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BUSINESS-GOVERNMENT RELATIONSHIPS IN THE PHARMACEUTICAL INDUSTRY: AN ANALYSIS OF A MULTINATIONAL CORPORATION IN COLOMBIA AND INDIA

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Abstract

Business government relationships are critical within the pharmaceutical industry while the growth in emerging markets leads to those being the most important revenue drivers. By conducting a case study about the multinational pharmaceutical corporation Novartis and its business operations in two emerging markets, Colombia and India, this paper examines the impact of Novartis on the outcomes of the two cases, based on the stakeholder theory, institutional theory and government-business bargaining principles, in the context of business-government relationships. It concludes with implications for business-government relationships, the importance of negotiations and proactive stakeholder management and lastly provides some guidance to Novartis.

Keywords: Business-government relationships, pharmaceutical industry, emerging markets, multinational pharmaceutical corporations, Novartis and IBGR

1. Introduction

The pharmaceutical industry represents one of the most complex, most valuable and most important industries in the world, as it generates revenue from the most valuable asset of humanity, namely human health and therefore also human life. However, human health is also a right which the Constitution of the World Health Organization (WHO) legally obliges all states parties to declare in conformity with the Charter of the United Nations that "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being…". Furthermore, the WHO states that it is a state's legal obligation "to ensure access to timely, acceptable and affordable health care of appropriate quality", consequently the role and objective of most governments is predetermined and can thereby exert direct impact and bargaining power on the pharmaceutical industry along with its multinational corporations (World Health Organization 2017). This particular dynamic between governments and companies within the pharmaceutical sector demonstrates the relevance of scientific, research-based contribution to the analysis of business-government relationships (hereafter referred to as BGR) in the pharmaceutical industry. The term of International Business-Government Relationships (IBGR) amongst the associated opportunities, potential benefits, risks and costs for companies as well as governments have already been comprehensively analyzed and described in literature. Boddewyn (2016) points out that sovereign agents, public policies and actions affect multinational enterprises (MNE) as well as negotiations that are crucial for accomplishing "order in a relation in which potential conflict threatens to undo or upset opportunities to realize mutual gains" (Williamson 1996). Correspondingly, it is important to examine how multinational companies can shape the outcomes of the relationship between the government and the company itself. A further limitation with regard to emerging markets enables an in-depth analysis of the research question and takes into account the increasing significance of emerging markets within the pharmaceutical industry. Gautam and Pan (2016) outline that

emerging market growth is a key revenue contributor to global pharmaceutical sales, amounting to $1.25 trillion in 2019, as they "account for almost one-quarter-to-one-half of the revenues for big pharma" (Statista 2020a). Moreover, global pharmaceutical markets face major discontinuities, partly because growth in developed markets will diminish while emerging markets gain growth and thus importance (McKinsey&Company 2020; Gautam and Pan 2016).

In order to examine the impact of MNEs on outcomes of business-government relations within the pharmaceutical industry, a case study about the pricing of the Swiss multinational corporation Novartis' former blockbuster drug Glivec in Colombia and India, is conducted. According to several institutions such as Morgan Stanley Capital International, Standard & Poor's and the Financial Times, Colombia and India are both rated as emerging markets (FTSE 2020; S&P Global 2020; MSCI 2020). The subsequent analysis of the outcomes of Novartis government relationship in both emerging markets contributes to the case study methodology and is built upon the stakeholder theory, the institutional theory, business-government bargaining and further negotiation principles (Meyer and Peng 2016; Williamson 1996; Boddewyn 2016; Peng et al. 2008; Miles 2017). Secondary research is used to provide an overview of the company, its drug Glivec, the business environment and the government's framework conditions, in terms of the pharmaceutical market, the health system, health expenditure and funding in both countries. The description of both cases, Colombia vs. Novartis as well as India vs. Novartis, is primarily based on newspaper articles, business and pharma magazines but also includes articles of journals and non-profit organizations. In the face of current events, BGRs can be of major importance as governments around the world compete for the Covid-19 vaccine. Additionally, all stakeholders – government, healthcare companies and payers – are challenged to ensure sustainable access to healthcare, especially in emerging markets where pricing is a key challenge (Gautam and Pan 2016). Given the aforementioned factors concerning relevance and actuality, the objective of this

work project is firstly to analyze the BGR of Novartis and the Colombian as well as Indian government respectively, secondly to examine Novartis' impact on the outcomes and its implications in both cases and thirdly, to provide some guidance for Novartis and other multinational pharmaceutical corporations in regard to negotiation approaches and IBGR in emerging markets, based on the case study.

2. About Novartis

Novartis is a Swiss multinational pharmaceutical company with headquarters in Basel and was created in 1996, as a result of a merger between Ciba-Geigy and Sandoz, two chemical and pharmaceutical companies from Basel, whereas the roots of Novartis and its predecessor companies date back more than 250 years. The corporation sells its products in approximately 155 countries around the world, reaching 799 million patients worldwide in 2019, a slight increase compared to the previous year when 765 million patients were reached. Furthermore, Novartis ranks as third biggest pharmaceutical company in the world in 2020, measured by its revenue of $47.4 billion and a net income of $11.7 billion in 2019 (Novartis Website 2020; Haqqi 2020). In the same year, Novartis employed 103,914 full-time employees, distributed over the two global operating divisions Innovative Medicines and Sandoz as well as the three cross-divisional organizational units: the Novartis Institutes for BioMedical Research, Global Drug Development, Novartis Technical Operations and Novartis Business Services (Statista 2020b). The Innovative Medicines Division is a global leader in providing patent-protected medicines to patients as well as physicians and entails research, development, manufacturing, distribution and sale of patented prescription medicines. It is organized into the two global business units Novartis Pharmaceuticals and Novartis Oncology. The Sandoz Division is the second largest manufacturer of generics in the world, dedicated to the development, manufacturing, distribution and sale of prescription

medicines along with pharmaceutical active substances which are not secured by valid and enforceable patents of third parties (Ecks 2008). Retail Generics, Anti Infectives and Biopharmaceuticals are the three franchises in which Sandoz is organized on a global scale. (Ecks 2008; Novartis Website 2020)

2.1 Glivec

Novartis' cancer drug Glivec (imatinib mesylate/imatinib) is an oral kinase inhibitor, used to treat Chronic Myeloid Leukemia (CML) and Gastrointestinal Stromal Tumours (GIST) among other rare cancers. The medicine does not permanently cure cancer, it only slows the disease progression which means the duration of the treatment is lifelong, whereas the life expectancy of a patient without the supply of the drug is utterly short. Glivec is approved in more than 116 countries across the world, nonetheless the company holds patents in only 35 countries worldwide. Patents for the predecessor of the current Glivec version were filed worldwide for the first time by Novartis in 1993, excluding India since patent protection was not offered in India at that time. (Glivec Website 2020; Gabble and Kohler 2014) In 2015, the active ingredient imatinib was added to the World Health Organization's (WHO) List of Essential Medicines under the complementary list that "presents essential medicines for priority diseases…" (World Health Organization 2019). The WHO declares essential medicines by considering public health relevance, evidence on efficacy and safety as well as comparative cost-effectiveness. In addition to that, essential medicines "are intended to be available with the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford" (WHO Website 2020).

As stated in Novartis' 2019 Annual Report, Glivec belongs to the Novartis Oncology business unit which is part of the company's Innovative Medicines division. Besides that, the drug belongs to the "Top 20 Innovative Medicines" of the company. In 2019, the Innovative Medicines division

accounted for $37.7 billion in net sales, an increase of 8% compared to the previous year, whereas Novartis Oncology delivered net sales of $14.4 billion with an increase of 7% and Glivec alone accounted for $1.3 billion in net sales with a decrease of 19% in comparison to 2018. This decline is mainly driven by generic competition in most major markets which resulted in the drug losing its top-seller status over the last years. In fact, Glivec used to be the company's blockbuster drug for several years until it lost the exclusivity for patented products in 2016, nevertheless it is listed under "Novartis' top 10 drugs based on revenue" in 2019 (Statista 2020c). Among Novartis oncology products, Glivec is still one of the strongest turnover contributors, thus belongs to the corporation's key marketed products in oncology. The net sales of Novartis' Innovative Medicines Division are distributed to the four sales regions in 2019 as follows (Appendix 1): The US is the largest market with a net sales volume of $13.8 billion, an 16% increase compared to the previous year. Europe net sales amounted to 12.9 billion and increased by 4%, however it used to be Novartis' largest market within the Innovative Medicines Division until 2019 and still is in terms of Group net sales. Asia, Africa and Australasia share net sales of $8.5 billion, an increase of 4% and lastly, Canada and Latin America's net sales sum up to $2.7 million, an increase of only 1%. Net sales of the "Emerging Growth Markets", which are all markets except of the established markets USA, Western Europe, Canada, Japan, Australia and New Zealand, increased by 6% in 2019, primarily attributable to double-digit growth in China. (Novartis Annual Report 2020; Novartis Website 2020)

