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Pharmaceutical market in emerging countries in 2014-2019

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Table of acronyms used in the paper

ACRONYM	FULL TEXT
Anti-TNF	Anti-tumor necrosis factor
APIs	Active Pharmaceutical Ingredients
BPH	Benign Prostatic Hyperplasia
BRICS	Brazil, Russia, India, China, South Africa
BSE	Bovine Spongiform Encephalopathy
CAGR	Compounded Annual Growth Rate
CNS	Central Nervous System
COPD	Chronic Obstructive Pulmonary Disease
CVD	Cardio-Vascular Disease
DALY	Disability-Adjusted Life Year
FDA	Food and Drug Administration
GSK	GlaxoSmithKline
IHD	Ischemic Hearth Disease
KOL	Key Opinion Leader
LRI	Lower Respiratory Infection
M&A	Merger&Acquisition
MDGs	Millennium Development Goals
MNC	Multinational Company
NCD	Non Communicable Disease
NCE	New Chemical Entity
NGO	Non-Governmental Organization
NME	New Molecular Entity
NOB	Non-Original Biologic
OECD	Organization for Economic Cooperation and Development
PPP	Purchasing Power Parity
PWC	PriceWaterhouseCoopers
R+D	Research and Development
SMEs	Small and Medium Enterprises
SWOT	Strengths – weaknesses – opportunities - threats
TB	Tuberculosis
TRIPS	The Agreement on Trade Related Aspects of Intellectual Property Rights
VRIO	Value – Rarity – Imitability - Organization
WHO	World Health Organization
WTO	World Trade Organization

1. Introduction

Medicine is for people, not for profits, said George Merck, boss of the Merck Company, a huge American pharmaceutical firm. His face and the, now famous, phrase were captured by the *Time* magazine in 1952. As he admitted in an article published by the same magazine, the choice was false. More or less around that time, after the World War II, big pharmaceutical companies began a golden age in drug development, manufacturing vaccines, antibiotics and other treatments aiming to improve people's lives.

This golden age still continues for the Big Pharma. A monopolistic position, medical innovation, patent protection, and an increasing number of patients worldwide allow the pharma companies to make billions of USD every year. Nobody will be so innocent to say that they do it for people! They do it for money.

In the face of crisis, few industries are profitable and well-functioning, but there are some that still keep on generating benefits and offering work places. The pharmaceutical industry is one of the most profitable sectors on our globe, among construction of railways, automotive industry, IT services and electronic devices, financial data services and oil and gas extraction[1]. Total global spending on medicines will exceed one trillion USD in 2014 and reach almost $1.2 trillion in 2017. By 2017, the global spending on medicines will have almost doubled the spending in 2007[2]. Contrary to industries that are based on natural resources, such as the petrochemicals, the pharmaceutical companies have a bright future: due to the increasing global population and unhealthy environments we live in, the number of patients is continuously increasing.

In the present dissertation, we will describe the pharmaceutical market and try to answer the question What are going to be the tendencies in diseases, production of drugs and spending on medicines over the next 5 years? in order to define opportunities for national and local pharmaceutical companies in emerging countries, opposed to multinational companies in developed nations.

[1] Willron (2013).
[2] Rickwood et al. (2013).

The methodology applied in this paper is an empirical study based on available reports and statistics published by important institutions and consulting firms, such as the World Health Organization, World Bank, Organization for Economic Cooperation and Development, PriceWaterhouseCoopers and IMS Institute for Healthcare Informatics. After presenting a summarized information extracted from their studies, we develop our own model and draw conclusions.

Due to the geographic segmentation of producers, the pharmaceutical market is highly monopolized with few possibilities to reach the leader position by emerging economies. The laws on patents and high requirements on quality (ISO certifications and WHO standards) increase these difficulties. Patents and the monopolistic position makes this industry highly profitable for the top ten players in developed countries. However, with the expiration of patents for some important drugs, a new market has emerged for national and local companies in developing nations. They can provide generics to emerging and African countries, number one buyer of these medicines. Through governmental tenders and international NGOs, *pharmerging* countries and African nations buy between 70-95% of generics.

The increasing importance of *pharmerging* countries has several reasons: the growing number of population assures more patients, cheap labor used in contractual agreements with MNCs from developed economies makes them competitive, and an increasing number of national pharmaceutical firms provides profits. Africa, in change, is a hedge against a possible slowdown in *pharmerging* and developed economies. Although it is a high risk market, it presents very good opportunities to invest in the future.

In reference to diseases, there is a shift in the number of patients from infectious diseases to chronic non-communicable diseases, due to better medical facilities worldwide, trained professionals and higher standards, as well as actions undertaken by the WHO, such as the Millennium Development Goals and the universal health coverage. However, these tendencies in diseases might be altered by demographic, migratory, legal, political, corporate, and climate changes, for instance: growing global population, high migration to cities, new laws on patents for drugs, political situation in unstable regions, incentives for creating national companies in *pharmerging* countries, and global warming.

It is important to underline that our goal was to show differences in consumption of medicines during a period of 5 years (2014-2019); nevertheless, we have not noticed big

modifications. It is because at least two to three decades are necessary to make this market alter.

The first part of this paper consists of a conceptual description of the industry, taking into account four main elements: the producers, products, demand and buyers. It is supposed to help the reader better understand the functioning of the pharmaceutical market and familiarize him/her with some medical terms. In Section 3, we present our empirical study, supported by medical reports and statistics. After the reader is acquainted with the drugs market, we introduce him into the current situation of this sector, the world of most widespread diseases currently, Indian national companies outsourced by big Western MNCs, top treatments and governmental spending on drugs. In Section 4, we develop interferences from the empirical study and present the most viable options in production of drugs for national and local companies, and tendencies in purchases of public and private agents. We finish with the theory of Mike W. Peng explaining why Africa fails to establish MNCs and is in the last place in medical innovation.

The basic ideas and results of this research can be useful for all pharmaceutical companies, especially national companies in *pharmerging* countries and local companies on the African continent, when deciding about the portfolio of products and preparing strategies for the future.

2. Conceptual description of the pharmaceutical industry

In order to understand better the pharmaceutical industry, we will start with a tabular explication of its functioning followed by detailed definitions.

Table 1: Conceptual segmentation of the pharmaceutical industry

1. Supply: Producers	MNCs	Developed countries
	National companies	*Pharmerging* countries
	Local SMEs	Africa
2. Product: Drugs	Patent	Yes (Branded product)
		NO (Generics)
	APIs	NCEs and NMEs
		Biopharmaceuticals
3. Demand: Diseases	NCDs	Chronic diseases
		Occasional ailments
	Communicable diseases	
4. Buyers: who pays?	Patients	Private clinics
		Medical insurance
	Governments and institutions	Social Security, National Health Systems
		WHO, UN

Source: Author's elaboration

As we can see in Table 1, the pharmaceutical industry can be described by four main elements: supply, product, demand and buyers. Each of these will describe the corresponding area or agent in the pharma industry. And so, supply refers to the producers distributed geographically: MNCs are located in advanced countries, national companies represent *pharmerging* countries and local SMEs are prevalent on the African continent. Secondly, the products are drugs segmented by two factors: the patent protection and the APIs. Medicines that are protected by a patent are branded pharmaceuticals; however, if the patent expires, the drug is a generic. Thirdly, medicines may contain chemical or biological active ingredients: if they are chemical, they will go under the NCEs or NMEs; in the contrary case, if the APIs are from biological origin, they are called biopharmaceuticals. Fourthly, diseases are divided in two main groups: NCDs and communicable diseases. We will focus on the subgroups of NCDs, which are chronic diseases and occasional ailments, and the communicable diseases in general. Lastly, there are two groups of buyers: private and public agents. Private agents are patients that pay

themselves through private clinics or medical insurance. Public agents refer to governments and international institutions that provide patients with medicines.

2.1 Supply: Producers

The pharmaceutical market is organized by the producer, not the product, as in the majority of cases. In industries such as agriculture, fashion or entertainment, the place where the product is manufactured is the decisive factor. However, the pharmaceutical industry, the same as the industry of luxurious items, is distributed geographically according to the producer. And so, MNCs are in developed countries, the national companies are prevalent in emerging countries, and local companies (SMEs) are the biggest group in Africa. We can think of several reasons for this occurrence: developed nations require quality certifications, a lot of investment and legal procedures to start a pharma business. Four or five decades ago, it was only possible in, what we call today, developed countries. So, the big multinationals have started years ago to establish the position where they are now.

Developed countries such as US, Japan, Germany, France, Italy, Spain, and UK are countries that spend most on medicines and health systems in general[3]. Some of these countries experience, at the moment, austerity measures and do not grow as fast as in the past, as well as spend relatively less money on their health system (apart from switching to generics which automatically result in smaller quantities spent on governmental tenders), although there is still a positive increase in the general spending compared to the past. The top 10 pharma companies originate in the developed countries: Pfizer (US), GlaxoSmithKline (UK), Novartis (Switzerland), Sanofi-Aventis (France), AstraZeneca (UK), Hoffmann – La Roche (US), Johnson&Johnson (US), Merck&Co. (US), Abbott (US), Eli Lilly&Co. (US) (positions may change due to annual profits fluctuations). In the course of this paper, we will refer to several of them.

The MNCs will not be our main focus throughout the paper as we guess that their own strategic departments have developed projections for the near future and are aware of all the risk factors that are going to be exposed in our research.

