University of Amsterdam

# The Lack of Pricing Policy in the VIG Code of Conduct

## A Case Study in Times of Corona

Robin Veenman
Student number: 12811300
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Supervisor: Dr. Franca van Hooren
Second reader: Dr. Luc Fransen

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## List of frequently used abbreviations

ACM: Authority for Consumers and Markets / Autoriteit Consument & Markt

CEO: Corporate Europe Observatory

CSR: Corporate Social Responsibility

EFPIA: The European Federation of Pharmaceutical Industries and Associations

EMA: European Medicines Agency

FtV: Farma ter Verantwoording/Pharmaceutical Accountability Foundation

HAI: Health Action International

IFPMA: International Federation of Pharmaceutical Manufacturers' & Associations

NGO: non-governmental organization

PR: public relations

R&D: research and development

TNC: transnational corporation

VIG: Vereniging Innovatieve Geneesmiddelen / Association of Innovative Medicines

R&D: research and development

Wemos: WErkgroep Medische Ontwikkelingssamenwerking/Working Group on Medical Development Cooperation

WHO: World Health Organization

SOMO: Stichting Onderzoek Multinationale Ondernemingen /Centre for Research on Multinational Corporations

## 1. Introduction

In attempt to counter the negative publicity that the pharmaceutical industry has been receiving in the Netherlands, the VIG published a code of conduct on the 31st of January, 2020. The VIG stands (in English) for the 'Association of Innovative Medicines' and represents 42 of the transnational pharmaceutical companies (e.g. 'Big Pharma') in the Netherlands. Meaning that said code is signed by- and Representative of all the 42 companies represented by the VIG.
This code of conduct has been greatly discussed and criticized for one predominant reason, which to most seems to be the hot potato: the fact that it does not mention the industry's pricing policy. It seems counterintuitive to publish a code of conduct without pricing policy when the pricing policy of the industry has been subjected to extensive criticism for a considerable number of years now. Notably, the code devotes 25 pages to discussing every aspect of CSR (Corporate Social Responsibility) but prices. Hence, it is important to establish the history of origin of this particular code of conduct and to hereby understand why certain decisions have been made, that ultimately resulted in a code without pricing policy. Therefore, this study sets out to answer the following question: *why does the VIG code of conduct not touch upon the industry's pricing policy?*
To answer this question I can tie in with the existing literature regarding codes of conduct from other industries which endeavors to explain how these codes have become what they are (Fransen, 2010; Kolk, Tulder, & Welters, 1999; Lexchin & Kawachi, 1996; McDermott, Noah, & Cashore, 2007), why some roads were (not) taken (Bartley, 2003), and why and how specific decisions have been made (Bartley, 2003; Horner, 2019).

Due to the importance and the number of stakeholders involved in their business, transnational corporations (TNCs) have always been at the vanguard regarding the discussion of CSR (Jackson & Rathert, 2017). When it comes to CSR, previous literature suggests that the implementation of CSR standards is motivated by strategic motives of these TNCs to manage and boost stakeholder impressions (Colle, Henriques, & Sarasvathy, 2014; Matten, 2003; Jackson & Rathert, 2017; Shamir, 2005). Additionally, private governance has been conceptualized as a specific trend in CSR (Bartley, 2003; Matten, 2003; Jackson & Rathert, 2017). Private governance, opposed to state regulation, is defined as "the ability of private actors to devise and implement behavioral norms that regulate their activities" (Jackson & Rathert, 2017).

While previous literature has identified the growing prominence of private governance within varying industries, such as forest products and apparel (Bartley, 2007), this is less well established within the pharmaceutical sector (Horner, 2019). The existing literature has received criticism regarding its extensive focus on a limited number of well-known examples of private governance initiatives, without touching upon those that have not yet developed or have been slower to develop (Bartley, 2003). Hence, this thesis endeavors to address the rather unchartered territory of the incorporation of CSR standards through a voluntary, private governance initiative within the pharmaceutical industry in the shape of a code of conduct.[1]

Analyzing codes of conduct is an established phenomenon which belonged to the first wave of CSR scholarship. The complexity of this analysis differs per sector and can become rather challenging when it regards the pharmaceutical industry. This is mainly due to the fact that, when it comes to CSR, the pharmaceutical sector is located in the midst of a complex 'soup' of contributing factors that the industry needs to take into account when doing business in a socially responsible manner. While for a fashion company sustainability might be the predominant pillar of its CSR, the pharmaceutical industry has to take into account not only sustainability but, for example, also the ethical validity of their selection for clinical trials, their promotion, and the (global) accessibility of their products (medicines). The latter being the ultimate societal challenge for pharmaceuticals as the insufficient access remains a considerable problem, in spite of the industry's thriving position in society (Horner, 2019).

The pharmaceutical sector is unlike others as it is often considered to have a particular ethical responsibility towards the public: "to provide affordable drugs to all those in need" (Nussbaum, 2009). It is this segment of CSR which is often argued not to be lived up to by the pharmaceutical industry (Leisinger & Wagner, 2013). However, the pharmaceutical industry has been increasing its attention for CSR during recent years. Especially within the Netherlands the topic of ethics within Big Pharma companies has been rather 'hot'. The most recent development of pharmaceutical CSR being the VIG code of conduct.

## 1.1 Problem statement and relevance

While the COVID-19 pandemic is in itself an enormous challenge to national governments all around the world, it has also exposed many other shortcomings of our contemporary societies.

[1] For the remainder of this thesis it is important to note that when I am speaking of a code of conduct I am referring to *corporate* codes of conduct.

One of those being the fact that the pharmaceutical industry has changed from an industry of drug production to an investment industry (Fernandez & Klinge, 2020). Even though the pharmaceutical industry has not been receiving much praise in general during the foregoing years, the vulnerability of its business model has been laid bare as a consequence of the current corona crisis. Recent research conducted by SOMO (the Centre for Research on Multinational Corporations/Stichting Onderzoek Multinationale Ondernemingen) has shown that pharmaceutical companies have become dependent on "cheap loans and rising stock market prices" (Fernandez, 2020a). Additionally, research from the Corporate Europe Observatory (CEO) also revealed that large pharmaceutical companies opposed an initiative from the European Commission for biopreparedness (i.e. to be "ready for epidemics such as the one caused by the new coronavirus, COVID-19") in 2018 (Corporate Europe Observatory & Global Health Advocates, 2020). Next to that, it became evident that various pharmaceutical companies globally were considerably delayed in their research towards a vaccine for the coronavirus due to the fact that they had sold their vaccine research facilities (Commons Network, 2020). Hence, "the global race to find a cure for COVID-19 and a vaccine is slowed down considerably by the fact that the system we have now runs on market incentives and patent monopolies" (Commons Network, 2020). What is more, a statement made by the 'corona-minister' in the US, Alex Azar, said that the US government would not be able to ensure the affordability of a potential cure/vaccine for the coronavirus. For 'price controls will not help attract private investors', which are of valid importance to the development of a cure, according to Azar (Silverman, 2020).

*"This business model benefits shareholders and corporate executives but impedes truly effective and efficient healthcare, an issue which gains particular urgency in the midst of a global pandemic" (Fernandez, 2020b).*

Not only in the US, but also in the Netherlands the pharmaceutical industry has been tested on its moral compass. For example, pharmaceutical company Roche initially refused to share the recipe that is used in corona test kits, which effectively lead to Dutch hospitals struggling for weeks in lack of a sufficient amount of tests (Lengton, 2020). After having received extensive criticism to their initial decision, Roche decided to provide the government with the recipe nonetheless (Kreling, 2020). A similar situation occurred in the United States when

pharmaceutical company Gilead applied for an *orphan designation*[2] for the potentially effective drug *remdesivir* (Kooiman, 2020).[3] Due to the fact that there were still very few cases of the coronavirus in the United States at the time of Gilead's application, one could argue that it could technically pass for a rare disease at that specific location in time. However, when the public got word of this, Gilead -similar to Roche- received such extensive criticism that the company decided to withdraw the application (Kooiman, 2020).

Especially within the Netherlands the timing of this pandemic and its respective exposure of the pharmaceutical sector's unhealthy business model is uncanny. For, the Dutch Minister of Medical Care had long been attempting to achieve change within the pharmaceutical sector's pricing policy. Both in the case of a vaccine against COVID-19 and in many others that do not relate to the current pandemic, pharmaceuticals are inclined to set the highest possible price rather than a price that would both cover the R&D costs as well as result in a reasonable profit for the company (cost-plus pricing) (W. Bannenberg, Weggen, & Veenman, 2020). Indeed, excessive prices for medicines are problematic for high-income countries such as the Netherlands because this is where the pharmaceutical companies demand the highest prices for their products. Consequently, the costs of *intramural medicines*[4] have been increasing with an average percentage of 8,3 per year during the past five years, and are now at risk of becoming unaffordable for the Netherlands (Nederlandse Zorgautoriteit, 2020). While the global top-20 pharmaceuticals claim to follow corporate CSR standards, this does not reflect on their pricing policy in the Netherlands (W. Bannenberg et al., 2020). This respectively results in the hazardous probability of restricted access to healthcare (Algemene Rekenkamer, 2020). It is already the case within the Netherlands that patients with either a rare disease or cancer are unable to get the treatment that they need because the medicine that they need is either too expensive, or because the government is still negotiating with the pharma company on what a 'fair price' for the medicine would be (W. Bannenberg et al., 2020).