3. Colombia vs. Novartis Case

In 2012, Novartis' cancer drug Glivec received a patent in Colombia which was due to expire in mid-2018. A previous patent application for the drug in Colombia was rejected in 2003, resulting in the production of 197 percent cheaper generics than Novartis' Glivec as reported by the health

ministry. In the beginning of 2016, the Columbian government requested from Novartis to lower the price of the drug's active ingredient Imatinib that is used to treat leukemia and other cancers. The aim of this price reduction is to support the overburdened healthcare system in Colombia. However, initial price negotiations between Novartis and Colombia, including the Minister of Health and Social Protection Alejandro Gaviria have not been successful, whereupon the country stated that it may advocate a compulsory license, nevertheless further negotiations were still possible at this point. Consequently, competitors such as generic companies would be allowed to produce and sell lower-cost versions of Glivec while Novartis would lose its patent-secured monopoly position in the Colombian pharmaceutical market. In April 2016, the price of a 400 milligram imatinib tablet amounted to approximately $43 and around 2,500 patients in Colombia were treated using imatinib. The government proposed a price reduction to Novartis of $18.50 per 400 milligram tablet which was rejected by the company. According to Gaviria, Novartis didn't want "to negotiate under the threat of compulsory licensing" (Symmes Cobb and Acosta 2016a). (Reuters 2016; Bruns 2016; Symmes Cobb and Acosta 2016b)

Other countries such as India, Brazil and Thailand have been strongly criticized by pharmaceutical companies and the U.S. government for enforcing compulsory licensing which could infringe patent law. The Glivec case in India will be described afterwards. In Washington, Colombian diplomats were worried about possible political and economic consequences from the U.S. regarding compulsory licensing, namely reductions in proposed funding for the Peace-Colombia aid package, worth $450 million with the prerequisite of an end to the long-lasting conflict with the Marxist rebels. The news agency Reuters has been informed by Novartis that it has been actively seeking a resolution at that time, otherwise Colombia might face a compensation payment in favor of Novartis. After renewed negotiations lasting two weeks, Colombia and the pharmaceutical company could not reach an agreement in terms of price conditions. (Symmes Cobb

and Acosta 2016a; 2016b; Reuters 2016; Bruns 2016) Besides that, misunderstandings and differences of perception marked the ambiguity about the conclusion of negotiations, especially from Novartis' perspective. As negotiations broke down, Columbian authorities decided to set the new price of Glivec unilaterally using a public interest declaration. This allows health regulators and experts to inspect the case and set a lower price at which Novartis is legally required to sell the drug. The company stated that they "have remained fully committed to finding a resolution that benefits patients, innovators and the Colombian healthcare system" (Symmes Cobb and Acosta 2016a). Furthermore, compulsory license and declarations of public interest "can be important and legitimate tools to be used only in exceptional circumstances…", however circumstances in the Colombian healthcare system could not be classified as exceptional according to Novartis (Bruns 2016). Another argument of the company addresses that other non-infringing generic versions of imatinib are available on the market and could be purchased by the government in order to reduce its healthcare budget. In addition to that, there is no Glivec shortage or any other indication in terms of Glivec access issues in Colombia. Novartis calls attention to the usage of these tools in price negotiations which "would create a damaging precedent that could apply to all patent-covered innovations – pharmaceutical or otherwise" while receiving approval from other pharmaceutical organizations. (Bruns 2016; Symmes Cobb and Acosta 2016b)

Approximately one year later, on April 12, 2017, the Business & Human Rights Resource Center reported about leaked documents written by Novartis to the Ministry of Trade which reveal the corporation's willingness or threat to involve an international investment arbitration court "for an alleged violation of the bilateral investment agreement between Switzerland and Colombia (BIT)" (Business & Human Rights Resource Centre 2017). Based on a provision in Bilateral Investment Treaties, named Investor-State Dispute Settlement (ISDS), Novartis as an investor in Colombia is legally entitled to bring a case against Colombia to a private international arbitration tribunal

instead of involving local courts first. The extend of the documents impact is difficult to analyze and evaluate, nonetheless the Columbian health authorities did not continue their efforts to obtain compulsory licensing shortly after Novartis notification and only focused on reducing the price of Glivec through declaring public interest. (Miller 2015; Business & Human Rights Resource Centre 2017) Finally on December 20, 2016, the Colombian government lowered the price of Glivec by 44 percent. The new price of each 400 milligram tablet of the cancer drug costs $27.6 compared to the original price of $49 (Reuters 2016).

4. India vs. Novartis Case

The Novartis Glivec case in India dates to 1997, when the company introduced a new formula of the imatinib drug to the market which claims 30% more bioavailability than the previous version, meaning that the absorption in the bloodstream increases by 30%. Hence, the company applied for a patent that was filed under the India's "mailbox" provisions and enabled patent applications of companies while the Indian government transformed into a revised intellectual property legal system by order of the World Trade Organization (WTO) until 2005. At the same time, generic manufacturers were producing and selling Glivec in India at less than 10% of the patented version's price, forcing Novartis to influence the Indian government to take a stance on the protection of intellectual property rights. Therefore, Novartis was granted Exclusive Marketing Rights (EMR) by the Indian government in 2003 until the patent application for Glivec was subject for review. These EMR halted most of the generic version production, leading to extensive access barriers for patients needing affordable cancer treatment. An objection against Novartis' patent application, including its examination in 2005, was filed by various generic manufacturers as well as non-profit organizations such as the Cancer Patients Aid Association (CPAA). There were also protests against the company's EMR status in India at the same time. (Gabble and Kohler 2014) In January

2006, the Indian Patent Office rejected Novartis' patent application for Glivec under Section 3(d) of the Indian Patents Act, on the grounds that it "did not demonstrate any significant changes in therapeutic effectiveness over its pre-existing form, which was already patented outside India" (Gabble and Kohler 2014). Section 3(d) in the Indian Patents Act aims at preventing "evergreening", a procedure in which companies obtain new patents based on only minor modifications compared to existing drugs (BBC 2013). Precisely, it states that reformulations of already existing medicines must indicate "significantly enhanced efficacy" in comparison to the previous version of the drug to be eligible for extended patents (Chandra 2011). However, the meaning or extent of the word "efficacy" is not further defined, neither in the Indian Patents Act nor in its implementing rules. As a result, the interpretation of "efficacy" is critical to this case. Despite this, Section 3(d) of the Indian Patents Act was mainly included to protect public health interests. (Gabble and Kohler 2014)

In response, two lawsuits against the Indian government were filed by Novartis in May 2006, one against the rejection of its patent application and the second against Section 3(d) on the basis that it was incompatible with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), ratified by India in 1994. The Madras High Court decided against the company's attempt to overturn Section 3(d) in August 2007, followed by the dismissal of Novartis' appeal against the rejection of its patent application, resolved by the Indian Intellectual Property Appellate Board in 2009. Subsequently in the same year, the corporation filed a new case in the Indian Supreme Court claiming the base of these decisions. In early April 2013, the Indian Supreme Court's final decision led to the rejection of Novartis' patent case while the chances of a precent being set are high and so are the risks involved. (Gabble and Kohler 2014) According to BBC (2013), the monthly treatment costs of Glivec in India amounted to approximately $2,600, whereas the monthly treatment costs of the generic equivalent amounted to approximately $175. The company

announced that the Supreme Court's decision "discourages future innovation in India" and the former vice-chairman as well as managing director of Novartis India, Ranjit Shahani, added "this [ruling] is a setback for patients that will hinder medical progress for diseases without effective treatment options" (BBC 2013). Under Novartis' view, Section 3(d) of the Indian Patents Act was not applicable to Glivec in the first place. The corporation claimed that the initial patented version of the imatinib drug, served as only the first development step of the current formula and could not be dispensed to patients. Novartis also challenged the validity of this Section 3(d) under the TRIPS Agreement and argued that India's vague patent laws can result in stifling innovation within the pharmaceutical industry. A further argument of Novartis and other pharmaceutical companies points out that research and development processes take a long time and demand huge investment costs in the pharmaceutical industry, implying the importance of a solid system protecting intellectual property rights and enabling companies to compensate for these expenses. (Gabble and Kohler 2014)

To analyze the impact of BGRs in the case of India vs. Novartis, it is essential to consider the Indian government's perspective as well. The objective of certain provisions in India's patent laws, as Section 3(d), constitutes the protection of the population's access to medicines (Médecins Sans Frontières 2005). Moreover, the monthly treatment costs of the patented Glivec version exceeds three times the average annual income in India, thus the pricing of the cancer treatment represented probably the most significant factor of the Indian government's position on Novartis's Glivec case. Therefore, the Indian government's interpretation of international intellectual property protection laws was adapted to India's public health needs, namely about 300,000 patients who used the drug in 2013. (Gabble and Kohler 2014) Lastly, the patent rejection decision has "global significance since India's generic drug industry, pegged to be valued at $26 billion, supplies much of the cheap medicine used in the developing world" (The Associated Press 2013).

