Master's Thesis

A Generalized Double Diamond Approach to the Global Competitiveness of the Pharmaceutical Industry
− A Comparison between Korea and Japan −

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Abstract

A competitive pharmaceutical industry is integral for the continued improvement of any country's social and health resources and can be a source of sustained economic growth. As South Korea faces economic slowdown and increased social and health costs from an aged population, it is necessary to examine the current state of the industry's competitiveness to determine how its global position can be enhanced. The following study identifies the determinants of South Korea's competitiveness by applying the Generalized Double Diamond Model and conducts a comparative analysis with the globally competitive country of Japan. Given the extent to which the pharmaceutical industry is globalized, the study explores both domestic and international variables at country and industry level ranging from 2015 to 2019. The results indicate that although South Korea almost matches Japan in terms of domestically determined competitiveness, there are significant international strategic differences that are hindering South Korea from becoming as globally competitive as Japan.

Keyword: Pharmaceutical Industry, South Korea, Japan, International Competitiveness, Generalized Double Diamond Model
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Table of Contents

Figures and Tables

Figures

Tables

Chapter 1. Introduction

Innovation-based high technology industries, such as semiconductors, automobiles and telecommunication devices, have hugely driven South Korea's social and economic development, and boosted the economy from one of the poorest in the world in the 1950s, to one of the largest (Kim and Lee, 2019). Amongst OECD countries, South Korea ranked second in terms of R&D investment as a proportion to the national GDP and sixth in terms of the global market share of ICT products (KHIDI, 2018). However, the country now faces increasing uncertainty as to its ability to continue depending on its export led growth strategy in the aforementioned industries (White, 2019) given the price competitiveness of new entrants. South Korea will not be able to compete in terms of cost or scale with the manufacturing industries of developing countries and must focus on higher value-add activities and sectors that will draw in capital investment from abroad. As Roach and Lam argue, South Korea has a comparative advantage in "technology and design, not in resource-intensive heavy-manufacturing industries, which will inevitably lose market share to competitors [like] China" (Roach and Lam, 2010). The South Korean government has therefore determined the pharmaceutical industry to be a future growth engine for its economy (KHIDI, 2018).

Globally, pharmaceutical exports increased the most out of all manufactured goods, growing at a rate of 4.3 percent between 2008 and 2018 (WTO, 2019, p.11), and the market is predicted to continue growing at a compound annual growth rate of 4.6 percent between 2020 and 2027 (Grandview Research, 2020). For South Korea, the pharmaceutical industry is set to continue growing between 3 to 6 percent into 2021 and is predicted to increase employment at double the rate of the entire manufacturing sector (KOTRA, 2019) with the government forecasting over 170,00 jobs being created in the industry between 2018 and 2025 (KHIDI, 2018). However, the growth of the pharmaceutical industry promotes more than just the economic development of a country as it ensures the development of the health and social resources that feature in the UN's sustainable development goals (Lakner et al., 2019). South Korea already faces increased pressure to sustain its Universal Health System and critics foresee a difficulty in the health sector meeting the growing health demand from its rapidly aging population. Given the impact this industry is desired to have on South Korea's economic and societal development, it is necessary for policymakers to have a full understanding of the state of the industry and which determinants of competitiveness will ensure its long-term growth.

Though research into the competitiveness of pharmaceutical industries is extensive, most studies focus on either mature markets like the US, Japan or the EU, or on newly emerging developing markets such as China, India, Iran etc. Though the US, Japan and the EU have long benefited from first-mover advantages and economies of scale that fostered a competitive R&D environment, the pharmaceutical industry continues to undergo structural changes that are opening up the opportunity for new players to capture international market share (Gambardella et al., 2000). This study thus fills in a gap in the existing literature of research into the rapidly growing South Korean pharmaceutical industry by comparing its competitiveness with the mature Japanese industry.

Previous research has already indicated the need to compare the levels of international competitiveness of Japanese and South Korean manufacturing industries, given their geographical proximity, limited mutual foreign direct investment, factor endowments, and comparable level of economic development (Fukao et al., 2016). South Korean firms in the electrical and automotive industries, such as Samsung Electronics and Hyundai Motors, have already surpassed their historically mature Japanese counterparts on the international playing field. Therefore, it is interesting to see whether the as yet still developing Korean pharmaceutical industry has the potential to follow the trajectory of the above-mentioned industries. In addition, it will be interesting to determine which factors are predominantly impacting its level of competitiveness when compared with the more established Japanese pharmaceutical industry.

According to data on the Total Value of Pharmaceutical Exports (Millions, US$) taken from UN Comtrade, both countries have factored in each other's top three pharmaceutical export destinations worldwide from 2017-2019 and are therefore greatly influencing demand conditions and sales volumes in each other's pharmaceutical industry. Moreover, the World Health Assembly Resolution (WHA 67.22) placed emphasis on the regional collaboration of Asia Pacific countries to "promote collaboration and strengthen the exchange of information on best practices in the development, implementation and evaluation of medicine policies and strategies that enhance access to affordable, safe, effective and quality-assured essential medicines"(Kwon et.al, 2015). As a regional leader in the industry, an analysis into Japan's pharmaceutical market conditions and the policies implemented by the government can therefore help determine which strategies South Korea should implement to succeed in the future. With this in mind, this study aims to identify the strengths and weaknesses of the Korean Pharmaceutical Industry by analyzing its performance in a domestic and global setting. So as to establish useful implications and suggestions for its improvement, the more internationally competitive Japanese Pharmaceutical industry will serve as a point of comparison.

The contribution of this study is thus twofold. Firstly, this paper quantifies the international competitiveness of the Korean and Japanese pharmaceutical industries and suggests a series of proxy variables by applying the Generalized Double Diamond Model (referred throughout the rest of the study as the GDDM model). Secondly, the study assesses the competitiveness of South Korea in relation to Japan. The study finds that the domestic competitiveness of the Korean pharmaceutical industry is comparable to Japan's, with little difference across all determinants. The main difference between the industries arises from international competitiveness. If South Korea is to succeed in catching up with Japan as an international leader in the pharmaceutical industry, it should ensure that policies incentivize FDI inflow and outflow.

The study begins with an introduction to the global pharmaceutical industry and an overview of both the South Korean and Japanese pharmaceutical industries. Following literature reviews of existing studies on factors contributing to the competitiveness of the pharmaceutical industry, there is an introduction to Porter’s diamond model and the chosen model for this study, the GDDM model. The subsequent sections then present the utilized data and variables before concluding with the results of the study.

Chapter 2. Background

2-1. Overview of the Global Pharmaceutical Industry

The pharmaceutical industry is facing a period of rapid transition as cell and gene therapies, that could revolutionize the lives of many whose medical needs have previously been unmet, are obtaining their marketing approvals and are entering into the commercial markets (EvaluatePharma, 2019). Looking at 2020, pharmerging markets, those who are increasing their levels of consumption of pharmaceutical goods but are still lacking in terms of market maturity, are consuming two-thirds of the world's medicines in terms of volume. Healthcare access across the world continues to expand, and Aitken and Kleinrock estimate that "over 50 percent of the world's population will consume more than 1 dose per person per day of medicines, up from one third of the world in 2005, driven by India, China, Brazil and Indonesia" (IQVIA, 2019). This consumption predominantly stems from generic, non-branded and over the counter medicines whose affordability is ensuring that essential medicines are accessible for poverty-stricken populations.

In contrast, mature markets are consuming newer medicines for non-communicable diseases[1] and promising therapy areas like Oncology[2], Immunosuppressants[3], or Dermatologicals, which tend to have a higher per unit price point both for the manufacturers during production, and for consumers and the public healthcare system (IQVIA, 2019). By looking at the top ten therapy areas in terms of predicted sales volume in 2024, the table below shows that Oncology, Immunosuppressants, and Dermatologicals are indicated to be the largest growing therapy areas in the market between 2018 and 2024 in terms of worldwide sales, respectively growing 11.4 percent, 16.9 percent and 12.6 percent.

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[1] Non-infectious or non-transmissible diseases
[2] Therapeutic cancer treatments, excluding supportive care (definition provided by IMS)
[3] Suppression of immune response, often for use in organ transplant (definition provided by IMS)

Table 1: Worldwide Prescription Drug & OTC Sales by Evaluate Therapy Area (2018 & 2024): Top 15 Categories & Total Market

Therapy Area	Worldwide Sales ($bn)			Worldwide Market Share		
	2018	**2024**	**CAGR % growth**	**2018**	**2024**	**Change (+/-)**
Immunosuppressants	14.2	36.1	12.6	14.3	19.4	5.0
Dermatologicals	15.8	32.1	16.9	1.6	3.0	1.3
Oncology	123.8	236.6	11.4	1.8	2.6	0.8
Vaccines	30.5	44.8	6.6	3.5	3.7	0.1
Sensory Organs	22.3	30.5	5.3	2.6	2.5	-0.1
Anti-coagulants	19.3	24.6	4.1	2.2	2.0	-0.2
Anti-diabetics	48.5	57.6	2.9	5.6	4.7	-0.9
Bronchodilators	28.0	30.7	1.6	3.2	2.5	-0.1
Anti-virals	38.9	42.2	1.4	4.5	3.5	-1.0
Anti-rheumatics	58.1	54.6	-1.0	6.7	4.5	-0.9

Source: Edited from EvaluatePharma, 2019, p. 20

What holds true for both mature and emerging markets is the disruptive force that technology enabled healthcare delivery will have. Not only will technology aid in reducing infrastructure costs for large scale production of medicines, but new technological developments, such as big data and AI are ensuring that patients of even niche and previously untreatable diseases are being involved in the development of genetically personalized treatments (Aitken and Kleinrock, 2015). According to Aitken and Kleinrock (2015), these technologies will result in "greater availability of [biopharmaceutical] information and predictive analysis", telemedicine, health applications, wearables and sensors, to provide real time patient information.

Though technological advances are making these much sought after medicines a reality, they pose a huge threat to the pricing and reimbursement systems that have been essential to sustaining the industry's growth since its inception. Though the demand from emerging economies and aging populations are believed to be integral to the 2024 prediction of the prescription drug market reaching $1.18trn in sales, and IMS' expectation of a 24 percent increase in the volume of used medicine over the next five years (Aitken and Kleinrock, 2015), the universal health coverage systems present in middle and high-income countries will continue to suffer under the increased spending needed for the emerging and more expensive drugs, and may restrict price setting capabilities of pharmaceutical companies (EvaluatePharma, 2019). As reported in the OECD's 2018 Pharmaceutical Innovation and Access to Medicines report, most OECD member countries have some form of a centrally regulated health coverage scheme in place that provides positive lists of medicines that are covered and thus reimbursable. These government-initiated schemes finance "nearly 55 percent of retail pharmaceutical spending in OECD countries" (OECD, 2018). These increasing budgetary constraints in the face of slowing economic growth, will in addition shift the cost of medicines to the patient directly, increasing their engagement in the treatment selection process and scrutiny of the costs and effectiveness of treatments. Moreover, around $198bn sales are forecasted to be at risk from 2019 to 2024 as the patents of incumbent products that provided companies with consistent revenues will reach the end of their exclusivity period (EvaluatePharma, 2019). As this will be a major setback for drug manufacturers, it is more important than ever that companies capitalize on the available market opportunities both domestically and internationally.

When looking at the existing business environment in the pharmaceutical market Evaluate Pharma calculated the overall global market share of the top ten companies in terms of prescription drug sales in 2018 to have been at 41.7 percent: Pfizer (5.5 percent), Novartis (5.3 percent), Roche (5.4 percent), Johnson & Johnson (4.7 percent), Merck & Co (4.5 percent), Sanofi (4.2 percent), Glaxo-SmithKline (3.7 percent), AbbVie (3.9 percent), Takeda (2.1 percent) and AstraZeneca (2.5 percent). With prescription sales of over $345.4 bn, these ten multinational companies monopolized the global market and thus were individually key to maintaining the competitiveness of the pharmaceutical market in their domestic countries (Evaluate Pharma, 2019). For example, Takeda has been vital to improving the reputation of Japan's pharmaceutical market, being the only Japanese and non-American or European company to enter the top ten performing pharmaceutical companies in the world.

