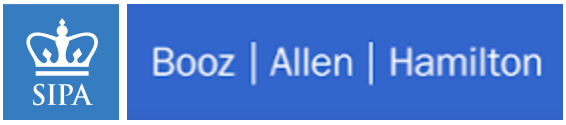

Key Drivers of Regulatory Risk in the Pharmaceutical Industry

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Abstract:

When entering emerging markets, large pharmaceutical companies must take an array of factors into account. An emerging country's regulatory frameworks can have major implication for the pharmaceutical company's business. This report analyzes two major components of regulatory risk for the pharmaceutical industry: marketing restriction and patent protection. By developing a model for each of the above-mentioned variables, we are able to triage countries according to low, medium and high thresholds of regulatory risk and growth of health expenditure. Our study enables a pharmaceutical company, with characteristics similar to Pfizer, to determine which countries to invest in. We then apply our findings and create strategies for the following countries: China, Russia, and Turkey.

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Introduction

The pharmaceutical industry offers growing opportunities in emerging markets, but is paired with challenges such as volatile and unstable governments and changing regulations. This paper focuses on drivers of regulatory risks in the pharmaceutical Industry in emerging markets. We attempt to answer two key questions:

1) What are the major drivers of regulatory risk in emerging markets for the pharmaceutical industry?

2) How do these regulatory risks affect the strategy of large multinational pharma firms wanting to enter or expand in these markets?

To identify opportunities and threats, we examine existing regulations and potential change in the regulatory environment. The regulatory issues we focus on are 1) Patent Protection laws and 2) Marketing Regulations. Finally, our objective is to create a toolset to assess the regulatory risk in these emerging markets to map the regulatory environment and growth of health expenditures in emerging markets and triage the countries into high, medium, and low risk tranches.

Section 1: Literature Review of Drivers of Regulatory Risk in the Pharmaceutical Industry

a. Overview of the Pharmaceutical Industry

The pharmaceutical industry has had an outstanding performance record of innovation and profitability over the past fifty years. The industry's research and development processes have created a market for innovation between research start-ups, development-stage firms, and multinational companies. Between 1940 and 1950, the pharmaceutical industry transformed itself from a collection of several hundred, small, marginally profitable firms to a small group of large, highly profitable firms. During the mid-90's, the success of the stock market made obtaining large amounts of capital available at reasonable rates which created even further consolidation.

The restructuring of the United States' Food and Drug Administration (FDA) also had a tremendous impact in the industry's profitability, providing companies with the ability to bring drugs to market quickly. A tremendous lobbying effort on the part of the pharmaceutical

industry resulted in the reduction of the average approval time for new drugs from two or three years to one year or less. A prime example of the quick approval process was the 42-day approval of reverse transcription drugs for HIV that stems the progression of the virus.

However, the golden ages of the pharmaceutical industry are gone. Even an improved global economic climate is unlikely to slow efforts of developed countries' move to control spending on drugs. Moreover, "regulatory requirements—particularly the linkage among the benefits, risks, and cost of products—will increase, while the industry pipeline shows little sign of delivering sufficient innovation to compensate for such pressures."[1] These factors suggest that the pharmaceutical industry is heading in a direction where its profit margins will be substantially lower than they are today. This dramatic situation requires multinational pharmaceutical executives to think beyond mergers and acquisitions. A bolder, more strategic approach to the industry's operating model must be made in order to generate further growth and profitability in the medium and long term.

b. Patent Regulation Risks

Patents and intellectual property rights in the pharmaceutical industry are vital dynamics in the industry's investment decisions. Patent rights provide the pharmaceutical companies ability to harvest their investments in innovation and research and development (R&D) through limited-time legal monopoly rights to manufacture, license and market the drugs. As a result, patents are perceived as critical in the drug and chemical industries which may reflect the nature of R&D performed in these sectors[2]. If a drug is protected with a patent or a series of patents, no other company can produce or sell any drug with the same ingredients--assuming that the intellectual property rights are protected effectively. Without patents, no company would develop new drugs, which in fact require high sunk costs (due to development stages, pre-clinical and clinical phases, approval process, etc.) before production.

[1] Hunt, Vivian. Manson, Nigel. Morgan, Paul. A wake-up call for Big Pharma: Lower profit margins suggest a need for new business models. (December 2011). Retrieved March 7, 2015. http://www.mckinsey.com/insights/health_systems_and_services/a_wake-up_call_for_big_pharma

[2] CRS Report for Congress Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition and Patent Term Restoration Act of 1984 ("The Hatch-Waxman Act") Updated January 10, 2005 p. 5, http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/rl3075601102005.pdf

After the expiration of patents, new generic drugs[3] can enter into the market created by the incumbent company. This can create competition in the market, with a downward pressure on prices and the profits of the innovator pharmaceutical company.

Since patents are vital in the pharmaceutical industry, one of the primary concerns of the multinational pharmaceutical companies entering emerging markets is the protection of intellectual property rights. If there are systematic problems in the protection intellectual property rights in a country where other companies or even state owned enterprises could break patent of a drug, patent holder companies may prefer not to market theirproducts in that country.

However, "many low income economies claim that patent protection for pharmaceuticals will result in substantially higher prices for medicines, with adverse consequences for the health and well-being of their citizens [while] research-based global pharmaceutical companies, argue that prices are unlikely to rise significantly because most patented products have therapeutic substitutes "(Chaudhuri, Goldberg and Jia 2003, 1) [4]. The challenge is difficult due to the fact that a large percentage of the population in developing countries cannot afford high medical costs, so their governments are inclined to support legislation, or the lack thereof, to keep prices low. Unfortunately, the precedents set by the regulatory bodies in these countries can often deter multinationals and investors.

Another dimension of pharmaceutical patents in developing countries is that those countries generally have weak protection schemes. For example, Kramer (2002) argues that many developing countries have historically provided little or no intellectual property rights protection for pharmaceuticals. India, for instance, offers patents on the pharmaceutical processes, but not on drug products. It has also developed a large industry to reverse engineer existing drugs[5]. The countries' development status are important indicators of the patent protection level of a jurisdiction. Thus, relevant variables related to the national income level

[3] Generic drugs are defined as drug products that is comparable to a brand listed drug product in dosage form, strength, quality and performance characteristics, and intended use.

[4] Chaudhuri, S., Goldberg, P. K., & Jia, P. (2003). *Estimating the effects of global patent protection in pharmaceuticals: a case study of quinolones in India*(No. w10159). National Bureau of Economic Research.

[5] Kremer, M. (2002). Pharmaceuticals and the developing world. *Journal of Economic Perspectives*, 67-90. p.74

(GDP per capita) and industry-specific indicators connected to the health expenditures may be important drivers in the regulatory risks of the countries related to patent infringements.

c. Marketing Regulations

While pharmaceutical products are related to health and wellbeing, companies in this industry are profit-seeking organizations focusing not only in R&D, but also in marketing, sales and competition. Among these three areas, advertising/promotion is one the largest factors driving sales. For example, research in the US on returns on investments for print and television direct-to-consumer pharmaceutical ads revealed that "on each dollar invested in [direct-to-consumer] (DTC) advertising, the average return was $1.69 for TV ads alone; $2.51 for magazine advertising and $2.11 for campaigns involving a mix of print and TV ads (HAI, 2001)[6].

However, "when product sales are given priority over public health, promotion can lead to over-prescribing as well as poor quality prescribing and medicine use [which] in turn, leads to an increased risk of adverse effects and higher health-care costs"[7]. Promoting rational use of medicines Health Action International (HAI) argues that "pharmaceutical promotion influences how doctors and pharmacists choose to prescribe and dispense medicines, whose decisions may, however, lead to suboptimal treatment choices that damage public health and escalate health care costs."[8] In this regard, HAI supports the ban on pharmaceutical advertising claiming that[9]

1. DTC advertising drives up prescription drugs costs, threatening the sustainability of national health care services and universal access to health care as a fundamental human right.
2. DTC advertising fails to inform. It does not provide the impartial, objective information consumers and patients need for informed health care decisions.

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[6] Direct-to-Consumer Prescription Drug Advertising The European Commission's Proposals for Legislative Change Health Action International (HAI-Europe), December 2001 http://www.haiweb.org/campaign/DTCA/BMintzes_en.pdf

[7] Lexchin J. and L. Ziganshina (2015) Regulation of Pharmaceutical Promotion: Why Does Regulation Matter? Politics of Medicines, Free Online Encyclopedia http://www.politicsofmedicines.org/articles/regulation-of-pharmaceutical-promotion-why-does-regulation-matter

[8] http://www.haiweb.org/03_other.htm

[9] Direct-to-Consumer Prescription Drug Advertising The European Commission's Proposals for Legislative Change Health Action International (HAI-Europe), December 2001 http://www.haiweb.org/campaign/DTCA/BMintzes_en.pdf

3. DTC advertising compromises public safety.
4. DTC advertising promotes the medicalization of normal life. The most heavily advertised drugs are for long-term use by large target audiences, often for mild conditions and 'lifestyle' problems that may not need drug therapy.

Thus, being closely related to individuals and society's health and among the most important expenditure items not only for government budgets but also for individuals, advertisement in pharmaceutical industry is one of the most regulated markets in the world. Advertisement regulations are generally observed as restrictions on commercials on media, promotions to doctors, and consumers and some rules concerning sale and presentation of the products. The differences in advertising regulations among countries are also one the challenges that multinational pharmaceutical companies face. While advertising and direct-to-consumer promotions are not restricted in some countries, many countries have strict marketing limitations.

Some studies attempt to explain advertisement restrictions and differences amongst countries. Lexchin and Ziganshina (2015) argue that countries' different capacities to regulate medicines are among the reasons for differences in regulation of pharmaceutical promotion between countries. In their study on US pharmaceutical market, Palumbo and Mullins (2002) note that "[...] as patients became more involved in their treatment, drug companies expanded their promotional efforts to include consumers."[10] Temin (1979) attributes the robust growth of the pharmaceutical Industry to loosening of marketing regulations[11].