5. Colombia's Pharmaceutical Market

An overview of the Colombian pharmaceutical market is essential in order to analyze the BGR between Novartis and the Colombian government on the basis of the Glivec case. In terms of market size, Colombia's pharmaceutical market was valued at $4.795 billion in 2019 and continues to grow by 3% until 2022, as forecasts indicate. This is in line with the development of Colombia towards becoming an export hub for pharmaceutical products, an opportunity which Novartis and other multinational pharmaceutical corporations like Abbott, Pfizer, Fresenius Medical Care and Sanofi have already identified. These multinational companies amongst others account for more than 25% of Colombia's pharmaceutical sector exports amounting to $358.4 million, a volume of 58,000 tons in 2019 along with a 10.8% growth compared to the previous year. In addition to that, Colombia is known for its strong clinical research environment, namely 121 research centers in accordance with the Colombian Association of Clinical Research Centers. In fact, the country has been chosen by major pharmaceutical companies as a clinical research location for studies in regard to the COVID-19 pandemic due to the quality of clinical research centers as well as Colombia's demographic diversity. (Invest in Colombia 2020)

From an investment perspective, Colombia's pharmaceutical market entails great potential because of its sustained market growth from 2014 to 2017, when sales grew at an annual average growth rate (CAGR) of 5.3%, based on local currency (COP). Dynamic growth covers the following segments of this market with their respective CAGR's in Colombia between 2014 and 2017: Generics with 4.9%, over-the-counter (OTC) products with 4.8% and patented medicines with 5.9%. Bogota serves as a hub for its pharmaceutical market, accounting for 49% jobs in this sector, 47% of exports and 82% of imports. Also, 66% of manufacturers and 65% of wholesalers are located in the country's capital as well as Novartis. Besides that, the city supports an agenda

towards progressive pharmaceuticals and health services, attracting investments of international corporations. In the area of pharmaceutical products regulation, Colombia is recognized as a global forerunner, supported by its international reference entity, the National Institute of Surveillance of Medicines and Drugs (INVIMA) which is highly accredited by the Panamerican Health Organization. (Invest In Bogotá 2020) In 2013, a report about Novartis global company profile in consumer health, published by Euromonitor International (Passport), indicated that Latin America belongs to the regions with the greatest growth potential, therefore expanding to emerging markets within Latin America was predicted to be one of the company's strategic priorities (Euromonitor International 2013).

5.1 Health System

Colombia's health system consists of a private sector and social security sector. The General Social Security Health System, named Sistema General de Seguridad Social en Salud (SGSSS) in Spanish, was introduced by the Colombian government in 1993 and provides health care to about 97.6% of the country's population today. The enrollment in the SGSSS is mandatory, whether it is within the private or social security sector which comprises the three following plans. The contributory plan of the SGSSS covers independent works, salaried workers and pensioners while the subsidized plan covers anybody who is in need. A third plan covers about 5.4%, namely employees from particular institutions. (Pan American Health Organization 2020)

However, it is also important to mention that the pharmaceutical market in Colombia is exposed to corruption, as the country is currently ranked 96th out of 180 countries conforming to the Corruption Perceptions Index of Transparency International (Transparency International 2019). Regarding the pharmaceutical market, corruption is a major impediment to improving access to quality medicines and enhancing the healthcare system. That's why the WHO started the initiative "Good Governance for Medicines (GGM) in 2004 in an effort to address this complex and versatile

challenge by precisely addressing the importance of transparency to prevent corruption in the health sector. The GGM programme consists of a 3-step model implementation being adapted to the country context through firstly assessing the transparency within the pharmaceutical sector and secondly developing a national GGM framework which determines the legal and political structure as well as the basis for the legal binding implementation. The third phase is about implementing and translating the developed GGM framework into practice by fully integrating it within the Ministries of Health (MOH). Colombia is among the 37 countries participating in the country specific framework development and implementation of the GMM programme at different stages. (Baghdadi-Sabeti and Serhan 2010)

5.2 Health Expenditure and Funding

According to the "Health at a Glance 2019" report, published by the Organisation of Economic Co-operation and Development (OECD), the following data about Colombia's health expenditure and funding is provided. Colombia's health expenditure per capita in 2018 is ranked fourth last amongst 44 countries and accounted for $960 while the average of OECD countries accounted for $3,994 (Appendix 2). The country's health expenditure measured as percentage share of GDP amounted to 7.2% in 2018. In comparison, the OECD countries average amounted to 8.8% (Appendix 3). The funding of health care through different finance schemes comes usually from various sources, however government schemes are primarily financed by general revenues, mainly taxes being allocated to the different levels of government through a budgetary process. Nevertheless, other schemes as social health insurance in which particular population groups are dependent on financial support in terms of insurance contributions as well as general budget support for the insurance fund, can also benefit from contributions of governments. The private health insurance scheme consists of individuals who pay regular premiums into a fund in order to get their medical care paid. Depending on the country and health system, government's subsidies

or employers may contribute to a proportion of the premium. Factors like the type of health system, government policy and composition of the population determine the degree of public funding of health. In 2017, Colombia's health expenditure was funded proportionally through the following types of financing: 68% by compulsory health insurance, 16% by out-of-pocket, 10% by voluntary health insurance and 6% by the government scheme. The compulsory health insurance proportion is well above the OECD countries average of 37% whilst the out-of-pocket proportion is less compared to the OECD countries average of 21% (Appendix 4). In terms of public funding, Colombia's health expenditure from public sources, measured as a percentage share of total health expenditure, amounted to 68% in 2017 which is close to the OECD countries average of 71% (Appendix 5). (OECD 2019)

As displayed in the OECD's "Health at Glance: Latin America and the Caribbean 2020" report, one of the biggest drivers of health expenditure in Latin America and the Caribbean (LAC) is the pharmaceutical sector, where medicines constitute a substantial financial burden for not only governments but also for people. This contributes to policy concerns, however there is an opportunity of increasing efficiency in pharmaceutical spending, namely the development of the generic market. Colombia belongs to the countries in LAC in which health expenditure has grown more rapidly than income (Appendix 6). Moreover, the main funding source of Colombia's overall health expenditure was the government's health expenditure with a share of 73.5%, very close to the OECD country's average of 73.6% in 2017, with a slight increase since 2010 (Appendix 7). The type of healthcare system, the political priority of the health sector and the fiscal scope of a government represent several factors that influence the amount of public funding allocated to health. There are other governmental public services competing against healthcare, such as housing, education and defense which the government's funding is responsible for as well. Due to the economic situation and political decision-making, healthcare budgets may change from year to

year. In 2017, Colombia's general government health expenditure accounted for a share of 13.4% of total government expenditure, decreasing since 2010, whereas the average of OECD country's accounted for 24.5% (Appendix 8). (OECD; The World Bank 2020) The comparison between Colombia and the average of OECD countries will be used to demonstrate the emerging market aspect linked to the country's pharmaceutical market, as OECD member countries mainly reveal high-income and most of them are classified as developed markets. Since 2020, Colombia belongs to the exceptional member countries due to its emerging market classification.

6. India's Pharmaceutical Market

As the second case study about Novartis and its cancer drug Glivec takes place in India, it is also important to provide an overview of India's pharmaceutical market to be able to analyze as well as compare these two cases and to identify similarities and differences that could have an impact on the BGRs within both cases. India's (National Investment Promotion & Facilitation Agency 2020a) provides the following information about its pharmaceutical market which represents the third biggest pharmaceutical market worldwide in terms of production volume, accounting for 10% of the global industry and the 14th biggest in terms of value. As the world's largest provider of generics, holding a share of 20% in global supply volume, and the largest vaccine producer worldwide, supplying 62% of global vaccine demand, the market size of India's pharmaceutical industry amounts to $36 billion in 2020. Thereof, generics account for a 70% revenue share and patented drugs for a 21% revenue share. Exports of India's pharmaceutical market were $19.3 billion between 2018 and 2019 with a year-to-year growth rate of 10.72%. The market is expected to grow to $100 billion by 2025 along with its strong network of 3,000 pharmaceutical manufacturers as well as approximately 10,500 manufacturing facilities and a current growth rate between 7% and 8%. Within the last two decades, foreign direct investments (FDI) in the

pharmaceutical sector steadily increased to a cumulative worth of $16.54 billion between April 2000 and June 2020, including major investments from multinational pharmaceutical corporations such as Novartis, Pfizer, GlaxoSmithKline and Johnson&Johnson. This trend has been promoted and accelerated by government policies, namely concerning FDI as well as India's Pharma Vision 2020. In regard to the FDI policies, the Indian government allows 100% FDI for greenfield pharmaceuticals under the automatic route which means that foreign investors or Indian companies do not require any government approval for the investment. When it comes to brownfield investments in the pharmaceutical industry, the Indian government allows 74% withing the automatic route and 26% through the government route. The government route requires approval from the Indian government prior to the investment through FDI proposals that are examined by the respective Ministry. The "Pharma Vision 2020" was launched by the Indian government's Department of Pharmaceuticals with the objective to make the country a global leader in end-to-end pharmaceutical production while creating substantial value for its economy. (India Brand Equity Foundation 2020)

The "Pharmaceuticals" report of India's National Investment Promotion & Facilitation Agency subdivides the growth drivers of the pharmaceutical market in several demand-side and supply-side factors. The demand-side factors are Accessibility, Affordability, Epidemiological Factors and Medical Tourism. The accessibility of medical products and services remains a barrier in India, especially for the patients living in rural areas, therefore an investment over $200 billion in medical infrastructure will be carried out over the next decade contributing to market growth. As regards to the growth driver affordability, around 73 million households are expected to shift to the middle class within the next 10 years. Additionally, the Ayushman Bharat National Health Protection Scheme (NHPS) as well as the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) scheme fund and work on the availability of affordable medicines respectively, both will be discussed in

more detail in the following section about India's health system. Epidemiological Factors include a patient pool that is expected to rise over 20% within the next decade due to population growth, lifestyle changes and new diseases boosting demand for medication. Lastly, India's Medical Tourism industry forecasts a growth of $13.3 billion until 2022. The supply-side factors also promote growth in India's pharmaceutical industry and comprise Patented Drugs, Medical Infrastructure, Cost Efficiency as well as Talent Pool. Patents for branded generics account for cumulative global sales of over $251 billion and are expected to expire until 2024. This progression contributes to further fostering India's pharmaceutical market, holding great potential especially for the country's generics market. Besides the already mentioned infrastructure investments by the government, pharmaceutical corporations have increased spending to penetrate the rural markets in India as well. In terms of cost efficiency, India's production costs are almost 33% lower compared to the US whilst labour costs are between 50% and 55% lower compared to western countries. In addition to that, India's talent pool of pharma and biotech professionals is the second largest worldwide, right after China. (National Investment Promotion & Facilitation Agency 2020b) All in all, both supply-side as well as demand-side factors not only create opportunities for domestic companies but also attract multinational foreign companies to India's pharmaceutical sector.