However, EvaluatePharma predicts a growing share of sales in companies outside of the top ten, with their market share increasing from 58.3 percent in 2018 to 64.9 percent by 2024 (Evaluate Pharma, 2019). Large pharmaceutical firms actively acquire technology and fund clinical trials that will enable the commercialization of drugs. Whilst they benefit from economies of scale by optimizing their capital costs and can utilize revenue streams from existing products to fund R&D programs, they are susceptible to fluctuations in their stock price and can be less favorable to high-risk investments. Though the global market is dominated by these mega multinational Pharmaceutical companies, the OECD argues that small and mid-cap firms and institutions are particularly important during the translational research stage[4], and are often backed by either venture or private equity capital to discover compounds and create patents or intellectual property rights that can then be licensed or acquired by other larger firms (OECD, 2018). The development process of a new drug can take on average 8 years, and is favored to investment from private investors and governments given the high risk and high cost requirements as the probability that a drug will receive marketing approval when entering into phase 1 of clinical trials is around 14 percent (OECD, 2018).

A successful and competitive pharmaceutical sector therefore can be seen to require the collaboration of different sized private and public businesses and institutions with sectoral specialization in order to engage in successful pharmaceutical R&D programs, procurement, and commercialization of manufactured medicines. Now more than ever, pharmaceutical companies are operating a more flexible business model and are outsourcing activities along the value chain including clinical trial procedures to Contract Research Organizations, logistics to distribution firms, and go-to-market procedures to marketing specialists. Beyond

[4] Medical research that facilitates the practical application of scientific discoveries to develop and impleme nt new ways to treat, diagnose, and prevent disease (definition provided by merriam-webster.com)

intra-pharmaceutical cooperation, there is a high level of interaction between pharmaceutical companies and institutions and general agents in the health sector by way of healthcare insurers, healthcare providers like hospitals or clinics, private or public in nature, doctors, pharmacists, and with the growing support of data capture platforms, patients. The WTO reported that, according to the most recent data on world exports of chemicals and pharmaceuticals from 2015, “47.8 percent of value added is created in the chemical and pharmaceutical sector while more than half originates from other industries in the supply chain” (WTO, 2020). Alternative services contributed greatly to the value added that arose from the pharmaceutical industry; Services accounted for over thirty percent of Trade in Value Added (TiVA), with distribution services and business activities through whole and retail trade accounting for the predominant share of services TiVA. The remaining industries that contribute to the TiVA in the supply chain of the chemical and pharmaceutical sector are Primary and Manufacturing industries by way of mining, agriculture, refined petroleum, food, and others.

Given the integral role that pharmaceutical companies play in improving the overall quality of their domestic healthcare industry and the involvement of diverse sectors in its supply chain, it is important that their home markets are providing them with an environment that supports innovation and intra-sectoral collaboration to ensure that shortcomings are addressed. It is thus interesting to look at the pharmaceutical industry beyond individual companies and analyze the changing competitiveness of countries in the industry.

When looking at the current performance of pharmaceutical markets, the United States remains as the top contender with $501.2 billion in sales, amassing over 56 percent of the total sales generated by the top ten performing countries (IQVIA, 2019). Though European countries like Germany, France, Italy, the UK and Spain have maintained a stronghold in terms of pharmaceutical sales, it is interesting to see the participation of emerging contenders in the top ten markets, such as China and Brazil. As shown in the table below, these two countries have shown the largest growth since 2018 with 9.1 percent and 9.3 percent respectively. Interestingly though Japan still has significant sales in 2019, its year-on-year growth is comparatively low for this list of countries and has increased only by 2.3 percent. This suggests that though Japan remains one of the largest markets, it has begun losing out to emerging contenders.

Table 2: Top 10 Pharmaceutical Markets Worldwide by sales and growth, 2018/2019

Country	Sales 2019 (billions, US$)	Percentage Growth over 2018
United States	501.2	4.4
China	94.9	9.1
Japan	79	2.3
Germany	51.9	6.7
France	35.2	2.9
Italy	32.9	3
United Kingdom	26.4	7.8
Spain	24.3	5.1
Brazil	24.3	9.3
Canada	22.6	5.4

Source: IQVIA MIDAS, MAT (2019)
Notes: Prices are reported at the ex-manufacturer level (price when sold from manufacturer to the wholesaler or direct to pharmacies). Percentage growth, constant $.

In CPhI's 2019 Pharma Industry Rankings, a survey of 350 of the top experts in the industry was conducted to evaluate the performance and current standing of countries in the pharmaceutical industry. When collated across all indicators, such as "innovation", "competitiveness" "growth potential", "API manufacturing" and "finished product", the top three scoring countries were USA (7.56/10), Germany (7.37/10) and Japan (7.16/10). What this means is that these countries were determined to have the highest capacity for producing both raw materials and final products, as well as an existing infrastructure that supports the continued development, growth and competitiveness of its pharmaceutical industry. Despite impressive growth coming from countries like China and India whose growth potential has been evaluated to far exceed the current western leaders, the top three countries consistently outperform contenders in quality of manufactured APIs and finished products and the innovativeness of their pharma and biopharma markets. These countries have benefited from being early movers in the industry and gained market maturity that enabled them to sustain their competitive advantage in these aspects. However, despite the small size of its market, Korea was identified as a “rising star” in the pharmaceutical industry, placing second only to China. Key contributors were improvements in its manufacturing capabilities of both finished products and APIs, the improved knowledge of biologics professionals and the growth potential its biologics manufacturing industry has. These are interesting indicators that suggest a growing importance of less mature pharmaceutical and biopharmaceutical markets as competitive manufacturers and not just consumers, particularly those outside of the Western Hemisphere (CphI Insights, 2019).

The Asia Pacific (APAC) region is poised to play a large role in the pharmaceutical markets continued growth. In terms of pharmaceutical companies alone, Cortellis found that there were over 46,509 across in APAC. When analyzing the development productivity of the region’s member countries, Japan was found to be the leader, with over 500 drugs in active development more than Mainland China and with Japanese pharmaceutical companies having on average around 14 products in the pipeline (Cortellis, 2019). Its existing maturity is a great contributor to its continued success as the leader in the market, but countries like Mainland China and Korea are viable contenders who seek to increase their share in the pharmaceutical market both within the region and beyond. According to Cortellis, Japan achieved the highest composite score, outperforming the other countries in the region in all three categories: Drug Development, Early stage partnering and maturity. The drug development indicator utilized was a composite value of the R&D activity of companies including values such as the number of drugs in the pipeline, those that have progressed to commercialization. Early stage partnering referred to the number of publication and patent activities and academic deals. South Korea was however, once again seen as a key challenger to Japan, in particular due to the strong development of its biotechnology sector. Though Korea has the potential to become an innovative leader in the field, it lacks maturity as “the number of recently launched drugs and [those approved in an] IP4 region (US, Europe, Japan or Mainland China), and the percentage of “Buy” and “Sell” deals […] in one of the IP4 regions” was comparatively lower than that of Japan and Mainland China.

2-2. Overview of the South Korean Pharmaceutical Industry.

Since the establishment of the first modern Korean pharmaceutical firm in the 1890s (KHIDI, 2018), Korea’s pharmaceutical industry has been growing extensively, particularly in terms of production and exports (as shown in Table 3). From 2015, 10 Korean products have passed the FDA and EMA’s review processes and blockbuster medicines like *KANARB* by Boryung Ic, *Suspect* and *Noltec* by Ilyang Pharm.co.ltd, and *Zemiglo* by LG Chem being launched worldwide.[5] There have also already been 11 technology transfer deals to Japan, China, US with deal values ranging from 44million usd to 910million.[6]

In particular, the growth of the Korean pharmaceutical market has been supported by the growth of biomedicine, which experienced a 35.6 percent export growth from 2012 to 2017 (KOTRA, 2019). South Korea’s high bio-pharmaceutical production of 330,000 liters (KHIDI, 2018) is due to the large capacity of companies operating in

[5] Ibid
[6] Ibid

Songdo. The city exceeds the production capacity of leading international markets in Singapore, Ireland and San Francisco, and this is attributable to the large production facilities and R&D capabilities of companies like Samsung Biologics and Celltrion (KOTRA, 2019). What is interesting to note however, is that the shift towards biosimilar medicines has been a recent development, as Korea had historically produced generics in order to benefit from cost efficiencies (Ribbink, 2013).

Table 3: Size of South Korea's Pharmaceutical Market (2012-2017, Unit: KRW Billion)

	2012	**2013**	**2014**	**2015**	**2016**	**2017**	**Average annual growth rate**
Production	151,140	163,761	164,194	169,696	188,061	203,580	5.3%
Export	23,409	23,307	25,442	33,348	36,209	46,025	14.5%
Import	58,535	42,789	54,952	56,006	65,404	63,077	1.5%
Market Size	192,266	193,243	192,354	192,354	217,256	220,632	2.8%

Source: Ministry of Food and Drug Safety (MFDS), KPMBA //Market Size= Production – Export + Import

The industry is however supported by a sophisticated healthcare infrastructure. The country's healthcare system is supported by a universal National Health Insurance that provides coverage for an estimated 98 percent of the population (KoNECT, 2017). In reference to a study released by KoNECT, South Korea is said to have world class health care facilities with over "93,000 practicing clinicians, 3,600 hospitals with 43 teaching hospitals and approximately 60,000 clinics across the nation" (KoNECT, 2017). With such a sophisticated healthcare system, it comes as no surprise that the standards of living are comparable to other high-income OECD countries, and that the country now is subject to a fast aging society where the average life expectancy is 82.7 years. This is just over a year shy of Japan's world leading life expectancy of 84.2 years.

Table 4: Health Statistics 2019

Country	Life expectancy	Avoidable mortality	Chronic disease morbidity	Self-rated health
	Years of life at birth	Deaths per 100 000 people (age standardized)	Diabetes prevalence (% adults, age standardized)	Population in poor health (% population aged 15+)
OECD average	80.7	208	6.4	8.7
Japan	84.2	138	5.7	14.1
Korea	82.7	159	6.8	17

Source: OECD Health Statistics 2019.

With a high quality clinical environment, an aging population that faces chronic diseases and unmet medical needs similar to Western populations, and a high population density that surpasses the US by over fifteen times (KoNECT, 2017), South Korea has a market that is highly suited for clinical trials. Twenty two of South Korea's major healthcare organizations have already been awarded global certifications for clinical trials, ranging from university hospitals to medical centers, which has propelled Korea from 12th place in 2011 to 8th place in the world for global clinical trial site numbers in 2015(KHIDI, 2018). According to KDRA the clinical trial environment is also supported by the R&D efforts of approximately 150 universities, 19 preclinical trial organizations, 163 clinical trial facilities and 6 public research institutes, including but not limited to Korea Institute of Science and Technology.

Another interesting development is that leading companies in the industry are adopting disruptive technologies in line with Industry 4.0 to increase production quantities and guarantee high quality and precision. Companies like Hanmi and Daewoon Pharmaceutical are readily adopting IoT to transform their factories into smart factories with improved logistical capacities (KOTRA, 2019).

However, the sales of the Korean pharmaceutical companies have historically been domestically driven with an export surplus having occurred the first time in 2019. Korean pharmaceutical companies have also been experiencing losses as a result of the government’s cost driven pricing policies and need to expand their market presence in order to continue operating (Ribbink, 2013). Now more than ever, Korean companies seek international market share and should therefore be aware of the factors that are impeding their performance abroad.

2-3. Overview of the Japanese Pharmaceutical Industry.

Japan has the second largest healthcare market in the world, driven predominantly by the need to sustain its declining and ageing population, with over 20 percent of its population being over the age of sixty-five. With this demographic crisis, Japan serves as a model for countries who are beginning to face a similar decline or population shift, and so the country is said to actively be seeking out innovative healthcare solutions and will therefore attract a lot of international attention as a market for foreign pharmaceutical companies to enter into (Beaumont, 2015). Moreover, the population’s large demand for branded medicines, coupled with a robust health infrastructure and internationally adjusted drug approval system, has made the market highly favorable for multinational companies (BMI Research, 2018). As of 2019, the industry was valued at 12.4 trillion yen with an industry growth rate of 7.8 percent from the previous year (Gyokai-search.com, 2020).