[3] The numerical spending is described deeply in Section 3.

Currently, emerging countries have a lot of financial power and cheap labor, and thus are playing an important role in the global trade as exporters. In reference to the pharmaceutical industry, the so called *pharmerging* countries are developing economies whose annual GDP per capita is less than $25,000: India, Brazil, Turkey, Mexico, Russia, Indonesia, and China[4]. Their national companies specialize in the production of pharmaceuticals and many times are outsourced by the MNCs mentioned above. These countries are expected to carry industry growth and contribute mightily to profitability for the next decade[5].

Finally, the African local SMEs represent 99.5% of all firms established on the continent[6]. The African regions suffer from a set of factors that inhibits the permanent installation of big national companies (factors such as bureaucracy, corruption, unstable political systems, weakly developed business environment, lack of crucial infrastructure, etc.) and the only viable business model as for now is a local firm. Due to complex entry regulations in some countries and laws impeding the entrance of foreign companies in others, many MNCs have established branches on the African continent, invested in local companies (FDI) or joined the market through M&As and joint-ventures. This is the case of Aspen and Cipla Medpro, companies funded from such an acquisition, two of the three largest pharmaceutical companies in Africa right now.

2.2 Product: Drugs

We are going to present two basic classifications of drugs that are relevant for our paper: according to the patent protection and the APIs. We will contemplate branded drugs (which are protected by a 20 years patent) vs. generics (the patent is expired, any company can produce this drug) and NCEs/NMEs vs. biopharmaceuticals. The main difference between the last two is the active pharmaceutical ingredient: in the first ones, it is a chemical particle, and in the biopharmaceuticals, it is taken from the nature.

Patents in most countries last for 20 years (under the international law of Intellectual Property, TRIPS by WTO). After the expiration of a patent, the protection is removed and

[4] PWC (2007).
[5] The growth of *pharmerging* countries is described deeply in Section 3.
[6] Fjose et al. (2010), p. 5.

any pharmaceutical company can produce the medicine in question, under another name. A drug produced in such process is a generic and usually called after the most relevant API or the disease it pretends to cure. For example, the generic drug Ibuprofen, produced in Spain by pharmaceutical companies KERN Pharma or Actavis Spain, can be also bought in the pharmacies as branded product under the name of *Ibupirac*® produced by Chemopharma. Its API is ibuprofen, the same as in the generic drug, but the name and the producer change, as well as does the price.

Branded products are always more expensive than generics (7 to 10 times more expensive). It is because the companies having a patent are monopolies or oligopolies producing this drug and can set any price they want. Big pharma companies face now a strong competition given that many patents for their products have expired[7] and it makes them erode most of the monopolistic income when enjoying this protection. Producers of generics have a lot of room to play because the margin of the branded products was set very high. To avoid this competition, pharmaceutical companies have developed different strategies to continue selling their products, for example establishing a KOL at hospitals and clinics who are in charge of recommending this company's products to managers and physicians or advising the direction to vote for this brand in a tender. More strategies on how to maintain the leader position in a market or prolong the duration of a patent are explained in Section 3.

When speaking about patents, we have to mention the compulsory licensing: sometimes, in serious situations of national range (such as the avian flu virus or another pandemic, bovine spongiform encephalopathy (BSE), commonly known as mad cow disease, or the African swine fever), pharmaceutical companies are forced to issue a license to domestic firms in order to produce as much vaccines as possible. This type of licensing is allowed by TRIPS. Of course, the mother company will be paid for it, but the money paid by the government is usually less and late. Also, the formula for the medicine is revealed, causing even more harm. An example for an external event that may alternate a company's profits and strategy plans is the case of Roche's Tamiflu vaccine and the avian flu in Taiwan in 2005[8].

[7] Names and numerical examples given in Section 3.
[8] Schmit (2005).

Out of the different types of medicines, we are going to focus on the chemically synthetized, so called New Chemical Entities or New Molecular Entities, and biopharmaceuticals, which include biosimilars and non-original biologics (NOBs). A biopharmaceutical, also known as a biologic medical product or, more simply, as a biologic or biological, is any medicinal product manufactured in or extracted from biological sources. Biopharmaceuticals are distinct from chemically synthesized pharmaceutical products. Examples of biopharmaceuticals include vaccines, blood or blood components, allergenics, somatic cells, gene therapies, tissues, recombinant therapeutic protein and living cells[9]. The biopharmaceuticals are relatively new and researches and clinical trials are still hold.

Now, an interference between both classifications is possible: a branded product can be a NME or a biopharmaceutical, the same as a generic. However, we will exclude from our paper the biopharmaceutical generics since, until the present moment, no research or production have been undertaken in this direction due to a very basic reason: profitability. Generics are supposed to be the cheapest option available on the market, whereas biopharmaceuticals are an innovative product of the future, and still require a lot of investment in clinical researches. Obviously, an expensive innovative branded drug cannot end up as a cheap generic very quickly.

2.3 Demand: Diseases

In this paragraph, we are going to suggest a very simple classification of diseases. It is not supposed to be very detailed nor taken from the medical point of view; our goal is to make a difference for sometimes ambiguous cases and help readers that are not familiar with medical terms to better understand the characteristics of diseases. It is also designed to demonstrate diseases which treatments provide the highest profits for the pharmaceutical companies.

The non-communicable diseases are not transferable from one person to another and originate in the proper body of the patient, not in an infection or the intake of a medicine. It is mainly caused by environmental conditions, such as living in an asbestos

[9] American Medical Association complete medical encyclopedia (2003), p. 203.

construction, or a long-term intake of harmful substances, for example tobacco. The 4 main non-communicable chronic diseases are: cancers, CVDs, respiratory diseases and diabetes. Chronic means that they last for a long period of time. There are also short-term or occasional ailments inside the same group of NDCs, such as fever, cough or pain, for example headache.

The communicable diseases we will contemplate are HIV/AIDS, malaria, TB and hepatitis B and C. Some studies consider them as chronic communicable diseases[10], although for our purposes we will not distinguish between chronic and non-chronic communicable diseases.

We will not consider in our dissertation plastic surgery (it is not a disease), although it represents a very profitable sector, nor road injuries (the same, it causes deaths, but is not a disease), nor dental care. Some cancers that occur in the buccal area are reflected in our study; the same applies to teeth pain, which would go under the area of pain in general. However, small surgeries such as implants, or ailments (caries, mouth sores, root canal cleaning or infections) are not of our interest as it is more of esthetic medicine or comfort than real threat for the patient's life.

The last term to introduce in this part is the concept of orphan diseases. These are diseases that have not been adopted by the pharmaceutical industry because they provide little financial incentive for the private sector to make and market new medications to treat or prevent them. An orphan disease may be a rare disease (according to US criteria, a disease that affects fewer than 200,000 people) or a common disease that has been ignored (such as tuberculosis, cholera, typhoid, and malaria) because it is far more prevalent in developing countries than in the developed world. We will refer to orphan diseases in Section 3.

[10] Farmer (2013).

2.4 Buyers: Who pays?

This part has two main agents: the governments, international institutions, private clinics and medical insurance agencies. In the first case, the governments in different countries and global institutions are who pays the medicines, staff and facilities to administrate drugs. In the second case, it is the patients who pay for medicines through medical insurance or private clinics.

Governments can administrate drugs through two main channels: Social Security or National Health Systems. Usually, the National Health Systems, which is public, is a part of the Social Security. However, there are countries, such as US, that do not have national health systems or are in transition to create one. In this case, the Social Security can refund some medical treatments that a patient had undergone, when presenting bills.

International organizations, for instance the United Nations, WHO, Red Cross, and the NGO *Médecins sans frontières*, are mainly present in poor countries administrating drugs and providing basic health care. In order to assure a universal health coverage to all the populations in the world, the WHO has initiated the Millennium Development Goals. It is an agreement between all the world's countries and all the world's leading development institutions in order to meet the needs of the world's poorest. We will go into details of this agreement in Section 3.

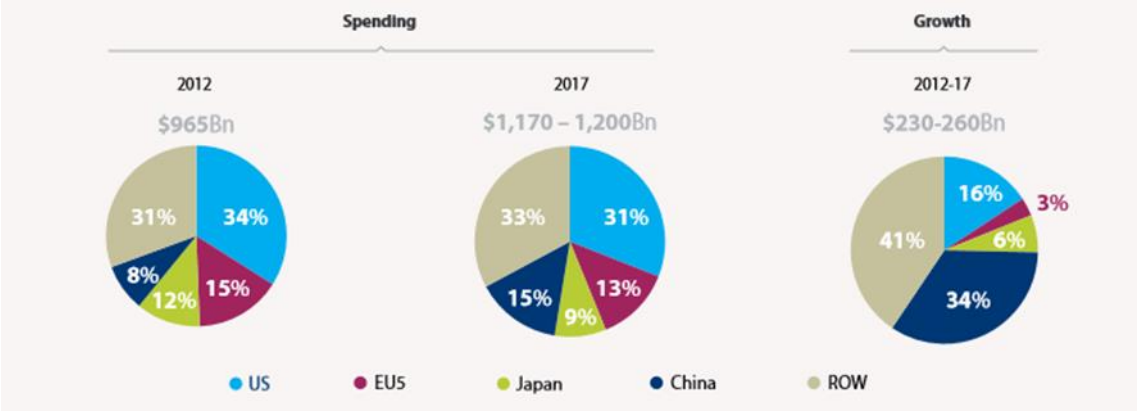
3. Empirical description

Once the readers are familiar with the functioning of the pharmaceutical industry and the medical terms referring to diseases and pharmaceuticals, we can move to the empirical description. We will maintain the same structure as above, speaking about the four main elements of the pharmaceutical industry, but giving data and numbers.