Section 2: Methodology of Developed Model

a. Data

We initially compiled data on 157 countries for twenty-two social, economic, and industry indicators. We extracted data from the World Bank, World Health Organization (WHO), Property Rights Alliance, the Economist Intelligence Unit, and Transparency International for these indicators. Marketing restriction data for 81 countries was acquired from Google

[10] Palumbo, F. B., & Mullins, C. D. (2002). Development of Direct-to-Consumer Prescription Drug Advertising Regulation, The. *Food &* Drug *LJ*, *57*, 423.

[11] Temin, P. (1979). Technology, regulation, and market structure in the modern pharmaceutical industry. *The Bell Journal of Economics*, 429-446.

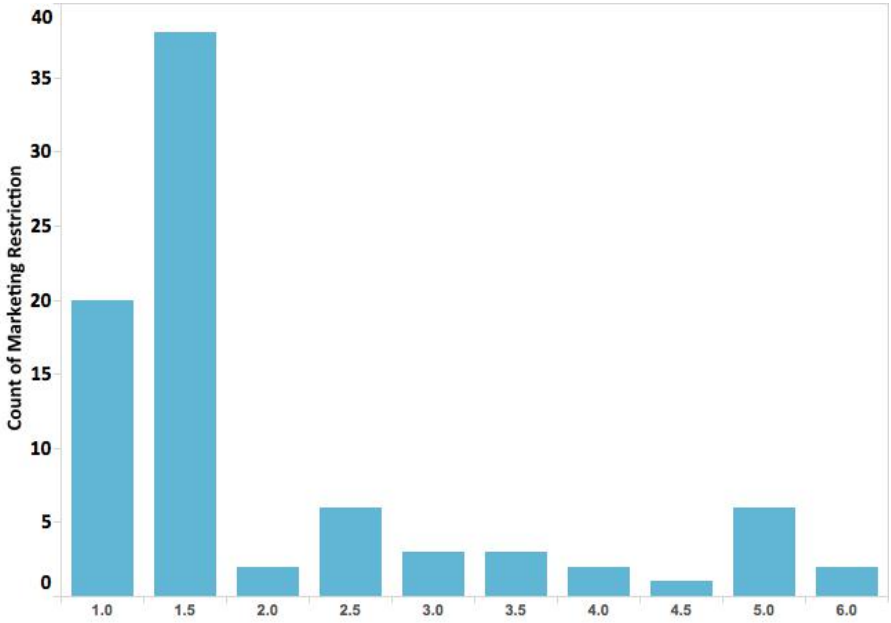
Advertising Policy, where it contained individual scores for Prescription Drugs regulations, Online pharmacies regulations, pharmaceutical manufacturers (OTC) regulations, medical services regulations, clinical trial recruitment regulations, abortion drugs regulations. We then created a marketing regulation index, scored from 1 to 6. We also acquired data for intellectual property rights (scored from 1 to 10) from the Property Rights Alliance for 131 countries. These two indexes serves as indicators for the dependent variables: marketing restriction and patent protection.

Our final model controlled for economic development using the World Bank's GDP per capita indicator as discussed earlier in our literature review. We divided healthcare expenditure as out of pocket/private health expenditure and government health expenditure.

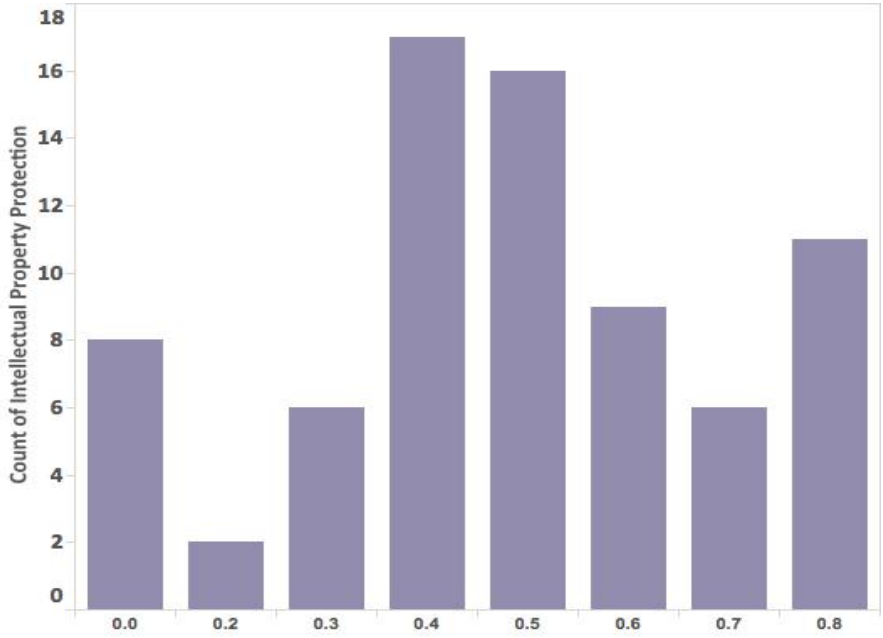
Quality of these domestic institutions also matter and are an important dimension. To control for this we also include the CPI from Transparency International. The CPI is a composite index that aggregates data gleaned from a number of on-the-ground sources and polls to determine how observers of public sector institutions perceive levels of corruption. This addresses the quality concern raised by The World Bank in regards to its Ease of Doing Business Index.

Lastly, we used the growth of health expenditure from the World Bank data catalog as a measurement of market size. Overall, we examined 22 variables individually, but a majority of these did not make it into our final model due to their insignificance.

Graph 1: Histogram of Marketing Restriction[12]



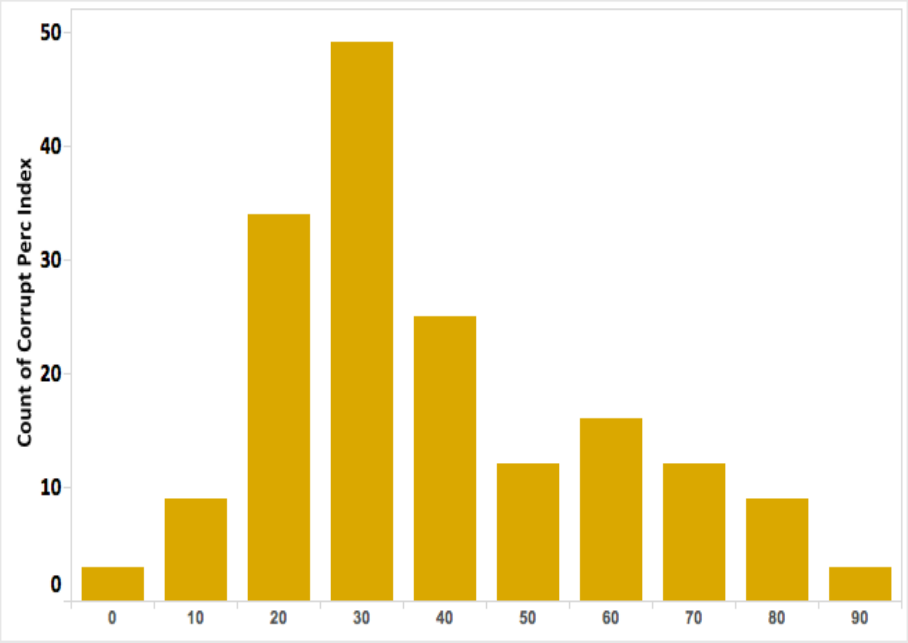
Graph 2: Histogram Intellectual Property Protection[13]



[12] Histogram shows the distribution of the marketing restriction scores (1-high, 6-low) for 81 countries. More countries have higher marketing restrictions.

[13] Histogram shows the distribution of intellectual property protection index (0.1-low, 1-high) for 81 countries.

Graph 3: Histogram Corruption Index[14]



b. Model

We began our statistical analysis by examining the dependent and independent variables. This involved analyzing the mean, standard deviation, and extreme values for each variable. The next step of our study involved examining bivariate relationships between our key dependent variables: marketing regulation index; intellectual property rights index; and our key explanatory variables. We also conducted a similar bivariate analysis for each independent variable. Our initial bivariate regression results and our key explanatory variables and control variables resulted in many significant results. On re-examining literature, we determined that various social, economic and industry indicators have an impact on our dependent variables.

Our next step was to conduct bivariate hypothesis testing to assess the relationship of our dependent variables with each independent variable individually. These variables included GDP (nominal), GDP (per capita), income level, year on year (YOY) inflation, exchange rate volatility, CPI, democracy index, urban population, population growth, labor participation, LPI,

[14] Histogram shows the distribution of the corruption perception index(0-low, 90-high) for 175 countries. Most countries hoover around a score of 20 to 40.

health care spending, health care spending per capita, healthcare spending out of pocket, healthcare spending government, rule of law index, poverty index and corporate tax rates.

Another key question regarding key independent variables, GDP and population, was whether to use absolute GDP or the log GDP. To test this, we ran a regression between natural log and the dependent variable. On obtaining results and reconciling it with existing literature, we concluded that the natural log of absolute values would be the best possible dependent variable for our study.

Upon assessing the strength and direction of each independent variable, we developed an initial multivariate model that included all thirteen explanatory variables. With this model, although we obtained a significant F-score, we obtained very few significant t-scores. This indicated multicollinearity. Upon analyzing the VIFs, we realized that the GDP and trade had high VIF scores (trade: 28.93 and GDP 21.45).

We then constructed various regression models and also ran a multiple correlations to test the robustness and accuracy levels of various models including all the remaining variables including GDP (per capita), income level, YOY inflation, exchange rate volatility, CPI, democracy index, urban population, population growth, labor participation, LPI, Healthcare spending (government, individual and total) and corporate tax rates. We ran a pair wise correlation test and removed highly correlated variables. Additionally, due to the widening gap between adjusted r-squared and non-adjusted r-squared, we made the decision to exclude some variables in our analysis.

