences; What is a 'generic?'; Non-standard bioequivalence; Local Industry protection; Acceptance of generics;

Opportunities: IP enforcement & FTAs; Improved Quality Control; Promotion of generics; Mandatory substitution;

Threats: Economies may not grow as expected; Non-equivalence & copycats.

-An Opportunity for the Young Portuguese Pharmacist

A prediction of a growing Pharmaceutical sector is logically accompanied by an expectation of a reinforcement of human resources in this area, and Pharmacists are known to be a very valuable asset in many areas of the Pharmaceutical industry, whether it's quality control, production control, medical affairs, research and development, regulatory affairs, sales, marketing or business development. Therefore, this growth creates opportunities for new professionals to strive in new markets.

Young Portuguese Pharmacists may greatly benefit from the internationalization of Pharmaceutical companies from Portugal to Colombia by fulfilling these companies' needs, which would give them a considerable amount of experience in dealing with foreign markets. This experience might prove itself a major catapult of their careers in the Pharmaceutical Industry.

The Portuguese Pharmaceutical companies and the Young Portuguese Pharmacists (as former students) may take advantage of the connections Universities in both Portugal and Colombia, through RedEmprendia. RedEmprendia is a network of Universities that promotes innovation and entrepreneurship. Currently, the Portuguese Universities in this network are the Universities of Coimbra, Lisbon and Porto. These Universities might be a useful connection to the University of Antioquia and to the National University of Colombia, due to the fact that they're also part of RedEmprendia. Through this network, internship programmes might be a good way to align the Industries' human resources needs with the Universities job offers opportunities.(33)

The Community Pharmacy sector in Colombia also seems to have some needs to be fulfilled. The National Pharmaceutical Policy from the 30st of August 2012 argues that there is an insufficient qualification of the personnel in Colombian pharmacies and drugstores. (31) In

2005, a study predicted that 67% of the drug dispenser personnel in pharmacies and drugstores in Bogotá didn't have technical or professional education, and that the act of dispense was ill performed in more than 55% of all cases.(34)

In 2012, the ratio Pharmacist per 100.000 habitants was 10,4, a very low number when compared to Portugal 146,2. (7,35)

Although there's a young, well educated work force, Colombia's lacking in scientifically trained professionals. This lack of scientifically trained human resources might be an obstacle in the entrance of some Businesses in Colombia. On the other hand it might just be an opportunity for Professionals from other Countries to fill in these gaps and bring foreign knowledge into a Country whose Government is making strong efforts to stimulate and incentive science, but still admits that innovation isn't in the Colombian genes.(15)

Conclusion

In my opinion, based on all the evidence and data researched aforementioned, Colombia is a vast market with a lot of potentialities for the Pharmaceutical Industries to avail. The economic growth, combined with the rising healthcare access, overall improvement of the population's conditions, and an opening for investment are a sign of vitality and future of the Colombian Pharmaceutical market.

This market has been following up on the overall development of Colombia, with predicaments of a steady increase over the next years. This stable situation is ideal for companies planning to have a long-term investment, especially in the Pharmaceutical Industry. The regulatory landscape and the structure of its health system are favourable for companies that can bring both investment and savings to the government, such as generic companies. The favourability of these companies by the local government is, sometimes, a concern for major multinational companies, which state that such decisions hold back innovation and delay the entrance of new health products.

By having such opportunities and market niches to explore, Colombia presents itself as an interesting case for Pharmaceutical Industries and Young Pharmacists to explore, beneficiating all parties by being a part of the development of the market.

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Annex I

Article 27 from TRIPS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.