3.1 Supply: Producers

Previously, we said that the pharmaceutical market is a geographically distributed market. In Figure 1, we can see the geographical distribution of global spending on medicines, which confirms our theory of the market distribution according to producers:

Figure 1: Geographic distribution of medicine spending (USD billion)



Source: Rickwood et al. (2013)

Developed countries spend most on medicines: US, Japan, Germany, France, Italy, Spain, and UK are countries that account for 61% of global spending in 2012. They are expected to be responsible for 53% of global contribution in 2017.

Pharmerging countries, such as China and India, contribute a substantial part. Since their GDP is rising towards Western levels, there will be more and more consumers from emerging economies. In India, for example, the population grows over the years, and so does the GDP and, respectively, the GNI per capita (Table 2).

However wildly they differ from one another in culture or politics, the seven pharmerging markets (India, Brazil, Turkey, Mexico, Russia, Indonesia, and China) have in common more than just their above average growth in the pharma sector. They also share disease profiles that are markedly different from that of the major pharma markets (read: high income countries). Their GDP is expanding, along with public health programs and access to medicines for their populations. And the main focus of each market is on traditional areas and generics. Only the emerging economies account for 3.5 billion people, or almost 50 percent of the planet. While much is made of their exploding middle-class population—and its potential buying power—in fact less than one tenth of these 3 billion can afford Western medicine. Still, that adds up to 300 million— a population close to that of the United States.

Table 2: GNI per capita, GDP (USD), population and life expectancy (years) at birth growth in India

	2008	***2009***	***2010***	***2011***	***2012***
GNI per capita, PPP (current international $)	3,800	4,100	4,500	4,840	5,080
Population (Total)	1,174,662,334	1,190,138,069	1,205,624,648	1,221,156,319	1,236,686,732
GDP (current US$)	1,224,095,295,162	1,365,372,433,342	1,708,450,861,364	1,880096,894,406	1,858,740,105,864
GDP growth (annual %)	4	8	10	7	5
Life expectancy at birth, total (years)	65	65	66	66	66

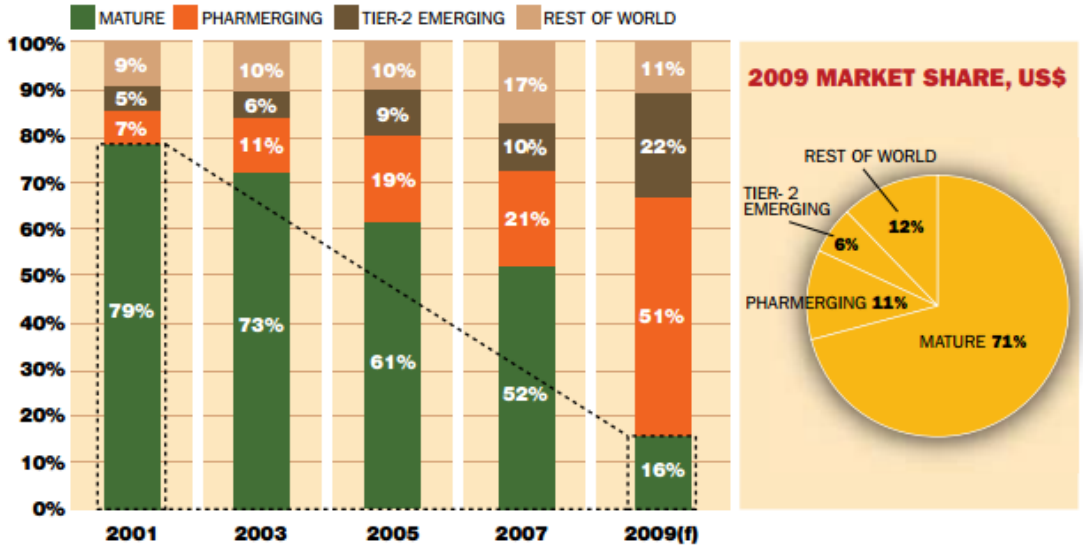
Source: World Development Indicators

In fact, the first projections for the *pharmerging* countries were that they would contribute three quarters of global growth in 2009 (mainly production, Figure 2) and could account for as much as one-fifth of global sales by 2020 (PWC, 2007, p. 5).

We should not forget about the growing upper class in the emerging countries whose PPP is as high as a middle class citizen in developed economies (US, Canada, EU) or even higher. Law and Bhattacharya (2011, p. 3) demonstrate that this class represents the same patterns for spending as the Western upper-middle class and upper class and follows the

same model when treating diseases as the developed markets: seeks private insurance, buys branded products, travels abroad for consultations or to treat chronic diseases and undergo operations, invests a lot of money in private clinics, best facilities and brings home professionals of international fame.

Figure 2: The growth gap. Pharmerging and tier-2 emerging markets will contribute three quarters of global growth in 2009



Source: Hill (2009)

In reference to the last producer, Africa is a place where one can replicate the low-cost, high-efficiency business model countries such as India (to say one of the *pharmerging* countries) have honed at home some 15 years ago. In fact, Africa has many similarities with India or China: it has hundreds of millions of underserved consumers eager to buy products tailored to their needs. Consumer spending in Africa may double, to as much as $1.8 trillion by 2020. It is not any more *the* poor continent with an exponentially growing population. It is acquiring purchasing power, mobile subscriptions and working-age men and women. However, as for now, it is still coping with come important hurdles: the very time-consuming bureaucracy (registering, pricing, distributing the product) and lack in information on medicine consumption, in addition to corruption, unstable political systems, weakly developed business environment, and lack of crucial infrastructure are some of the troubles the continent is coping with.

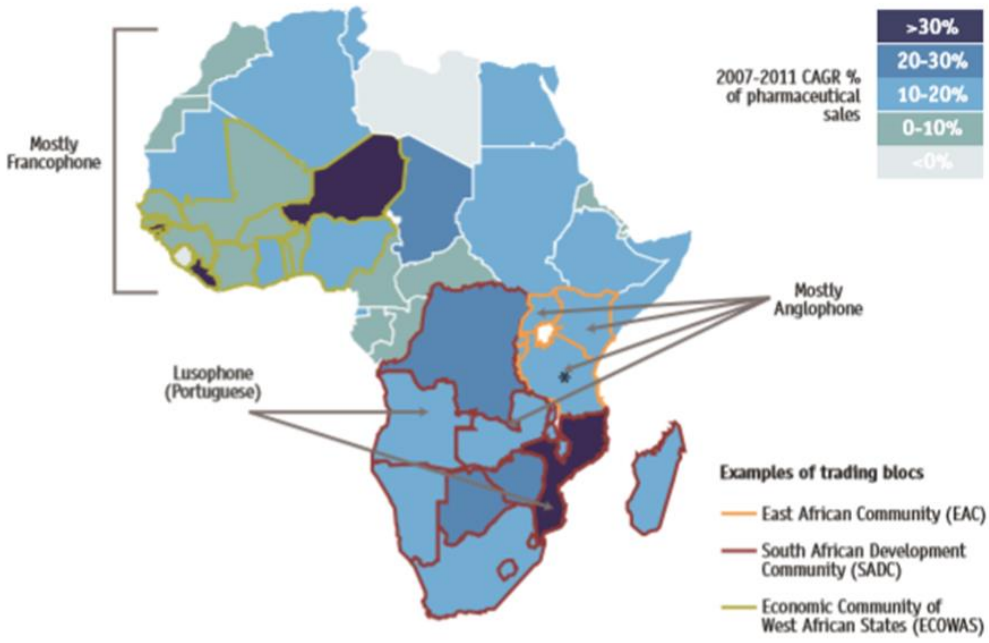
Speaking about Africa, we have to underline that this market is the center of interest of many countries and companies. The appeal of Africa does not lie in its size – the continent accounts for just 3% of the global economy – but in the dynamics that drive sustainable

growth at a time when the major established pharmaceutical markets face a more uncertain future due to financial crisis or patent expirations. Africa is a hedge against a possible slowdown in *pharmerging* countries and developed economies which are now in plain growth. If some day these economies take a U-turn, then at least there are other markets which are growing. The growing middle class on the African continent is going to be the main consumer in few years which, at the same, will expand the demand for medicine consumption.

Of course, not all the African countries have the same rate of growth and are equal in terms of pharmaceutical growth. The main players, based on their spending on pharmaceuticals, are southern and eastern states: South Africa, members of the South African Development Community (SADC), East African Community (Tanzania, Uganda and Kenia) and Eastern states, such as Egypt, Sudan, Ethiopia and Somalia, among others. It is visible in Figure 3.

As we can see, Africa is not only different in terms of pharmaceutical growth. It is highly heterogeneous in terms of language and trading blocks. On one side, this variability offers quite a lot opportunities. On the other hand, one cannot apply the same models as in the developed or emerging countries to make profits. Understanding the differences is clue to success.