This led us to our final model for Marketing Regulations and Intellectual Property Rights. The final models are as follows and are detailed in section 3.

Marketing restrictions = 1.989734 - 0.004878 corruption perception index + 1.90e-06 GDP per capita - 0.0514132 ln(GDP) - 0.0004428 public health expenditure + 0.0031165 out-of-pocket health expenditure

and

Intellectual property rights = -.2226599 + .051534 corruption perception index + .0000159 GDP per capita + .1777028 natural log of population - 0.0068522 out-of-pocket health expenditure + .0104575 public health expenditure

Section 3: Model Findings (based on Quantitative Analysis)

In conducting our statistical analysis, we are essentially trying to answer what drives the differing regulations across various countries. In doing so we are also try to understand what drives regulatory changes. Our statistical analysis take the formal form of :

H_0: Size of economy, per capita income, health care expenditure and corruption perception have no impact on pharmaceutical regulatory risks.

H_1: Differences in pharmaceutical regulatory risks can be explained by size of economy, per capita income, health care expenditure and corruption perception.

a. Assessing the Regulatory Environment

Marketing Regulations :

Marketing restrictions = 1.989734 - 0.004878 corruption perception index + 1.90e-06 GDP per capita - 0.0514132 ln(GDP) - 0.0004428 public health expenditure + 0.0031165 out-of-pocket health expenditure

The model we have developed has allowed us to make the following conclusions:

1. Countries with higher perceived corruption, on average, tend to have higher marketing restrictions
2. Countries with a higher GDP/market size, on average, tend to have lesser marketing restrictions
3. Countries with higher out-of-pocket health expenditure, on average, tend to have higher marketing restrictions
4. Controlling for market size, out-of-pocket health expenditure, public health expenditure and perceived corruption, on average, GDP per capita has no significant impact on the marketing restrictions

5. Controlling for market size, out-of-pocket health expenditure, GDP per capita and perceived corruption, on average, public health expenditure has no significant impact on the marketing restrictions

Intellectual Property Rights:

Intellectual property rights = -.2226599 + .051534 corruption perception index + .0000159 GDP per capita + .1777028 natural log of population - 0.0068522 out-of-pocket health expenditure + .0104575 public health expenditure

The model we have developed has allowed us to make the following conclusions:

1. Countries with lower perceived corruption, on average, tend to have better patent protection
2. Countries with a higher GDP per capita, on average, tend to have better patent protection
3. Countries with a higher population, on average, tend to have better patent protection
4. Countries with a higher public healthcare expenditure, on average, tend to have better patent protection
5. Controlling for GDP per capita, population, public healthcare expenditure and perceived corruption, on average, out of pocket health expenditure has no significant impact on the marketing restrictions
6. Nonetheless, at a 90% confidence level, countries with a higher out of pocket health expenditure, on average, tend to have poor patent protection

Chart 1: Stata Output for Marketing Restriction

regres mar_reg corrupt_perc_index gdp_per_cap lngdp hlth_exp_public hlth_outofpoc

Source	SS	df	MS
Model	2.18	5	0.44
Residual	1.69	66	0.03
Total	3.87	71	0.05

Number of Observations	72
F (5,116)	17.06
Probability >F	0
R-Squared	0.56
Adjusted R-Squared	0.53
Root MSE	0.16

Marketing Restriction	Coefficient	Standard Error	t-Statistics	P>|t|	95% Confidence Interval
Corruption Perception Index	-0.0048780	0.002	0.001589	0.003	-0.008
GDP Per Capita	0.0000019	0.000	0.000002	0.232	0.000
Natural Log of GDP	-0.0514132	0.011	0.010864	0.000	-0.073
Public Health Expenditure	-0.0004428	0.001	0.001342	0.743	-0.003
Out-of-Pocket Health Expenditure	0.0031165	0.001	0.001005	0.003	0.001
Constant	1.9897340	0.311	0.310734	0.000	1.369

Chart 2: Stata Output for Intellectual Property Protection

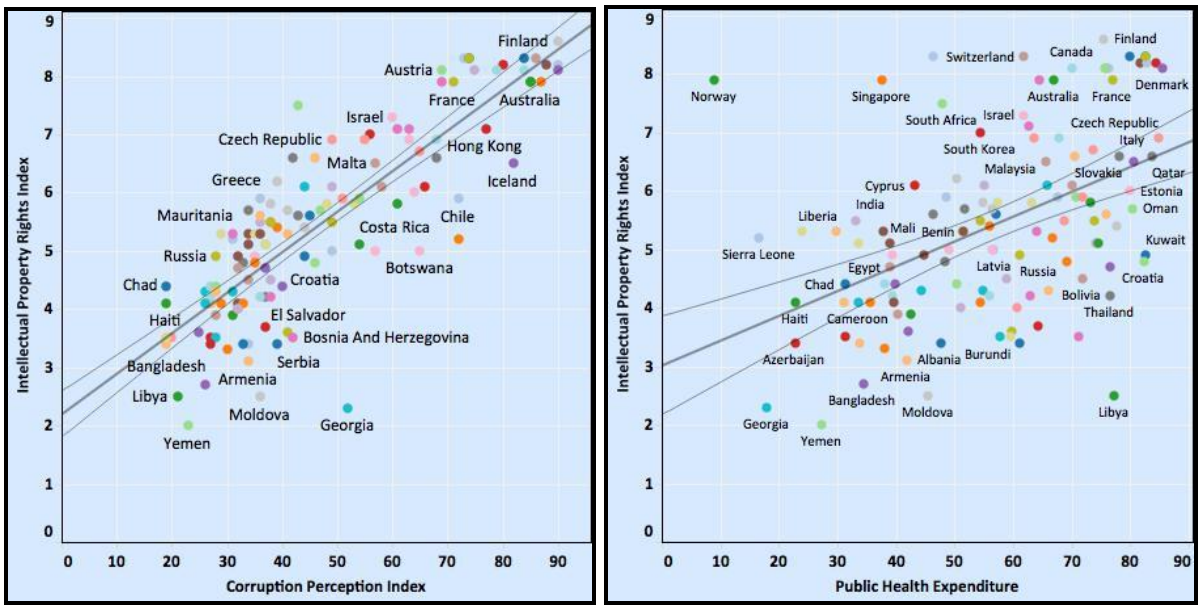
regres intellectual_property_rights_ind corrupt_perc_index gdp_per_cap lnpop

Source	SS	df	MS
Model	230.31	5	46.06
Residual	73.00	116	0.63
Total	303.31	121	2.51

Number of Observations	122
F (5,116)	73.19
Probability >F	0
R-Squared	0.76
Adjusted R-Squared	0.75
Root MSE	0.79

Intellectual Property Protection	Coefficient	Standard Error	t-Statistics	P>|t|	Beta
Corruption Perception Index	0.052	0.007	7.740	0.000	0.621
GDP Per Capita	0.000	0.000	2.670	0.009	0.204
Natural Log of Population	0.178	0.048	3.710	0.000	0.178
Health Expenditure Out of Pocket	-0.007	0.004	-1.880	0.063	-0.091
Public Health Expenditure	0.010	0.005	2.030	0.045	0.115
Constant	-0.223	1.009	-0.220	0.826	

Graph 4: Scatterplots[15]



i. Marketing Restriction

The map below shows marketing restrictiveness for 81 countries. Interestingly, not all emerging markets have similar marketing restrictiveness. For example, Brazil and Mexico practice less restrictions on pharmaceutical marketing in comparison to India, Russia, Turkey or China. South Africa, the United States, Canada, Japan, and the United Kingdom are amongst the countries with the least pharma marketing restrictions.

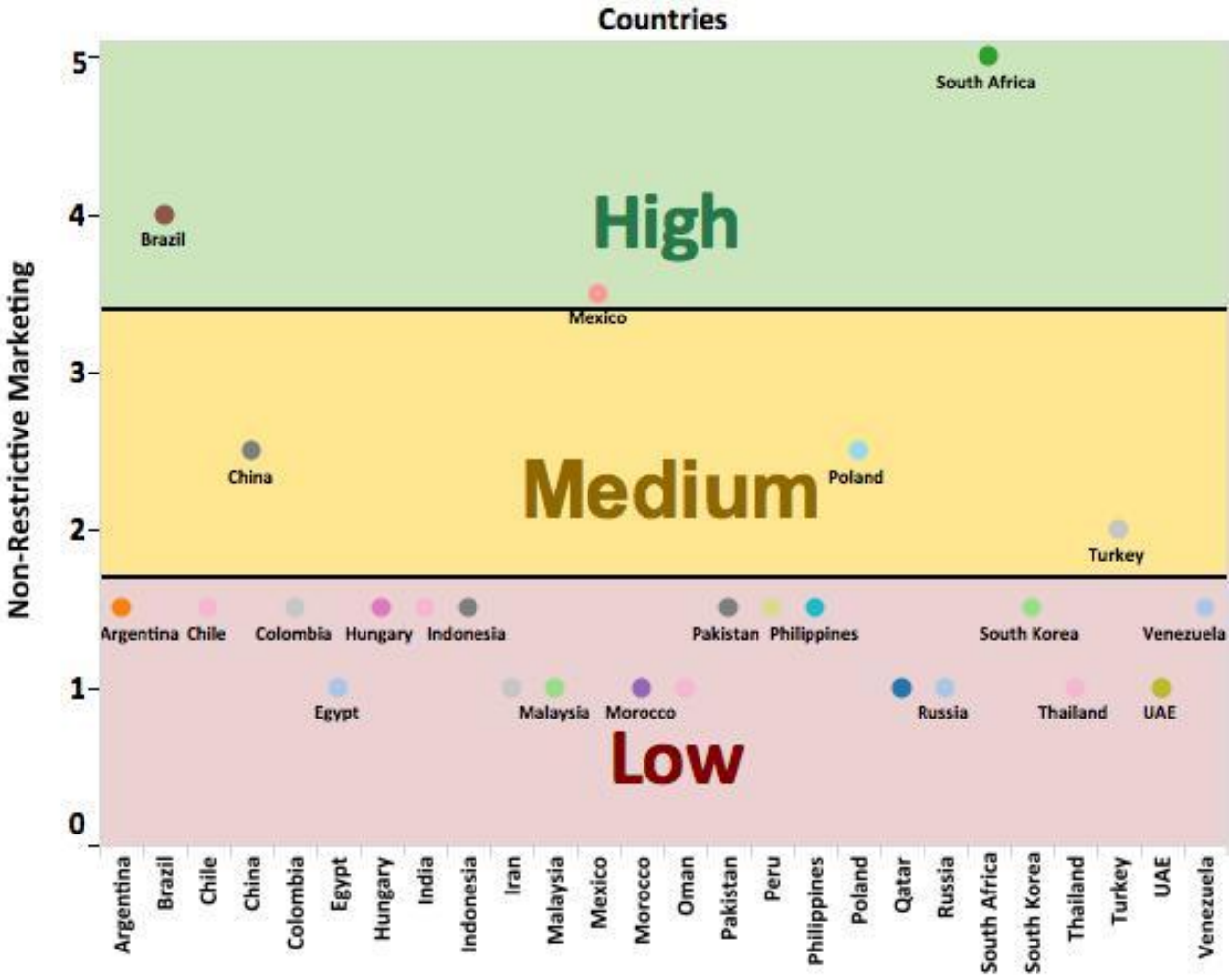
[15] Graph 4 shows the scatterplots for intellectual property rights index, public health expenditure, and corruption perception index. Intellectual property rights are positively correlated with corruption perception and public health expenditure.