6.1 Health System

According to (Chokshi et al. 2016), India's health system constitutes of public and private healthcare service providers with most of the latter being concentrated in urban regions, providing secondary and tertiary healthcare services whereas public healthcare services are mainly concentrated in rural areas and are based on a three-tier system depending on population norms. Since India has a federal system of government, governance, funding and operations of its healthcare system is split between the federal and state governments. The three-tier system consists

of primary healthcare encompassing essential medical services, secondary healthcare which is comprised of medical specialists and tertiary healthcare covering hospitals as well as specialty care. Being built upon the Report on the Health Survey and Development Committee from 1946, it provides preventive and curative health care with the goal of ensuring access to primary care independent of individual socioeconomic conditions. Nonetheless, the deficiencies of the public healthcare system in accessibility and affordability have contributed to the concurrent development of the private healthcare system and its services. (Chokshi et al. 2016) This results in the large share of out-of-pocket health expenditure which goes hand in hand with the government's overall significantly low spending on healthcare, as described in the section health expenditure and funding.

However, there has been a change over the last decade towards an increase of the government's healthcare budget and several government initiatives promoting accessibility and affordability for especially the poor and vulnerably populations in India. One of the more recent initiatives is the Ayushman Bharat scheme, also known as Pradhan Mantri Jan Arogya Yojana (PM-JAY), which was approved by the central government in March 2018 and has been recognized around the world as an important step for India to achieve universal healthcare coverage. The scheme's main objective is offering hospital coverage to the country's poor or low-income population, accounting for 40% in India. The PM-JAY is part of the NHPS that serves individuals in the bottom two income quintiles. (Tikkanen et al. 2020) As stated by India's National Investment Promotion & Facilitation Agency, the NHPS is projected to benefit 100 million poor and vulnerable families with a secondary and tertiary healthcare cover of approximately up to $6,900 per family per year. Thereby, it is regarded as the largest healthcare program in the world, funded by the government. Another initiative was lunched by the Department of Pharmaceuticals, Ministry of Chemicals and

the Indian government in 2008, the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) scheme with the objective of providing quality generics at affordable prices (Department of Pharmaceuticals 2020). This has resulted in savings between 50% and 90% for the Indian population and enhanced the ease of availability of generic drugs via the nationwide PMBJP Kendras (National Investment Promotion & Facilitation Agency 2020b). Both initiatives may need to be considered by multinational pharmaceutical corporations like Novartis when doing business in India, in order to understand the overall dynamics of India's healthcare system among with its opportunities and challenges directly linked to the country's pharmaceutical market.

6.2 Health Expenditure and Funding

Conforming to the OECD's "Health at a Glance 2019" report, India's health expenditure per capita is ranked last, amounting to $209 in 2018 (Appendix 2). In the same year, India's health expenditure as a share of GDP was 3.6%, thus the country with the second lowest share, just behind Indonesia (Appendix 3). In 2017, India's health expenditure was financed proportionally as follows: 65% out-of-pocket, 22% by the government scheme, 3% by compulsory health insurance, 2% by voluntary health insurance and 8% by other finance schemes. The out-of-pocket proportion is by far the largest amongst all 44 countries, also compared to the OECD country's average of 21% (Appendix 4). India's health expenditure funded by public sources, measured as a share of total health expenditure, amounted to 26% (Appendix 5). As a result, India is the country with the lowest proportion of public funding sources in terms of total health expenditure and far behind the OECD countries average of 71%. The "Health at a Glance: Asia/ Pacific 2020" report of the OECD and WHO indicates that health spending growth has surpassed economic growth in many Asia-Pacific countries from 2010 until 2017. India is one of the countries in which health expenditure has grown more rapidly than income, leading to an increased share of health care expenditure from total expenditure (Appendix 9). However, within those 7 years there has not been any change in

health expenditure by the compulsory insurance scheme as well as the government scheme, measured by the unchanged share of GDP slightly above 1% (Appendix 10). As mentioned before, the main funding source of India's health expenditure is out-of-pocket, which also explains why there has not been any change in health expenditure funded by the government scheme and compulsory insurance scheme as a share of total health expenditure between 2010 and 2017. The country's share of total health expenditure paid through both schemes remained constant with around 25% (Appendix 11). Another consequence of India's financing schemes composition, in regard to health expenditure, is that less than 4% of government expenditure was allocated to health care within the same timeframe of seven years. In comparison to the OECD countries average of 24.5%, India healthcare system clearly lags behind (Appendix 12 and 8). (OECD; World Health Organization 2020)

7. Case Comparison and Outcome Analysis

Both the Colombian and the Indian case of Novartis' cancer drug Glivec differ significantly in terms of their outcome and corresponding BGRs. In order to conduct an in-depth analysis, it is vital to identify and understand the interests of stakeholders involved, especially of the respective governments and Novartis. Therefore, not only an overview of both country's pharmaceutical markets from the corporate's perspective was given, but also the framework conditions of both country's health systems as well as health expenditure and funding, from the government's perspective, were discussed. The following similarities and differences of both cases may help to understand and classify the IBGR between Novartis and both countries as well as to examine Novartis' impact on the outcomes in both cases in the next step. These similarities and differences of both cases include their business environment and government's framework conditions, the

pharmaceutical market, the health system, the health expenditure and funding of Colombia and India.

In the case of Colombia vs. Novartis, a patent for Glivec has already been granted by Colombia's government and approved by the Dirección Nacional de Derecho de Autor de Colombia (National Directorate of Copyright of Colombia) in 2012, while the India vs. Novartis case differs distinctly from the first one as the course of the patent application for Glivec in India in 2005 is the key component of the second case. Considering the negative outcome for Novartis in the Indian case, namely the final patent rejection of Glivec ruled by the country's Supreme Court in 2013, a question can be raised whether the Colombian government followed the Gleevec case in India and whether the outcome of the Indian case had an impact on the Colombian government's request regarding the price reduction of Novartis' Gleevec drug. However, the answer to this question cannot be concluded given the available sources, thus it remains a possible assumption. Nevertheless, it is necessary to compare both cases, as the business and government framework conditions of Columbia and India within the pharmaceutical sector share several similarities. From a corporate perspective, the pharmaceutical markets of both countries hold great potential and represent attractive markets for FDI within the pharma industry. Reasons for that are the growth potential of both pharmaceutical markets indicated by forecasts, the development of Colombia towards becoming an export hub for pharmaceutical products as well as India's position within the global pharmaceutical market, also with respect to being the world's largest provider of generics. Besides that, India's Pharma Vision 2020 along with its described growth factors, FDI policies and already existing strong network of pharmaceutical manufactures as well as medical manufacturing facilities, have contributed to the constant growth of FDIs in the county's pharmaceutical market. In comparison to India, Colombia's pharmaceutical market is driven by its strong clinical research environment, the CAGR in its three segments generics, OTC and in particular patented medicines,

as well as its institutional environment, mainly dominated by the international reference entity INVIMA and the capital's agenda towards progressive pharmaceuticals and health services. Corruption within the pharmaceutical industry is one of the potential risks in both countries which companies like Novartis should be aware of when doing business in emerging markets. Although, both Colombia (96th) and India (80th) rank relatively low on the Corruption Perceptions Index, only Colombia participates in the framework development and implementation of the GMM programme.

In regard to the government's framework conditions, the health systems as well as health expenditure and funding of both countries have a crucial impact on the regulations of respective pharmaceutical markets and their overall conditions. Additionally, the structure of the healthcare system shapes political decisions of various government officials in relation to the country's pharmaceutical sector. The healthcare systems of both countries differ considerable as Colombia's has a compulsory health insurance, the SGSSS, which covers almost the whole population by accounting for 97.6%, whereas India's health system consists of public and private healthcare service providers, nonetheless it has the largest share of out-of-pocket health care payments in 2017 and is about four times higher than Colombia's out-of-pocket share. However, recent initiatives of different government delegates in India such as the PM-JAY and PMBJP have resulted in an increase of the government's healthcare budget. Considering the following health expenditure and funding indicators: Health expenditure per capita, health expenditure as share of GDP, health expenditure from public sources as share of total health expenditure and change in health expenditure by government and compulsory insurance scheme as a share of total government expenditure, one can conclude that the overall health expenditure in Colombia and India is considerably low compared to the OECD country average. By taking into account the funding of health expenditure through public sources and its development, India lags certainly far behind

while Colombia almost reaches the OECD countries average. Colombia also ranks slightly above India in terms of the overall health expenditure indicators. The fact that India belongs to the worst performers amongst 44 countries highlights the government's limited leeway for its health budget and funding sources as well as its dependency on low-cost medicines and the generics' market importance. In both countries, health expenditure has grown more rapidly than income which implies another health budget limitation for the Columbian and Indian government. Given the comparison of various indicators, from the corporate and government perspective, the progressions and outcomes of both cases demonstrate the utmost complexity of IBGR and their significance in emerging markets as Columbia's and India's indicators differ to some extent strongly from those of the developed markets, in most cases.