Figure 3: Spending on pharmaceuticals in 2007-2011 on the African continent (percentage)



Source: Logendra et al. (2012)

3.2 Medical spending per capita and global launches of drugs

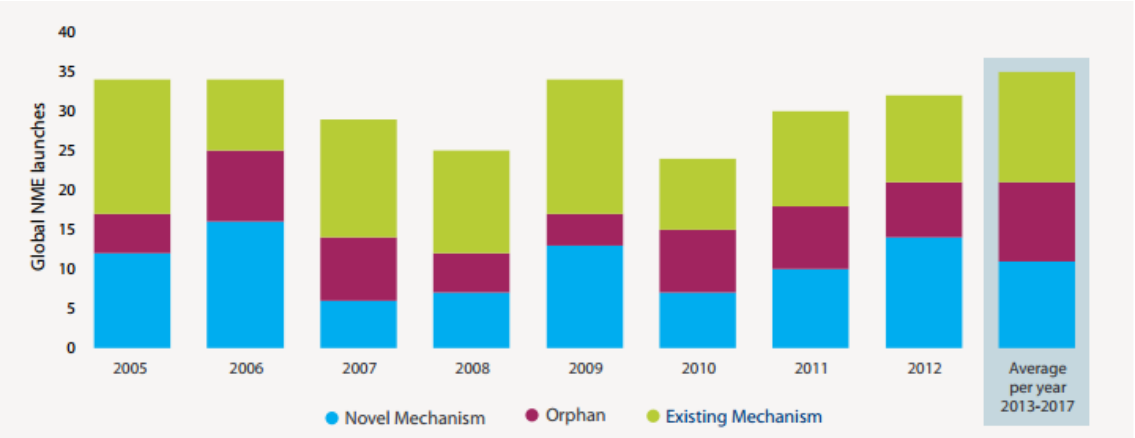
There exist two more factors that correlate with the geographical distribution according to the producer: the annual spending on medicine per capita and the number of medicines launched in the markets.

Medicine spending per capita and growth rates are different in high income and low income countries. We can demonstrate it in a very simple calculus that it is true: the population of the developed economies together is smaller than the population of one *pharmerging* country: Europe, US, Japan and South Korea account together for 1,237,148,868 people while China has 1,390,510,630 inhabitants[11]. Now, the first group spends more money that the second, we have seen it above in Figure 1, so that the comparison is very obvious. Developed nations spend more money per capita on medicine than emerging countries.

Rickwood et al. (2013, p. 6) shows the same: whereas in countries with a GNI of $25,000 or more per capita (advanced countries) the average spending on medicines is of $400-$1,000, in countries with an annual income below $25,000 (emerging countries), the spending lies in the interval of $10-$300.

Another factor that correlates with the geographical distribution of the pharmaceutical market is the number of medicines being launched in developed and emerging countries.

Figure 4: Global Launches of NMEs in 2005-2012



Source: Rickwood et al. (2013)

[11] World Population Statistics (2014).

In Figure 4, we can see that novel mechanisms and existing mechanisms are drugs that are being commercialized most. They refer to innovative medicines (novelty mechanisms), mostly sold in developed countries, and existing drugs, sold in both: developed and emerging countries. Orphan diseases, typical for the African continent, are the smallest group of interest. This figure demonstrates that majority of drugs is being produced for developed countries, followed by emerging economies, and, at the very end, African countries.

Unsurprisingly, pharma companies tend to focus on treating ailments which affect developed, wealthy nations, and not the afflictions of those countries with less money. As such, it is often the case that highly treatable, yet serious diseases, are left unstudied, because there is little profit to be made from the communities in which these diseases are most prevalent. Table 3 shows that drugs to prevent or help patients in high income countries are being launched and R+D studies to increase their effectiveness are being held (on average, 63 drugs in the late-stage R+D pipeline and 48 new drug launches). Many common diseases in emerging markets, such as malaria, neonatal sepsis and diarrhea, have been paid less attention: there are fewer products in the pipeline (26 on average) and fewer launches (11 on average) (Table 3, Rickwood et al. (2013)).

Table 3: Disability-adjusted life year percentage in high income countries and globally, R+D pipeline, new launches

High Income Countries	
Disease	DALYs %
IHD	8.2
Stroke	4.7
Depression	4.3
Lung Cancer	3.5
COPD	3.2
Musculoskeletal	3.1
Diabetes	2.8
Alzheimer's	2.3
Anxiety	1.9
Colorectal	1.8
Alcohol	1.8
LRI	1.7
Breast Cancer	1.4
Osteoarthritis	1.3
Other Circulatory	1.3
Migraine	1.3
Asthma	1.2
Other Neoplasm	1.1
BPH	1.0
Stomach Cancer	1.0

Global			
Disease	DALYs %	Pipeline	Launches
IHD	5.2	183	191
LRI	4.6	53	73
Stroke	4.2	41	45
Malaria	3.3	17	6
COPD	3.1	48	24
Depression	3.1	44	58
Other HIV	2.7	45	33
Tuberculosis	2.0	53	5
Diabetes	1.9	120	89
Neonatal Sepsis	1.8	4	0
Diarrhea	1.6	6	6
Lung Cancer	1.3	141	18
Musculoskeletal	1.2	7	6
Anxiety	1.1	11	11
Alcohol Abuse	1.1	25	9
Meningitis	1.0	12	21
Asthma	0.9	67	29
Migraine	0.9	21	19
Liver Cancer	0.8	53	4
Other Neurological	0.7	14	9

Commonality of interest

The concept of disability-adjusted life year in Table 3 measures the overall disease burden, expressed as the number of years lost due to ill-health, disability or early death[12]. For example, 4.7 years are lost in high income countries due to strokes. It means that a person that suffered from a stroke and died, could have lived 4.7 years longer if he/she didn´t have it.

3.3 Product: Drugs

In the previous section, we have classified the medicines according to the patent protection and the APIs. A pharmaceutical enjoying a patent protection is a branded product, whereas when this patent expires and any company can manufacture the drug, it becomes a generic. We provide some numerical data for brands and generics.

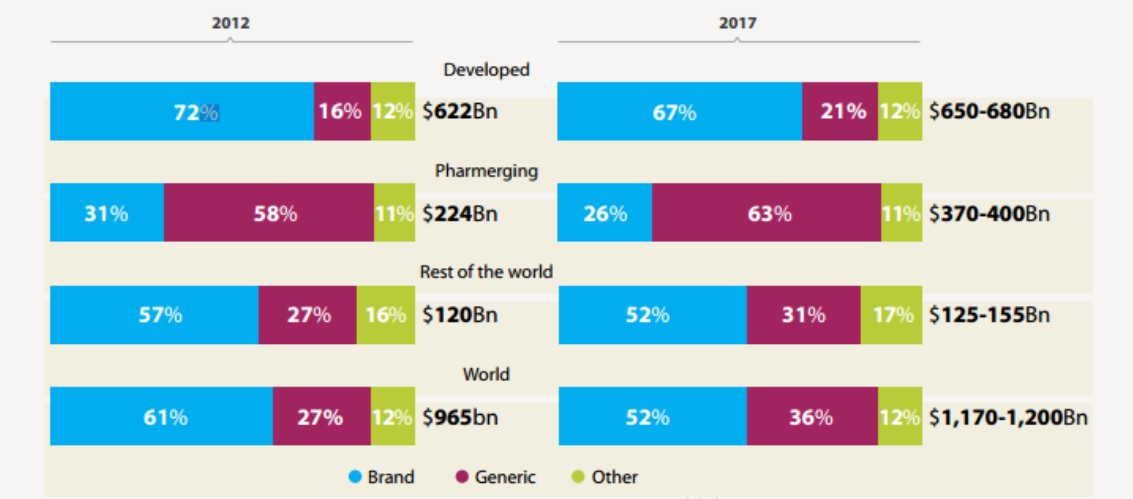
The global predictions for generics are very positive: The mix of total global spending on medicines will shift toward generics over the next five years, rising from 27% to 36% of the total by 2017, even as brands will continue to account for more than two thirds of spending in developed markets. The estimation of Rickwood et al. (2013, p.23) is that generics will gain importance and increase the market share in favor of the branded pharmaceuticals: those whose patents have expired and which have been present in the markets for a long time. Innovative and specialty treatments and biopharmaceuticals will continue being sold, most probably as branded products. Figure 5 represents this situation.

On the other side, the use of generics will be at its highest point in *pharmerging* markets where 63% of the spending on medicines will go to generic products. The most probable answer to this phenomenon is the price of the product: emerging economies are unstable organisms which do not dispose of a big budget for social issues. This is why the governments cannot spend huge amounts of money on drugs and prefer buying cheaper medicines in tenders, the same as international institutions that go for quantity and not quality, believing that generics are safe and effective. Also, the emerging markets are still behind developed economies as for innovation in medicine and, in face of growing number of patients, opt for using traditional solutions.

[12] American Medical Association complete medical encyclopedia (2003), p. 475.

On the opposite site from generics, there are the patented drugs. Some popular drugs, such as Lipitor and Viagra, lost patent protection in 2011 and 2012, making Pfizer losing a lot of money. Other drugs whose patents are going off in 2013-2016 are listed in Stone (2013).

Figure 5: Global Spending in Drugs: Brand, Generic, Other in 2012-2017 (USD billion)



Source: Rickwood et al. (2013)

The leading pharmaceutical companies will lose between 14% and 41% of their existing revenues as a result of patent expiries, according to PWC (2007). More numbers are available in Table 4.