Map 1: Marketing Restrictiveness in the Pharmaceutical Industry[16]

Out of the 81 countries from above, only 27 emerging market countries are included in the graph below. These countries are triaged into high, medium, or low tranches based on the level of marketing non-restrictiveness. We will apply our model findings in section 5 to a select few case study countries, such as Russia, China, and Turkey to assess the situation of marketing regulations in specific markets.

[16] Map created using the marketing restriction index.. Marketing restrictiveness is scored from 1 (most restricted) to 6 (least restricted). Highest marketing restricted countries are color coded as darker green, medium marketing restricted countries as yellow, and least restricted countries as darker red.

Graph 5: Non-Restrictive Marketing Index on Emerging Markets [17]

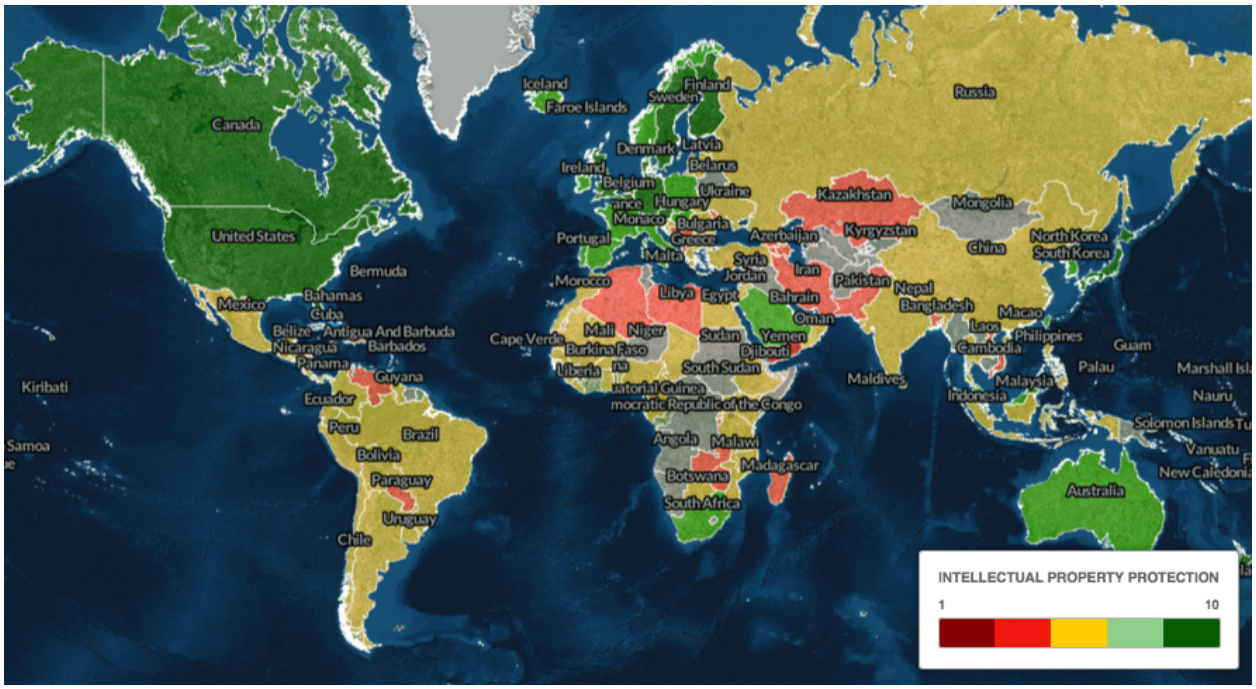


ii. Intellectual Property Protection

The map below shows the level of intellectual property protection on 81 countries on a scale of 1 (least protection) to 10 (most protection). United States, Canada, Australia, and most of the countries in Western Europe have the highest intellectual property protection laws while the Asian and Latin American countries are in the middle. The Middle Eastern and North African countries have the least intellectual property protection.

[17] The graph shows the level of restrictive marketing in the pharmaceutical industry for emerging markets, scored from 0 to 5.1. Countries in the red region, with a score of 0 to 1.7, are categorized as high marketing restrictions. Countries located in the yellow region or with medium marketing restrictions, are scored from 1.7 to 3.4. Lastly, countries in the green region have the lowest marketing restrictions, with a score of 3.4 to 5.1.

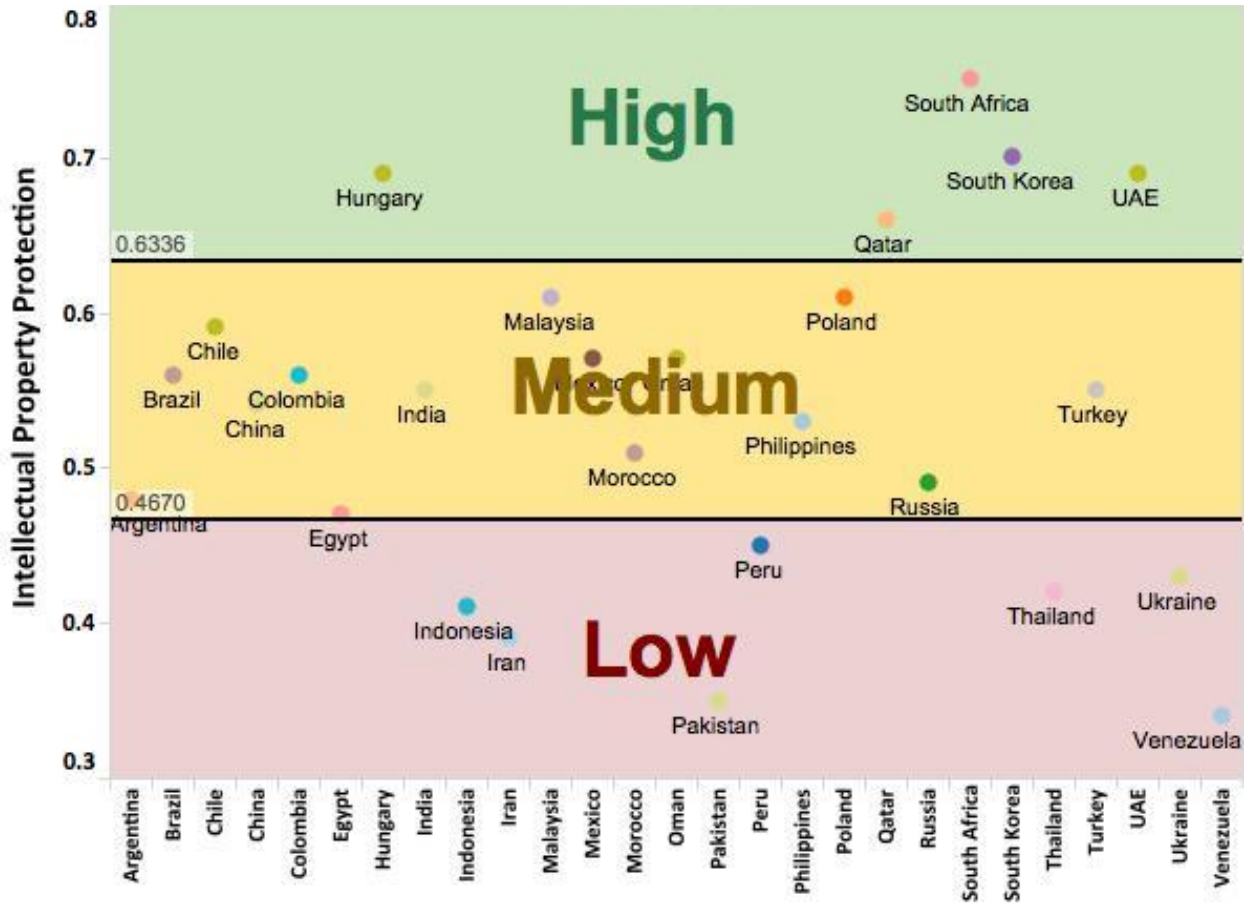
Map 2: Intellectual Property Protection[18]



Out of the 81 countries from above, only 27 emerging market countries are included in the graph below. These countries are triaged into high, medium, or low tranches based on the level of intellectual property protection. The score was transformed from 1 to 10 to 0.1 to 1. The range was then changed to 0.3 to 0.8 because none of the emerging markets country have a score of higher than 0.8 or lower than 0.3.