Furthermore, the Colombia vs. Novartis case is a good illustration of the political dimensions that price negotiations can bring, such as the involvement of Colombian diplomats in Washington who have also put political pressure on the Colombian government. Novartis' reasoning of only using Compulsory Licensing in exceptional circumstances is not accurate as it's not consistent with the provisions of the TRIPS Agreement which Colombia, India and Switzerland has signed. According to the WTO, the Doha Ministerial Declaration on TRIPS clarifies the agreement's flexibilities within the pharmaceutical sector. Apart from that, countries "are free to determine the grounds for granting compulsory licenses and to determine what constitutes a national emergency" (Meyer and Peng 2016). Colombia's significant low health expenditure per capita in comparison to the treatment cost of Glivec which used to amount $15,000 a year, about twice as much as the average Colombian worker's income, advocate the government's motives in declaring Glivec as a matter of public interest (Gabble and Kohler 2014). Similar circumstances apply for the India vs. Novartis case, in which the monthly treatment cost of Glivec were almost 15 times higher than the monthly treatment cost of its generic competitors while 40% of India's population earned less than $1.25 a

day at that time (Gabble and Kohler 2014). Therefore, it can be concluded that the driving reasons for the governments' actions of both countries are quite consistent, although the outcomes differ substantially.

7.1 Stakeholder Theory

The stakeholder theory provides a framework "that can help examine the connections between various stakeholders and the organization" (Silverman 2016). The objective of the stakeholder theory is to identify the legitimate interests of groups or individuals who can affect the companies' objectives and business operations through their activities (Bruns 2016). As the government perspectives and interest of both countries have already been identified in the previous section, the next step involves the corporate perspective. In order to examine the extent of Novartis' impact on the outcomes in both cases and to provide some guidance for Novartis in regard to the company's general approach with the Columbian and Indian government as well as its pricing approach, the stakeholder theory describes two key questions: What is the company's purpose and what is the company's responsibility towards its stakeholders to promote cooperation and avoid actions that could have a negative impact on the company's objectives? These two questions could be adopted by Novartis as a framework to positively shape the outcomes of BGRs in the future. Moreover, economic and social value can be added when corporations as Novartis and stakeholders as the Colombian and Indian government come together voluntarily to collaborate and ensure that respective interests are met. (World Health Organization 2019) The political stakeholder theory emphasizes the importance of a proactive approach, in which companies respond to any concerns addressing the MNE' operations in the host country (Novartis Annual Report 2020). Applying this to the Novartis' Glivec cases, it seems that Novartis has not proactively addressed the interests and concerns of both governments which is why there is room for improvement, from the corporate perspective.

7.2 Implications for negotiations

Negotiations represent a central component of any IBGR and also play a major role in the Colombia vs. Novartis case, in particular price negotiations which have not been successful, thus contributing to the outcome of the case. Regarding the India vs. Novartis case, proactive negotiations could have possibly influenced the outcome in a positive way for both the corporation and the government since negotiations do have the potential to create economic and social value, similar to the stakeholder theory. Business-government bargaining is one of the pillars of the institution-based view, which describes and analysis the interactions between corporations and the institutional environment and considers these as the result of a company's business strategy in emerging markets. Accordingly, Novartis has an impact on the outcome of the IBGR with respect to Colombia and India and should align its respective business strategies for both emerging markets with the institutional environment, mainly related to price negotiations. Implications for Novartis in regard to its negotiation and IBGR approach, require taking into account the following negotiation principles. Firstly, understanding, accepting and capitalizing differences amongst negotiation partners is crucial and can contribute significantly to the outcome of the negotiation. As the pricing of Glivec remains the key underlaying issue in both cases, it is important for Novartis to understand its reason and background by applying the frameworks of the stakeholder theory and the institution-based view while considering the government's perspective, including the health systems, health expenditure and funding of both countries respectively. This also includes understanding and accepting the differences of emerging markets within the pharmaceutical industry. The next negotiation principle is about avoiding distributive bargaining if possible and instead identify opportunities for integrative bargaining, because so-called package deals allow more flexibility regarding the outcome and are more likely to create value due to potential trade-offs and different interests of negotiating parties. However, the Columbia vs. Novartis case

represented a single-issue negotiation, in which only the price matters resulting in a relatively limited bargaining room for Novartis and the Columbian government. Lastly, the level of information can fundamentally determine the outcome of a negotiation and points out that it is in corporations' interest to shape outcomes through the previously mentioned principles for successful negotiations.

8. Conclusion

This case study clarifies that the relationship between Novartis and the Columbian as well as Indian government had an impact on the results of both cases. The fundamental factor contributing to both outcomes is the company's approach with regard to its business strategy and implementation, more specifically its pricing and negotiation methodology. Thereby, it seems that Novartis has completely neglected the essential differentiation criteria of a developed market compared to an emerging market, related to the pharmaceutical industry, and rather demonstrates a reactive or partly even passive stakeholder management approach. Given the major discontinuities and challenges of the global pharmaceutical industry, it is crucial for Novartis to realign its business strategy with the institutional environment and with the factors that influence the pharmaceutical industry, including the health system, health expenditure and funding within emerging markets. The large number of different institutional stakeholders involved in both cases indicates the impact and extent of BGRs within the pharmaceutical industry. Furthermore, both cases have illustrated that the impact of BGRs along with the results can be deal making or deal braking. As this paper focuses on stakeholder management and conduct of negotiations in correspondence with business-government relationships, the underlying issue of pricing in both cases is not further discussed. Therefore, future primary research about pharmaceutical companies' pricing methods in various emerging markets is important to address one of the industry's major challenges.

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Appendices

Appendix 1 – Novartis net sales by region

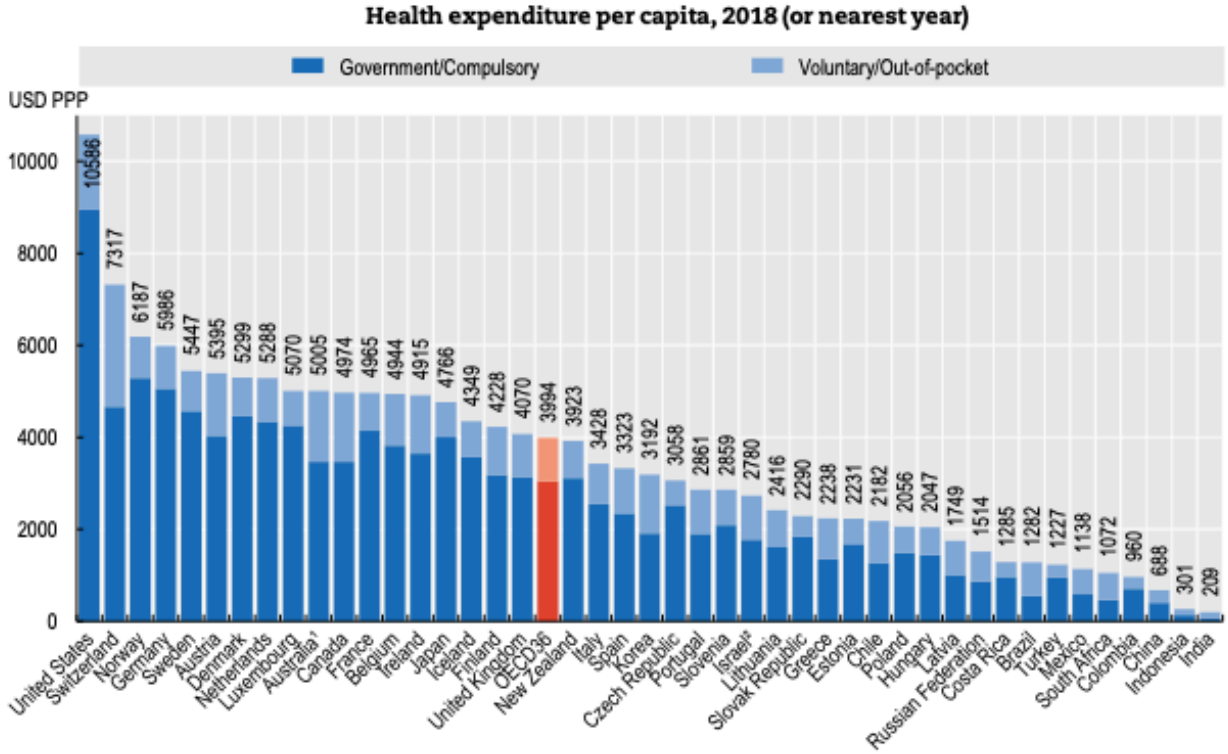
Segmentation – net sales by region[1]

	2019 USD m	2018 USD m	Change (2018 to 2019) USD %	2017 USD m	Change (2017 to 2018) USD %
Innovative Medicines					
Europe	12 818	12 296	4	11 127	11
US	13 789	11 864	16	10 857	9
Asia/Africa/Australasia	8 458	8 097	4	7 702	5
Canada and Latin America	2 649	2 635	1	2 592	2
Total	**37 714**	**34 892**	**8**	**32 278**	**8**
Of which in Established Markets	28 573	26 258	9	24 174	9
Of which in Emerging Growth Markets	9 141	8 634	6	8 104	7
Sandoz					
Europe	5 115	4 963	3	4 633	7
US	2 491	2 754	– 10	3 278	– 16
Asia/Africa/Australasia	1 341	1 363	– 2	1 391	– 2
Canada and Latin America	784	779	1	758	3
Total	**9 731**	**9 859**	**– 1**	**10 060**	**– 2**
Of which in Established Markets	7 111	7 233	– 2	7 383	– 2
Of which in Emerging Growth Markets	2 620	2 626	0	2 677	– 2
Group					
Europe	17 933	17 259	4	15 760	10
US	16 280	14 618	11	14 135	3
Asia/Africa/Australasia	9 799	9 460	4	9 093	4
Canada and Latin America	3 433	3 414	1	3 350	2
Total	**47 445**	**44 751**	**6**	**42 338**	**6**
Of which in Established Markets	35 684	33 491	7	31 557	6
Of which in Emerging Growth Markets	11 761	11 260	4	10 781	4

[1] Net sales from operations by location of third-party customer. Emerging Growth Markets comprise all markets other than the Established Markets of the US, Canada, Western Europe, Japan, Australia and New Zealand.