Table 4: Losses of big pharmaceutical companies due to patent expirations in 2010-2012 (USD billion)

Company	2010		2011		2012		Share of Revenues (%)
AstraZeneca	Arimidex	($2.2bn)*	Seroquel	($4.7bn)	Symbicort	($3.7bn)	38**
BMS			US Plavix Avapro	($4.8bn) ($1.3bn)	Abilify	($2.1bn)	30
GSK	Advair	($3.8bn)			Avandia	($2.5bn)	23
Eli Lilly			Zyprexa	($4.8bn)			22
Merck	Cozaar/ Hyzaar	($3.2bn)			Singulair	($4.5bn)	22
Novartis	Femara	($1.1bn)			Diovan	($6.0bn)	14
Pfizer	Aricept	($800m)	Lipitor Xalatan	($12.1bn) ($1.6bn)	Viagra Detrol Geodon	($1.7bn) ($860m) ($1.1bn)	41
sanofi-aventis	Taxotere	($2bn)	US Plavix Avapro	($3.8bn) ($2.1bn)	Lovenox	($3.1bn)	34

Source: PWC (2007)

As anticipated in Section 2, big companies undertake actions to prolong the life of a patent or maintain the same sales volume. There are administrative and marketing actions to achieve this goal, apart from some illegal activities. We will describe all of them.

A very efficient way to postpone the entrance to the market of generic medicines is to apply to the administration for an additional period of protection, mostly 5 years, due to the delays caused during the registration process of a patent and approvals for the commercialization of a specific product. This approval is present in many FTAs between the US and South American countries such as Colombia, Panama and Peru.

For an illegal action to protect the patent accounts the agreement to pay a generic competitor certain amount of money to hold its competing product off the market for an agreed period of time. These so-called "pay-for-delay" contracts have arisen as part of patent litigation settlement agreements between brand-name and generic pharmaceutical companies. However, consumers lose: they keep on paying the higher price for a branded product, in many cases 7 to 10 times more as for a generic drug.

The most numerous group of actions undertaken by companies to prevent a decrease in sales is the marketing group. Firstly, firms create a premium price based on the brand's prestige. Big companies are aware of the fact that the majority of patients doesn't know the market and the different prices or even that a generic has been commercialized for the same drug they're using. They take advantage of this fact and reinforce publicity and marketing actions for their brands. Secondly, pharmaceutical companies undertake advertising campaigns designed to demonstrate that imitations do not have the same quality of the original product, which technically is attributed to differences in bioequivalence and relevant drug absorption.

Also, we have to consider the consumer's perception. Sometimes he/she prefers to stick to one brand medicine due to brand loyalty or habits. Philip Kotler in his big work Marketing Management defines loyalty as:

A deeply held commitment to rebuy or repatronize a preferred product or service in the future despite situational influences and marketing efforts having the potential to cause switching behavior[13].

[13] Kotler (2009), p. 163.

There are several actions a company can undertake to retain the customer, particularly promising to deliver benefits in form of value, effectiveness and safety (for pharmaceuticals). In case of other products, it could be social benefits or a very reliable, 24/7 service. The goal of the firms, in reference to the customers, should always be to increase the Customer-perceived value (CPV) which is:

The difference between the prospective customer's evaluation of all the benefits and all the costs of an offering and the perceived alternatives[14].

The higher this value, the higher the willingness of the customers to rebuy our product.

Another group of customers mentioned by Kotler are the *hardcore loyals*[15] who always buy the same product: they believe strongly in the quality of the product and identify its strengths, what makes them stick to it. What's more, they do not know how their bodies would react to a new product, in this case a drug, and prefer not testing it, although the APIs are proved to be the same. Pharmaceutical companies may be very interested in localizing this group of customers and retaining them.

Summarizing: although generics may be up to 10 times cheaper, there is no assurance that they will always be the option to be chosen. However, pharmaceutical companies should reconsider their sales strategies for the next five years, because generics will be gaining more weight in the pharmaceutical market continuously, despite the obstacles.

The second classification refers to the APIs: NCEs/NMEs vs. biopharmaceuticals. According to Rickwood et al. (2013), an increasing number of new molecular entities (NMEs) is estimated to address unmet needs in specialty disease areas and orphan diseases, as well as target smaller patient populations that suffer from: arthritis, systematic fibrosis, melanoma, ovarian cancer, multiple sclerosis, hepatitis C, and malaria. Innovation, the ultimate engine of growth for the global provision of medicines, is projected to see a revival of activity through 2017 after a slow-down due to the crisis. Although the majority of NMEs mainly address patients in high income countries, some of the emerging countries have improved their economic situation and offer very profitable opportunities to pharmaceutical companies like new treatment options, including malaria, neonatal sepsis and tuberculosis.

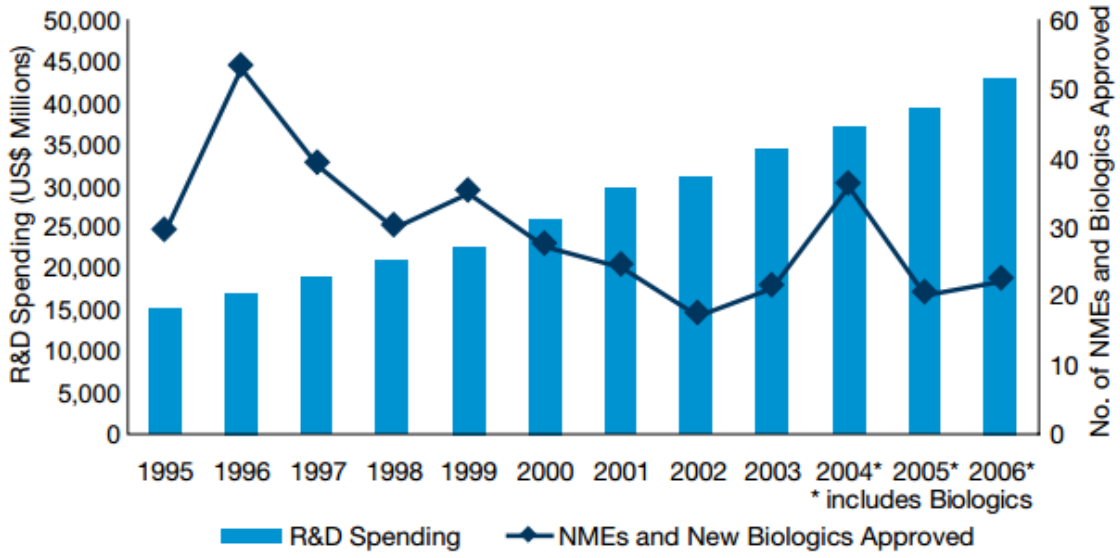
[14] Idem, p. 161.
[15] Idem, p. 264.

However, the number of new NMEs approved by the FDA will decrease although a lot of money will be invested in R&D in the next few years. It is true that the overall number of NMEs is higher, still many drugs are not approved (Figure 6). It is because:

a) Populations are aging and have higher expectations,

b) Consumers are more educated and informed than ever, demanding more innovative therapies which the pharma industry is unable to meet. Until now the "only" task of medicines was helping patients enjoy longer and healthier lives.

Figure 6: R+D spending has soared, but the number of NMEs and biologics approved by the FDA is falling down

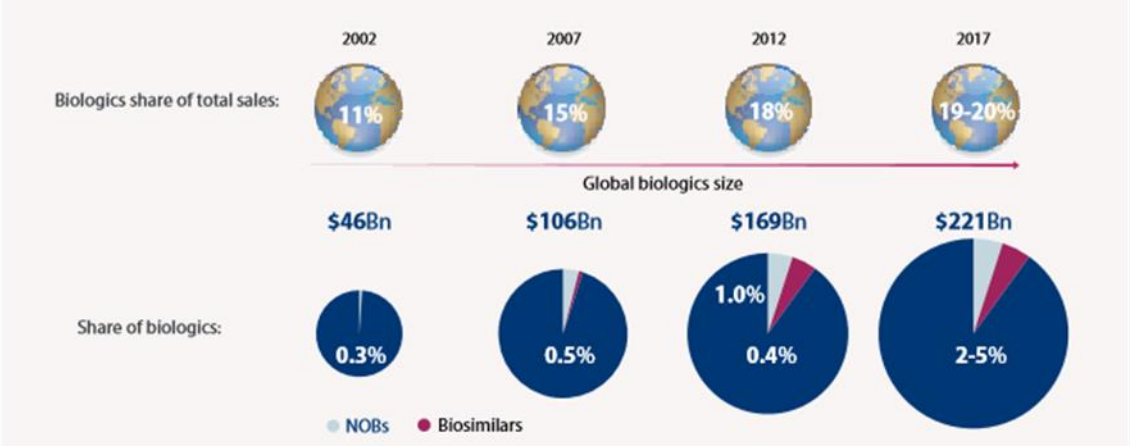


Source: PWC (2007)

Another reason for this decrease is the existence of policies on reimbursement for new pharmaceuticals, and APIs: many times the drugs in question are not eligible for a reimbursement in national health programs and so pharma companies drop it, or the proposed APIs don't meet all the requirements approved by FDA.

Most of the drugs currently available on the market are chemically synthetized medicines (either pills, injections or liquids, but NCEs). However, one anticipates that biopharmaceuticals will be gaining market share continuously. According to Figure 7, one projects that biologics will account for a 20% of global total sales in 2017.