In short: the pharmaceutical industry profits from a problematic system that causes an inaccessibility to essential medicines for numerous people (Algemene Rekenkamer, 2020; Klijs

[2] An *orphan drug* is a drug that treats a rare disease and is often difficult to create. As a result, the R&D costs are often very high, yet the demand for the drug is not high as only few people have the disease. Therefore, the *orphan designation* was developed which gives a company a 10-year right to market exclusivity of the drug. In this way, the company is able to make up for the costs that it previously invested in R&D.

[3] The orphan drug market is extremely lucrative for pharmaceutical companies: it is expected to generate 158 billion euros in profit in the year 2020 alone (Brau & Tzeng, 2018).

[4] Intramural medicines are medicines used in hospitals as a constituent to the entire treatment and are therefore a part of specialist medical care. These medicines are purchased from the hospital's budget, which is effectively reimbursed by the health insurer. As opposed to *extramural medicines*, which are acquired in a pharmacy on an individual basis, at the hand of a prescription by a doctor (Zorginstituut Nederland, n.d.).

& Hilten, 2020). Pharmaceutical companies receive public funds to develop drugs, or purchase drugs that were already developed by institutions funded by public funds (such as universities), yet do not have to adhere to any requirements of either accessibility or affordability in exchange for these funds (Klaver & Eickhout, 2020; Schipper, De Haan, & Cowan, 2019). Next to that, pharmaceutical companies are granted monopoly positions for newly developed orphan drugs, with which they can set any price they like for a duration of numerous years (10 years in the Netherlands and in Europe in general). The strategic use of this system has made the pharmaceutical industry one of the most profitable industries in the world (Klaver & Eickhout, 2020). However, our society is paying their bill: the health care premiums are ever-increasing due to the fact that the government has to pay excessive prices for new medicines, while not even all the medicines are included in the health care package because some are simply unaffordable (Klaver & Eickhout, 2020).

At the beginning of this year, before the first case of COVID-19 was detected in the Netherlands, the aforementioned issue was already receiving a significant amount of attention as a result of the publication of the VIG code of conduct. As was stated before, there was a public discontent at the absence of pricing policy within the code, as this was the at the center of the debate for most. However, it is not particularly surprising that the VIG code of conduct did not mention anything about prices, for according to Lexchin "pharmaceutical codes of conduct have never done so" (J. Lexchin, personal communication, April 14, 2020). While the body of literature on the topic is not very extensive, previous research into pharmaceutical codes of conduct has brought various common aspects to light, which I will elaborate on further down this thesis. However, there is one common aspect which has never been mentioned nor researched: the fact that codes of conduct never mention pricing policy (J. Lexchin, personal communication, April 14, 2020). Now that we are in the midst of a pandemic, looking at the industry's behavior is more relevant than ever. For, as was demonstrated above, the novel corona crisis reveals the various shortcomings of the current system that the pharmaceutical industry operates in and profits from.

Therefore, the initial reaction to the absence of pricing policy in the VIG code of conduct, from those who are critical of the pharmaceutical industry, has been that it is absent due to the fact that the VIG's members are not willing to do anything that could limit their profits. However, such an assumption is too short-sighted to make without careful examination. For, it is important to note that the pharmaceutical industry also adds significant value to our societies and does good with various inventions that are able to save lives (Leisinger & Wagner, 2013).

Hence, it is important to perceive the phenomenon from various perspectives before drawing any conclusions as to why pricing policy was left out of the VIG code of conduct.

## 2. A review of the literature

*"Codes of conduct tend to be placebos which are likely to be less than a responsible company will do of its own volition and more than an irresponsible company will do without coercion"*

- Former Director of Shell International Geoffrey Chandler (Health Action International, 1982).

### 2.1 CSR

De Colle et al. define CSR standards as a "wide set of national and international standards" that have in common: "…to advance the social, ethical and environmental performance of organizations by codifying aspects of organizational behavior" (Colle et al., 2014).

A significant part of the existing literature is critical of CSR and conceptualizes it as a social construct that corporations use to strategically orchestrate 'CSR-approved' projects that will improve their corporate image and will enhance stakeholder approval (Colle et al., 2014; Matten, 2003; Kolk et al., 1999; Shamir, 2005). Additionally, CSR standards are often characterized by a lack of enforcement and a failure of initiating systematic change and can consequently be altogether ineffective (Colle et al., 2014; Kolk et al., 1999; Shamir, 2005).

Both Matten and Shamir define the increasing pressure on corporations to be compliant with aspects of 'social responsibility' as a consequence of their expanding global power as private authorities (Matten, 2003; Kolk et al., 1999; Shamir, 2005). The significance of corporations on the global level respectively deteriorates the role of governments as the provider of public goods. Hence, the business world is reacting to this with the implementation of CSR and has respectively performed a variety of "corporate citizenship" demonstrations (Shamir, 2005).

Although various action networks have attempted to install concrete and enforceable guidelines that ensure corporate compliance of CSR, corporations have been more successful in stating that CSR would bear more fruit through voluntary regulation (Matten, 2003; Kolk et al., 1999). "In accordance with this interpretation of CSR, corporations have begun to develop voluntary codes of socially responsible conduct and to adopt "mission statements" and "social auditing schemes," all of which are designed to confirm that corporations do bear social responsibilities" (Matten, 2003). Shamir defines (this non-enforceable version of) CSR as a "constructivist

theater", "a symbolic resource that is alternately and often competitively used by a variety of players and for a variety of purposes" (Shamir, 2005).

The work of Fransen provides a valuable overview of the different perceptions of CSR. While there is an extensive number of scholars that are pessimistic of "voluntary business action through so-called Corporate Social Responsibility" (Fransen, 2010), one should not neglect the ones that are optimistic about the possible effects of CSR and "welcome voluntary business action towards societal goals in general" (Fransen, 2010) (see for example: Davis, 1973; Lytton, 2014). In between the 'pessimists' and the 'optimists' are the 'pragmatists', who believe that if "companies respond to societal critique, this can provide fast leverage points for labour advocates in alleviating labour crises" (Fransen, 2010) (see for example: Polishchuk, 2009; Sprinkle & Maines, 2010).

### 2.2 CSR within the pharmaceutical industry

Lexchin and Kawachi argue that one of the main sources of criticism of the pharmaceutical industry is the fact that it is one of the most profitable in the world. And while it always argues that it cannot lower its prices due to the fact that the costs for R&D are exceptionally high, it is able to spend more on advertising than it does on R&D ($10 billion a year in the United States versus just over $7.1 billion for research and development) (Lexchin & Kawachi, 1996). Additionally, the importance of public regulation within the pharma industry is partly due to the fact that this industry is "of perhaps greater significance than almost any other industry – because of its key role for public health" (Lexchin & Kawachi, 1996). The other part is dependent on the completely different manner of consumption of its products. Horner argues that there is "little consumer information or choice and thus less scope for consumer power, given many products are subject to prescription by a doctor" (Horner, 2019).

There seems to be a general consensus amongst authors that the exceptional societal position of the pharmaceutical industry results in a moral imperative to act in a socially responsible manner (Horner, 2019; Leisinger, 2005; Lexchin & Kawachi, 1996; Nussbaum, 2009). Nussbaum identifies the fact that the pharmaceutical industry is both highly admired as well as highly criticized as a result of the industry's ability to provide cures to life-threatening diseases, "but is incapable of providing cure to everyone at affordable prices" (Nussbaum, 2009). Lexchin and Kawachi even argue that the pharma industry needs to be regulated more than others due to the fact that the products offered by pharmaceuticals differ from other products in

the sense that "the person who orders the medication is not the person who consumes it or pays for it" (Lexchin & Kawachi, 1996).

Leisinger states that companies have a vested interest in making sure that society thrives and therefore have an inherent obligation to contribute to this (Leisinger, 2005). For, a prospering society is much better for business than the other way around. Not merely from an ethical perspective but also from a business perspective is it important for the industry to act responsibly (Leisinger & Wagner, 2013; Nussbaum, 2009). As, "The long-term viability of a pharmaceutical company depends on its wise use of resources and its behavior as a corporate citizen in a globalized society" (Leisinger & Wagner, 2013). Additionally, Leisinger states that the pharmaceutical industry is in fact a highly significant actor in society that already contributes positively to society in many aspects (Leisinger, 2005). For example: "the medication they provide has the ability to help to prevent and/or cure diseases as well as prevent mortality and improve quality of life, the sector ensures jobs, pays fair salaries and social benefits, they contribute towards pension and insurance systems and the development of new (technical) solutions, and due to their high profits their taxes make significant financial contributions to the state" (Leisinger & Wagner, 2013).