It can be said that Japan established itself as a mature international contender by being an initial signatory of the *1994 Agreement on Trade in Pharmaceutical Products* whereby the select few countries agreed to “eliminate customs duties and all other duties and charges, as defined within the meaning of Article II. 1 (b) of the General

Agreement on Tariffs and Trade (1994), on ALL items" that fell under "finished pharmaceutical product" and "Pharmaceutical active ingredients and chemical compounds" categories (WTO, 2020). Japanese companies have historically focused on innovative drug development, developing anticancer and enhanced immune class drugs with huge investments into cutting-edge technologies like checkpoint inhibitors (CPhI, 2018) Furthermore, Japan gained a leading global R&D position in regenerative medicine after the 2012 Nobel prize was awarded to Professor Shinya Yamanaka of Kyoto University. His discovery of induced pluripotent stem cells provided Japan with a first entrant competitive edge that it has since upheld (Pharmavitae, 2018). The industry's innovation system has also continued to improve in efficiency and trial sites have become more compliant with international standards. Japan has also increased its attractiveness as a clinical trial destination by reducing Priority and Standard Review timelines below twelve months and start-up timelines to approximately four to six months (JCRO, 2018).

In contrast with South Korea, Japanese pharmaceutical companies previously avoided the generics industry in favor of the higher profit margins that could be obtained in the exclusivity period of branded products. However, as the government has sought cost reduction through stringent pricing policies, pharmaceutical companies are being driven to enter the generics market. Branded products require high investment levels that might not be compensated as a result of the artificially low prices set by the government, and so companies see the generics market as a source of additional revenue (Beaumont, 2015).

In recent years, there has also been a growing number of Japanese companies who have chosen to become multinational with midsize and large companies looking to foreign markets for additional sales. In 2017, fourteen of the most competitive and listed

Japanese pharma companies experienced an increased share of overseas sales, rising from 39 percent in 2012 to 49 percent (Nagatani, Tomoko et al. 2018). Takeda Pharmaceutical Co. Ltd, Japan's largest pharmaceutical company, acquired the Irish Pharmaceutical Shire in January 2019 in its mission to establish itself as an international contender. Given the tough pricing system Japanese companies face in their domestic markets, companies have been incentivized to expand internationally to ensure alternative revenue streams in countries where pricing regulations are less restrictive. As the below table shows, from 2010 to 2015, there has been a steady increase in the number of pharmaceutical companies, number of production plants and marketing activities by Japanese Companies in Oversea markets.

Table 5: Overseas Business of Japanese Pharmaceutical Companies

Year	**No. of Pharmaceutical Companies**	**Manufacture (Production Plant)**	**Marketing (Including Import)**
2010	337	121	248
2011	334	119	256
2012	363	135	275
2013	371	137	283
2014	378	130	286
2015	384	136	295

Source: JPMA, DATABOOK 2019

This additional revenue is integral to the continued survival of these firms, who need to be at the forefront of research and medical development in order to replace their incumbent products before they reach expiration. When seeking to boost domestic sales, Japanese companies will need to demonstrate that their innovation has been a result of local efforts and that their prices are in line with the requirements of the state healthcare system (PharmaVitae, 2018)

Chapter 3. Literature Review

There is an abundance of literature that address the fundamental drivers of competitive advantage for firms and countries in the pharmaceutical industry. From the selected studies, the factors can predominantly be categorized as: economic and regulatory environment (Galović, 2015; Agrawal, 1999; Keyhani et al., 2010; Gambardella, Orsenigo and Pammolli, 2020), organizational and operational strategies of individual firms (Ku, 2015; Mishra and Jaiswal, 2017), R&D and patent quality (Kuwashima, 1999; Lakner et al., 2019; Gambardella, et al., 2020; Chung et al.,2019), human capital (Shabaninejad et al., 2014) and patent quality (Chen and Chang, 2010).

3-1. Economic and Regulatory Environment

By changing the macro-environment through regulations that incentivize innovation and promote international trade, studies show that the government exerts a large influence on the competitiveness of pharmaceutical corporations and their ability to explore internationalization strategies (Pease, 2005; Galović, 2015; Agrawal, 1999; Keyhani et al.,2010; Gambardella, et al., 2020). Galović (2015) evaluated the international trade patterns and competitiveness of predominantly European OECD countries from 2004-2009. To understand the level of trade specialization of the industry in each market, Galović (2015) chose indicators such as Intra-industry trade, contribution to trade balance to address structural aspects of the countries' economies, export-import ratio, trade balance, exports of manufactured goods and the import penetration of the sector. When looking at trade balance, it was found that countries like Ireland who had favorable fiscal environments, by way of tax systems and intellectual property laws had a very high trade balance and became a favored location for foreign investment. Moreover, the presence of the manufacturing plants of leading international firms contributed to Ireland’s rising export import ratio and ensured that the Irish pharmaceutical industry was implementing the most state of the art equipment and technology and could therefore perform value add activities that were higher up the value chain. Germany’s pharmaceutical sector was strengthened by the country’s manufacturing sector and the country’s existing high-quality transportation and communication networks, as well as a reliable energy supply. Galović highlighted the importance of above-average shares of R&D activity which enabled “faster adjustment to new conditions on the international market and an increase in international competitiveness” (Galović, 2015). While the findings are valuable and suggest important improvements for the countries analyzed, the study limited its coverage to predominantly developed countries in Europe. As it did not consider conditions that are prevalent in regions outside of that geographical and economic zone, the research cannot be accepted as fully applicable for other countries.

Agrawal (1999) set out to empirically evaluate to what extent the pharmaceutical industry is impacted by the national economic and regulatory environment. The author aggregated data collected from multinationals to determine on a country level basis how factors like GNP, population, price regulation, and approval time impact market size, and industry focus, growth and concentration. Strict price regulation schemes were found to significantly negatively affect the market size and its performance, particularly as the artificially reduced prices could disincentive drug innovation by reducing the return on capital companies below a reasonable level.

Keyhani et al. (2010) also explored the impact of pricing regulations on the production of new molecular entities (NMEs) to determine whether the absence or existence thereof was conducive to increasing pharmaceutical innovation. Though some would assume that pricing regulations would be detrimental to a country’s innovation potential, the authors determined that “many countries with significant price regulations were important innovators of pharmaceuticals; therefore, our data suggests that country-specific pricing policies probably do not affect country-specific innovation.” Instead the authors suggest that it is more important for the country to promote investments in “human capital, education, technology, information structure etc.” that will incentivize pharmaceutical R&D.

Gambardella, Orsenigo and Pammolli, (2020) evaluated the performance of the European Pharmaceutical industry, looking at its performance in relation to the US and Japan. The authors concluded that the performance of the European pharmaceutical industry is perhaps more susceptible to residual factors beyond labor, capital and R&D input growth such as the European regulatory systems and pricing policies or the demand structure across European countries. When analyzing the sales performance of pharmaceutical companies, the authors concluded that both US and European firms were most reliant on their domestic markets and their ability to generate sales from New Chemical Entities and a more diverse product portfolio. What is important is for countries to maintain an innovative edge on their competitors and have sufficient access to international technology and research sources if they cannot develop those domestically. Overall, the most impactful variables were related to the institutional environment that supports workers, intellectual property rights and patents, and the health care system, as well as competitor intensity and the structure and scale of the biomedical industry. The limitation to this research however is the time period under analysis as the data is over twenty years old and so does not reflect a contemporary state of the markets.

3-2. Organizational and Operational Strategies of Individual Firms

As previously mentioned, outsourcing elements of the pharmaceutical supply chain is boosting the ability of firms to compete both domestically and internationally, given the larger propensity they then have to work on innovative projects. Ku (2015) analyzed the competitiveness that individual companies can gain by adopting disruptive business models. Big Pharmas have struggled with their antiquated vertically integrated business models to maintain high enough levels of R&D productivity to counteract losses from patent expiries and generics substitution. To suit the desire of venture capitalists to mitigate the high risk and high price of the long drug discovery process, specialty Pharmas are focused, smaller and more agile than their big pharma counterparts. These focus on compound research, marketing of niche medicines or providing knowledge of delivery technologies. Venture Capitals and Big Pharmas have increased their competitiveness and revenue by systematically acquiring, buying or selling the license rights of and to these specialty pharma companies for R&D programs, particularly those in the later stages of clinical development. Furthermore, to avoid revenue loss by generic substitutions, biologics were argued to be a potential pathway for companies to ensure continued success given that the process of commercialization for biologics is much faster than that of smaller molecules and that they have a higher success rate in the later stages of clinical trials. Though the research presents an interesting analysis of operational strategies at a corporate level, it does not address the impact such behaviors can have on the competitiveness of the industry within a given country, or the demand conditions that are needed for different business models to thrive.

Beyond just temporary partnerships, big pharma companies are actively engaging in mergers and acquisitions. Mishra and Jaiswal (2017) sought to examine the impact of M&A activity on the competitiveness of the Indian pharmaceutical industry. Though large Indian pharmaceutical firms have historically had enough resources to conduct inhouse R&D to ensure their survival domestically and internationally, smaller domestic firms did not. Without this technological capacity to conduct R&D, the exports of the smaller firms were less competitive as they struggled to stimulate their growth and had to outsource the value creating R&D activities. Thus, the transfer of technology and therefore increase in inhouse R&D capacity of the firms that resulted from M&As was argued to be a key factor in improving the competitiveness of Indian pharmaceutical firms. The authors chose to utilize the multi-directional structure-conduct performance framework in order to capture both the conduct of the firms and the structural aspects of the market. In terms of findings, Mishra and Jaiswal concluded that the level of international competitiveness of firms in terms of exports is positively related to the number of M&A deals a firm is involved in. Furthermore, market share, marketing and distribution efforts also exert a positive and significant influence on the international performance of Indian pharmaceutical firms.

3-3. R&D and Patent Quality

Kuwashima (1999) focused on the organizational factors that exert an influence on R&D performance. Through analyzing statistics and surveys interviews that were conducted with large Japanese pharmaceutical companies, Kuwashima concluded that the transfer of knowledge gained from the experience of conducting clinical development projects was hugely impactful on creating organizational capabilities that contribute to productive R&D programs, and therefore result in competitive advantages in clinical development. It is after all through experience that companies can better determine the appropriate protocol to follow during clinical trials, and at what stage development projects are no longer efficient or beneficial.

Lakner et al. (2019) conducted an econometric analysis on how competitiveness of the pharmaceutical industry in developed countries is related to R&D financing resources and scientific performance (through patents and publications). As the industry is knowledge-intensive, continued innovation is integral to ensuring the longevity of both firms and the overall success of the pharmaceutical industry of a country. As the data collected from the OECD and Web of Science for this analysis was related to firms (in particular large-scale firms), the authors concluded that the injection of additional support for R&D activities (financial and institutional) from the government is vital to increase the long term competitiveness of the industry. Though drawing an important conclusion in relation to the allocation of resources, the study has highlighted that there is some limitation in analyzing the competitiveness of the pharmaceutical industry over a shorter time frame and that alternative models or modes of analysis such as the "panel-cointegration method" may result in more accurate results. The authors also suggest that the impact of innovation could be different for firms that focus on generic products.

Chung et al. (2019) analyzed the impact of R&D on Korean companies in the pharmaceutical industry by using quantile regressions. By applying this method, the authors found that R&D intensity and not R&D scale will positively impact firm growth rates if they are already experiencing fast growth. In addition, the authors found that, as ensuring patent rights is integral for growth, it is of central importance for firms to view increased R&D investments, improved R&D productivity and strengthened patent rights as "strategic assets" and that favorable policies be implemented by the government (Chung, et al., 2019).

By analyzing the impact of patent quality indicators on corporate market value in the pharmaceutical industry, Chen and Chang (2010) were able to determine that the relative patent position and the number of patent citations was significantly related. The higher the patent count and number of patent citations, the higher the market value of companies was. The significance of this approach is linked to the nature of the pharmaceutical industry being dependent on the creation of knowledge and benefitting heavily from investment in intangible assets. Patent quality and number are therefore fundamental to increasing the competitive advantage of companies, and by extension that of their countries in the pharmaceutical industry. With the application of patents, companies gain market exclusivity, and generate revenue that can then be converted into further R&D projects. Though beneficial to determining the value patents have in the industry, this study was limited to the US and might therefore not address the additional factors relevant to other countries.

Given the importance of R&D, it could be assumed that companies would therefore look to invest the larger part of their revenues into R&D rather than into other business areas. However, Gambardella, Orsenigo and Pammolli (2020) found that the European industry is more labor intensive than Japan and the US given it's higher labor costs and labor intensity that has risen from the significantly higher presence of less R&D intensive firms than in the countries chosen for comparison. The focus on labor intensive firms also suggests that the European firms are partaking in lower value add activities, which gives interesting implications for the development path companies should take if a country would like the industry to move up the value chain.