Figure 7: The biologics market 2002-2017 (USD billion)



Source: Rickwood et al. (2013)

3.4 Demand: Diseases

In Section 2, we have presented the classification of diseases in a very simplified way. In this Section, we will deepen this subject providing numbers for: the leading causes of death, biggest therapies areas, health care use among different age groups, as well as name main risk factors for mortality. Although the main risk factors for mortality are not essential for our paper, we would like to raise awareness among our readers and prevent them from these risk factors.

The leading risk agent for mortality is high blood pressure, responsible for 13% of deaths globally, and the childhood underweight is the leading risk factor for burden of disease and is responsible for over 2 million children dying per year, mainly in low-income countries. But these are not the only relevant figures. Also environmental risks such as unsafe water, sanitation, hygiene and indoor smoke from solid fuels cause around 2 million children deaths per year; not to mention the low fruit and vegetable intake, physical inactivity, alcohol and tobacco intake, overweight and obesity, high cholesterol, and high blood glucose. All of the above factors are responsible for more than half of the deaths due to heart disease, the leading cause of death in the world[16].

However, our intention is to focus on the most widespread diseases in the world, not the leading risk factors for mortality. In the section that follows, we will not differentiate

[16] Mathers (2009), p. V.

between adults and children, but treat them as a global sample (WHO always differentiates between children under the age of five and the rest of population, mainly because one of its priorities is to decrease mortality among children under five). For our purposes, we have used statistics that show the leading causes of death globally, not data about people becoming sick and people in actual treatment. There is one reason for our choice: data about numbers of deaths is more reliable than data about people having some disease. Usually, deaths are registered, while some people with diseases such as cancer or HIV infection are not aware of having it because they are not visible (no symptoms in first stages). According to Table 5, CVDs are number 1 cause for death in the world. It is followed by infectious diseases (HIV infections/AIDS, TB, hepatitis B and C, diarrhea, malaria), cancer of all types (breast, prostate and lung cancer being the most widespread ones[17]), respiratory diseases and injuries (including road accidents, poisonings and falls, among others, which we won't consider in this study; nor will we contemplate neonatal conditions such as preterm birth complications, birth asphyxia etc.)

Table 5: 10 Leading broad causes of death (thousands)

World

2011				
Rank	**Broad Causes**	**Deaths (000s)**	**% deaths**	**Deaths per 100,000 population**
1	Cardiovascular diseases	16586	30,4	239
2	Infectious diseases (incl. respiratory infections)	10066	18,4	145
3	Cancers	7870	14,4	113
4	Injuries	4971	9,1	72
5	Respiratory diseases	3881	7,1	56
6	Neonatal conditions	2420	4,4	35
7	Digestive diseases	2180	4,0	31
8	Endocrine, blood, immune disorders, diabetes mellitus	1901	3,5	27
9	Neurological and sense organ conditions	1351	2,5	19
10	Genitourinary diseases	1107	2,0	16

Source: GHE (2013)

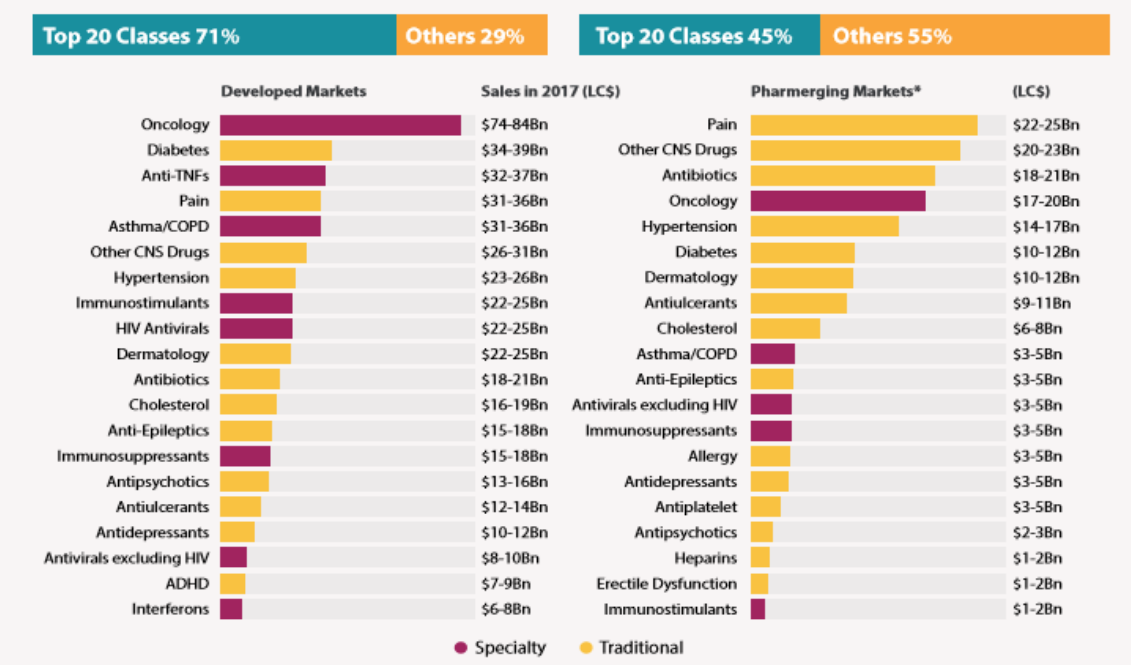
Although the WHO states that the most common diseases in the world are the above ones, it does not coincide with the production of drugs by pharmaceutical companies, which we will see next in Figure 8. Of course, not all of the medicines generate the same benefits and it is obvious that trade and capital flows are always ahead of the people. Despite the fact that they occur less frequently (according to Table 5), oncology and diabetes (number

[17] World Cancer Research Fund International (2014).

3 and 8, respectively, in Table 5) receive more attention than infectious and respiratory diseases (number 2 and 5, respectively, in Table 5) (in high income countries). Summarizing, diseases with a lower percentage of deaths receive more attention from pharmaceutical companies than diseases responsible for more deaths. It demonstrates perfectly that oncology and diabetes must be more profitable for the pharma companies.

Figure 8 represents how disease areas are expected to differ depending on the region (a prediction for 2017). On the left hand side, the developed markets are estimated to invest primarily in oncology and diabetes drugs, while on the right, the *pharmerging* markets, anticipate to focus on pain, antibiotics and Central Nervous Systems (CNSs) drugs. Also, we can say that it is more probable that developed markets will invest more in specialty drugs than the *pharmerging* markets. Half of the first ten projected areas are specialty areas whereas, in *pharmerging* countries, they are only two out of ten.

Figure 8: Estimated spending by therapy area in 2017 (USD billion)



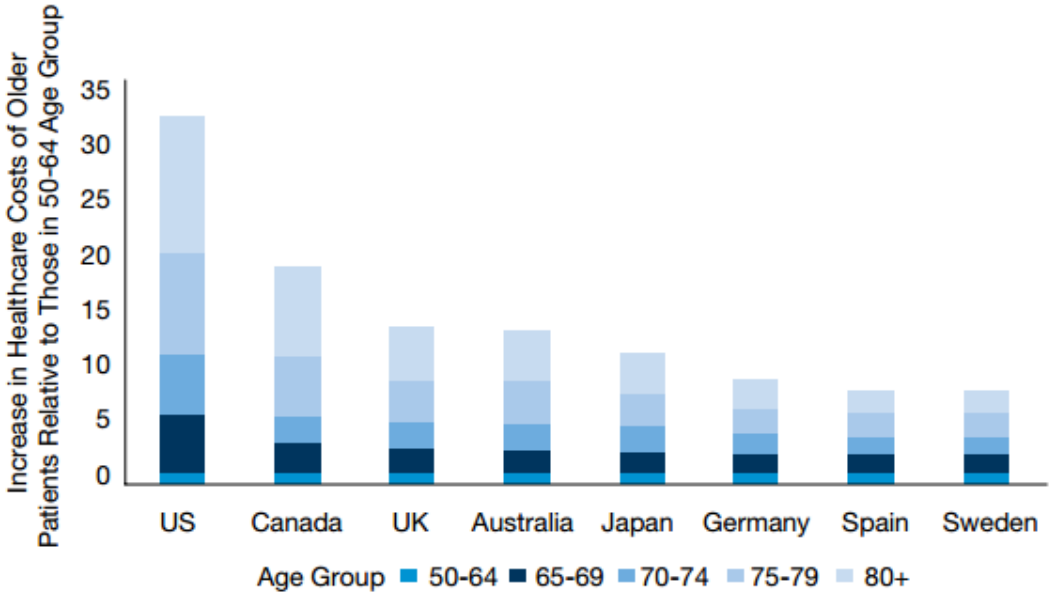
Source: Rickwood et al. (2013)

Two reasons are responsible for this situation: populations in developed markets get older and gain on weight, making cancer and diabetes illnesses number one (the so called *diseases of affluence*), apart from other chronic diseases that require a long time treatment. As stated in PWC (2007):

By 2020, about 719.4m people – 9.4% of the world's inhabitants – will be 65 or more, compared with 477.4m (7.3%) two years ago. Older people typically consume more medicines than younger people; four in five of those aged over 75 take at least one prescription product, while 36% take four or more. So the grey factor will boost the need for medicines dramatically.