### 2.3 Pharmaceutical CSR in the shape of a code of conduct

In general, the existing body of literature shows that the installment of a corporate code of conduct is inadequate to address the issues at hand (Bartley, 2003; Fort, 2014; Fransen, 2010; Kolk et al., 1999; Lexchin, 2003; McDermott et al., 2007; Sillup, Trombetta, & Klimberg, 2010). Especially within the pharmaceutical sector, codes of conduct are not renowned for their success. Fort states that while all big pharmaceutical companies have a code of conduct, that does not mean that they are effective. In fact, they more often harm the company's 'trustworthiness' than restore it (Fort, 2014). Fort argues the following: "Codes of conduct do little, if anything, to actually prevent illegal or unethical behavior unless they are backed by an authentic, sincere commitment to conduct business in an exemplary way. Rhetorical codes to ethical conduct may even create a more cynical view of corporate responsibility if sincerity and actions fail to match politically correct verbiage" (Fort, 2014). Research conducted by Lexchin and Kawachi indicates that generally, self-regulation is "motivated by the threat of external control, primarily by the government, of one's competitive practices" (Lexchin & Kawachi, 1996). Additionally, Sillup states that in practice, self-regulation has proven to be generally ineffective, both in the pharmaceutical industry as well as in other industries (Sillup et al.,

2010). Essentially, voluntary codes do not possess that deterrent effect and respectively do not prevent any undesirable behavior of the industry (Lexchin & Kawachi, 1996). According to FDA Deputy Commissioner Mary Pendergast: "The potential financial rewards for violative promotional activities . . . are great, and the risks of serious sanction minimal" (Pendergast, as quoted in Lexchin & Kawachi, 1996).

### 2.3.1 The rise of codes of conduct within CSR

The concept of CSR first emerged in the United States, at the start of the 20th century. The idea originated from successful businessmen, like Carnegie, who believed that the making of profits should no longer be the sole purpose of a company (Kolk et al., 1999). This belief was spiked by anti-trust legislation that appeared as a result of the growing imbalance in society, generated by the continuously growing power of companies (Holmes, as cited in Kolk et al., 1999). CSR, in the shape of private governance, has granted companies the opportunity to "devise and implement behavioral norms that regulate their activities" (Jackson & Rathert, 2017), in such a way that benefits their business as well as society and is less invasive than government regulation would be. Hence, many firms -both national and multinational- grasped this opportunity when it emerged a century ago, and are still doing so today. However, time has shown that "despite the large number of codes already drafted around the world […] the status of these codes is still unclear and their operationalization is probably inadequate to address the regulatory challenges of globalization" (Kolk et al., 1999). The discussion of whether TNCs were able to regulate themselves through a code of conduct started as early as the 1970's (Kolk et al., 1999), when various international organizations started to develop a code of conduct, and is still alive today. While the original intention of drafting a code of conduct was to formulate a set of mandatory guidelines, this was soon lost at the "lack of international consensus about the function, the wording and […] potential sanctions against non-compliant firms" (Kolk et al., 1999). Consequently, mandatory guidelines transformed into voluntary codes, which proved to generally miss the mark more often than not.

## 2.4 Process-tracing codes of conduct

While the majority of the literature regarding codes of conduct is consistent on many aspects, the amount of literature available on the topic is not very large. Although there are multiple works available on codes of conduct within other industries (Erwin, 2011; Jackson & Rathert, 2017; Jenkins, 2001; Kolk et al., 1999; Murphy, 2004; Pitt & Groskaufmanis, 1990), there are

only a few available on those produced by the pharmaceutical industry (Horner, 2019; Lexchin, 2003; Lexchin & Kawachi, 1996; Sillup et al., 2010) and even less on the formulation process of codes of conduct (Bartley, 2003; Fransen, 2010). While their focus area is irrelevant to my topic, the manner in which the last-mentioned authors have conducted their research is similar to mine. Fransen conceptualizes that which I refer to as a code of conduct as 'private labor regulation' and focuses on the clothing industry (Fransen, 2010), while Bartley refers to it as 'private regulation' and concentrates on the forest products and the apparel industry (Bartley, 2003). Both Fransen and Bartley have attempted to answer the question why private governance is accepted and which (both external and internal) factors contribute to the fact that it is often the preferred form of regulation for corporations (Bartley, 2003; Fransen, 2010). Both authors conclude that this is due to the fact that "the spread of private business governance in itself is a manifestation of neo-liberalism on a global scale, signaling the rising power of transnational business, escaping binding and enforced public regulation" (Fransen, 2010). Additionally, both authors set out to uncover the pathways through which initial conditions of the industry in question were transformed into the self-regulatory end-results. While Fransen analyses the content of the codes on their level of effectiveness by assessing whether they fulfill certain criteria, such as labor standards, control and implementation specificity (Fransen, 2010), Bartley does not delve into the contents of the code itself but analyses which roads were taken prior to the construction of the codes (Bartley, 2003). Therefore, both works have set an example for my own, meanwhile neither did precisely what I have set out to do in this study.

## 3. Method Section

This study was conducted by use of grounded theory: a mix of both inductive and deductive methodology, and has consequently resulted in both freedom as well as limitations. While the research has been inductive during the primary data-analysis -after which I collected theory that connected to what the data illustrated-, deductive methodology was used to analyze the research results in a systematic manner. This use of mixed methods provides one with both flexibility and stringency. The flexibility is found both in the possibility for earlier findings to inform the connecting theory established in a later stage, as well as the generalizability of the end results of the study. The stringency is found in the fact that the theory available on the topic was not highly extensive and could have limited my perspective to the extent that the data I found was unable to teach me something outside of the scope of my own perception.

### 3.1 Methodology

This thesis presents the results of a historical case study of the VIG code of conduct, by means of an outcome-oriented use of process-tracing (Beach & Pedersen, 2013). This means that I endeavor to explain the outcome of the absence of pricing policy within the VIG code of conduct "by building a causal explanation" (Beach & Pedersen, 2013). I focus on the reasons provided by the actors for certain actions, as well as the (both intended and unintended) consequences thereof (Zeitlin, 2020). Consequently, connecting the *how* and the *why* to both internal as well as external explanations.

My analysis is two-fold. In the first part I conducted a content analysis of relevant documents. The second part consisted of interviewing relevant stakeholders to the construction of the code. These interviews were open-ended and semi-structured 'elite interviews' (Lilleker, 2003). For my content analysis I evidently analyzed the VIG code of conduct itself, but also other relevant documents that have helped me understand how this code came into being. This is a broad and diverse selection of documents, going from media statements by the VIG regarding the code of conduct or by the former Dutch Minister of Medical Care & Sports: Bruno Bruins[5], to initiative notes from political parties and minutes from meetings or 'vragenuurtjes' (Question Time in the Dutch Parliament) addressing Minister Bruins. Similar to Bartley (2003), I looked at the process of drafting this code of conduct over time – hence, approaching a contemporary issue in a historical manner. I have identified the various available options considered by the stakeholders of the code and respectively focused on the "roads not taken" (Bartley, 2003). I have done so with the objective of understanding why the path of *not* including any statement on pricing policy was taken, while other options were disregarded or fell apart, despite the substantial threat of governmental intervention hanging over the industry's head. Thus, why did options that were initially perceived as valid alternatives not make it to the finish line? By taking into account the different perspectives of various actors and sources of varying nature, I have been able to present a valid and reliable account of the process (Zeitlin, 2020).

Due to the fact that previous research conducted by Bartley is closely related to the research that I have done, I decided to follow the same theoretical framework as used by Bartley.

[5] While Minister Bruins (People's Party for Freedom and Democracy) was still the one in charge of Medical Care & Sports at the beginning of this study, the world found itself in the midst of a pandemic a few months after the start of this research: that of COVID-19, or the corona virus. On the 18th of March 2020, the Minister fainted during a debate regarding the current corona crisis, as a result of overtiredness. His recovery would take up too much time, which the Netherlands did not have in its situation at the time, which is why Hugo de Jonge (Christian Democratic Appeal) took over the position as the Dutch Minister of Medical Care.