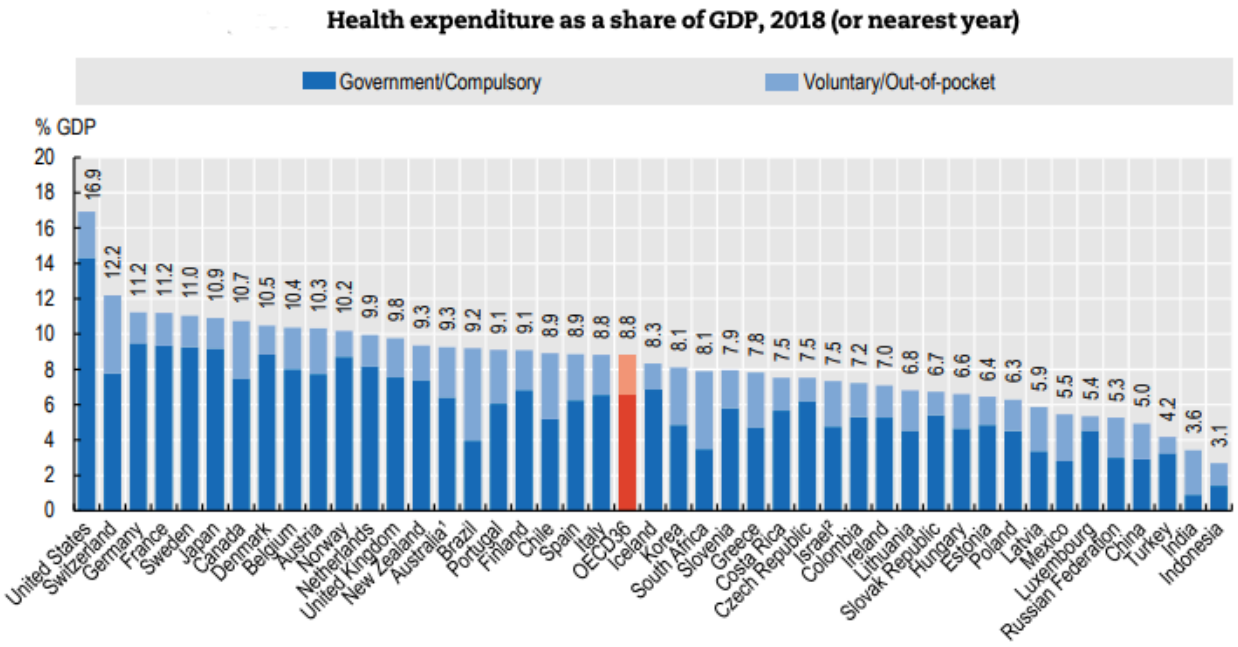
Source: Novartis Website. 2020. “Novartis.” 2020. https://www.novartis.com/.

Appendix 2 – Health expenditure per capita in 2018



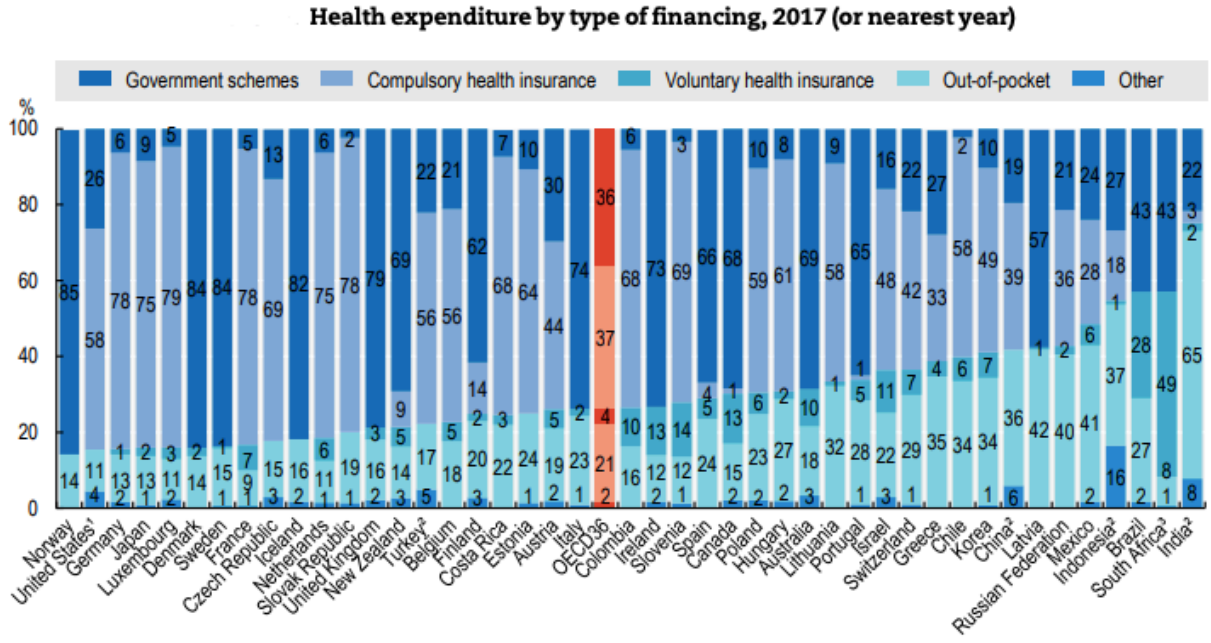
Source: OECD. 2019. *Health at a Glance 2019: OECD Indicators*. https://www.oecd-ilibrary.org/docserver/4dd50c09-en.pdf?expires=1608585054&id=id&accname=guest&checksum=C337BF964CE53E00EF7CD6D936A4FB3F.

Appendix 3 – Health expenditure as a share of GDP



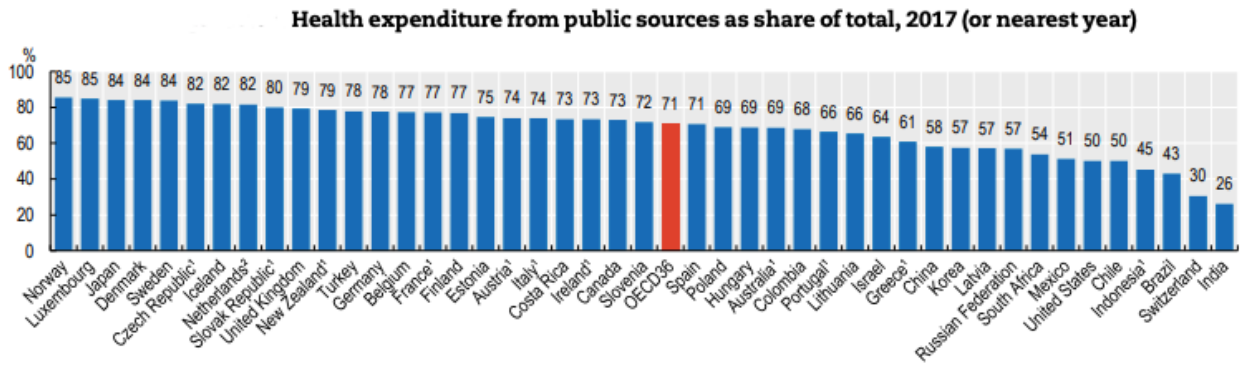
Source: OECD. 2019. *Health at a Glance 2019: OECD Indicators*. https://www.oecd-ilibrary.org/docserver/4dd50c09-en.pdf?expires=1608585054&id=id&accname=guest&checksum=C337BF964CE53E00EF7CD6D936A4FB3F.