3-4. Human Capital

Shabaninejad et al. (2014) conducted a study on the industry-level factors that influenced the competitiveness of the Iranian Pharmaceutical Industry by way of a questionnaire and the FUZZY TOPSIS analysis method of the resulting data. To capture a broader view of the industry, managers across departments (IT, R&D, quality assurance and control, marketing, sales, finance etc.) in pharmaceutical firms across Iran. Though broad in their initial analysis of the factors that can impact the competitiveness of the industry, with variables including "strategy and operation effectiveness, supporting and related industries and clusters, capacity for innovation etc." (Shabaninejad, Hosein, et al., 2014), the authors excluded factors pertaining to the demand side of the industry. Moreover, the authors allude to the impact that the state sponsored, or private health insurance companies have on the competitiveness of the pharmaceutical firms, as they influence the extent to which costs are carried over to the patients. Another limitation is the potential applicability of the results, given the more niche domestic situation that Iran finds itself in as a middle-income country, and the small sample of respondents whose answers founded the data upon which the analysis was conducted.

3-5. Internationalisation

Laurens et al. (2019) argued that in order for a firm to maximize their economic benefit when bringing a new product to the market, they should extend their patents to as many international markets as possible. By selling their products in various markets, they will best be able to offset the high level of tangible and intangible costs required in the drug discovery process. A final conclusion of the study alludes to the importance of worldwide IP coverage, and that pharmaceutical companies must take the international exposure of their patents seriously in order to maximize their revenue and ability to offput copy-cat products from their competitors during the patent-lifetime of their newly released pharmaceutical product. Similarly, Pradhan (2006) argues in favor of the internationalization of companies with respect to the Indian pharmaceutical industry. Through “greenfield direct investment, overseas acquisitions, strategic alliances and contract manufacturing”, Indian companies have been able to surpass the level of commercial success that they would have experienced otherwise domestically, and in addition, this provided them with an opportunity to go beyond the growth limitations and R&D potential that have arisen as a result of the regulations and policies that have been implemented by the Indian government. In addition, Bergman indicates that MNCs have positively contributed to the competitiveness of the Indian pharma industry, and that FDI contributes to firms adopting managerial efforts, marketing techniques and quality control mechanisms to put them on an equal footing with their international peers. However, in order for foreign ownership to truly increase the competitiveness of the companies, the multinational companies need to have invested enough fixed capital in the industry to experience the desired returns.

These authors have all established specific factors that contribute to the competitiveness of the pharmaceutical industry, but do not simultaneously and sufficiently evaluate all that can be impacting the level of competitiveness of a country. As the literature review has shown, the performance of the pharmaceutical industry is impacted not only by the characteristics and strategies of individual firms, but also factors at the national level. Therefore, there is an opportunity to utilize a model that provides a comprehensive view of the pharmaceutical industry, and one that can identify specific areas that would contribute to the improvements of a country’s performance.

The theoretical model chosen for this study, which will be explained in the following chapter, is based on a model that has already been proven to be valuable and relevant when determining sources of competitiveness in the pharmaceutical industry. Olmeda and Sosa Varela (2012) conducted a study to determine which factors determine international competitiveness of countries in the pharmaceutical sector by utilizing components from the Global Competitiveness Index sourced from the Global Competitiveness Report. By looking at reports ranging from 2001 up until 2008, the authors employed Michael Porter's competitiveness model, the diamond model, to determine which countries were most competitive in the industry and whether there were factors that played a more important role. By conducting a tolerance test and a discriminant analysis on all the variables, they proved that for countries who desire to attract investment into their pharmaceutical industry, their competitiveness was affected by the factor conditions, supporting industries, demand conditions, and firm strategy, structure and rivalry. It was shown that factor conditions of a country are integral to determining the level of competitiveness as perceived by international pharmaceutical companies. Though this study was decisive in supporting the validity of utilizing Porter's Diamond model when determining the competitiveness of the pharmaceutical industry, it did not evaluate the level of competitiveness of individual countries and its dataset is somewhat outdated.

The table below shows comparison of the determinants analyzed by some of the utilized previous studies and the generalized double diamond model and demonstrates that they have insufficiently addressed all the necessary dimensions.

Table 6. A Comparison of Previous Studies and the Generalized Double Diamond Model

Studies	Factor Conditions	Demand Conditions	Related and Supporting Industries	Firm Strategy, Structure and Rivalry	Government and Chance
Gambardella et al., 2020	O	O	O	O	
Ku, 2015				O	
Kuwashima,1999				O	
Olmeda and Sosa-Varela, 2012	O	O	O	O	O
Mishra, and Jaiswal, 2017				O	
Lakner et al., 2019	O			O	O
Shabaninejad et al., 2014	O		O	O	
Agrawal, 1999	O			O	O
Galović, 2015			O		O
Keyhani, 2010	O				O
Chen and Chang, 2010			O		
Bergman, 2006	O			O	
Pradhan, 2006				O	O
Laurens et al., 2019			O	O	

Chapter 4. Theoretical Model and Data

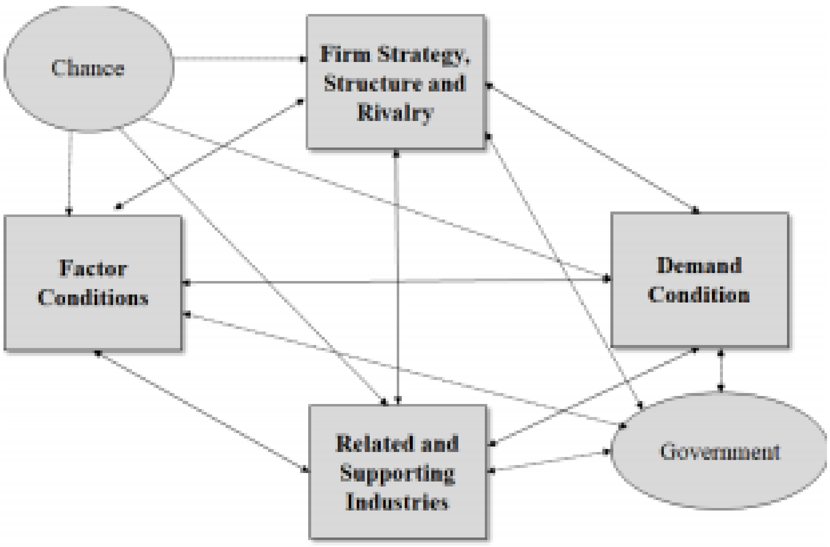
4-1. Theory

Given the extent to which the industry is highly internationalized (Shabaninejad et al., 2014;), this thesis aims to analyze the industrial competitiveness of Korea and Japan through the generalized double diamond model (Moon et al., 1995). Within the context of this model, Moon, Rugman and Verbeke (1995) defined national competitiveness as the "capability of firms engaged in value added activities in a specific industry in a particular country to sustain this value added over long periods of time in spite of international competition".

The original model created by Porter (1990) identified the main factors influencing the competitiveness of ten countries in particular industries over a four-year period. In order to do so, Porter identified four endogenous dimensions that would address the most important aspects impacting an industry's competitiveness: *factor conditions, demand conditions, related and supporting industries, and firm strategy, structure and rivalry.*

Factor conditions are production factors that are split into both basic and advanced and taken into account physical, human and capital resources that were either passively inherited or were actively developed within a country (Porter, 1990). Basic factors include natural resources or the general population, whereas advanced factors are highly specialized and tend to be more important in the creation of competitiveness of a sophisticated or knowledge-intensive industry. These include the state of research and development by way of the researchers involved, or the overall expenditure. Demand conditions demonstrate the quality and quantity of demand in the market for the produce or services of an industry. This can be related to the scale or characteristics of the consumers in the market by way of the sophistication of their demand. Porter (1990) said that it is through this sophisticated demand that companies are forced to realize their full potential and experience competitive advantages. Related and supporting industries are industries or suppliers that either support or depend on the analyzed industry and can impact its level of competitiveness. These suppliers are said to “create advantages in downstream industries” through the provision of “cost-effective inputs”, the exchange of information and ideas, as well as through “technical interchange” (Porter, 1990). Given the growing interconnectedness of industries through the creation of globalized supply chains, value is not created solely in one industry, and therefore the performance of companies in industries that do contribute, by way of their technology or implementation of the pharmaceutical industry, must be considered. The final variable, firm strategy, structure and rivalry, depicts the conditions present in a market that determine the development, management and degree of rivalry between firms. The role of the government and of chance as exogenous dimensions, must also be considered when forming the diamond model, as these indirectly shape the competitive environment.

Figure 1. Porter’s Diamond Model

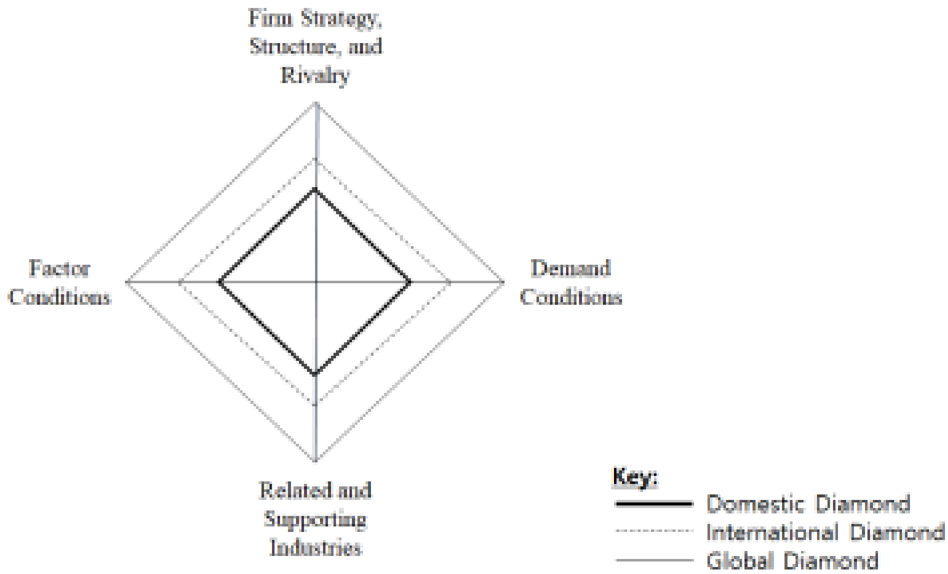


Source: Porter (1990)

However, a limitation to the original diamond model is that Porter's analysis focused mostly on the conditions faced by firms in their domestic market and did not take into account companies who were more multinational in nature. The firms of smaller countries in particular must consider the international market conditions as well, and so the competitiveness of a country's industry is shaped by more than just domestic conditions (Cho and Moon, 2013). In order to address this gap in analysis, Moon et al. (1995) extended the model to include a global diamond (the external diamond) as well as an international diamond (dotted diamond). This development aided comparisons between the domestic and international performance of an industry to better determine strategies for improvement. Existing studies have compared Fashion industries in Korea, China and Japan (Son, 2014; Son and Yokoyama, 2013), Korea's apparel industry (Jin and Moon, 2006), Vietnam's garment and textile industry (Vu and Pham, 2016), Korea and Singapore's competitiveness by (Moon et al., 1998), Taiwan and Korea's competitiveness by (Liu and Hsu, 2009), Latin-American countries (Castro-Gonzáles, 2016), Visregard countries by (Molendowski and ŻMuda, 2013), the Chinese Telecommunication industry (Moon and Yu, 2004), the IT industry in Japan and Korea (Moon, 2000) and Samsung and Sony by (Moon and Lee, 2004). Furthermore, whilst the original diamond model sees the role of the government as an exogenous factor, Moon, Rugman and Verbeke (1998) argued for the large impact that policies created by the government can have on the level of competitive advantage that a nation can experience. This study therefore incorporated a deeper analysis of the institutional context and government policies of both countries, but did not analyze the impact of chance on the industry.

As shown in Figure 2 below, the domestic diamond and international diamonds sit within the global diamond. The domestic diamond, in the dotted line, will differ according to the size of the country and how competitive it is in the industry.