Bartley used a "branching tree" model of analysis, following the historical institutionalists that went before him. This is also a suitable model for the analysis of this study as it lays out the entire record of what other possible trajectories there initially were, which paths were eventually taken and which were not. Hence, this framework is particularly useful for uncovering ground zero of the process, "before 'lock-in' effects, path dependence, and diffusion" took over (Bartley, 2003). In order to conduct this analysis, Bartley used three data sources. Primarily, he gathered a variety of archival documents on certification programs. These included: "charter documents, reports, internal memos, Webpages, and articles from trade journals" (Bartley, 2003). Secondly, he made use of research previously done on the industries which he focused on, next to: "social movement campaigns, policy processes, and private regulatory initiatives" (Bartley, 2003). Thirdly, he did in-depth interviews with 37 key informants. While he started with a much smaller number of interviews, he used "snowball sampling" to discover more individuals that could be potential informants to him, limiting himself to a selection of those who had been involved in the construction of the certification programs from the beginning (Bartley, 2003).

While time restrictions to the course of this research have impeded the possibility of conducting as many as 37 in-depth interviews, I also limited myself to interviewing solely those who have been involved in the formulation of the VIG code of conduct from the very beginning, and academic experts in the field of pharmaceutical codes of conduct. Other than that, I focused on a similar selection of document types and made extensive use of the existing body of research available on the topic. However, where Bartley's research ends, my analysis goes further. While Bartley has looked into the chain of events leading up to the development of the codes on which he chose to focus, and why these developments all formed the path to a self-regulatory code of conduct rather than any form of government regulation, he does not touch upon the content of those codes. This study, on the other hand, followed Bartley's methodology in tracing those initial steps of the development of the code but subsequentially also used that same methodology to retrieve the information on why the VIG code of conduct took its current shape; without pricing policy.

### 3.1.1 Interviewing process

Prior to the reader's review of the research results, it is important to reflect on the interviewing process, for this will provide a noteworthy addition to the conclusion. Other than that, there are two external factors to the circumstances of this thesis which the reader should take into

account. Firstly, the current corona crisis has resulted in the world's heightened attention for the pharmaceutical industry, looking at it through a magnifying glass. Second, the interviewees were aware of my position as a research intern for the Pharmaceutical Accountability Foundation, working from the office of Wemos (WErkgroep Medische Ontwikkelingssamenwerking/Working Group on Medical Development Cooperation). Both of these organizations are knowledgeable of- and critical towards the pharmaceutical industry.

When I started contacting potential interviewees for the research I invited the following experts: Marcel Canoy, Joel Lexchin and Wilbert Bannenberg. Next to that, I invited the VIG itself, the external consultant from Berenschot, and all 42 member companies from the VIG. The invitation contained some information on me, my academic background and informed one about the fact that I was a research intern at the Pharmaceutical Accountability Foundation, working from the office of Wemos. Additionally, it explained my research objectives for the internship and thesis. All of the invited experts, the spokesperson of the VIG, and the external consultant agreed to participate in the research. However, none of the VIGs member companies agreed to an interview and all referred me to the VIG itself. It is not possible to say whether the VIGs member companies would have agreed to an interview under different circumstances. Yet, their reluctance to participate could have been influenced by the current pandemic and its respective heightened focus on the pharmaceutical industry. For, this enlarged focus consequently increases the criticism on the sector, which makes it more vulnerable than usual. Next to that, the reluctance from the member companies could also have been influenced by my personal positioning with regards to discussions concerning their industry. Due to the fact that both the Pharmaceutical Accountability Foundation and Wemos are critical of the pharmaceutical industry, it is not unlikely for the member companies to be wary of a negative outcome of my research, due to their expectation of personal bias. Ultimately, I succeeded in interviewing the following participants:

| **Expert** | **VIG** |
|---|---|
| Marcel Canoy | Representative 1 |
| Joel Lexchin | Representative 2 |
| Wilbert Bannenberg | |

The external factors explained above could also have contributed to the following two events that I believe are worthy of discussion. Even though the consultant from Berenschot initially

agreed to participate in the research, the participant eventually cancelled the interview one day before the interview was supposed to take place. This is due to the fact that the participant required a signed secrecy form that stated that none of the research results would be used for publication. I was unable to sign such a statement for a variety of reasons and this resulted in withdrawal of participation. By that time, the interview with the spokespeople of the VIG had already been conducted. However, two weeks after the interview I received word from the VIG with the request to state that the data gathered from the interview would not be used for publication. Due to the fact that I could, once again, not do so I replied with both an explanation of why I could not confirm the request, as well as a copy of the processed research results from the interview in question. I invited the VIG to come back to me regarding any dissatisfaction there might be from their side regarding the paragraph, in order for me to rephrase it in a mutually satisfying manner. I additionally stated that the organization could withdraw its participation in the research in case they had changed their minds. To date, I have not yet received a reply and consequently decided to maintain the research results in their original form.

I acknowledge that during the period of my research I have worked with individuals with a strong normative stance on the subject. However, it is worth mentioning that regardless of my internship position I have attempted to obtain a complete picture of the situation and take different perspectives into account, throughout the process of the research. Whilst conducting my literature review and content analysis I have read a great variety of works, covering arguments both in favor and against private certification systems for TNCs, in support of the pharmaceutical industry's current system and opposed to it, critical of CSR and in favor of it. Next to that, I have closely followed all the news reports that were published with regards to the pharmaceutical industry, including those of the VIG itself. During my interviews I have asked open-ended, non-leading questions. While I did interview experts that are critical of the pharmaceutical industry, I also interviewed the VIG itself and was additionally supposed to interview the external consultant who contributed to the code. I was also supposed to have a second interview with two different people from the VIG, together with Wemos employees, but this was postponed due to the situation regarding the corona crisis.

### 3.2 Case selection

The Dutch pharmaceutical code of conduct is the most recently published code of the pharmaceutical sector. Therefore, the VIG had much material to build on and learn from in order not to receive the same criticism as the foregoing codes. Indeed, the VIG code distinguishes itself on several fronts. At first glance, the code does not seem entirely

unpromising. As a matter of fact, the code actually sets the bar rather high for the pharmaceutical sector with strong passages that are further explained with examples (M. Canoy, personal communication, April 9, 2020). It distinguishes itself in the sense that it has an independent Advisory Board to monitor the members' compliance with the code. However, if one reads the small print it becomes evident that this Advisory Board can merely provide the member companies with non-binding advice (Boersma, 2020). Only the VIG can actually make a decision or take action. Additionally, it is not the companies' behavior which is monitored by the Advisory Board but their self-evaluated annual reports (Boersma, 2020). Not only does the company itself write this report, the manner of assessment of the company's compliance to the code is determined by the company itself as well (Boersma, 2020). Hence, the code primarily strikes as a more modern and better-defined document than the ones that came before it. Yet, it seems that the main improvement the VIG has made to its code is the 'placebo-effect' (Blühdorn, 2007) as it does not ensure that companies will adhere to it. Therefore, I argue that the VIG code of conduct is essentially self-regulated and is in that respect not the first in its kind.

Research conducted by Lexchin and Kawachi has shown that self-regulation has proven to be generally ineffective, both in the pharmaceutical industry as well as in other industries (Lexchin & Kawachi, 1996). Within the pharmaceutical industry however, these codes have the following in common:

1. They are reactive rather than proactive, motivated by the threat of external control;
2. They lack transparency;
3. They incorporate vague language to provide companies with a significant amount of leeway;
4. They do not incorporate effective sanctions against member companies failing to adhere to the code (Lexchin & Kawachi, 1996).

Besides the IFPMA and the EFPIA codes of conduct (published in 1981 and 1992), various countries have effectively adopted national, self-regulated codes of conduct for their pharmaceutical industry (Globalhealthpr et al., 2013). For examples of national codes of conduct for the pharmaceutical industry that were self-regulated, contained the aforementioned characteristics and have proven to be ineffective, one could look at those of Australia, the UK, Canada or the United States (Sillup et al., 2010).

While it is not possible yet to determine the effectiveness of the recently released pharmaceutical code of conduct of the Netherlands, it is possible to establish that it does contain the aforementioned characteristics that ineffective codes are proven to have in common. Which I shall be doing in paragraph 4.2.

### 3.3 Theoretical framework

Based on Bartley's theory, I expect to find both *social movement pressures* as well as the domination of neo-liberal agendas of the 'modern' *institutions of globalization*[6] to serve as explaining factors for the development of the VIG code of conduct in its current form. The first meaning that "certification systems emerged in a context of social movement activity and public controversy about the social or environmental dimensions of the industry" (Bartley, 2003). The latter being due to ideologies of neo-liberalism and the states' respective interaction with institutions accordingly. This resulted in a shift from governmental or intergovernmental to private kinds of regulation (Bartley, 2003).