[18] Map created using the property rights protection index (score from 1 to 10), with data from Property Rights Alliance. Countries with the highest intellectual property protection are shaded in darker green while countries with the lowest intellectual property protection are shaded in darker red. Countries shaded in yellow, lighter red, and lighter yellow are somewhere in the middle.

Graph 6: Intellectual Property Protection Index on Emerging Markets[19]



Together, intellectual property protection and marketing restriction were added together to create another index called the regulatory favorable environment index. Intellectual property protection and marketing restriction were first converted to a score out of 1 (as the highest), weighted at 50%, to create a regulatory favorable environment score of 1 (being the most favorable). China, Qatar, and Chile were amongst the highest, while Cuba, Russia, and Venezuela were the lowest. This will be explored below in graph 4.

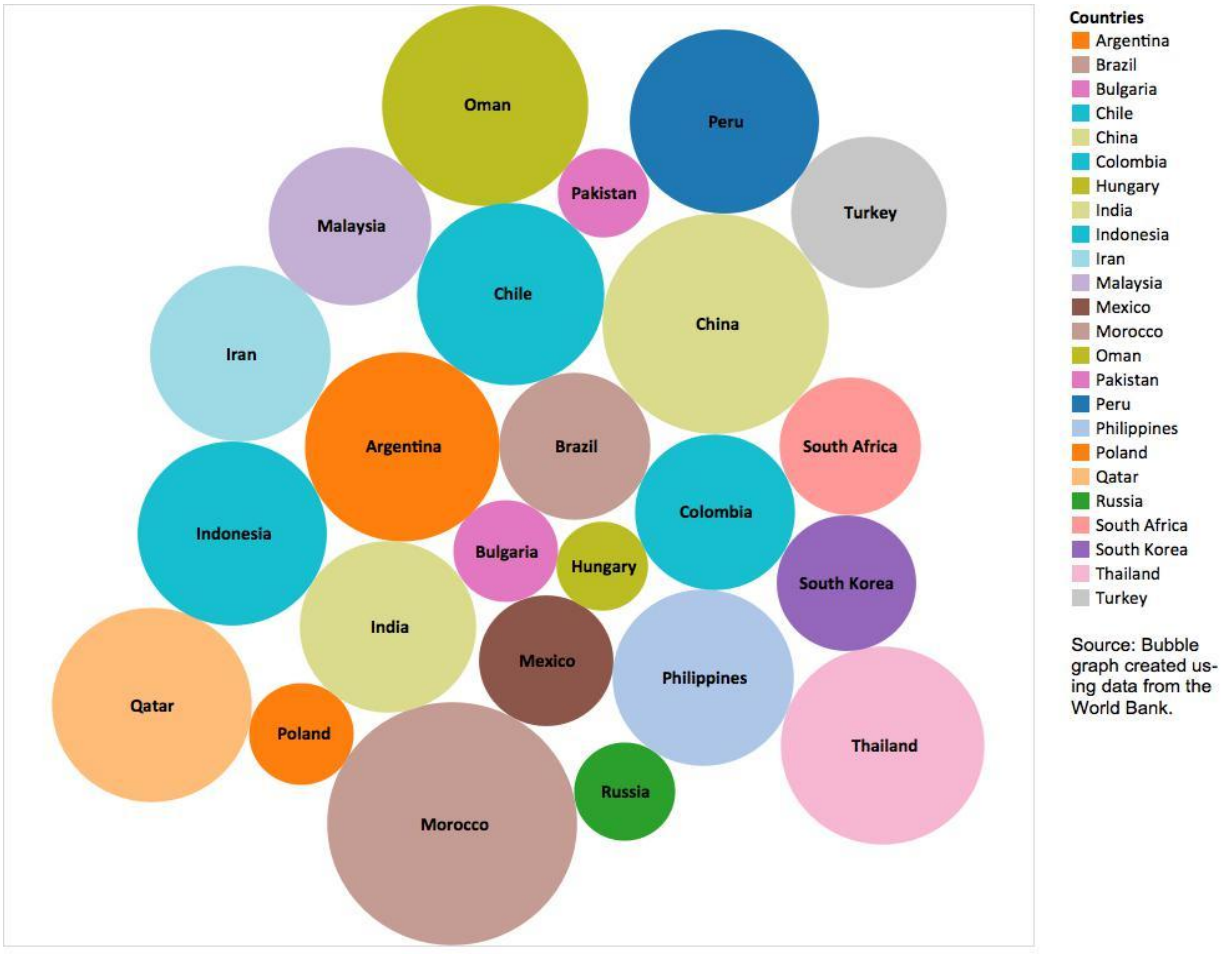
[19] The graph shows the level of intellectual property protection in the pharmaceutical industry for emerging markets, scored from 0.3 to 0.8. Countries in the red region, with a score of 0 to 1.7, are categorized as high marketing restrictions. Countries located in the yellow region or with medium marketing restrictions, are scored from 1.7 to 3.4. Lastly, countries in the green region have the lowest marketing restrictions, with a score of 3.4 to 5.1. Data source from Property Rights Alliance.

b. Identifying Market Growth Potential

i. Health Expenditure PPP Growth from 2009 to 2013

Market potential is another variable that is crucial in our model. To measure market potential, we used data from the World Health Organization on health expenditure measured in PPP from 2009 to 2013 for 27 emerging markets countries. The growth rate was calculated from 2009 to 2013, which is used as an indicator for market potential. Below shows a bubble graph of the relative size of health expenditure growth for emerging market countries. China has one of the highest health expenditure growth while Russia has one of the lowest.

Graph 7: Health Expenditure Growth (PPP)[20]



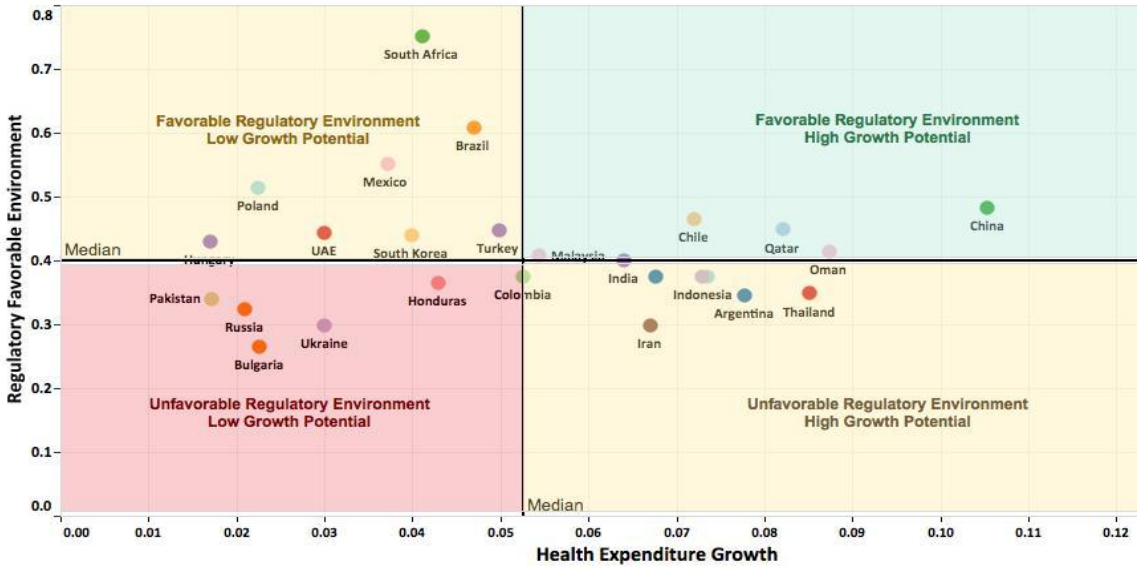
[20] The bubble graph shows the relative size of 27 emerging market countries' health expenditure growth from 2009 to 2013. Data from the World Bank.

ii. Regulatory Favorable Environment Index and Absolute and Growth of Health Expenditure

Graph 8 shows a two-by-two quadrant of the regulatory favorable environment and market potential variables for 27 emerging markets countries. Countries in the green quadrant represent favorable regulatory environment and high growth potential, which are the ideal countries for pharmaceutical companies to invest in. These countries include China, Chile, and India. On the other hand, countries on the yellow quadrants show favorable regulatory environment and low growth potential or unfavorable regulatory environment and high potential growth. These countries include Brazil, South Africa, and Turkey. These may still be of interest for pharmaceutical companies to invest in. As for the countries in the red quadrant, which represents countries in the unfavorable regulatory environment and low growth potential, there is no reason to invest in these countries, unless there are a shift in regulatory policy or market potential. This includes Russia, Ukraine, and Venezuela.