Figure 2: The Generalized Double Diamond Model



Source: Moon et al. (1998)

4-2. Data

The main purpose of this study is to determine which factors are impacting the level of domestic and international competitiveness of the Korean and Japanese Pharmaceutical industry. Utilizing Government level and firm level data, statistical proxy variables were then created for each competitive dimension required to shape the domestic and international diamond models. As outlined by Cho and Moon (2013), each dimension will be created as an index through proxy variables that were chosen based on their relevance to the pharmaceutical industry. As the literature review has demonstrated, there are several factors that significantly contribute to the competitiveness of the pharmaceutical industry of any country, such as the economic and regulatory environment (Galović, 2015; Agrawal, 1999; Keyhani et al., 2010; Gambardella, Orsenigo and Pammolli, 2020), organisational and operational strategies of individual firms (Ku, 2015; Mishra and Jaiswal, 2017), R&D and patent quality (Kuwashima, 1999; Lakner et al., 2019; Gambardella, Orsenigo and Pammolli, 2020; Chung et al., 2019; Chen and Chang, 2010), and Human Capital (Shabaninejad et al., 2014). Extracting the factors outlined in previous research into the pharmaceutical industry and that of other research applying the generalized double diamond model, the study operationalized 32 proxy variables. The following table outlines the data source and related research of the selected proxy variables.

Table 7: Descriptive Data for Diamond Variables
(including Data Source and Related Research)

Factor	Market	Sub-Factor	Proxy Variable	Measurement	Source	Related Studies
Factor Conditions	Domestic	Basic	Average Wage (cl) 2017- 2019	3 year average 2017-19, USD$ per hour	IMD world competitiveness	Vu and Pham, 2016; Olmeda and Sosa-Varela, 2012
			Annual growth rate of output per worker (cl) 2017-2019	3 year average 2017-19, annual growth rate %	ILO	Cho and Moon, 2010; Olmeda and Sosa Varela, 2012
		Advanced	R&D expenditure (il) 2016-2018	3 year, 2016-2018, US$ Mil, PPP, BERD	OECD ANBERD database	Keyhani, 2010; Castro Gonzales, 2016; Liu and Hsu, 2009
			R&D personnel p/mil pop (cl) 2016-2018	3 year average 2016-2018, p/mil inhabitants	Unesco Institute for Statistics	Liu and Hsu, 2009; Son and Yokoyama, 2013; Cho and Moon, 2010
	International	Basic	Outbound FDI (cl) 2017-2019	3 year average 2017-19, US$mil	UNCTAD	Cho and Moon, 2013; Galović, 2015; Liu and Hsu, 2009; Cho and Moon, 2010
			Outbound FDI growth rate index (cl) 2017-2019	3 year average 2017-19, FDI * growth rate	UNCTAD	Cho and Moon, 2010
		Advanced	Inbound FDI (cl) 2017-2019	3 year average 2017-19, US$mil	UNCTAD	Cho and Moon, 2013; Shabaninejad et al., 2014; Galović, 2015; Liu and Hsu. 2009; Moon and Yu, 2004; Mol and Zmuda, 2013; Cho and Moon, 2010
			Inbound FDI	3 year average	UNCTAD	Liu and Hsu,

			growth rate index (cl) 2017-2019	2017-19, FDI * growth rate		2009; Cho and Moon, 2010
Demand Conditions	Domestic	Size	Pharmaceutical Spending (il) 2015-2017	3 year average 2015-17, % of health spending	OECD	Keyhani, 2010; Castro-Gonzales, 2016
			Total Sales as percentage of GDP (il) 2016-2018	3 year average, 2016-18, % of GDP	export.gov/ khidi.or.kr	Moon and Yu, 2004
		Quality	Market sophistication index (cl) 2016-2018	3 year average 2016-2018 index, /100	Cornell INSEAD WIPO, Global Innovation Index	Cho and Moon, 2010
			GDP/capita (cl) 2017-2019	3 year average 2017-19,	OECD	Vu and Pham, 2016
	International	Size	Share of World Market (il) 2016-2018	3 year average 2016-18	OECD, Worldbank	Son and Yokoyama, 2013
			Export Value (il) 2017-2019	3 year average 2017-19, US Millions (UN COMTRADE)	UN Comtrade	Mol and Zmuda, 2013 (per capita)
		Quality	Number of Country for Pharma exports(il) 2017-2019	3 year average 2017-19, total number	UN Comtrade	Cho and Moon, 2010
			Percentage of Export without top 3 (il) 2017-2019	3 year average 2017-19, %	UN Comtrade	Cho and Moon, 2010
Related & Supporting Industries	Domestic	Hard (Industry Infrastructure)	ICT development index (cl) 2015-2017	3 year average 2015-17 index/10	ITU/ UN International telecommunication union	Kim, 2018; Moon and Lee, 2004
			Health Infrastructure index (cl) 2017-2019	3 year average 2017-19, index/10	IMD World Competitiveness	
		Soft (Innovation Infrastructure	Domestically granted patents (il) 2015-2017	3 year average 2015-7, indiv unit, by A61 class	fiveIPoffices	Chen and Chang, 2010
			Domestically published academic articles (il) 2017-2019	3 year average 2017-19, indiv unit	Elsevier Scopus Database	Chen and Chang, 2010
	International	Hard (Industry Infrastructure)	Medical Equipment export (il) 2017-2019	3 year average, 2017-19, US$	UN Comtrade	
			High Technology Exports (cl) 2017-2019	3 year average, 2017-19, (current US$ Billions)	The World Bank	
		Soft (Innovation Infrastructure)	Scimago Ranking (cl) 2017-2019	3 year Average 2017-19, Total docs	ScimagoLab	Moon and Lee, 2004
			Granted Patents (il) 2015-2017	3 year average 2015-17	fiveIPoffices	Cho and Moon, 2010; Chen and Chang, 2010

Firm Strategy, Structure & Rivalry	Domestic	Rivalry	Intensity of local competitors (cl) 2015-2017	3 year average 2015-2017, score/7	World Economic Forum, Global competitiveness report	Olmeda and Sosa Varela, 2012
			Number of pharmaceutical manufacturers(il) 2015-2017	3 year average 2015-2017	JPMA Databook, MFDS	Moon and Yu, 2004; Cho and Moon, 2010
		Strategy & Structure	Social Responsibility of Business Leaders (cl) 2017-2019	3 year average 2017-19, index/10	IMD World Competitiveness Ranking	Moon and Yu, 2004; Cho and Moon, 2010
			Sophisticated production process(cl) 2015-2017	3 year average 2015-2017, score/7	World Economic Forum, Global competitiveness report	Olmeda and Sosa Varela, 2012
	International	Rivalry	Control of international distribution(cl) 2015-2017	3 year average 2015-2017, score/7	World Economic Forum, Global competitiveness report	Olmeda and Sosa Varela, 2012
			Number of clinical trials listed at WHO ICTRP(cl) 2017-2019	3 year average 2017-19, number of trials	WHO ICTRP	Shabaninejad et al., 2014
		Strategy & Structure	Ranking of world's best performing ceo (cl) 2017-2019	3 year average 2017-19, number in list	Harvard Business Review	Kim, 2018
			Image Abroad (cl) 2017-2019	3 year average 2017-19, index/10	IMD World Competitiveness	Castro-Gonzales, 2016

Four proxy variables were chosen for each factor to create a domestic and an international diamond. Where possible, variables specific to the pharmaceutical industry were utilized. Where data was unavailable, country-level values were then taken instead. For clarification purposes, industry level variables have been labeled as (il), and country level data is labeled as (cl). All listed variables were calculated as a three-year average and were predominantly within the timeframe of 2017 to 2019 to ensure that conditions were comparable and would not be impacted by unaccounted for factors from other years. However, some variables implemented data from earlier time points, namely 2015 and 2016, as these were the most recently published figures that could be attained whilst the study was being conducted.

The data values were then converted into proxy values that formed the basis of the competitiveness indexes of each factor. The exact calculation process will be outlined in the results section of the study. These collected values of all four factors for the domestic and international markets were then drawn to scale as diamonds, to ensure that a comparative analysis was possible.

4-3. Diamond Variables

4-3-1 Factor Conditions

As explained previously, these variables depict the competitive factor conditions existing in the pharmaceutical industry or national context. To begin with, basic and advanced factors must be considered for both the domestic and international diamonds. The pharmaceutical industry is dependent on highly skilled workforce who seek adequate wages in compensation for their labor. If an industry would like to retain and attract the talent required to develop highly innovative products that will ensure its international competitiveness, then sufficient monetary compensation per worker should be ensured (Suresh and Krishnaraj, 2015). Thus, to take this into consideration, the *average total wage* in US dollars was utilized from the OECD. As outlined by Cho and Moon (2010), and Olmeda and Sosa Varela (2012) it is important to consider the productivity of workers when analyzing the state of basic domestic factors of a country, and therefore the *Annual growth rate of output per worker* expressed as a percentage was selected.

When looking at basic international factors, it was important to look at the Outbound rate of FDI. As industry specific FDI values could not be found that were comparable in range or calculation method for both Japan and Korea, it was necessary to use country level data. In order to support the international growth of the industry, domestic companies should be expanding into foreign markets and establish their presence through investments and alliances with international pharmaceutical firms. Following Cho and Moon (2010), the second chosen factor is the outbound *FDI growth rate index* that factors in the level of growth that has occurred from 2017 to 2019.

The pharmaceutical sector is highly dependent on R&D intensity, with funding from both private and public sources who support research across all stages from basic and early-stage to clinical trials that will permit newly developed drugs to be brought onto the market. According to an OECD report, OECD countries spent on average 12 percent of their gross value added on R&D which is comparatively higher than other manufacturing sectors (OECD, 2019). As such it is important to look at the level of R&D expenditure occurring in the industry by businesses. To demonstrate this, *Business enterprise expenditure on R&D (BERD) in the pharmaceutical industry* from 2016 to 2018 was selected from the OECD's ANBERD database. Song and Leker (2018, p.169) argued that "firms with higher R&D (research and development) expenditures have a tendency to greater external exploitation of technological knowledge than firms with low R&D spending", and therefore a higher level of BERD would be indicative of more competitive firms. When looking at R&D, it is then important to also include the number of workers. Both South Korea and Japan have thrived economically not because of the prevalence of natural resources, but from the availability of a highly skilled workforce. The amount of *R&D personnel per million inhabitants* from UNESCO Institute for statistics was thus selected to demonstrate the quantity of talent that is available in the domestic market.

For the international diamond, *inbound FDI* and the *inbound FDI growth rate index* were selected utilizing data from the UNCTAD database, in accordance with the works of several authors (Cho & Moon 2013; Shabaninejad et al., 2014; Galović 2015; Liu & Hsu 2009; Moon & Yu 2004; Mol & Zmuda 2013; Cho & Moon 2010). As previously mentioned, it is integral that there is sufficient investment and attraction from abroad so that pharmaceutical companies can allocate the necessary resources for innovative product development if their domestically acquired investment sources should be insufficient. Moreover, it will help to increase the international standing of companies if international competitors are made aware of increased investment into Japanese or South Korean institutes, products or pharmaceutical technologies.

Table 8: Variables for Factor Conditions

Factor	Market	Sub-Factor	Proxy Variable	Data Value		Measurement
				Japan	Korea	
Factor Conditions	Domestic	Basic	Average Wage (cl) 2017-2019	38,298.33	40,885.67	3 year average 2017-19, USD$ per hour
			Annual growth rate of output per worker (cl) 2017-2019	0.30	2.00	3 year average 2017-19, annual growth rate %
		Advanced	R&D expenditure (il) 2016-2018	13,381.14	1,652.28	3 year, 2016-2018, US$ Mil, PPP, BERD
			R&D personnel p/mil pop (cl) 2016-2018	6,954.96	9,263.78	3 year average 2016-2018, p/mil inhabitants
	International	Basic	Outbound FDI (cl) 2017-2019	178,164	35,940	3 year average 2017-19, US$mil
			Outbound FDI growth rate index (cl) 2017-2019	20,013.49	506.91	3 year average 2017-19, FDI * growth rate
		Advanced	Inbound FDI (cl) 2017-2019	11,795.67	13,554.00	3 year average 2017-19, US$mil
			Inbound FDI growth rate index (cl) 2017-2019	1,162.26	-2,186.94	3 year average 2017-19, FDI * growth rate

4-3-2 Demand Conditions

The level of demand for an industry is an integral factor to target when attempting to increase its overall competitiveness. The scale of demand for a country's pharmaceutical industry drives both driving expenditure and consumption of pharmaceutical goods. In addition, rapid growth in the domestic market can drive companies to increase their adoption of new technologies, without fear of misallocating their budget, and invest in building more efficient and larger facilities to support the increased production levels (Porter, 1990, p. 94). Therefore, for the domestic diamond, *Pharmaceutical spending*, and the *Total Sales as a percentage of GDP* were selected. Scale is also important in the international context, and therefore, the *market share of Korean and Japanese pharmaceutical industries as a percentage of the world market* and *total value of exports* were utilized.