#### 3.3.1 Social movement pressures

Additionally to Bartley identifying social pressure as one of two main reasons for the emergence of private certification for companies, Sikkink also recognizes social pressure as a determining factor. She distinguishes four categories of TNC regulation by means of a code of conduct. The first category, the one that both the VIG and the IFPMA code of conduct are in, is the *industry codes* (Sikkink, 2020). These codes "are often preemptive codes' responses to criticism of industry practices, they attempt to ward off external regulation by showing that the industry is capable of regulating itself"(Sikkink, 2020). Also Jenkins points out that influencing the public attitude plays a highly significant role in the framework within which codes of conduct have been established (Jenkins, 2001). For, the increased importance of "brands and corporate reputation makes leading companies particularly vulnerable to bad publicity" (Jenkins, 2001).

#### 3.3.2 Neo-liberal institutions of globalization

The embracement of legally binding rules for TNCs started to slow down already during and after the economic crisis of the 1970's (Fransen, 2010). "This is often understood as the starting point of what both popular and academic publications refer to as the neo-liberal perspective on

[6] These *institutions of globalization* are defined by Fransen as: "a neo-liberal regulatory framework on the global level coupled with increased societal pressure for responsible social and environmental conditions of production in developed countries" (Fransen, 2010).

global production: global (rather than domestic) markets are understood as the source of growth on the domestic level…" (Fransen, 2010). Hence, developed parts of the world such as Europe and the United States started opting for "deregulation and freedom for markets" (Fransen, 2010). It was a period in time during which considerable transformations occurred, noticeable on various fronts: "the economic role of the state, […] policies toward TNCs and foreign direct investment" (Jenkins, 2001). Both this ideological shift, combined with the globalization of economic activity (e.g. trade liberalization and attracting foreign investments), meant that the role of the government became one less capable of performing regulatory affairs in recent years (Jenkins, 2001).

It is in this context that corporate codes of conduct became the manifestation of the novel emphasis on self-regulation and CSR. "Instead of the social and environmental impacts of big business being seen as issues primarily for governments to deal with, they are now regarded as matters of corporate responsibility for which companies themselves, or their trade associations, should set standards" (Jenkins, 2001).

More scholars have stated that globalization has caused a shift of institutional roles regarding states and corporations (Bartley, 2003; Matten, 2003; Sassen, 1996; Shamir, 2005). As corporations have been finding themselves increasingly more often in the position of political actors, new forms of governance have emerged as a result (Bartley, 2003). The rise of globalization, combined with the ideologies of neo-liberal capitalism has resulted in extensive implications for the way in which states are able (and willing) to regulate corporations. Whereas government intervention could possibly lead to more desired effects, the implementation of a self-regulatory code instead is often still the preferred option by both companies as well as governments (Bartley, 2003). This has to do with "political action in a new global institutional context, dominated by neo-liberal agendas and rules about free trade" (Bartley, 2003). For, these institutions of globalization have influenced the upsurge of private certification in various ways (Bartley, 2003).

Another scholar who argued that globalization has caused a shift of institutional roles regarding states and corporations is Blühdorn. While Blühdorns focus is mainly on the eco-political paradigm, his theory of *symbolic politics*[7] is also applicable to the political paradigm of the pharmaceutical industry. According to Blühdorn, there is a disparity in eco-politics between

[7] When I speak about symbolic politics I am referring to its original definition, as introduced by Edelman or as defined by Blühdorn as type BII.2: "… a matter of political elites making strategic use of symbols, myths and rituals in order to deceive and control the mass public in order to maximize their own interests" (Blühdorn, 2007).

that which is promised to the public, opposed to what is actually executed. This is the case regarding both governments as well as politicians, and additionally for private actors as well as companies. “Due to the fact that our current (in this case: Dutch) society has granted large companies a significant podium, they have become highly relevant actors to our societies and most importantly to sustaining that which has proven to be unsustainable: the leading force of consumer capitalism” (Blühdorn, as cited in Veenman, 2020). Blühdorn inquires what to him seems to be the bedrock to this “eco-political inefficiency” (Blühdorn, 2007). “This root cause would be the use of *symbolic politics*, which he defines as political and economic elites advertising matters which they are not committed to do, which consequently results in not doing what was promised would be done” (Veenman, 2020). He argues that the common description of symbolic politics narrates the ideological and equivocal story of eco-political injustice and seperation and disguises the post-ecologist willpower to defend the detrimental system of democratic consumer capitalism (Blühdorn, 2007).

Overall, what Bartley refers to as the neo-liberal institutions of globalization is essentially a framework of ideas, manifested in society by a societal state-of-mind that adheres to ideals of neo-liberalism and capitalism, as a result of globalization. This has ultimately resulted in a change in the societal division of roles in which the government has granted some of its power to the private sector. This as a consequence to the increasing importance of TNC’s, which are perceived as the source of economic growth on a domestic level. Due to the fact that the word *institutions* can make one think about more physical establishments, rather than an idea framework, I chose to replace the word *institutions* for the word *manifestations*, as I feel that this describes it more accurately. Hence, for the remainder of this thesis I shall be speaking of the *neo-liberal manifestations of globalization*, yet its meaning shall remain the same.

### 3.3.3 Why self-regulation? Why not?

The foregoing theory brings me to the following two questions; 1: Why is self-regulation still preferred if it is well-known that this does not result in the desired outcome? And, 2: Why is this phenomenon problematic?

In order to answer the first question I shall, once again, be looking to the research of Lexchin and Kawachi. For, according to them , this curious phenomenon can be explained by both financial and practical incentives.

1. On the one hand, “fiscal pressures in almost all countries have prevented government agencies from effectively policing pharmaceutical promotion. Government regulatory agencies rarely have the resources to make it economically rational for individual firms *not* to cheat” (Lexchin & Kawachi, 1996).
2. On the other hand, the government also has “a lack of necessary expertise compared to industry” (Lexchin & Kawachi, 1996).

Thus, a self-regulatory code of conduct is both a more practical as well as a more ‘economically responsible’ option. Additionally, “government regulators also reason that in a highly competitive industry, the desire of individual companies to prevent competitors from gaining an edge can be harnessed to serve the public interest through a regime of voluntary self-regulation run by a trade association” (Lexchin & Kawachi, 1996). On top of that, unequal proportions with regards to the access to resources -both regarding expertise and liquidity- can lead to situations in which government seems less suitable to generate and enforce regulations than the private sector. For the private sector could, on some occasions, more easily generate fees to cover the necessary costs than government would be able to (Lytton, 2014).

The answer to the second question that I posed: “Why is this phenomenon problematic?” is that the trouble with this phenomenon lies within the contrasting goals between the government and the private sector. While the aim of the government is predominantly to protect public health, that of the pharmaceutical industry is to get a competitive advantage and to maximize its profits (Lexchin, 2003). Due to the industry’s importance to the public health and the previously illustrated problematic system that it operates in, *symbolic* codes of conduct that are guided by profit maximization rather than the public interest are not sustainable. Research directed at the advantages of private certification points out that reliable forms of private certification are able to “resist incentives to put profits ahead of protecting the public” (Lytton, 2014). Yet, Lexchin points out that the pharmaceutical industry “will always be tempted to exploit the privilege of self-regulation by producing a socially sub-optimal level of compliance with regulatory goals. Experience has repeatedly shown this to be the case in the marketing of pharmaceutical products” (Lexchin, 2003). Hence, there is a conflict of interest inherent to self-regulatory private certification systems within the pharmaceutical industry.

# 4. Historical outline

## 4.1 The IFPMA code of conduct

The discussion regarding codes of conduct within the pharmaceutical industry dates back to the year 1981, when the first IFPMA (International Federation of Pharmaceutical Manufacturers' Associations) code of conduct was composed. While this code was formulated as a means to hold off a WHO (World Health Organization) Global Pharmaceutical Code of Conduct and government regulation through an implementation of the industry's self-regulation, Health Action International (HAI) reacted to it in 1982 by formulating another, revised code. HAI had been advocating government regulation of the pharmaceutical sector and criticized the IFPMA code of conduct on several fronts: its need for interpretation, monitoring and enforcement. The need for interpretation arose from the absence of any stringency in the entire code. The majority of the provisions were remarkably vague and consequently depended on the way in which they were interpreted for their practical implications. Next to that, the absence of any sort of monitoring of the national member associations' compliance to the code meant that there was no assurance of pharmaceutical companies actually adhering to the code. Finally, the fact that there was no reference in the code to the consequences that would be suffered by the company that were to violate the code made that it would be impossible to establish how effective it is. The foregoing factors lead to HAI's main point of criticism: "The IFPMA omits the three essential ingredients of any code of conduct" and should therefore not even qualify as a code of conduct as it is "considerably less authoritative" (Health Action International, 1982).

Additionally, HAI was critical on the IFPMA's attitude during the entire process. First and foremost, the pharmaceutical industry had shown no sign of accepting the continuously increasing criticism that it had been receiving (Health Action International, 1982). This oblivious attitude to the criticism resulted in the fact that the pharmaceutical sector did not have to acknowledge that its credibility -which was evidently under threat at the time- provides a vital commercial asset to the industry which needed to be restored (with the help of a code of conduct) (Health Action International, 1982).