This is also visible in Figure 9:

Figure 9: Older people consume more healthcare than younger people do



Source: PWC (2007)

Specialty treatments are being held in hospitals and researches in private institutions, a situation that many times is impossible in *pharmerging* countries. This is why the last still focus on traditional medicine, although this situation has started to change. An interesting point to make is that the top 20 areas in developed markets get 71% of the overall spending on medicines, whereas only 45% in *pharmerging* countries, according to Figure 8.

We also should bear in mind that populations grow rapidly in emerging countries, such as India and China, attracting pharmaceutical companies with a high number of possible consumers. If we have a look on the population growth rates in the BRICS countries (plus Indonesia) and compare them with the United States, EU28 or OECD countries, it is clear that they are the fastest growing countries as for population. The two exceptions would

be Russia and China, probably because of the policy of one child (Table 6, data only available until 2012).

Table 6: Population growth rates (annual growth in %)

		2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
	United States	1,12	0,99	0,93	0,86	0,93	0,93	0,97	0,96	0,95	0,88	0,83	0,73	0,75
	EU 28	0,23	0,24	0,29	0,42	0,45	0,43	0,40	0,41	0,39	0,31	0,31	0,17	0,09
	OECD	0,73	0,72	0,70	0,70	0,64	0,70	0,55	0,58	0,75	0,68	0,72	0,66	..
	Brazil	1,50	1,48	1,44	1,38	1,32	1,26	1,19	1,12	1,05	0,99	0,93	0,87	0,82
	China	0,59	0,58	0,58	0,58	0,58	0,59	0,60	0,62	0,63	0,63	0,63	0,63	0,63
	India	1,68	1,65	1,62	1,59	1,54	1,49	1,43	1,38	1,34	1,32	1,30	1,29	1,27
	Indonesia	1,45	1,45	1,45	1,45	1,44	1,44	1,44	1,43	1,42	1,38	1,34	1,30	1,26
	Russian Federation	-0,42	-0,42	-0,46	-0,45	-0,40	-0,38	-0,33	-0,17	-0,04	0,03	0,04	0,08	0,17
	South Africa	1,47	1,49	1,48	1,47	1,46	1,43	1,42	1,40	1,34	1,24	1,11	0,97	0,84
	World	1,26	1,25	1,24	1,23	1,22	1,22	1,21	1,21	1,21	1,20	1,19	1,18	1,17

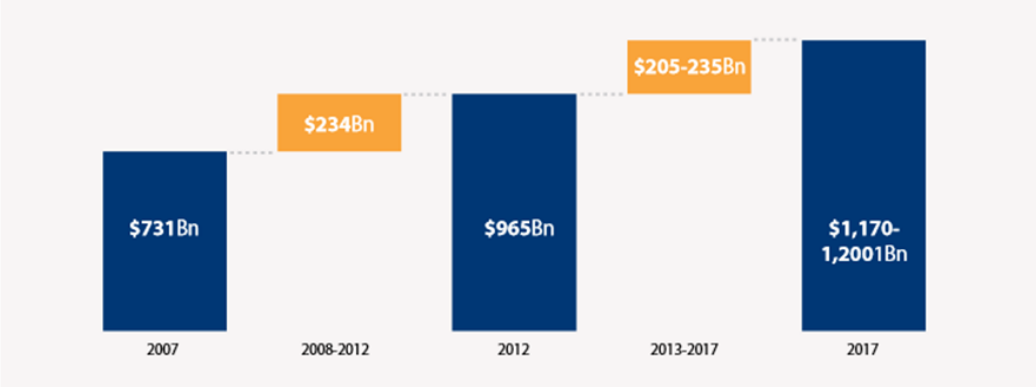
Source: OECD (2014)

These numbers can boost the demand for medicines drastically. Pharmaceutical companies should foresee this demand and have in stock the mostly bought drugs in emerging markets.

3.5 Buyers: Who pays?

We have seen previously that the two main agents who pay are the governments and international institutions, as well as patients through private clinics and medical insurance agencies. Figure 10 shows the global spending on medicines of both agents in 2007 and 2012 and the estimated growth for the period: 2013-2017:

Figure 10: Global spending on medicines in 2008-2017 (USD billion) and estimated growth



Source: Rickwood et al. (2013)

Once we have introduced governments as one of the agents responsible for drug bills in Section 2, we would like to focus on some governmental policies on health care undertaken in emerging countries to show that spending on medicines and medical care by the governments is projected to increase in the near future.

Domestic policies on health systems in the emerging economies play an important role for the spending on pharmaceuticals. For example, China implemented a four-year plan (2012 to 2015) for the prevention and control of chronic diseases. In India, by 2016, health insurance is planned to reach half of the Indian population (630 million people), mainly by broadening basic healthcare provision to families living below the poverty line. Russian government is responsible for a significant investment in healthcare, which announced plans to increase healthcare spending from 5.6% of GDP in 2012 to 7.5% by 2020, including a national health insurance scheme covering drugs in the retail setting[18].

Comparable to *pharmerging* markets, government, but also NGOs and private sector in Africa invest in the health systems across the continent, strengthening the infrastructure, capacity building, treatment provision and specialized services (Logendra et al. (2012).

In reference to international institutions that assure health care to a huge number of people, we would like to introduce the World Health Organization (WHO) and its actions undertaken to change limited access to health care, such as the Millennium Development Goals, and one of its tools, the universal health coverage. MDGs is an agreement between all the world's countries and all the world's leading development institutions in order to meet the needs of the world's poorest. Among them, we find three goals that are of our particular interest, which are: reduce child mortality, improve maternal health (both indirectly linked to the pharmaceuticals), and combat HIV/AIDS, malaria, tuberculosis and other major communicable diseases (directly linked to pharmaceutical companies). The last one has to do with the desire to lower the number of new infections, provide health care for people living with HIV, expand access to antiretroviral therapy in poor countries, and disseminate knowledge of HIV transmission, especially among young people. As for malaria, the main goal is to diminish deaths from this disease[19].

In order to achieve the MDGs and in the face of unequal access to health systems around the world, the WHO is trying to introduce the universal health coverage which goal is to

[18] Hill (2013).
[19] Dye et al. (2013), p.iv-v.

offer all the populations equal access to treatments and medicines without a risk of financial ruin or impoverishment.

In 2005, all WHO Member States made the commitment to achieve universal health coverage. The commitment was a collective expression of the belief that all people should have access to the health services they need […]. Working towards universal health coverage is a powerful mechanism for achieving better health and well-being, and for promoting human development[20].

What is more, apart from the principal goal of providing with health coverage all the people in the world, its secondary objective is to improve the quality of live and ensure peace and security around the globe. It sounds logical: if the majority of countries offer the same life quality, migration for medical reasons is going to decrease and so will do political conflicts.

How the WHO wants to introduce the Universal Health Coverage? Along with the increasing GDP in emerging countries and a higher spending on public health systems, which automatically will cover more people with appropriate services, WHO's General Director, Mr. Margaret Chan, suggests improve the efficiency of the services offered instead of cutting on the public systems in this period of austerity[21]. Continuously, better hiring procedures would assure more health professionals and a higher quality of services. *What matters is quality, not quantity*, she emphasizes[22]. There are other proposals of how and where to find money for larger health coverage: a higher use of generics, prophylaxis (healthy diet and more exercise) promoted by the governments, a better use of the resources, more incentives for the suppliers, available financing at low interest rates and simplified administrative procedures. She underlines the relevance of community-based interventions as a measure to improve overall health level and make the health coverage universal: conscious communities will boost healthy praxis among the populations and make them claim their rights for the health coverage. Specific data about the universal health service coverage and health systems can be found in point 4: Health Service Coverage, and point 6: Health systems (World Health Statistics, 2014).

[20] Idem, p. xi.
[21] Evans et al. (2010), p. vi-vii.
[22] Idem, p. vi.

In reference to private clinics and medical insurance, not all the countries offer basic health coverage so some patients opt to pay it from their own pocket. On the other side, sometimes only basic services are paid by the national health system, and additional services have to be paid by the patient. In these situations patients opt for private clinics disappointed with the public health system or because a specialist has been recommended by a family member or friend.

4. Interferences from the empirical description

From the empirical description, we can extract the following information for each market, presented in Tables 7.1 – 7.6, containing each decisive factor (type of producer, product, demand, buyers).

As we have discarded MNCs previously and, automatically, developed countries, we will consider for our models only *pharmerging* economies with their national companies, and African local companies. The tables below pretend to show in percentages the most viable options in drugs for each market and tendencies of purchases for public and private agents[23].

After having analyzed the pharmaceutical market in the *pharmerging* countries, it seems that the main focus is placed on chemically synthetized generics, about 70% of the overall production. Since these markets are shifting towards Western standards and many national companies are outsourced for production of brands for Western markets, the level of branded NCEs is not huge, but relevant, and accounts for 26% of the manufactured drugs (Table 7.1). As for demand in diseases, the unquestionable number one is traditional care (the non-communicable chronic diseases are a clear leader in the diseases (80%), followed by some infectious diseases in tropical zones and a small percentage of occasional ailments (pain, fever, etc.) (Table 7.2). In reference to tendencies in governmental and private purchases of medicines (Table 7.3), we can say that *pharmerging* economies cannot afford spending money on expensive drugs, but they want to improve the overall health coverage: the solution is to buy relatively cheap medicines such as generics. In Table 7.3 we can see that all the public spending goes for low-priced medicines. In private health care, patients spend an equal amount of money on both: low- and high-priced pharmaceuticals.