As Porter argued, it is then important to go beyond just scale and look at the existing quality of demand, as the country can increase its competitiveness within an industry if domestic demand is sophisticated (Porter, 1990, p. 89). In the pharmaceutical industry, this is particularly important, as consumption trends can shape production and investment flows into either niche therapeutic areas or incentivize firms to enter into the generic pharmaceutical segment. To measure the sophistication of the domestic market, the *Market sophistication Index* and GDP per capita were utilized in accordance with Cho and Moon (2010) and Vu and Pham (2016), as these indicate the extent to which consumers are educated and able to make informed decisions on the products they are consuming. Moreover, it is argued that higher income levels enable consumer power to purchase new and more innovative drugs to increase (Ribbink, 2013). To calculate the international sophistication of demand for the Japanese and South Korean pharmaceutical industry, the proxy variables used were the *number of countries for pharmaceutical exports*, and the *percentage of exports without the top 3 countries*. As Cho and Moon (2010) and Moon et al. (1998) argued, it's important to factor in the amount of exports that go to countries beyond the top 3 destinations. If the industry’s exports are dependent on a limited amount of foreign countries, the export markets and international demand are considered to be neither diversified, nor sophisticated (Moon et al., 1998).

Table 9: Variables for Demand Conditions

Factor	Market	Sub-Factor	Proxy Variable	Data Value		Measurement
				Japan	Korea	
Demand Conditions	Domestic	Size	Pharmaceutical Spending (il) 2015-2017	18.86	20.64	3 year average 2015-17, % of health spending
			Total Sales as percentage of GDP (il) 2016-2018	1.25	1.48	3 year average, 2016-18, % of GDP
		Quality	Market sophistication index (cl) 2016-2018	65.96	61.34	3 year average 2016-2018 index, /100
			GDP/capita (cl) 2017-2019	41,842.27	42,020.67	3 year average 2017-19,
	International	Size	Share of World Market (il) 2016-2018	7.88	1.94	3 year average 2016-18
			Export Value (il) 2017-2019	209,564,715.67	120,262,637.33	3 year average 2017-19, US Millions (UN COMTRADE)
		Quality	Number of Country for Pharma exports(il) 2017-2019	77	132	3 year average 2017-19, total number
			Percentage of Export without top 3 (il) 2017-2019	45.82	60.16	3 year average 2017-19, %

4-3-3 Related and Supporting Industries

As has already been argued, shared technology, innovation and information flows between industries can result in huge advantages for downstream industries (Jin and Moon, 2006). The pharmaceutical industry has undergone great change, and firms are now opting for open innovation strategies more than ever to monopolize on the raw materials, and manufacturing and distribution strategies of other industries. Both Japan and South Korea have benefited economically from high internet connectivity, developed IT infrastructure, and a reputable academic environment that has supported innovative development across IT, semiconductor and chemical industries.

In terms of a direct impact on the domestic competitiveness of the pharmaceutical industry, the chosen measurements are the *ICT development index*, and the *health infrastructure index.* These are considered to factor in the competitiveness of the industry's infrastructure. The healthcare infrastructure is necessary to help support clinical trials by way of patient access, medical sophistication and supporting research interests (PharmaBoardoom, 2019) but also ensures that the products produced by pharmaceutical manufacturers are being administered effectively. ICT infrastructure is an important indicator as the pharmaceutical drug delivery and research processes are progressively becoming dependent on real-time data transfer and the predictive capabilities of AI and other technologies that have shaped Industry 4.0. The pharmaceutical industry in both countries is highly dependent on international businesses and are therefore also impacted by the infrastructure or performance of related industries in foreign markets. To address the international competitiveness of these supporting and related industries, *medical equipment* and *high technology export values* were utilized. The readiness of foreign markets to consume these South Korean and Japanese products could be indicative of international consumer confidence in products from these countries that are related to health and are highly dependent on technological innovation in their development and production processes.

In addition, infrastructure and industries that support the innovative capacity of the pharmaceutical industry must be taken into account. It is therefore necessary to measure the existing academic and intellectual property infrastructure that is vital for countries to experience a competitive edge in the pharmaceutical industry. To form the domestic diamond, the number of *domestically granted A61* (pharmaceuticals under the IPC class system) *patents* and *domestically published academic articles in pharmacology, toxicology and pharmaceutics* were therefore selected as proxy variables. Patents ensure the exclusivity period needed for companies to generate the revenue that will then be reinvested in further research projects, manufacturing and logistics capabilities, or the acquisition of new talent or technologies. To determine the level of international competitiveness, the *Scimago journal and country rank in pharmaceutical science*, and the *total number of granted patents at the five IP offices (the CNIPA, EPO, JPO, KIPO and USPTO)* were selected.

Table 10: Variables for Related and Supporting Industries

Factor	Market	Sub-Factor	Proxy Variable	Data Value		Measurement
				Japan	Korea	
Related & Supporting Industries	Domestic	Hard (Industry Infrastructure)	ICT development index (cl) 2015-2017	8.41	8.86	3 year average 2015-17 index/10
			Health Infrastructure index (cl) 2017-2019	7.54	7.46	3 year average 2017-19, index/10
		Soft (Innovation Infrastructure	Domestically granted patents (il) 2015-2017	9,378	5,252	3 year average 2015-7, indiv unit, by A61 class
			Domestically published academic articles (il) 2017-2019	2,520	3,799	3 year average 2017-19, indiv unit
	International	Hard (Industry Infrastructure)	Medical Equipment export (il) 2017-2019	5,188,859,404	1,770,338,470	3 year average, 2017-19, US$
			High Technology Exports (cl) 2017-2019	107.16	171.01	3 year average, 2017-19, (current US$ Billions)
		Soft (Innovation Infrastructure)	Scimago Ranking (cl) 2017-2019	1,489.33	961.67	3 year Average 2017-19, Total docs
			Granted Patents (il) 2015-2017	13,519	6,313	3 year average 2015-17

4-3-4 Firm Strategy, Structure and Rivalry

To measure the final determinant, it is important to select variables that reflect the organization and operational strategies implemented by firms in the pharmaceutical industry, and whether they are domestically or internationally oriented. In terms of the domestic determinants, the *intensity of local competitors* and the *number of pharmaceutical manufacturers* were chosen to demonstrate the extent of competition in the industry. As Porter argued (1990, p.108), competitive advantage is gained when domestic rivalry is vigorous. Agility and sophisticated production technologies are becoming more and more important as pharmaceutical companies seek to maximize the effectiveness of their R&D expenditure and speed up time of innovative drug development to commercialization. Therefore, this study implements *sophisticated production processes* to therefore evaluate the strategy and structure of firms, as suggested by Olmeda and Sosa Varela (2012). The final variable, *social responsibility of business leaders,* takes into account cultural factors that will attract the necessary talent into the industry as per Moon and Yu (2004) and Cho and Moon (2010). For countries like South Korea and Japan who are dependent on a strong innovation ecosystem, insufficient talent acquisition and retainment will be largely detrimental to local entrepreneurship and will hinder the growth of the pharmaceutical industry (Schwab, 2019).

In terms of variables that determine the international performance of the industry, control of international distribution indicates the extent to which domestic firms own and control marketing and international distribution operations. As an effective and well-regulated clinical trials environment contributes to the improvement of technological competitiveness of the country and draws in global pharmaceutical companies who seek to conduct clinical research for innovative products (Ribbink, 2013), it is important to understand how many clinical trials are being listed on international registrars. Thus, the *number of clinical trials listed at WHO ICTRP* was selected. In terms of strategy and structure, the *ranking of the world's best performing CEO* and *image abroad* were chosen as international variables that demonstrate whether or not Korean and Japanese companies are being recognized as leaders by the international community and thus attractive for potential talent to work for, and for venture capitalists to invest in.

Table 11: Variables for Firm Strategy, Structure and Rivalry

Factor	Market	Sub-Factor	Proxy Variable	Data Value		Measurement
				Japan	Korea	
Firm Strategy, Structure & Rivalry	Domestic	Rivalry	Intensity of local competitors (cl) 2015-2017	6.20	5.90	3 year average 2015-2017, score/7
			Number of pharmaceutical manufacturers(il) 2015-2017	301	615	3 year average 2015-2017
		Strategy & Structure	Social Responsibility of Business Leaders (cl) 2017-2019	7.21	4.94	3 year average 2017-19, index/10
			Sophisticated production process(cl) 2015-2017	6.40	5.20	3 year average 2015-2017, score/7
	International	Rivalry	Control of international distribution(cl) 2015-2017	5.40	5.00	3 year average 2015-2017, score/7
			Number of clinical trials listed at WHO ICTRP(cl) 2017-2019	105	209	3 year average 2017-19, number of trials
		Strategy & Structure	Ranking of world's best performing ceo (cl) 2017-2019	6	0	3 year average 2017-19, number in list
			Image Abroad (cl) 2017-2019	7.11	7.55	3 year average 2017-19, index/10

Chapter 5. Results

5-1. Methodology

To create a scaled comparison between Korea and Japan, the study referenced the calculation method present in existing studies: Son (2014), Son and Yokoyama (2013), Jin and Moon (2006), Vu and Pham (2016), Moon, et al. (1998), Liu and Hsu (2009), Castro-Gonzáles (2016), Molendowski and ŻMuda, (2013), Moon and Yu (2004), Cho and Moon (2010, 2013), Moon (2000) and Moon and Lee (2004). For each proxy variable an index value was calculated. The maximum value it could have was 100, and this was given to the country with the higher value. The country with the lower value was given an index value that reflects its size in relation to the other country. For example, to calculate the index values for Korea and Japan for *Average Wage* (chosen as a basic domestic factor condition), first it was determined that Korea's wage was higher than Japan. Korea then received a value of 100. To calculate Japan's index value, it was then necessary to find Japan's average wage as a percentage of Korea's wage ((38298.33/ 40,885.67) x 100). The final index value for average wage was therefore 100 percent for Korea, and 94 percent for Japan. The index values are listed in Table 12 below:

Table 12: Index Values of Diamond Factors

<table>
<tr><th rowspan="2">Factor</th><th rowspan="2">Market</th><th rowspan="2">Sub-Factor</th><th rowspan="2">Proxy Variable</th><th colspan="2">Index Value</th></tr>
<tr><th>Japan</th><th>Korea</th></tr>
<tr><td rowspan="6">Factor Conditions</td><td rowspan="4">Domestic</td><td rowspan="2">Basic</td><td>Average Wage (cl) 2017- 2019</td><td>94</td><td>100</td></tr>
<tr><td>Annual growth rate of output per worker (cl) 2017-2019</td><td>15</td><td>100</td></tr>
<tr><td rowspan="2">Advanced</td><td>R&D expenditure (il) 2016-2018</td><td>100</td><td>12</td></tr>
<tr><td>R&D personnel p/mil pop (cl) 2016-2018</td><td>75</td><td>100</td></tr>
<tr><td rowspan="2">International</td><td rowspan="2">Basic</td><td>Outbound FDI (cl) 2017-2019</td><td>100</td><td>20</td></tr>
<tr><td>Outbound FDI growth rate index (cl)</td><td>100</td><td>3</td></tr>
</table>