However, in this day and age, this is not surprising anymore. Bartley previously pointed out that public governance revolves around reputation, which means that codes of conduct have the likelihood of "greenwashing" reality (Bartley, 2003). In other words, they might restore corporate images while leaving the daily affairs of the business unchanged. What is more, due to the fact that this type of regulation is privatized, it might not live up to the "democratic ideals of openness and accountability" (Bartley, 2003).

### 4.2 VIG code of conduct

Nearly 40 years later in the Netherlands not much seems to have changed, as the VIG code of conduct received the same points of criticism as the IFPMA did in 1982. Those exact points of criticism, which I previously listed in the foregoing paragraph, have additionally been identified by Lexchin and Kawachi in 1996 as characteristics that ineffective codes of conduct have in common (see paragraph 3.2). Although Lexchin and Kawachi phrased it differently than HAI did at the time, the exact same characteristics apply to the VIG code of conduct.

Similarly to the IFPMA code, the VIG code was established as a reactive measure rather than a proactive one, and was motivated by the threat of external control. I will elaborate further on this in the subsequent paragraph but the following explanation will provide one with the knowledge of what happened in a nutshell. In July of 2017, the pharmaceutical company Leadiant started marketing an already existing pill: chenodeoxycholic acid, under the name CDCA-Leadiant, for a price that was 500 times higher than it had been under the previous owner of the drug (Sluis, 2018). Simultaneously, three Dutch political parties: PvdA (labor party), GroenLinks (green party) and SP (socialist party) wrote an initiative note titled "big pharma: not healthy!" with the aim to restrict the level of power of the pharmaceutical industry (Dijksma, Kooiman, & Ellemeet, 2017). As a result, the political pressure on the pharmaceutical industry started increasing and word got out of possible legal restrictions of the industry. With this threat of government intervention hanging over its head, the VIG started talking about creating a code of conduct for its members and officially announced this on the 21st of September of 2018 (Tweede Kamer der Staten-Generaal, 2019).

Secondly, the VIG code of conduct lacks transparency. While the pharmaceutical industry itself announced that the code would constitute a reform for the industry with regards to transparency and affordability (Geest, 2020), the code does not mention pricing policy once. The code states that the members are committed to the List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector, established by the Platform on Transparency and Ethics (Boersma, 2020). However, this document explicitly states that transparency regarding pricing, profits and discounts do not belong to those principles (Geest, 2020). On top of that, the Advisory Board and the members of the VIG itself are the only parties that are able to complain and any complaints that are potentially filed will not published (Boersma, 2020).

Thirdly, the code contains vague language to limit the member companies as little as possible. The code does not contain any concrete guidelines or starting points. The guidelines included in the code are ethical principles that are both judged by the company itself as well as impossible

to legally enforce. For example, article 4.1 of the code states: "We focus on the quality of our products and services in the best interests of the patient" (Boersma, 2020), and the code contains various similar statements. Provisions as such cannot help but remind one of the IFPMA code of 1982, as it is "a statement so vague it is hard to accept it as anything much more than an advertising or public relations slogan" (Health Action International, 1982). For, *what* is quality? How is the quality of a product measured and by whom is it assessed? Who decides what is in the best interest of the patient, the VIG or the patient? As long as concrete guidelines are absent, phrases as the one in article 4.1 are open to interpretation, which is undesirable in a code of conduct.

Lastly, it does not incorporate effective sanctions against member companies failing to adhere to the code. The code is based on the principle "apply or explain," which means that if one of the members were to violate the code they have to explain why that has happened (Boersma, 2020). In case a company would be unable to account for its actions and fails to 'comply timely' the ultimate consequence of its actions would be to get expelled from the association (Boersma, 2020). This is undesirable for the VIG's members due to the fact that the expelled company would lose its influence on the association, will no longer be represented in its lobby and the name/image of the company in question will most likely be harmed due to negative publicity. However, the company will not suffer any monetary losses, can continue the practices for which it was expelled in the first place and remains able to lobby for itself. Hence, the negative consequences of eviction from the VIG are minimal.

All in all, the VIG code of conduct does not provide one with any plausibility that it will actually be adhered to, just as the IFPMA code of conduct did (not) at the time. And while, according to former Director of the Harvard University Multinational Enterprise Project Raymond Vernon, "there is nothing wrong with an approach of this sort", "it is trivial in comparison to the malaise with which it deals" (Raymond Vernon, as quoted by Health Action International, 1982). For, "the point is simply that, by their nature, voluntary codes do not work well, or do not work at all" (Raymond Vernon, as quoted by Health Action International, 1982).

### 4.3 The formulation of the VIG code of conduct

Primarily, I shall elaborate on the explaining factor of social pressure on companies with regards to the VIG code of conduct. Secondly, I shall delve deeper into the neo-liberal institutions of globalization that codes of conduct are founded on.

### 4.3.1 The pressure cooker

As was previously explained in the theoretical framework, Bartley, Sikkink and Jenkins identified social pressure to be a determining factor for companies to commence with self-certification. While it should be highlighted that the VIG itself has not acknowledged the increasing social pressure on the association to be the main motivation for the creation of the code, it does seem the most likely motivator. As prior to the formulation of the code, there had been an increasing pressure from NGOs, the media and the clients of the pharmaceutical industry: the general population of the Netherlands. When analyzing publications of the media and news reports, it becomes clear that the foregoing actors did not only target the pharmaceutical companies in their quest for change, they also effectively targeted Minister Bruins. Consequently, the pharmaceutical sector had been receiving increasing amounts of criticism and pressure from both social movements and the political spectrum before deciding on the formulation of this code. For example, research conducted in 2017 by Bas Leerink in service of the Dutch Council for Public Health and Society, showed that while there is a variety of ways for the government to increase the pressure on pharmaceuticals to lower their prices, these are rarely ever used (Berkhout, 2017). The options that were mentioned were, for example, that of the *magistral preparation*[8] and that of a *compulsory license*[9]. This publication was followed by another article which also claimed that "the high prices of medication is a monster with many heads, but not impossible to tame" (Meurs, 2018). This article also mentioned alternatives that would lead to lower prices, such as the worldwide, public availability of the asking price from pharmaceuticals in each country (Meurs, 2018). Other publications with various suggestions followed, such as: the implementation of a profit margin of 10%, adjusting patent laws or outsourcing the R&D of medication to universities (Beverdam, 2019).

Evidently, this uprising against the pharmaceutical industry and the way it did business was not unfounded. In fact, the roots of this public discontent are to be traced back to incidents within the pharmaceutical industry that received public attention. One of the most noticeable incidents concerns the previously mentioned drug that was used in the 1970's to treat gallstones with the

[8] If a patient does not have access to a certain patented medicine (because it is not available in the Netherlands or because it is not affordable for said patient, for example), the patient's pharmacist is legally allowed to manufacture the drug in question for that patient. This is called *pharmaceutical compounding* or *magistral preparation* (magistrale bereiding in Dutch).

[9] With a *compulsory license* (dwanglicentie in Dutch) the government can force a pharmaceutical company to grant a license of production for a patented drug to another company. This license is paid for by the receiving company, but the government has to agree on the requested amount.

active bile substance CDCA and was also used to treat a rare disease called CTX. While there are many alternatives for the treatment of gallstones, CDCA was a nonetheless valuable drug as doctors had since the 1980's been aware of the fact that the particular drug also works for the treatment of CTX. CTX is a rare chronic disease with no alternative medication (Steenbergen & Hordijk, 2018). This entire process essentially started in July 2017, when the pharmaceutical company Leadiant started producing an already existing pill, previously named Chenofalk, under the name CDCA-Leadiant for a price that was 500 times higher than it had been in 2008, the year in which Leadiant obtained the marketing authorization of the medicine from originator company Dr. Falk (Sluis, 2018). There was no reason for Leadiant to raise the price this much, Leadiant had not spent any money on R&D, as the medicine already existed. On top of that, during the years prior to the price increase, Leadiant had bought all the alternatives to the drug and had taken them off the market and obtained an orphan designation for it, providing the company with 10 years' market exclusivity of the drug (Steenbergen & Hordijk, 2018), opening up the possibility of such a drastic price increase.