Table 7.1 Supply: National companies

	NCEs	Biopharmaceutical
Brand	26%	4%
Generic	70%	0%

[23] All of the tables have been elaborated by the author.

Table 7.2 Demand: *Pharmerging* countries

	CRO	Non-chronic
NCDs	80%	5%
Comm. Diseases	15%	

Table 7.3 Buyers: *Pharmerging* countries

	Public	Private
High price	0%	10%
Low price	80%	10%

Speaking about the African market, we have seen previously in Section 3 that the main causes of death are infectious diseases such as HIV infections/AIDS, malaria, and TB. This is reflected in Table 7.4: the main emphasis, 80%, is placed on communicable diseases, followed by a growing sector of non-communicable chronic diseases (15%). Local companies provide mostly generics (95%) and only 5% of branded drugs (Table 7.5). This has an explanation in the political and financial situation of the agents: governments and global institutions go for quantity than quality in order to save the biggest number possible of lives (paying a lower price, you can get more of a product). The same is evident in Table 7.6: the purchases of cheap medicines by public agents account for 90% of overall spending, leaving the rest to private clinics.

Table 7.4 Demand: African continent

	CRO	Non-chronic
NCDs	15%	5%
Comm. Diseases	80%	

Table 7.5 Supply: Local companies

	NCEs	Biopharmaceutical
Brand	5%	0%
Generic	95%	0%

Table 7.6 Buyers: African countries

	Public	Private
High price	0%	5%
Low price	90%	5%

The above percentages reflect the present and might be acknowledged as likely to persist in the near future (5 years from now), since the pharmaceutical market is not likely to change very quickly. It takes a generation (about 20-25 years) to alter tendencies in diseases, as it occurs with celiac children or diabetic patients: about 2 decades ago nobody knew what it means to suffer from the celiac disease or being diabetic. Nowadays, they have both become very common and widespread problems.

What's more, it is possible that the above assumptions might be altered by demographic, migratory, legal, political, corporate, and climate changes, such as: growing global population, high migration to cities, new laws on patents for drugs, political situation in unstable regions, incentives for creating national companies in *pharmerging* countries, and global warming.

- Growing global population may not change significantly in 5 years, but it will do so in two decades. Depending on where the increase is the highest, more producers and drugs will appear in order to respond to the market demand.

- Secondly, people moving to cities, a very common currently phenomenon in emerging countries will be responsible for creation of new bacteria and diseases. Growing cities in emerging countries are a bustle and maintaining basic hygiene is many times impossible. The pollution makes these places very unhealthy to human lives and provokes higher mortality due to high density. (In change, in Western cultures, we see the contrary movement: out of the cities, looking for fresh air and a peaceful environment after a busy day. In emerging countries, living in the city is still perceived as a symbol of success.)

- Thirdly, the legal alternations in laws on patents may boost the production of branded drugs or, depending on the law, make the producers abandon this branch of industry.

- We should not forget about political issues, such as the current situation in Ukraine, which, in case of becoming a conflict of arms, may completely change the current production of medicines.

- It is possible that *pharmerging* countries will encourage the creation of national companies and strengthen their development as a way to open successful MNCs. Governments of these countries could create laws reinforcing these companies,

and not foreign companies. It has already happened in the past with the computer technology brand Lenovo®, which is currently the owner of IBM personal computer business (acquired in 2005) and Motorola Mobility (bought it January 2014), or Pearl River® pianos, Chinese pianos that achieved to become an international recognized brand for instruments.

- Lastly, climate change will have enormous implications for human health, especially for the burden of infectious diseases[24]. Many scientists believe that global warming could bring diseases such as malaria, cholera, diphtheria and dengue fever to more developed regions. That would provoke a come-back of diseases that so much has cost to decrease on global scale. If this happens, the production of innovative drugs, specialty area treatments and traditional care medicines would shift to anti-infectives.

[24] Shuman (2010).

5. Conclusion

In this part, we would like to introduce the theory of Mike W. Peng, an American scientist from the University of Texas at Dallas, and his institution-based view and the resource-based view. This theory, reinforced by cinematographic and literary examples, described next, give an explanation of why Africa fails to have strong national and multinational companies, why it is in the last place in innovation and progress in pharmaceuticals, and also what makes it a risky region to invest.

In order to answer the question Why do firms fail or succeed in different countries and regions?, Peng argues that the decisive factors are institutions and resources, which in turn govern global economics[25]. Institutions are the rules of the game - both formal and informal. Now, formal constraints include laws, regulations, and rules. Informal limitations are norms, cultures, and ethics, which can be continuously divided into normative and cognitive supportive pillars. Referring to the resource-based view, Peng suggests using the SWOT (strengths - weaknesses - opportunities - treats), but even more the VRIO framework (value - rarity - imitability - organization) when evaluating the companies[26].

Peng's theory is especially valuable when applied to international business. When going abroad, familiar rules of the game are often not available. To capture the hearts, minds, and wallets of customers in other markets, companies need to pay attention to the rules of the game there, especially unwritten informal ones. As Michael Peng says,

Coca-Cola and PepsiCo, whose products have been perfectly legal, have been singled out by activists in India for selling allegedly contaminated products.[27] Under certain institutional conditions, a cost leadership strategy can be accused of being unethical - think of the trouble Wal-Mart faced by pursuing the "everyday low price" strategy. Under other conditions, a cost leadership strategy may become illegal - in the Japanese bookselling industry, price fixing is legal while price competition is banned (!)[28].

[25] Peng (2013), p. 32.
[26] Idem, p. 100.
[27] Peng et al. (2008).
[28] Peng et al. (2009).

It all depends on the country we come from or operate in. If a corporate behavior is accepted in one country, it does not necessarily have to be so in another one. Unethical and illegal actions in one reality occur on daily basis in others.

Guns, Germs and Steel's author, Jarod Diamond supports this theory in his book. He states that not just geography, religion, history, and culture have a big effect on national wealth and on personal incomes, but also institutions. He goes further and makes us think about historic events that affected this region such as the colonization by European nations or the apartheid. Actually, the authors looked back over thousands of years of human history to examine fundamental questions behind why some societies built empires while others withered.

The history of interactions among disparate peoples is what shaped that modern world through conquest, epidemics, and genocide. Those collisions created reverberations that have still not died down after many countries, and that are actively continuing in some of the world's most troubled areas today. For example, much of Africa is still struggling with its legacies from recent colonialism. In other regions – including much of Central America, Mexico, Peru, New Caledonia, the former Soviet Union, and parts of Indonesia – civil unrest or guerrilla warfare pits still – numerous indigenous populations against governments dominated by descendants of invading conquerors.[29]

To keep it short, even if companies show all the required variables to succeed, depending on their location, they can fail due to national institutions. Or the other way round: although being located in perfect environment (business opportunities, geography for logistics and human knowledge), many firms will fail due to a weak VRIO framework.

Many of us who have seen *The Constant Gardener*, have been thinking about what attracts pharmaceutical companies to test drugs in African countries (the main focus of this movie in placed on illegal clinical trials led by multinational pharmaceutical companies, and the attempt to hide deaths caused by the drugs). The leitmotifs in other movies showing African realities are: dictatorship of Idi Amin in *The last king of Scotland*, diamonds mines in Sierra Leone during the Civil War 1996-2001 and a country torn apart by the struggle between government's loyalists and insurgent forces (*Blood Diamond*, the Rwandan genocide in 1994 in *Hotel Rwanda*[30]. The existing corruption,

[29] Diamond (1997), p. 16-17.
[30] Wikipedia (2014).

fights between tribes and lack of health systems play an important role, too. And here comes the theory of Peng: weak formal institutions are unable to fight deeply rooted corruption and mostly analphabet populations, provide an efficient health systems and security for its inhabitants. Although the continent is rich in natural resources, such as gold, oil, diamonds, ivory and rubber, they are exploited and neither miners nor inhabitants get profits from this industry. The benefits go to private hands, boost more corruption and start political and tribal disputes. Political parties remain in power for years (regimes) and force people to emigrate looking for better lives. In other regions, political systems change every year or more often, provoking protests and strikes, stopping production, supplies of electricity, and classes in school, causing unnecessary deaths.

Analyzed from the resource-based point of view, despite many natural resource and perfect geographic location (one could grow plants throughout the year thanks to the warm climate), Africa fails to be successful and foster health economic environment. The faulty factor are the weak institutions and lack of regulations or lack of organisms that would push through these regulations.

What implication does this theory have on the pharma industry? Pharmaceutical companies are taking advantage of the "unique" opportunity of leading drug trials in African regions without being stopped by weak institutions: firstly, people need money and what is easier than swallow a pill and get paid for it. Secondly, the majority of the people are analphabets, so they won't be able to read on the package about the side effects. Thirdly, it seems that African governments are so corrupt that they would take any money to allow the trials; they simply do not care about Africans.

The above factors make Africa an unstable region where doing business is very unsure and unpredictable. In one word, it is a high-risk market and many investors will cross it from the list. Also, continuous stops in production and supplies do not make this market very reliable. Finally, lack of investments result in lack of researches and Africa remains in the last place in innovation and progress in pharmaceuticals.

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