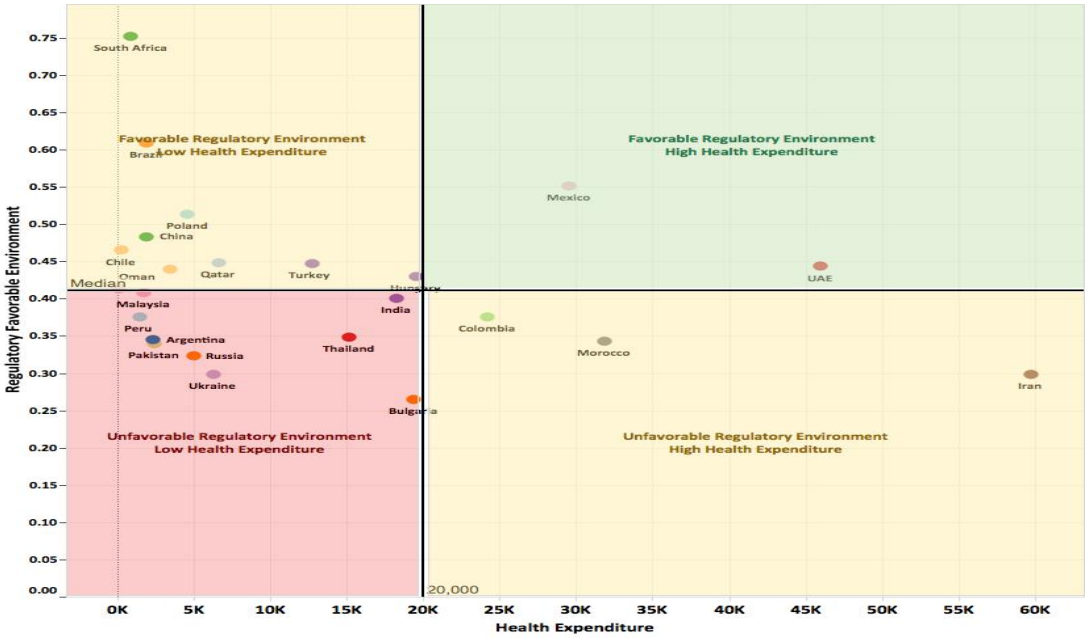
Another way to show this is by using health expenditure instead of the growth. By changing the x-axis, countries shift between the quadrants. United Arab Emirate and Mexico are the most favorable while Ukraine and Russia remained in the same quadrant.

Graph 8: Scatterplot of Regulatory Favorable Environment and Health Expenditure Growth[21]



[21] The two-by-two quadrant shows a scatterplot of the regulatory favorable environment (on the y-axis) and health expenditure growth(on the x-axis) for 27 emerging markets countries. The median reference lines are drawn through the median for both datasets to show the split between high and low regulatory favorable environment and the split between high and low market growth potential.

Graph 9: Scatterplot of Regulatory Favorable Environment and Health Expenditure[22]



Section 4: Policy Recommendations

a. Overview of Pfizer's Strategy

Pfizer Inc. is a research-based, global biopharmaceutical company. It aims to apply science and global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development and manufacture of healthcare products. Its global portfolio includes medicines and vaccines, as well as many of the world's best-known consumer healthcare products.

Pfizer has significant operations outside the United States. A significant change effected by Pfizer's new structure is the full integration of emerging markets into each of its three operating segments—the Global Innovative Pharmaceutical segment; the Global Vaccines, Oncology and Consumer Healthcare segment; and the Global Established Pharmaceutical segment. Emerging markets are an important component of its strategy for global leadership,

[22]The two-by-two quadrant shows a scatterplot of the regulatory favorable environment (on the y-axis) and health expenditure (on the x-axis) for 27 emerging markets countries. The median reference lines are drawn through the median for both datasets to show the split between high and low regulatory favorable environment and the value of 20K show the split between high and low health expenditure.

and Pfizer's commercial structure recognizes that the demographics and rising economic power of the fastest- growing emerging markets are becoming more closely aligned with the profile found within developed markets. Revenues from emerging markets accounted for 23% of Pfizer's total revenues in 2014. Pfizer established its Emerging Markets Business Unit in 2009 to meet the diverse medical needs of patients in emerging markets around the world in an innovative, socially responsible and commercially viable manner. The unit is focused on three strategic priorities: striving to drive incremental organic growth, pursuing strategic acquisitions and partnerships and seeking game-changing opportunities for innovation. Pfizer emerging markets spans more than seventy countries, across twenty time zones with 16,000 colleagues and the potential to reach approximately five billion people. The business unit has identified six priority markets – China, India, Brazil, Russia, Turkey and Mexico[23]. "We work extensively to identify countries with the strongest institutional safeguards that allow for tiered pricing and other tailored, flexible approaches to establishing the value of our medicines while also meeting the needs of different customers. Government engagement is vital to avoid price leakage," says Sandeep Duttagupta, Pfizer's Emerging Market Business Unit lead for emerging market access[24].

Pfizer identifies in its 10K that its future business growth depends on further progress in intellectual property protection. In emerging market countries in particular, governments have used intellectual property policies as a tool for reducing the price of imported medicines, as well as to protect their national pharmaceutical industries. There is considerable political pressure to weaken existing intellectual property protection and resist implementation of any further protection, which has led to policies such as more restrictive standards and more difficult procedures for patenting bio-pharmaceutical inventions, restrictions on patenting certain types of inventions (e.g., new medical treatment methods), revocation of patents, issuance of compulsory licenses, weak intellectual property enforcement and failure to

[23] Pfizer Expands Its Generics Portfolio Through Innovative Licensing Deals, Increasing Access To Medicines For Billions Worldwide. (2009, May 19). Retrieved May 8, 2015.

[24] Strategies for Emerging Markets: Seven Keys to the Kingdom. (2010). The Business Magazine of Pharma, 30(8), 5-5. Retrieved May 8, 2015, from https://www.imshealth.com/ims/Global/Content/Corporate/Press Room/IMS in the News/emerging_markets_seven_keys_to_kingdom2.pdf

implement effective regulatory data protection. Pfizer's industry advocacy efforts focus on seeking a more balanced business environment for foreign manufacturers, as well as on underscoring the importance of strong intellectual property systems for local innovative industries. The discrepancy in the intellectual property environment in different countries leads to different strategies employed by Pfizer in those markets. For instance, Pfizer has established R&D centers in China due to increased confidence in China's intellectual property environment. In India, however, the increasing tendency of the Indian Patent Office to revoke pharmaceutical patents in opposition proceedings, and restrictive standards for patentability of pharmaceutical products have made it difficult to protect many of Pfizer's inventions. "This is not only creating significant uncertainty in the market but it also undermines our ability to compete fairly in India, and our willingness to invest there," said Roy F. Waldron Chief Intellectual Property Counsel Pfizer, Inc[25].

Pfizer has established its own guidelines on business conduct. Some excerpts are as follows:

Promotional Activities and Interactions with Healthcare Professionals

All colleagues must follow Pfizer's policies on promotional activities and interactions with healthcare professionals applicable to their business unit, to ensure compliance with laws and regulations. All promotional materials and communications must be accurate, not misleading, and compliant with all applicable medical, legal and regulatory standards, including any applicable standards addressing substantiation, scientific rigor and fair balance. Strict regulations govern not only our promotional activities but also our educational and commercial relationships with healthcare professionals, including our interactions with physicians, nurses, pharmacists and others who administer, prescribe, purchase or recommend prescription medications.

Anti-Bribery and Anti-Corruption

No colleague nor anyone acting on Pfizer's behalf may ever make a payment or provide a benefit that is intended to improperly influence—or even appears to improperly influence—a

[25] Waldron, Roy F.. Written Testimony Before the United States House of Representatives Energy and Commerce Committee. (June 27, 2013), Retrieved April 30, 2015. http://docs.house.gov/meetings/IF/IF17/20130627/101056/HHRG-113-IF17-Wstate-WaldronR-20130627.pdf

government official, or to gain an unfair business advantage. Pfizer also prohibits "commercial bribery." Generally, commercial bribery is giving, offering or receiving something of value to or from an individual or company in exchange for improper commercial conduct. Pfizer prohibits any colleague, middleman or other agent from directly or indirectly engaging in any form of bribery.

b. Model Findings Applied to Specific Countries - China, Russia, and Turkey

Country	Position	Context	Strategy
China	**Low regulatory risk, high growth potential**	- Largest pharmaceutical market given the demographic trend - Governmental health care expenditure rising at a 12.1% CAGR - Chinese government incentivizing Pharma R&D Investment	- Push for more evenly enforced standards for foreign and Chinese companies - Lobby for smoother registration approvals - Consider the marketing activities of target companies when doing M&A or forming joint ventures
Russia	**High regulatory risk, low growth potential**	- Tightening of regulations - Less import-dependent for pharmaceutical products	- Don't invest in the pharma market at the moment - If acquiring opportunity of local companies arise, carefully consider the challenges of operating in the Russian market
Turkey	**Medium Regulatory risk, medium growth potential**	-Restrictions on advertising are comparatively moderate and inherent uncertainties due to amendments and multiple applications of different laws in the industry. -Rule of law on patents is strong thank to reforms, international treaties and EU referenced jurisdiction -Some problems in enforcement such as delays in lawsuits	-Recommendations of Association of Research-Based Pharmaceutical Companies may provide a good guideline to benefit from advertisements while avoiding breaching any law. - Challenges in enforcement of intellectual property law but Pfizer may still invest. -Lobby for better patent protection and more effective enforcement

Russia Strategy

Our model shows that given the regulatory environment in Russia, it would offer unfavorable growth opportunities for the pharmaceutical industry. The environment will remain challenging in the near future as growth prospects for Russia's economy are bleak. In addition, the weak Ruble means profits made in Russia are relatively low when converted back to the US Dollar. Moreover, Russia continues to regulate market access, pricing, and compliance extensively and competitive pressure within the industry is expected to intensify.

The government has also drafted laws to further regulate pharmaceutical marketing. For example, one of the biggest potential changes is that pharmaceutical representatives will be banned from visiting doctors during regular operating hours (when they see patients). If implemented, Pfizer will need to find alternative ways to interact with physicians outside of their workplace. It would also be very important for Pfizer to build a stable relationship with pharmacists to develop a loyalty to the promoted drug, as there is a possibility to purchase almost every drug (even Rx) in the pharmacy without prescription in Russia. Moreover, due to the severe number of restrictions for advertising in Russia, drugs themselves are not permitted to be advertised. However, Pfizer could potentially avoid these restrictions by not advertising the drug but the disease and a telephone hotline for further information.