As a result of the foregoing situation, combined with articles suggesting governmental regulations, the public of the Netherlands was faced with the undeniable fact that there were ways in which the government could tackle the excessive prices of (some) medicines. Additionally, the Dutch parties: PvdA (labor party), GroenLinks (green party) and SP (socialist party) had written the initiative note titled "big pharma: not healthy!" with the aim to restrict the level of power of the pharmaceutical industry, at the end of 2017 (Dijksma et al., 2017). This resulted in both an increased political- as well as public pressure on Minister Bruins to take action. Consequently, Minister Bruins wrote an open letter to the pharmaceutical industry in which he made an appeal to their sense of social responsibility. He also stated that he was going to talk to those pharma companies of which he was already aware that they were asking unjustifiably high prices for a needed medicine. If these companies would not be able to give a satisfactory and -above all- *public* statement, he would make this information publicly available without any kind of justification for the high prices (Bruins, 2019). While he emphasized his appreciation for the industry's innovation, he was no longer willing to accept the lack of transparency into the industry's pricing policy. The behavior that the pharmaceutical sector was showing did, according to Bruins, not match its vital societal position. Therefore, he also warned the sector that if it decided not to respond to the increasing social and political pressure that they were receiving at the time, this would not benefit them in the long run as Dutch investors were already withdrawing from the sector and more would follow if the transparency

deficiency would continue (Bruins, 2019). While the VIG had already announced that it would start the process of formulating a code of conduct in September 2018, this more recent threat of government intervention hanging over its head provided the association with a more pressing incentive to speed up the process. Minister Bruins wrote said letter on October 24th in 2019 and 3 months later a code of conduct had emerged.


### 4.3.2 The neo-liberal manifestations of globalization

Specifically regarding the pharmaceutical industry it is important to note the ethical changes the industry has gone through with the rise of the contemporary, neo-liberal and capitalist societies. For, while the pharmaceutical industry is now guided by profit, this did not always used to be the case. Gabriel points out that "the relationship between patents and prices, and other aspects of how patenting affects the commercial development of new drugs, the simple idea that innovation and profit should be linked together is a fundamental assumption in the way we think about the role of the pharmaceutical industry in contemporary society" (Gabriel, 2014). Looking at this phenomenon from a historical perspective, however, this is not necessarily a logical development. For, during the late 18th and early 19th century, the community of medical practitioners were bound by a strong set of ethics that were opposed to patents and trademarks. "Indeed, reputable companies refrained from patenting their products, and those few manufacturers that did were denounced by the medical community as quacks" (Gabriel, 2014). However, "Over the course of the late nineteenth and early twentieth centuries, what had once been the mark of unethical quackery was reinterpreted as an ethically legitimate component of scientific drug development" (Gabriel, 2014).

This transformation of values within the pharmaceutical industry clearly demonstrates the more general transformation experienced by both the private and public sector and their interaction with each other. It is this certain corporate reconstruction, following the end of World War I

and marking the beginning of the contemporary neo-liberal manifestations of globalization. This effectively resulted in a society in which TNCs are regarded as the source of global economic growth and effectively enjoy an increasing amount of political authority and freedom of regulation. However, the emphasis of CSR has had beneficial effects as well as it has downsides. Certain codes of conduct have made noticeable positive changes on companies' approaches to conducting business (Jenkins, 2001). Yet, the hazardous side to a code of conduct is that it can be perceived as something it is not, such as legislation. In that case, the code might merely serve the purpose of deflecting criticism and reducing the demand for external regulation (Jenkins, 2001). For, while codes of conduct have the potential of contributing to structural change and have been able to do so in the past, most codes of conduct merely serve a 'PR' (public relations) purpose and can be categorized as *symbolic politics* at most.

In the case of the VIG code of conduct it is interesting to look at these neo-liberal manifestations of globalization, combined with the previously identified 'greenwashing' concepts linked to the rise of these codes. For, as explained in the previous paragraph: "the pressure cooker", it is evident that the VIG code emerged as a result of an increasing social -and respectively political- pressure on the association. It was important for the VIG to come forward with a statement that would demonstrate its sound CSR policies in order to address the deteriorating public faith in its members. Simultaneous to the increasing social pressure on the VIG, this heightened pressure was also partly directed at the Dutch government. However, the Dutch government chose not to intervene in the situation and grant the VIG itself the opportunity to address pricing policy in its announced code of conduct. Thus, while the Dutch government does possess the means to undermine monopoly regulation in the pharmaceutical industry, it chose not to put these to use. For, within the neo-liberal manifestations of globalization, matters as such are no longer perceived as governmental concerns, rather as matters of CSR for which the companies or association should take responsibility and find a fitting solution (Jenkins, 2001). Consequently, the VIG developed said code seemingly with the aim of deflecting criticism and reducing the demand for external regulation. As there is no statement regarding pricing policy, the code does not go much further than the law to which the companies must already adhere and provides no means to external verification.

## 5. Results

As previously indicated by research from SOMO, pharmaceutical companies can hardly be identified as drug companies anymore. Rather, they have been transformed to *venture*

*capitalists,* as less than 25 percent of the newly developed medicines has been created within the companies themselves (Fernandez, 2020a). The remainder of the drugs is acquired from other pharmaceuticals, promising startups that mostly come from university funding, or early-stage investors. These take-overs are costing the pharmaceutical industry billions of euros, which the increasing drug prices are supposed to make up for (W. Bannenberg et al., 2020). Additionally, the Big Pharma companies spend more on profit distributions and marketing than on R&D. These are costs that are currently covered by our healthcare system while the pharmaceutical sector has a 21 percent *return on investment* (W. Bannenberg et al., 2020).

The pharmaceutical industry is invested in proving to society that they are not as bad as the media often makes them out to be (M. Canoy, personal communication, April 9, 2020). Respectively, the VIG code of conduct starts with: "Our behavior is open, responsible and in coherence with the best interests of patients and with that of the general public health" (Boersma, 2020). Yet, exorbitant drug prices that result in limited access to healthcare and the ever-increasing constraint on the accessibility to medicines do not align with "the best interests of patients and with that of the general public health" (W. Bannenberg et al., 2020). Still, the VIG has not made any attempt to address this issue within its code of conduct. According to the VIG, it was impossible for the association to reflect on the pricing policies of its members in the code as this would be in breach with cartel legislation (Geest, 2020). However, the Council for Public Health and Society/Raad voor Volksgezondheid en Samenleving (RVS) points out that the current system can and should be less costly as well as more efficient (Raad voor Volksgezondheid en Samenleving, 2017). In the following paragraph I shall illustrate the alternatives the VIG had to address its pricing policy in its code of conduct, i.e. the roads that were not taken. The second paragraph of this chapter shall be where I conduct my process-tracing as to why these roads were left untrodden. Subsequently, I shall discuss the findings of this chapter and shall finally draw a conclusion from the research results.

### 5.1 Roads not taken

It is important to note that a code of conduct is per definition a collection of ethical principles, rules and regulations regarding the behavior of the parties concerned. Hence, the inclusion of a pricing policy does in this case not mean to set a sector-wide price agreement. Not only would this be exceptionally complicated within the pharmaceutical industry due to the fact that prices of medicines are dependent on R&D costs, certain price agreements can also be considered illegal due to cartel legislation.

In response to the criticism that the VIG received from former Minister Bruins on the fact that the code did not touch upon the prices, the VIG has replied with the argument that it was not possible to do so, as this would not be in accordance with cartel legislation and the ACM would never approve it (M. Canoy, personal communication, April 9, 2020). I spoke about this in an interview with Canoy, who (amongst other things) works for the ACM (Authority for Consumers and Markets/Autoriteit Consument & Markt), which is the institution to assess any cartel agreements made in the Netherlands. According to Canoy, the argument of the VIG is "absolute nonsense". For, price agreements in a code of conduct was never the request from the Minister in the first place (M. Canoy, personal communication, April 9, 2020). "It seems like a trick to purposely misinterpret the statements from the Minister. This being that the Minister had implied that there should be concrete price agreements in the code of conduct while the Minister could never have implied such a thing as it would evidently be rather absurd to do so" (M. Canoy, personal communication, April 9, 2020).

However, Canoy argues, the VIG could definitely have included a few passages that would touch upon the prices without it being in conflict with cartel legislation. For example, the Leadiant case -in which a pharmaceutical company bought an old drug, took it off the market, slightly changed it and consequently introduced it again for a significantly higher price- is not alone in its kind, according to Canoy (M. Canoy, personal communication, April 9, 2020) (also see Bannenberg & Hoen, 2020). Thinking about cases as such, Canoy suggested that the VIG could have included a premise that stated that pharmaceutical companies will not apply for orphan designation on medicines for which no R&D was conducted (M. Canoy, personal communication, April 9, 2020). For, the orphan designation was developed to compensate pharmaceuticals for the fact that the drug had very few patients and could therefore not make up for its R&D costs, not for companies to make unwarranted profits on a drug that costs them very little to make (M. Canoy, personal communication, April 9, 2020). The ACM would never disapprove of such premises in the code. "For, why would we (ACM) do so? It would only be in the best interest of the consumer to include such a premise in the code, and the ACM would never obstruct principles that are favorable to the consumer" (M. Canoy, personal communication, April 9, 2020).