Appendix 4 – Health expenditure by type of financing



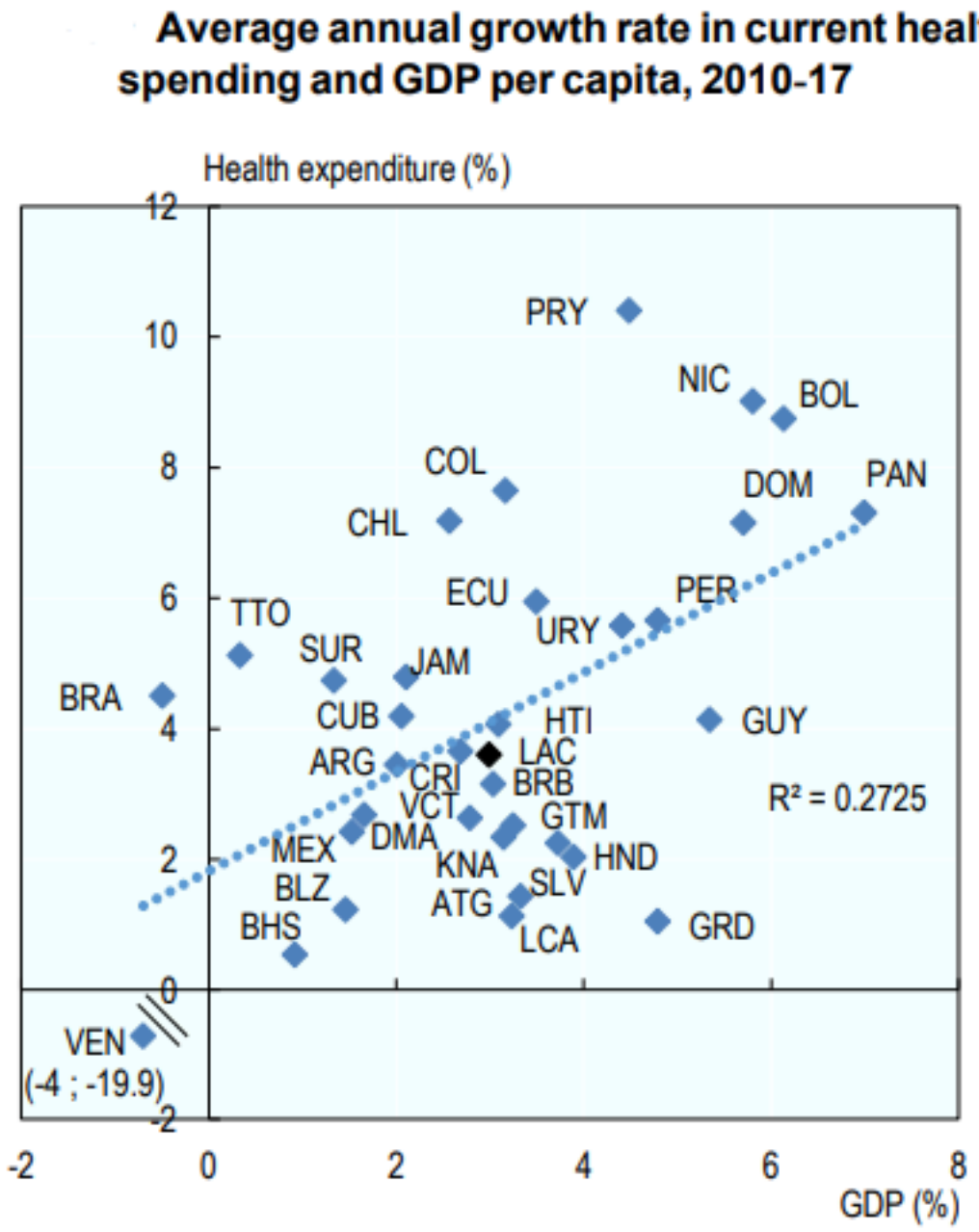
Source: OECD. 2019. *Health at a Glance 2019: OECD Indicators*. https://www.oecd-ilibrary.org/docserver/4dd50c09-en.pdf?expires=1608585054&id=id&accname=guest&checksum=C337BF964CE53E00EF7CD6D936A4FB3F.

Appendix 5 – Health expenditure from public sources as share of total



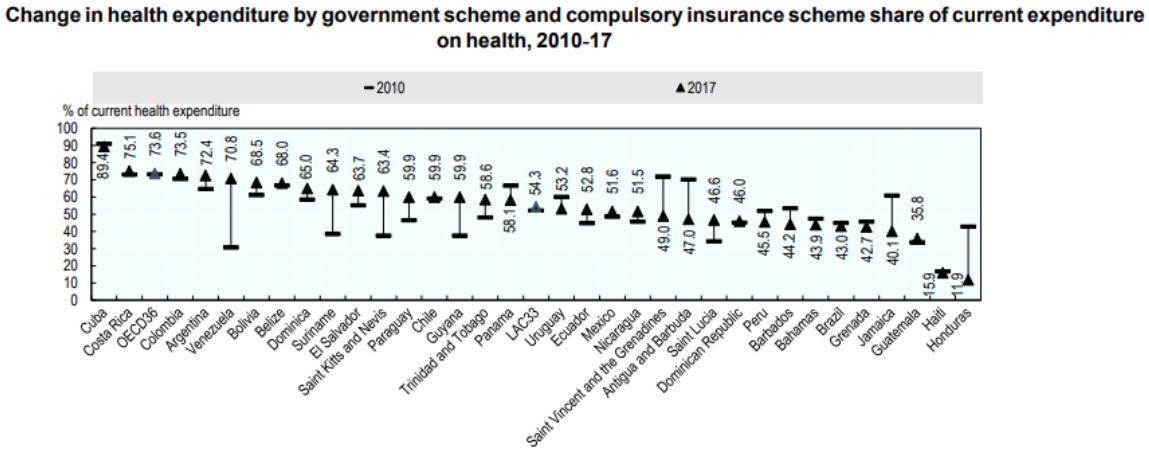
Source: OECD. 2019. *Health at a Glance 2019: OECD Indicators*. https://www.oecd-ilibrary.org/docserver/4dd50c09-en.pdf?expires=1608585054&id=id&accname=guest&checksum=C337BF964CE53E00EF7CD6D936A4FB3F.

Appendix 6 – Average annual growth rate in current health spending and GDP per capita



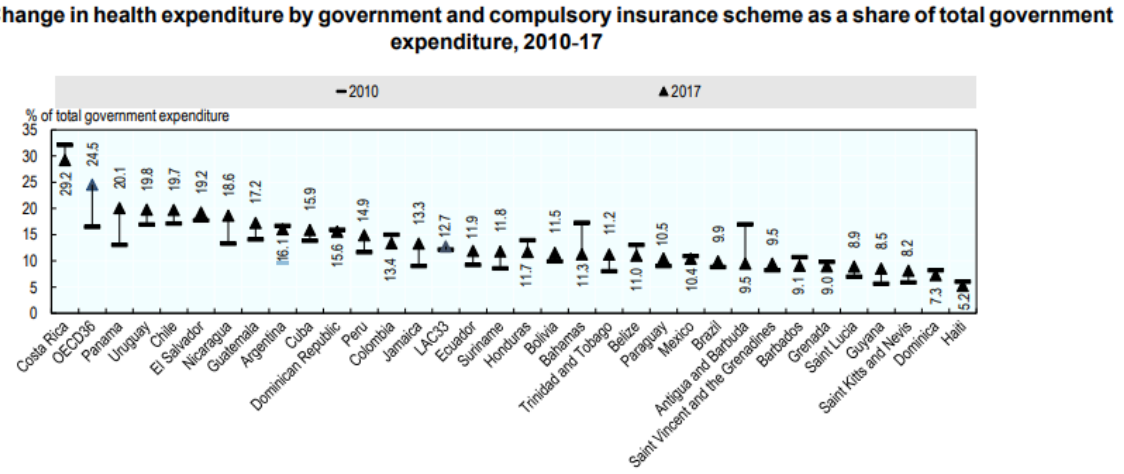
Source: OECD; The World Bank. 2020. *Health at a Glance: Latin America and the Caribbean 2020*. OECD Publishing, Paris. https://www.oecd-ilibrary.org/docserver/6089164f-en.pdf?expires=1608246403&id=id&accname=guest&checksum=AC3D941388F158BDE7EF83C243998F2D.

Appendix 7 – Change in health expenditure by government scheme and compulsory insurance scheme share of current health expenditure