Additionally, a large number of pharmaceutical patents are expected to expire in Russia over the next few years. Given the overall decrease in available R&D funding because of the credit crisis, Pfizer should be examining new strategies to remain profitable. Some cash-rich pharmaceutical companies who are looking to make acquisitions of products and other companies have taken advantage of the low valuations as the result of the global economic crisis. The current strength of the US dollar against the Ruble and the potential for further devaluation has also lowered acquisition prices in USD terms, which would allow Pfizer to make lower cost acquisitions of Russian products or companies. In other words, the current environment presents large challenges, but there may be opportunities to consider if Russia's economic environment improves.

In addition to well-known political risks such as corruption, any multinational pharmaceutical company operating within Russia would face trademark and patent protection issues. Like most intellectual property regimes, Russian law provides that the first to file and register a trademark gets the rights. However, there is no law prohibiting bad faith registrations by parties unaffiliated with the real trademark. Recently, Starbucks famously won a long legal battle in Russia to do business under their trademark. However, Starbucks' trademark expired under a provision providing for expiration of trademarks not used for three years following registration. Before Starbucks could re-register their trademark, it was registered by an unaffiliated businessman known for registering famous trademarks and selling them back to their affiliated companies at high prices.[26] Pfizer needs to ensure that trademarks they may want to buy or use in Russia are properly registered and have not expired in order to avoid the time and expenses of such a legal battle.

The current negative outlook for investing in Russia could become more favorable in the future due to certain programs being implemented. For example, the nationalization of Russia's healthcare system has resulted in less volatility, which in turn could translate into more consistent revenue streams for the pharmaceutical industry. The Russian government is also tightening existing regulations. Since April 2010, new maximum price regulations have been put into place and apply to all drugs included on the essential drug list (EDL) eligible for state purchases. In addition, the wider acceptance of experimental therapies and testing has allowed for increased drug R&D to take place. Further proposed changes in Russia's health insurance laws and health ministry may also increase the amount of R&D funding available for development of pharmaceutical products in Russia.

In 2012, hospital drugs and reimbursed drugs in Russia accounted for 5 billion USD and 2.5 billion USD respectively for a total of 7.5 billion USD. Plans for the government to broaden drug reimbursement starting in 2016 are being discussed, which would increase the number of eligible drug patients in Russia[27].

[26] Kramer, Andrew. After Long Dispute, A Russian Starbucks. The New York Times. (2007, September 7).Retrieved April 17, 2015.

[27] Blackbeard, Julie. Rubin, Max. Putin - pharma's friend or foe in Russia? PMLiVE. (2013, October 29). Retrieved April 20, 2015.

Moreover, in 2009, Russia's Ministry of Industry and Trade launched the Strategy Pharma 2020 in which the government targets improvement of Russian production to lower imports by 50%. This plan is significant as it aims to rely less on foreign imports, but rather increase job opportunities for Russians in the pharmaceutical industry. The low Ruble, as mentioned previously could mean lower profits in US Dollar terms, but on the flip side, paying Russian wages in Ruble for the manufacturing production could be beneficial in cost savings for international pharmaceutical companies. Large international pharmaceutical companies have already started to plan production in Russia, with investments reaching 1 billion USD[28]. Unlike large groups such as AstraZeneca and Novartis, which have directly invested over 100 million USD in manufacturing facilities in Russia, Pfizer has chosen to partner with Petrovax for local manufacturing. Bayer and AbbVie have also opted for manufacturing partnerships, with Medsintez and R-Pharm respectively.

For pharmaceutical companies looking to replace products that have expiring patents and make the most out of the favorably low valuations caused by the financial crisis, the benefits of acquiring pharmaceutical companies or development products in Russia could potentially outweigh the risks, but we advise for pharmaceutical to take a wait and see approach. Given the trademark and patent protection issues, multinational pharmaceutical companies seeking to capture this growth must be prepared to face the challenges of increasing regulation and competition within the Russian market.

China Strategy

Our model shows that China has a favorable regulatory environment and high growth potential, which implies that China is a sweet spot for multinational pharmaceutical companies to be in. Strong intellectual property protection and clearly defined marketing regulations will contribute to the transparency and efficiency of the pharmaceutical industry.

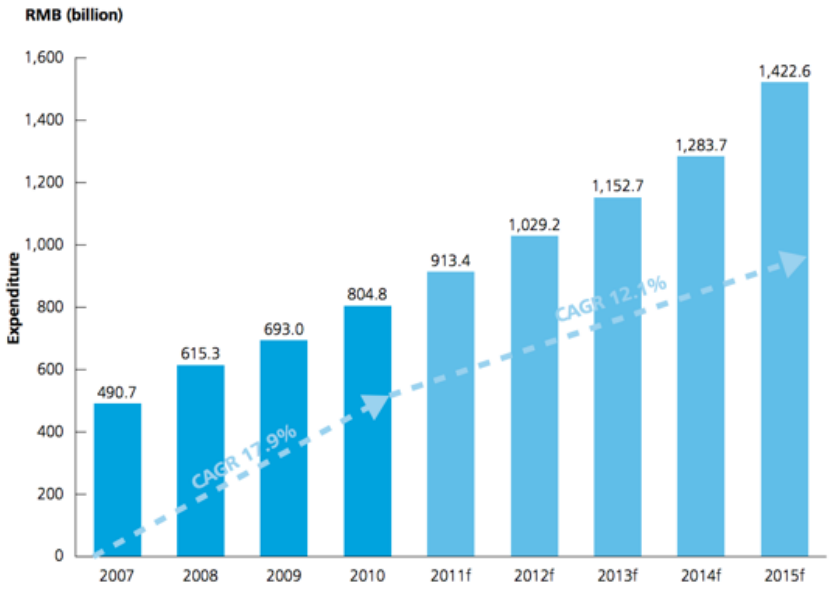
China is one of the largest pharmaceutical markets in the world because of its large population base. The combined forces of demographic development, government healthcare

[28] Embassy of Switzerland in Russia. Pharma 2020, The Strategy of The Pharmaceutical Industry of the Russian Federation. Retrieved April 20, 2015.

plan, the effort of improving health awareness among the public, market booming, and improving R&D capability helped the country to grow into a more attractive market nowadays. China has the largest elderly population in the world. This group of people represents a huge potential for a growing market for pharmaceutical companies, because the aging population will generate higher demand for health care services.

From the government side, since the reformation of healthcare, the expenditure is growing in China, one chart from WHO shows the trend that healthcare represents a growing curve. Chinese government officials have indicated they are trying to maintain the affordability of health care for its more than 1.3 billion citizens.

Graph 10: China government healthcare expenditure, 2007–2015[29]



Thanks to the vast available sites with low cost materials and labor force, China has for years been regarded as a favorable location for research due to the enormous pool of qualified research subjects. A growing number of companies have become increasingly attracted to the idea of having an R&D center in China. In a market-driven research, a survey from multinational

[29] The graph shows China's health expenditure from 2007 to 2015 with a upward growing trend. Data source from the World Health Organization (WHO).

drug firm executives, 90 percent of respondents said China is already a top five global strategic priority for their companies.

When it joined the World Trade Organization a decade ago, China was required to bring its Intellectual Property rights obligations in line with WTO's standards in order to gain certain trade benefits. Since then China has undertaken numerous efforts to ameliorate its IP laws. For instance, China launched a Medium and Long Range Science and Technology Plan, a National IP Strategy, and a National Talent Strategy.

We can see from the final output model that although China's regulatory environment is favorable, it is still not as good as some developed markets such as Switzerland and Norway, which suggests that there is still room for improvement. The State Intellectual Property Office of China (SIPO) issued more than 961,000 patents in 2011, but most of these were granted to domestic applicants[30]. This has created problems for international rights holders including pharmaceutical patents holders who complained about patent quality. Some multinational pharmaceutical companies such as Eli Lilly & Co. and Johnson & Johnson have also complained about the slow regulatory approval[31]. Multinational pharmaceutical companies in China should push for more evenly enforced standards for foreign and Chinese companies and lobby for smoother registration approvals.

Apart from patent regulations, the regulations on pharmaceutical marketing are also clearly defined in China. The Department of Drug Market Compliance of the State Food and Drug Administration (SFDA) takes charge of the central regulation of pharmaceutical advertising. Local authorities in the provinces or municipalities where the advertisements are to be broadcast or published will review the marketing material. Under the rules, patients and medical professionals are prohibited from promoting the efficacy and the use of treatments. Actors are banned from appearing as medical experts or disease sufferers in radio and television promotions[32]. In fact, Chinese anti-bribery and corruption legislation are similar to those of its better-known Western counterparts. Chinese government has made a lot of efforts to fight and investigate bribery cases related to the purchase and distribution of drugs, medical

[30] Intellectual Property Trends and Developments with China. (2013, January 28). Retrieved May 9, 2015.
[31] Burkitt, L. (2015, April 20). U.S. firms lobby China over business conditions. Retrieved May 8, 2015.
[32] Deloitte,. *The Next Phase: Opportunities In China's Pharmaceuticals Market*. 2015. Web. 8 May 2015.

equipment and services in the health sector. For example, GlaxoSmithKline was found guilty of bribing non-government personnel such as doctors to use its drugs in China, and the U.K. drug maker handed the largest ever corporate fine in China.

Pharmaceutical companies have been taken advantage of a favorable M&A environment to shore up their earnings. There has been a significant amount of M&A activity in China because multinational pharmaceutical companies all want to tap into the local market with great potential. For multinational pharmaceutical companies such as Pfizer who engage in M&A activity and joint ventures in China, it is important to take into account the marketing activities of the target companies because of the associated risk of assuming liabilities of their target companies' illegal or inappropriate practices, especially when China is cracking down on bribery and corruption in every possible industry. We suggest that multinational pharmaceutical companies should bolster local compliance procedures and sales structure to ensure that robust measures are in place to strictly conform to local anti-bribery laws. It is recommended to hire an external consulting firm to strengthen procedures.