			2017-2019		
		Advanced	Inbound FDI (cl) 2017-2019	87	100
			Inbound FDI growth rate index (cl) 2017-2019	100	0
Demand Conditions	Domestic	Size	Pharmaceutical Spending (il) 2015-2017	91	100
			Total Sales as percentage of GDP (il) 2016-2018	84	100
		Quality	Market sophistication index (cl) 2016-2018	100	93
			GDP/capita (cl) 2017-2019	99	100
	International	Size	Share of World Market (il) 2016-2018	100	25
			Export Value (il) 2017-2019	100	57
		Quality	Number of Country for Pharma exports(il) 2017-2019	58	100
			Percentage of Export without top 3 (il) 2017-2019	76	100
Related & Supporting Industries	Domestic	Hard (Industry Infrastructure)	ICT development index (cl) 2015-2017	95	100
			Health Infrastructure index (cl) 2017-2019	100	99
		Soft (Innovation Infrastructure	Domestically granted patents (il) 2015-2017	100	56
			Domestically published academic articles (il) 2017-2019	66	100
	International	Hard (Industry Infrastructure)	Medical Equipment export (il) 2017-2019	100	34
			High Technology Exports (cl) 2017-2019	63	100
		Soft (Innovation Infrastructure)	Scimago Ranking (cl) 2017-2019	100	65
			Granted Patents (il) 2015-2017	100	47
Firm Strategy, Structure & Rivalry	Domestic	Rivalry	Intensity of local competitors (cl) 2015-2017	100	95
			Number of pharmaceutical manufacturers(il) 2015-2017	49	100
		Strategy & Structure	Social Responsibility of Business Leaders (cl) 2017-2019	100	69
			Sophisticated production process(cl) 2015-2017	100	81
	International	Rivalry	Control of international distribution(cl) 2015-2017	100	93
			Number of clinical trials listed at WHO ICTRP(cl) 2017-2019	50	100
		Strategy & Structure	Ranking of world's best performing ceo (cl) 2017-2019	100	0
			Image Abroad (cl) 2017-2019	94	100

The competitiveness index was calculated by finding the average of each factor category. What is important to note is that these calculations are purely illustrative and serve only for the purpose of building the diamond model. The below table (Table 13) summarizes the competitive indices awarded to each factor for the South Korean and Japanese pharmaceutical industries:

Table 13: Competitiveness Index of the Diamond Model for the South Korean and Japanese Pharmaceutical Industries

Factor	Market	Japan	Korea
Factor Conditions	Domestic	71	78
	International	97	31
Demand Conditions	Domestic	94	98
	International	84	71
Related and Supporting Industries	Domestic	90	89
	International	91	61
Firm Strategy, Structure and Rivalry	Domestic	87	86
	International	86	73

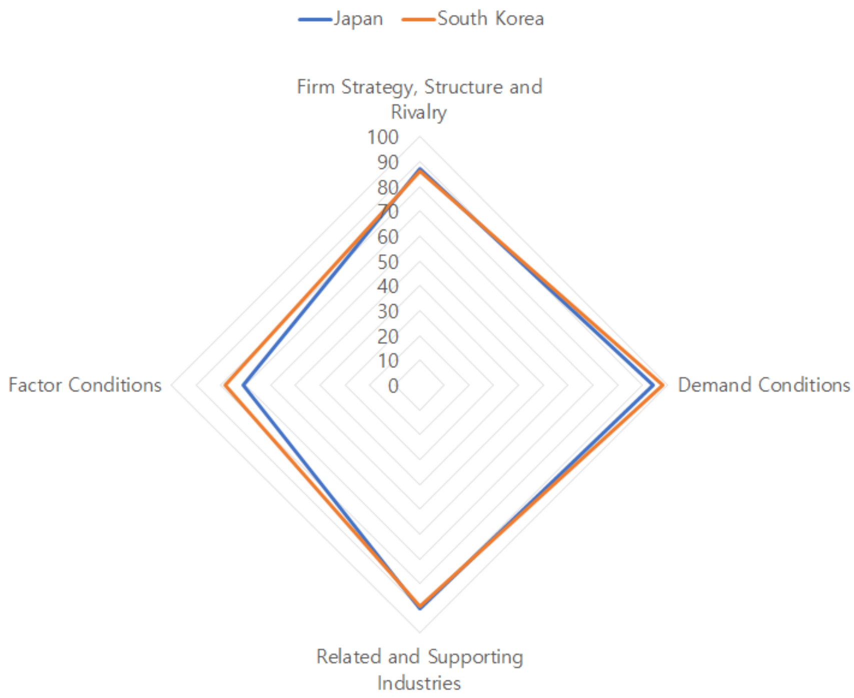
To visualize the results the indices were then used to create both a domestic and an international diamond figure. The international diamond takes into account the existing values of the domestic market, and therefore was constructed by combining both domestic and international indices for each determinant (Moon et al., 1998). As an example, when drawing the international diamond, the value for Japan's demand index was 178 (94+84) shown on Fig. 5. Moon et al. (1998) stated that the "difference between the international diamond and the domestic diamond is [therefore] the international or multinational determinants of the nation's competitiveness".

According to the results of this study, Korea has a marginally larger domestic diamond (Fig. 4) whilst Japan has a larger international diamond (Fig. 5). This suggests that, though both countries have a comparable level of competitiveness domestically, South Korea is consistently less competitive than Japan when international determinants are considered. Thus, it can be concluded that the reason for Japan's sustained lead ahead of South Korea as a more globally competitive pharmaceutical industry is a result of the superior performance of international parameters.

5-2. Domestic Diamond

In terms of domestic competitiveness, South Korea’s domestic diamond was larger than Japan and its pharmaceutical industry outcompetes Japan in two of the four determinants: factor and demand conditions. South Korea’s factor competitiveness was supported largely by the annual growth rate of output per worker and the number of R&D personnel per million of population, whereby Japan’s relative score was 15 percent and 75 percent respectively. South Korea therefore had an index of 78 percent (Fig. 3) whilst Japan was awarded 71 percent (Fig. 3). In terms of domestic demand, South Korea outperformed Japan across all variables bar market sophistication index, and therefore received a competitiveness index of 98 percent (Fig. 3) with Japan at 94 percent (Fig.3). What this shows, is that the pharmaceutical market is already contributing more to the country’s economy than Japan’s own industry is, given that Total Sales as a percentage of GDP is at 1.48 percent in South Korea and only at 1.25 percent in Japan. Equally, South Koreans are spending more on pharmaceutical products than Japanese consumers, with Japanese expenditure being around 91.4 percent of South Korean expenditure. As is visible on Fig. 3 and from Table 9, South Korea and Japan only had a one percent difference in terms of the competitiveness of related and supporting industries, and firm strategy, structure and rivalry, showing that neither country has a substantial level of competitiveness in those factors over the other.

Figure 3: Domestic Diamond of the South Korean and Japanese Pharmaceutical Industries



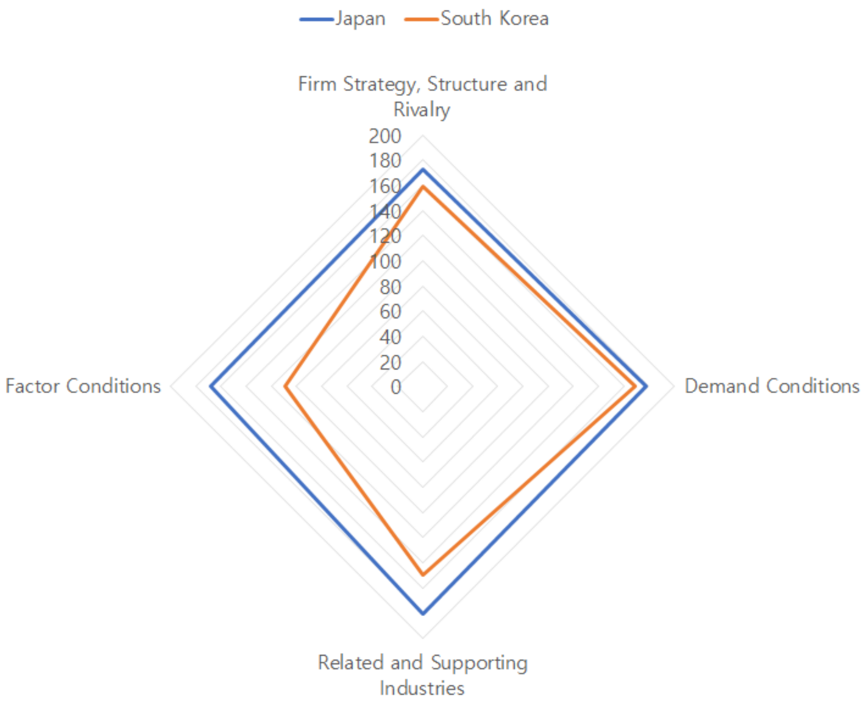
When looking at the International diamond model (Fig. 4), Japan's pharmaceutical industry is shown to be more competitive across all parameters than South Korea. Moreover, the shape of South Korea's international diamond is relatively similar to its domestic diamond, showing that its overall competitiveness is not being supported by its international activities, and reflects similar findings made by Moon et l.(1998). Though the difference between Japan and South Korea is more minimal for the determinants Firm Strategy, Structure and Rivalry (Fig. 4 ,9 percent difference), and Demand Conditions (Fig.4 ,14 percent difference), Japan greatly outperforms South Korea in terms of Factor conditions (Fig. 5, 59 percent difference) and Related and Supporting Industries (Fig.4, 31 percent difference). South Korea's weak position in Factor conditions demonstrates that South Korea has not conducted as much Outbound FDI as Japan, scoring a proxy value of only 20 out of 100 and 3 out of 100 for Outbound FDI growth rate index. Though South Korea in fact attracted more inbound FDI than Japan, which will help it attract foreign capital and technology (Moon et al., 1998), the growth rate index for inbound FDI in the selected time frame was negative, and therefore gave South Korea a index value of 0 percent. It is also important to note that these FDI values were on a country level and therefore are representative of the nation's ability to attract FDI and not the industry specifically. In terms of Related and Supporting Industries, Korea only outperformed Japan in terms of its High Technology exports, and therefore was less competitive overall. It was particularly weak in terms of innovation infrastructure, scoring a proxy value of 65 percent for its Scimago Ranking and 47 percent for the number of granted patents in the 5 international IP offices, suggesting that its patents and academic research was more dependent on local knowledge sources and not international collaboration.

Chapter 6. Discussion

6-1. The Importance of Internationalization for Industrial Competitiveness

In line with the conclusion made by Park and Lee when comparing South Korean and Chinese industrial policies and patenting behavior, South Korea was found to have a closed innovation system that utilized its domestic knowledge stock for new knowledge creation (Park and Lee, 2020). Moreover, in terms of firm, strategy, structure and rivalry, it is interesting to see that even though South Korea has almost double the number of pharmaceutical manufacturers that Japan has (615 and 301 respectively), they are not as well-known abroad or viewed as favorably as their Japanese competitors. Though they might be initiating international clinical trials, Japanese companies are outperforming their Korean counterparts in terms of a higher perceived level of control of international distribution, as well as more Japanese CEOs being selected as belonging to some of the world's best performing CEOs.

Figure 4. International Diamond of the South Korean and Japanese Pharmaceutical Industries



These results show that South Korea must focus on developing its multinational activities in order to secure the future success of its pharmaceutical industry. Japan's competitive advantage over South Korea in the pharmaceutical industry has been shown to be as a result of South Korea's weaker international performance across all determinants, resting predominantly on factor conditions and related and supporting industries. Though South Korea's pharmaceutical industry is quickly gaining competitiveness domestically, and is already more competitive in 2 out of the 4 factors of the international diamond, the industry should be conscious of the sustained competitive loss it will incur if it does not address the two aforementioned weaker factors of its international diamond as these are causing the industry to be at a significant competitive disadvantage when compared to Japan.

6-2. The Role of Government

Though government policies were not assigned empirical values in the calculation of the diamond model, they nevertheless play an important role in the competitive advantage South Korea and Japan experience in their pharmaceutical industries. As outlined by Moon et al. (1998), the government's interventionist policies contributed greatly to Korea's economic development and the evolution of its domestic and international business environment. In terms of the pharmaceutical industry, Valverde argued that a pre-requisite for the industry to successfully generate returns on the large investments made was access to the global market (Valverde, 2016). Moreover, it was noted that producers and countries consuming imported pharmaceutical goods are largely impacted by domestic pharmaceutical regulations of other countries. Pease (2005) also argued for the central role that changes in macro environment through regulatory reforms have had on increasing the competitiveness of pharmaceutical corporations and in driving their global expansion, particularly in the case of the

Japanese industry.

Japan's Ministry of Health, Labor and Welfare (MHLW) has been implementing reforms to contain ever rising health and pharmaceutical spending. With annual price reviews that favor the low production costs of Generic drugs, Japanese pharmaceutical companies are being forced to reevaluate their level of investment into branded drugs (BMIResearch, 2018). According to JPMA (2015) the uptake of "generic drugs accelerate the reduction in revenues from long listed products" and this directly impacts the ability of R&D focused pharmaceutical companies who rely on heavy investment in order to successfully innovate and discover new drugs. This has been met with criticism from both manufacturers who prefer the higher profit margins branded drugs provide, and healthcare consumers who have historically seen generic substitutions as ineffective and untrustworthy. Further detriment to the industry can also occur if the government raises sales taxes further, as was the case in 2014 where the imposition of a new value added tax reduced growth in the industry (IMS. 2015).