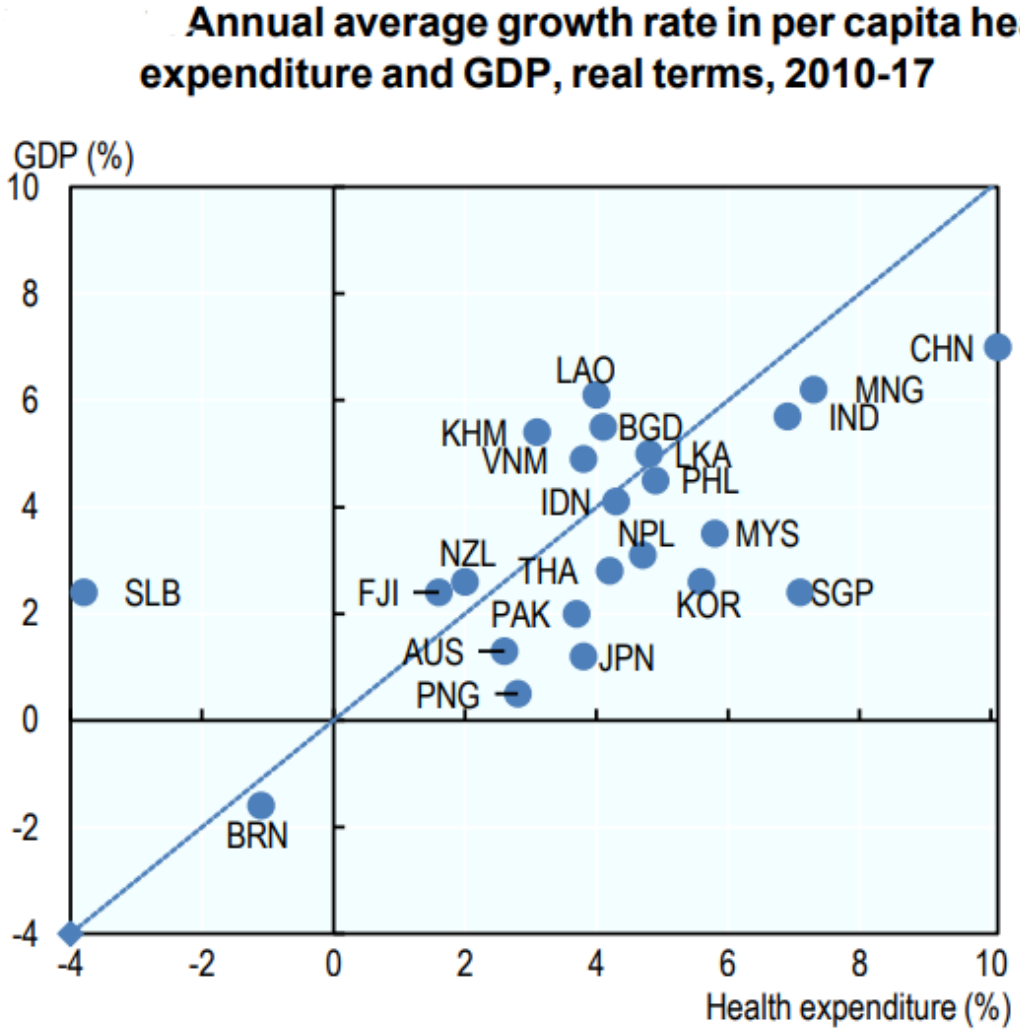
Source: OECD; The World Bank. 2020. *Health at a Glance: Latin America and the Caribbean 2020*. OECD Publishing, Paris. https://www.oecd-ilibrary.org/docserver/6089164f-en.pdf?expires=1608246403&id=id&accname=guest&checksum=AC3D941388F158BDE7EF83C243998F2D.

Appendix 8 – Change in health expenditure by government and compulsory scheme as a share of total health expenditure



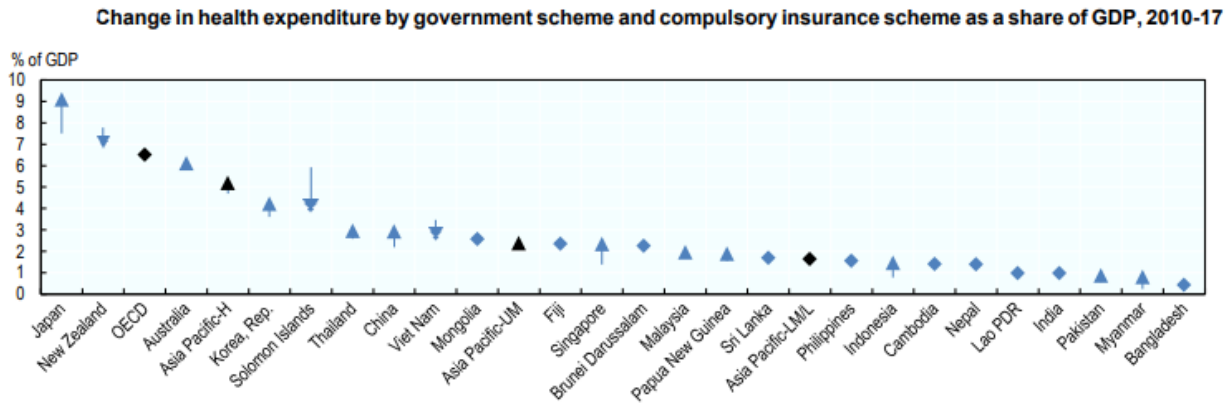
Source: OECD; The World Bank. 2020. *Health at a Glance: Latin America and the Caribbean 2020*. OECD Publishing, Paris. https://www.oecd-ilibrary.org/docserver/6089164f-en.pdf?expires=1608246403&id=id&accname=guest&checksum=AC3D941388F158BDE7EF83C243998F2D.

Appendix 9 – Annual average growth rate in per capita health expenditure and GDP



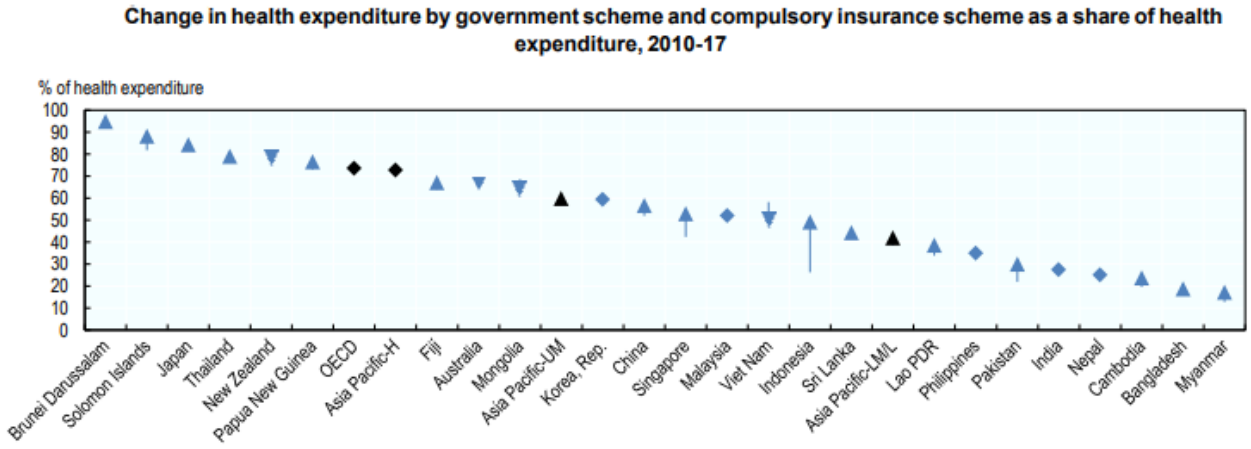
Source: OECD; World Health Organization. 2020. *Health at a Glance: Asia/Pacific 2020: Measuring Progress Towards Universal Health Coverage*. OECD Publishing, Paris. https://doi.org/10.1787/26b007cd-en.

Appendix 10 – Change in health expenditure by government scheme and compulsory insurance scheme as a share of GDP



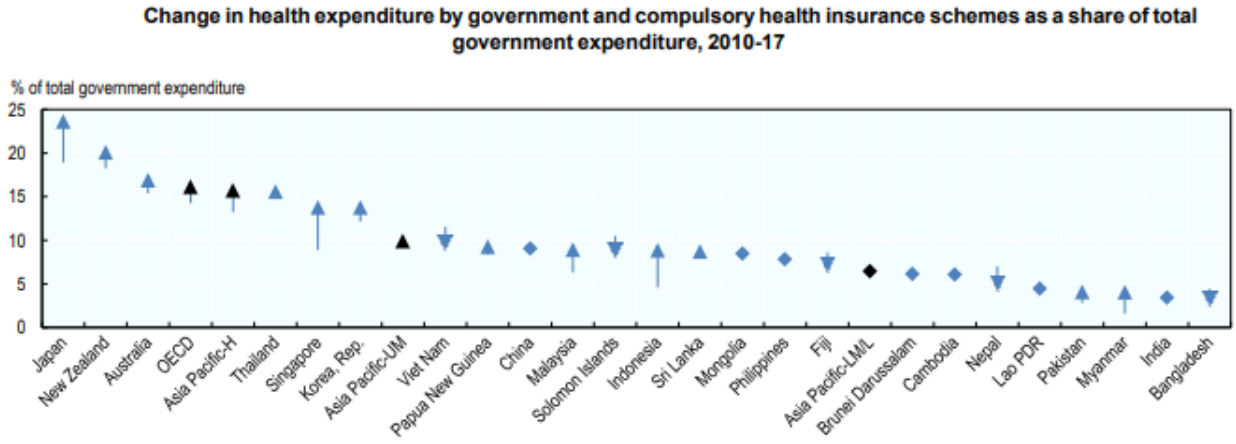
Source: OECD; World Health Organization. 2020. *Health at a Glance: Asia/Pacific 2020: Measuring Progress Towards Universal Health Coverage*. OECD Publishing, Paris. https://doi.org/10.1787/26b007cd-en.

Appendix 11 – Change in health expenditure by government scheme and compulsory insurance scheme as a share of health expenditure



Source: OECD; World Health Organization. 2020. *Health at a Glance: Asia/Pacific 2020: Measuring Progress Towards Universal Health Coverage*. OECD Publishing, Paris. https://doi.org/10.1787/26b007cd-en.

Appendix 12 – Change in health expenditure by government and compulsory health insurance schemes as a share of total government expenditure



Source: OECD; World Health Organization. 2020. *Health at a Glance: Asia/Pacific 2020: Measuring Progress Towards Universal Health Coverage*. OECD Publishing, Paris. https://doi.org/10.1787/26b007cd-en.