Turkey Strategy

Our model shows that Turkey has a moderate regulatory environment while it would offer moderate growth opportunities for the pharmaceutical industry. There are a number of factors Pfizer should take into consideration with increasingly complex regulatory environment.

Turkey is the 15th largest pharmaceutical market in the world with a share of 1% of the global market. It has low per capita GDP and per capita health (and pharmaceutical) expenditure compared to many developed countries, yet much like India and China, it has high health and pharmaceutical expenditure. In addition, there has been a dramatic upward trend in annual government pharmaceutical expenditures with an average increase of 15.6% between 1994 and 2011[33]. Almost 100% of the population is covered by a health insurance where the government-funded Social Security Institution acts as the biggest health insurance provider and single payer in the pharmaceuticals market.

[33] Pharmaceutical Market Report, Turkish Competition Authority, 2011, 57
http://www.rekabet.gov.tr/File/?path=ROOT%2f1%2fDocuments%2fSekt%C3%B6r+Raporu%2filacrapor.pdf

Similarly to many countries, physicians in Turkey have the power over the decision making of their patient's product. Additionally, Turkey's pharmaceutical industry is characterized with a central reimbursement mechanism and heavy regulation for marketing activities. On the other hand, unlike many countries, global pharmaceutical companies have a higher share compared to domestic firms in the Turkish market. Moreover, there is a price regulation structure, which is based on a pricing system referencing EU countries, and thus the global pharmaceutical companies need to consider this fact when building their strategy of introducing new drugs to Turkish market. Furthermore, intellectual property rules, which are comparatively new, low R&D investments and unstable legal structure, can be considered barriers to entry into the Turkish pharmaceutical industry[34].

Ministry of Health, as well as Drugs and Medical Devices Administration are the main governance bodies for pharmaceutical industry in Turkey. "The [Drugs and Medical Devices Administration] has sole authority for the registration, marketing approval and authorization, pricing, legal classification, and inspection of pharmaceuticals, manufacturers, wholesalers, and retail pharmacies. Additionally, as a member of the World Trade Organization (WTO), Turkey is subject to certain trade agreements" (Carswell 2012, 107-8)[35]

The regulatory environment of the Turkish pharmaceutical market can be regarded as moderately challenging. Every new drug needs to be registered and authorized in order to be introduced to the market. However, this three-step process (Advisory Commission for Authorization of Medicinal Products for Human Use, Advisory Commission for Technology and Pharmacology, Price Evaluation Committee) has significant delays in the official proceedings, which may create a lag of -sometimes- three years despite the maximum 210 days in theory. Prescription fraud and counterfeiting may be regarded as important challenges in the healthcare system despite some new efforts to reform the tracking system. There is strict pharmaceutical product promotion, but it is still unclear and became more regulated after

[34] Pharmaceutical Market Report, Turkish Competition Authority, 2011, 54

[35] Carswell, K. (2012) Turkish Pharmaceuticals: An Industry In Transition, Advance Directive VOLUME 21 SPRING 2012 PAGES 106-116 106 By: Keshia Carswell, Annals of Health Law

amendments in 2011. The main points on advertisement in the related law on pharmaceutical promotions can be summarized as below:[36]

- Advertisements of prescription medicines can only be published in medical magazines, with prior approval by the Ministry of Health Advertisements which misrepresent or exaggerate the curative properties of medicines are prohibited.
- Motion pictures on the scientific properties of a medicine can be demonstrated only in places approved by the Ministry of Health. According to Article 5/4 of the Pharma Promotion Regulation, healthcare professionals can appear in these motion pictures only with the prior approval of the Ministry of Health

Sales representative and congress sponsorships are among the most common and traditional marketing channels for pharmaceutical products in Turkey. Virtual sales representative visits, internet channels are also being used for promotion purposes[37]. In case of breach of promotion regulations the pharmaceutical companies may be warned and also can be prohibited from promotion activities. Broadcasting laws also sanction media services with monetary fines when applicable. In addition, Turkish Criminal Law, Consumer Protection Law and also Competition Law are applicable to the pharmaceutical promotion activities to some extent[38] -which create further uncertainties. Furthermore most multinational companies also choose to rely on their own internal compliance processes and also follow the promotional code of AIFD (Association of Research-Based Pharmaceutical Companies)[39].

Intellectual property rights in Turkey are developing but cannot be regarded as strong, yet.[40] Although the early legislation in the protection of patents dates back to 1879, the most

[36] Promoting Medical Products Globally, Turkey, Baker McKenzie, p.4
http://www.bakermckenzie.com/files/Uploads/Documents/Global%20Pharmaceuticals/Turkey.pdf
[37] IMS Heatlh Pharmaceutical Market Europe May 2011 p.61
https://www.imshealth.com/ims/Global/Content/Corporate/Press%20Room/IMS%20in%20the%20News/Documents/ICG_Turkey_Article.pdf
[38] Promoting Medical Products Globally, Turkey, Baker McKenzie, p.4
http://www.bakermckenzie.com/files/Uploads/Documents/Global%20Pharmaceuticals/Turkey.pdf
[39] IMS Heatlh Pharmaceutical Market Europe May 2011 p.57
https://www.imshealth.com/ims/Global/Content/Corporate/Press%20Room/IMS%20in%20the%20News/Documents/ICG_Turkey_Article.pdf
[40] Hancer and Erciyas (2014) argue that "It would be unfair to say that Turkish patent law lacks sufficient legal basis for strong protection. In fact, all of Turkey's IP-related laws and regulations, including the Decree Law No 551 Pertaining to the Protection of Patents (Patent Law), have become fully compliant with EU legislation and international treaties since the mid-1990s. The establishment of specialised IP courts has enhanced this practice. However, there are some pitfalls in practice and some gaps in the legislation that may sometimes reduce its ability to

important step for intellectual property rights was in 1995 when a new law for patent, trademark, industrial design, and geographic indicator was passed following the establishment of the patenting authority (Turkish Patent Institute) in 1994. However, despite the reforms in 2004 some pharmaceuticals companies have criticized provisions. For example, delays in the initiation of infringement suits until after the patent is approved and published[41] are criticized.

In patent infringement lawsuits a patent owner is not allowed to access the case files' content without having a court order or the counterparty gives consent. This means that the patent owner is not allowed to gather materials to make an accurate assessment of infringement and decide whether to act, but instead has to ask a court for a determination of evidence[42]. In addition to this, problems in pharmaceutical data exclusivity protection[43] and piracy are regarded as important issues related to the protection of intellectual property rights in the Turkish pharmaceutical market. As a result, in 2004 Turkey was elevated from the Special 301 Watch List to the Priority Watch List, due to concerns about lack of pharmaceuticals data exclusivity protection and continued high levels of piracy and counterfeiting of copyright and trademark materials[44]. Dereligil (2012) summarizes the main problems in the intellectual property rights in Turkish pharmaceutical market as follows[45]:

- The adoption of updated draft laws regulating intellectual and industrial property rights, including deterrent criminal sanctions, is still pending.
- The appeal stage before the Supreme Court is very long.

provide effective protection." http://www.worldipreview.com/article/strengthening-turkey-s-pharma-industry-with-ip

[41] US National Trade Estimater Report, Turkey, 2005, p.622 https://ustr.gov/archive/assets/Document_Library/Reports_Publications/2005/2005_NTE_Report/asset_upload_file512_7503.pdf

[42] Hançer and Erciyas (2014) http://www.worldipreview.com/article/strengthening-turkey-s-pharma-industry-with-ip

[43] "Data exclusivity refers to a set period of time after the marketing approval, during which no one else may rely on or use the innovator's data to obtain a marketing authorization for a particular product. It constitutes an important incentive to the research and development of new medicines." http://www.ifpma.org/innovation/ip-rights/data-exclusivity.html

[44] US National Trade Estimater Report, Turkey, 2005, p.622 https://ustr.gov/archive/assets/Document_Library/Reports_Publications/2005/2005_NTE_Report/asset_upload_file512_7503.pdf

[45] "Turkey: A "pharmerging" country" .http://www.patentlawyermagazine.com/turkey-a-pharmerging-country/

- The number of trained personnel is still not sufficient, although many judges, prosecutors, court experts, police forces and customs officers have been trained in patent issues.
- There have been strong lobbies and debates over the length of data protection and Supplementary Protection Certificates (SPC) so far.

Our model findings and the case study for Turkish pharmaceutical markets are compatible. Turkish pharmaceutical market has a moderate growth potential with mid-level regulatory risks regarding marketing and patents. In our study, we found that introducing new drugs and investing in Turkish pharmaceuticals market is profitable. However, the companies should take into account the relevant risks and build their strategy accordingly. Although the current legislation may not be very clear, the guidance of Association of Research-Based Pharmaceutical Companies may provide an important tool in order to avoid the related threats in advertising issues. Moreover, despite recent improvements in patent protection, the companies should still recognize the regulatory problems in the application of intellectual property law within the industry and develop their action plans accordingly.

Section 5: Conclusions

After analyzing the drivers of regulatory risks and formulating strategies for multinational pharmaceutical companies to enter into emerging markets, we conclude with the following:

- Pharmaceutical companies **must focus on countries** that are actively taking **measures to reduce corruptions**. Our findings reveal a **reduction in corruption levels** is associated with **improved regulatory environment**.
- Pharmaceutical companies must pay close attention to **out-of-pocket health expenditure**. Although out-of-pocket health expenditure represents higher market potential, it is usually **associated with higher regulations**.
- **China** is an important growth market for pharmaceutical companies, yet, companies must be **cautious of the new anti-bribery laws**.
- **Turkey**, with its improving regulatory environment and market size, represents an **important growth market** for pharmaceutical companies.

- Although **Russia,** in the long run is an important growth market, in the short run, we advise **to maintain the status quo**.
- Apart from Turkey and China, we also recommend to **expand in South Africa, Brazil, Malaysia, Colombia, Chile, India, Philippines, Indonesia, Qatar, Argentina, and Morocco.**