The government has therefore been tasked with counteracting the innovation drain that has resulted from generic usage and production and has responded by setting up AMED (Japan Agency for Medical Research and Development), the PMD Act and the SAKIGAKE Designation System. To ensure investment and interest in the Japanese market remains high, the government targeted what was previously one of the highest barriers of entry, namely the clinical development period and quality of clinical trials. Through the implementation of the SAKIGAKE Designation System in 2014, drugs and device approvals were greatly accelerated, and review times were cut to a level comparable to the leading markets of the EU and US. By shortening the initial clinical trial notification application process up to 21 months, the number of NME applications in Japan has risen to be almost double that of the US. Moreover, the scheme enabled the rapid authorization of "unapproved/off-label" drugs that were previously unapproved in Western countries (MHLW, 2014), as well as expediting National Health Insurance reimbursement discussions and tax incentives (The Economist Intelligence Unit, 2020). In unison with the PMD Act, that regulates the production, sale and importation of drugs, medical devices (noted as a relevant supporting industry within this study) and medical software, foreign companies are undertaking more collaborations than ever. As noted by Harvard Business Review, multinational giants like Boehringer Ingelheim, Eli Lilly, and Amgen have developed pioneering drugs in unison with Kyoto University, National Cancer Centre Japan and Astellas as a direct result of the PMD ACT. This increased interest in cross-country cooperation is driving further open innovation projects, and carrying out mergers and acquisitions, and organized partnership conferences that attempt to harmonize pharmaceutical legislation, approval and licensing regulations across countries (JPMA, 2015). Such internationalized cooperation plays a vital role in addressing international demand for Japanese pharmaceutical products. As Asian countries are forecasted to have higher market growth rates than advanced countries, such collaborations expedite the entrance and launches of Japanese pharma products and companies, and therefore can help cover the market loss they would otherwise experience in the more established Western markets.

A high human capital capacity is integral to ensuring effective innovation in life sciences and so the government has sought to ensure this does not stagnate out of fear that academic publications and patents would irreparably decline (The Economist Intelligence Unit, 2020). Japan has been experiencing a decline in the number of highly trained specialists available to conduct the necessary clinical research as many have been influenced by Japan's traditionally risk-adverse business environment and lack of support for pharmaceutical start-ups (The Economist Intelligence Unit, 2020). Thus, the MHLW and AMED have been working together to ensure the availability of necessary training for existing scientists and biostatisticians (JPMA, 2015). The Japan Society for the Promotion of Science (JSPS) and Ministry of Education, Culture, Sports, Science and Technology (MEXT) have also set up the KAKENHI Grants-in-Aid for Scientific Research programme to provide a budget for creative and pioneering research, that accounts for over 50% of all competitive funding assigned by the Japanese government (JSPS, 2019).

Finally, to address the ever changing technological landscape surrounding the pharmaceutical industry, the Japanese Government has sought to foster the integration of Big Data and AI in life science innovation by introducing the Next Generation Medical Infrastructure Law and through the 2019 Innovation Strategy. Patient records across the country will be made both anonymous and will become available for use by pharma companies, academic and public institutions. It is also hoped that improving the country's research infrastructure by increasing the availability and accessibility of data and technology, will support and encourage start-ups and smaller research institutes to undertake necessary experimental research. Such endeavors have previously been limited to Japan's traditionally larger leading pharma companies, given the country's "limited supply of risk capital and weak incubation function" (The Economist Intelligence Unit, 2020).

The South Korean government is the predominant source of funding for the healthcare system. The growing financial burden that is arising from increased demand and usage of medicines, has led to the adoption of a discriminatory pharmaceutical pricing and reimbursement system. South Korea implements a positive list system that filters through new medicines on terms of their cost effectiveness. To offset the negative impact such a cost focused strategy can have on the production of innovative and more expensive drugs, the government has amended the criteria to permit drugs that are exceptional in terms of providing treatment to unaddressed and serious diseases. All new medicines must therefore be evaluated by the National Health Insurance Service to determine their price, before arriving at the Ministry of Health and Welfare for final approval (Jang et al., 2017).

To counteract the detrimental effect this approval and pricing process can have on the desire for pharmaceutical firms to continue engaging in R&D intensive medical production, new measures have been adopted. Since 2002, the Clinical Trial Authorization process was initiated by the government, and has reduced clinical trial approval by ensuring that all applications can be simultaneously processed by the Ministry of Food and Drug Safety (MFDS), institutional review boards, and ethics committees(KoNECT, 2017). Moreover, the MFDS is now a participant of both Inspection Co-operation Scheme and International Conference on Harmonization to ensure that Korean manufacturing and quality management systems are in line with the standards of the international community (KHIDI, 2018).

More recently, the government renewed the *Special Act on Pharmaceutical Industry Promotion and Support of the Pharmaceutical Industry* to ensure that the industry continues to receive the support necessary for it to adopt new competitive technologies, increase employment, and become more internationally competitive (KHIDI, 2018). This act identified innovative pharmaceutical companies that surpassed other firms in terms of R&D investment, patents, specialization and manufacturing facilities, and rewarded them with additional support from the Government.

Based on the results obtained using the GDD framework in this study, important implications for the South Korean Government can be drawn. In order to further improve the competitiveness of the industry, the Government should focus their efforts on nurturing the industry's openness to international cooperation and development. Given Japan's more international recognition, also supported by the results collected in this study, certain regulations or government schemes can be benchmarked and utilized to suggest as yet not fully explored regulatory opportunities for the Korean government.

With prices of pharmaceutical products forecasted to continue dropping in order to account for ever-rising healthcare costs, the government should be wary of the innovation lag that such policy and pricing strategies has caused in Japan. Korean companies should also take heed of the vulnerability of Japan's smaller R&D based companies who weren't able to sustain their revenues with the introduction of policies that favored generics. Small firms also enhance R&D activities of more established firms who themselves are experiencing diminishing levels of innovation and so must be provided with a business environment that fosters their creation and success (Peruffo et al., 2014). Future policies should therefore strengthen public and private academic collaboration, and that between large and start-up/ spin-off companies, and support pioneering projects as the Kakenhi Grants-in-Aid scheme has done. The Korean government can also follow Japan's METI and recognize the risk-averse business environment present in Korea and lack of a strong international reputation in terms of business practices by improving listing systems for those who seek investment, as well as increasing communication channels and up-front investment conditions (The Economist Intelligence Unit, 2020).

Similar to South Korea, the Japanese pharmaceutical industry had previously been one of the country's most close and domestically oriented industries. This however fostered an over dependency of domestic players on the national market. These companies, who had been over reliant on domestically generated revenue, weren't able to make the needed increase in international activity upon the implementation of policies that opened the industry to the international markets and competitors and inevitably lost out to the larger companies who had already reinvested their pipelines in international activities (Slater et al., 2008). The high level of outbound investment conducted by Japanese firms, who actively sought to "diversify company holdings via overseas investment", and their international collaborations with other leading players on the global field proved to be a key contributor to Japan's higher level of international competitiveness when compared to Korea's pharmaceutical industry (Dwyer III and Jackson, 2020). Therefore, Korean officials should take note and ensure to increase funding, investment and industry collaboration opportunities for firms inside and outside of Korea.

Chapter 7. Conclusion

7-1. Conclusion

The purpose of this study was to determine the current level of competitiveness of the South Korean pharmaceutical industry and to measure its performance on a domestic and international front. In order to ascertain which areas South Korea should improve upon, the study utilized its global peer Japan as a benchmark for comparison. In order to determine which variables would be most suitable to reflect the contemporary conditions of the pharmaceutical industry, extensive analysis of existing academic literature and global competitiveness reports by international institutions and research organizations were conducted. The study implemented the Generalized Double Diamond Model as a theoretical framework in order to present a holistic overview of the entire industry and within the context of the countries chosen for study. As argued in the Literature Review, this was a departure from existing literature, as previous research into the industry did not seek to create a comprehensive snapshot of the industry but merely analyzed the impact of individual factors on the competitiveness of the countries analyzed i.e. Economic and Regulatory Environment, Organization and Operational Strategies, etc. In addition, previous literature had neglected to compare the countries chosen in this study, and so this study has helped further the existing analysis of the pharmaceutical industry by expanding the understanding of the South Korean and Japanese pharmaceutical markets.

As shown in the results section, South Korea and Japan have favorable domestic conditions to support the growth of their pharmaceutical market, but Japan is already seen to be less competitive than South Korea. This can be attributed to a lagging output growth rate, reduced numbers of domestically published articles, and from a demand perspective, the contribution of pharmaceutical sales to the economy's overall GDP. However, Japan outcompetes South Korea in terms of multinational activities and has therefore been able to sustain a global pharmaceutical competitive edge. In particular, South Korea must focus on supporting both outbound and inbound investment in the pharmaceutical industry to ensure that it can be globally competitive. The government's role in creating and implementing policies favorable to the innovative research and development, and attractive business environment for investment activities should not be underestimated for both South Korea and Japan. Korea must be quick to remedy its lack of international competitiveness as otherwise it could slow down its growth as high barriers and a historically insular domestic markets deterred the entrants of foreign companies into the Japanese market and has led to the slowdown in the industry's growth (CPhI, 2018).

As South Korea looks to ensure the sustained performance of its knowledge-based economy, and secure the health of its aging population, it is more important than ever that policies are put in place to strengthen the competitiveness of its pharmaceutical industry. South Korea's economic growth, innovation capacity and the public's accessibility to necessary medicine is likely to be compromised in the future if its pharmaceutical industry does prove to be competitive enough. If South Korea therefore wishes to surpass global peers like Japan on the global market, it must seek to address the leaks in its competitiveness as identified in this study. Policy recommendations presented in the study focus on addressing the limited international investment opportunities and incentives present in South Korea's pharmaceutical industry, as well as the need for innovative small companies and research institutes to be supported in the growth and internationalization strategies through education, funding and open innovation opportunities.

7-2. Limitations

The study still has some limitations that future studies can improve upon. Due to data limitations and differences in statistical methodologies, some variables utilized data from different time periods and were not specific to the pharmaceutical industry. As some data was at the country level, it could therefore lead to inaccuracies and misrepresent the actual state of the pharmaceutical industry. As FDI related variables were a deciding factor in South Korea's weakened international competitiveness, future research should seek out data related specific to the pharmaceutical industry. In addition, it would be beneficial to find variables that represent the business environment of the pharmaceutical industry and not just the country as a whole so as to better calculate the competitiveness index for the *Firm Strategy, Structure and Rivalry* determinant. A final limitation that can be drawn is related to the lack of existing research that compares Japan and South Korea's pharmaceutical industries. Though important conclusions could be drawn from the results obtained through this study, it is hard to validate all the findings as there is no prior existing comparison of these countries that utilizes the GDDM framework or that seeks to determine the level of competitiveness of these markets in a holistic manner.

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Korean Abstract

경쟁력 있는 제약 산업은 모든 국가의 사회 및 보건 자원의 지속적인 개선을 위해 필수적이며 지속적인 경제성장의 원천이 될 수 있습니다. 한국은 경기 침체와 고령인구의 사회보건비 상승에 직면해 있는 만큼 산업 경쟁력 현황을 점검해 글로벌 입지를 어떻게 높일 수 있을지 판단할 필요가 있다. 다음 연구는 일반화된 더블 다이아몬드 모델을 적용하여 한국 경쟁력의 결정요소를 파악하고, 세계적으로 경쟁력이 있는 일본과의 비교 분석을 실시한다. 이 연구는 제약 산업이 세계화되는 정도를 고려하여 2015년부터 2019년까지의 국가 및 산업 수준에서 국내외 변수를 모두 탐구한다. 국내적으로 결정되는 경쟁력에서 한국이 일본과 거의 어깨를 나란히 하지만, 한국이 일본만큼 글로벌 경쟁력을 갖추는 데 걸림돌이 되는 국제전략적 차이가 크다는 것을 보여주는 결과다.

Keyword: 제약산업, 대한민국, 일본, 국제경쟁력, 일반화된 더블 다이아몬드 모델
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