I also spoke to Joel Lexchin[10] about the various options the VIG had to address the prices in its code, without risking the sector doing anything that could be identified as 'cartel behavior'. In

[10] Joel Lexchin has been a teacher in Health Policy for 15 years (2001-2016) and has been researching and writing about pharmaceutical policy issues since the late 1970's. He has been the author and co-author of over 200 peer-reviewed journals

addition to Canoy's suggestion for the sector to waive the option of applying for orphan designation for drugs that already exist, Lexchin mentions the options of differential pricing and a citizens forum to discuss the price prior to it being raised (J. Lexchin, personal communication, April 14, 2020).

The first option, differential pricing, means that a company charges different prices for different groups. Pharmaceutical companies are already doing this on an international level, meaning that companies in Bangladesh charge a different price compared to what the same company charges in the Netherlands (J. Lexchin, personal communication, April 14, 2020). Thus, differential pricing takes into account the level of economy in different countries. Pharmaceutical companies could also do that within the Netherlands. For example the drug costs a certain amount of euros for a private insurance company, but has a different price if it is used by hospitals, children or pregnant women (J. Lexchin, personal communication, April 14, 2020). However, Lexchin points out that companies do not find this a very appealing option due to the fact that it is difficult to assess whether the right price is paid by the right individual/institution (J. Lexchin, personal communication, April 14, 2020).

The second -perhaps less invasive- option would be for the company to convene a panel of both patients and doctors prior to either establishing or raising a price for a specific drug (J. Lexchin, personal communication, April 14, 2020). The company would be transparent about the production process, saying: "this is what we have done with the product, this is the former price (in case of an existing drug that the company has discovered a new use for, for example), and this is what we would like to charge now, what do you think of that?" (J. Lexchin, personal communication, April 14, 2020). Consequently, the company would take that into account when deciding on a new price (J. Lexchin, personal communication, April 14, 2020).

Other options that Lexchin mentioned in passing were: the outsourcing of the development of the code to an independent organization, legislating the code and respectfully making it legally enforceable, or for the VIG to state that it would not hold on to a patent for longer than, for example, 3 years (it is currently 20 years in the Netherlands) (J. Lexchin, personal communication, April 14, 2020). While these are also valid options it seems unlikely that the VIG would implement any of these last three options as they are more invasive than the first two (J. Lexchin, personal communication, April 14, 2020).

articles, has been involved with various organizations (such as HAI and Healthy Skepticism in Australia), and is currently still working part-time as an emergency physician at one of the hospitals in Toronto (J. Lexchin, personal communication, April 14, 2020).

Lastly, I spoke to Wilbert Bannenberg[11] about the possible alternatives which the VIG had to include a statement on pricing policy in its code of conduct. Bannenberg points out that the code should have and could have stated that the members of the VIG shall put a "reasonable" price on their products (W. Bannenberg, personal communication, April 28, 2020). For, Bannenberg proposes a *cost-plus* model for the pharmaceutical industry, instead of its current model of *value based* pricing (W. Bannenberg, personal communication, April 28, 2020). Presently, the pharma industry determines the price of a drug based on the *value* it has for the patient. Lexchin pointed out that this value can be extremely high for people that have a serious illness that is either rare or difficult to treat (J. Lexchin, personal communication, April 14, 2020). This results in cases such as one that Canoy described: Zolgensma, a drug for the rare disease SMA (spinal muscular atrophy), that is currently priced at 1,9 million euros per dose (M. Canoy, personal communication, April 9, 2020).

It has already happened on multiple occasions that an excessive drug price has resulted in its inaccessibility for the patient (W. Bannenberg, personal communication, April 28, 2020).. While this is not illegal, Bannenberg argues that it is in fact immoral. "Nobody has an issue with the fact that drugs can be expensive. If there was an extensive amount of R&D connected to the drug, the price will be high. On top of that, it is also fine for the pharmaceutical industry to make profit, nobody said that that was not allowed. However, it is wrong to be making unreasonably high profits at the expense of the patient" (W. Bannenberg, personal communication, April 28, 2020). Hence, the proposition of the *cost-plus* model is: asking price = production costs + reasonable profit margin. Yet, this requires a certain level of transparency from the pharmaceutical industry, which it is -for some reason not quite certain- reluctant to provide (W. Bannenberg, personal communication, April 28, 2020).

In summary, the interviewed experts have made the following suggestions for the VIG to address pricing policy in its code of conduct without breaking any laws:

[11] Wilbert Bannenberg, an MD (Medical Doctor/arts) and a public health consultant with a rich history in health advocacy. While he is currently the chair of the Pharmaceutical Accountability Foundation, he also co-founded Wemos in 1981, is the founder of E Drug (2005), and has been an active member of HAI since 1982.

| Marcel Canoy | Joel Lexchin | Wilbert Bannenberg |
|---|---|---|
| •The VIG could have included a premise that stated that pharmaceutical companies will not apply for orphan designation on medicines for which no R&D was conducted. | •The code could have stated to make some sort of differential pricing agreements;<br>•The VIG could have promised to convene a panel of both patients and doctors prior to either establishing or raising a price for a specific drug. | •The code could have included a premise that the members of the VIG shall put a 'reasonable' price on their products. |

The following paragraph shall look into the reason for the absence of the foregoing options.

### 5.2 The lack of pricing policy, why?

In an interview with Representative 1 -head of communications at the VIG- and Representative 2 -legal advisor of the VIG, we talked about the initial idea of formulating a code of conduct and the respective formulation process. The VIG stated that the idea came from the 'young innovators' -the younger members of the VIG- in 2017, because they felt that the association should make a statement regarding its social responsibility and which values it supports (Representative 1 & Representative 2, personal communication, April 21, 2020). This proposition was supported by the rest of the association and this is when the process started. The process of the formulation of the code was described by Representative 1 as one with two phases. During the first phase the association identified the core values from which it wanted to work (Representative 1, personal communication, April 21, 2020). These were identified by talking to the VIG's members; which values they deem important and how they work during their day-to-day operations (Representative 1, personal communication, April 21, 2020). These conversations took place in focus groups. Next to that, the VIG spoke to externals (such as Berenschot) about what to include and what to exclude in such a code of conduct.

The second phase was the implementation of the code: "how the identified values could be translated into norms" and the legal situation in respect to that (Representative 1, personal communication, April 21, 2020). This is where the VIG made use of external advisors, such as Representative 2 and Berenschot. Other than that, the VIG spoke to its members to determine whether they would be able to live up to such norms and values if they were to be included in the code (Representative 1, personal communication, April 21, 2020). This was done in one

large pilot group during which the participants completed an assessment. This assessment then concluded whether the VIG's members lived up to such premises.
After the formulation of the code the VIG also decided that this would not be a static instrument that would be neutral to change, but rather a growth model subject to change. Thus, while the VIG's members have now committed to comply with the code in its current shape, it can always be expanded with supplementary norms and values that the VIG wishes to add (Representative 1, personal communication, April 21, 2020).
Finally, the VIG assembled an Advisory Board that would be able to help with the further growth of the code of conduct (Representative 1, personal communication, April 21, 2020).

The fact that the construction of the code must have been a strenuous process became evident when the process was still ongoing. VIG director Gerard Schouw pointed out that the formulation of a stringent code would likely be harmful to the VIG member-companies, as this would put them in a disadvantageous position on the market of new and expensive drugs, compared to pharmaceutical companies not associated with the VIG ("Berenschot helpt farmasector bij opstellen van gedragscode," 2018). The VIG did not produce the code of conduct by itself but eventually resorted to hiring an external company (Berenschot) to assist them in the process, a year after the VIG started with the initial process. Whether the pricing policy was at the root of the reason to hire an external consultancy is yet to be discovered, but it is safe to say that pricing did provide a critical segment of the code – as it was both the most significant point of critique prior to the creation of the code, as well as the only part to be left out in the final product.

### 5.2.1 Pricing policy

In the interview with the VIG I asked why the decision had been made not to include pricing policy in the code of conduct. Their answer was manifold and they gave the following reasons:

1. "The broader set of norms that is included in the code already covers the fact that our members are required to act in a socially responsible manner, setting a reasonable price for their products is hereby automatically implied" (Representative 1 & Representative 2 personal communication, April 21, 2020);
2. "It is difficult to make statements about reasonable prices and it is doubtful whether these statements actually belong in a code of conduct. For there are a number of

restrictions that need to be taken into account" (Representative 1 & Representative 2 personal communication, April 21, 2020);

3. "It is well-nigh impossible to determine what an excessive asking price would be and is already assessed by the competition authority: ACM" (Representative 1 & Representative 2 personal communication, April 21, 2020);
4. "As a trade association, the VIG does not determine the pricing policy that our members are allowed to set" (Representative 1 & Representative 2 personal communication, April 21, 2020).

While both the first and the last reason generate the impression that including any statement on pricing policy had been out of the question from the start, the VIG stated that the intention was there initially, it turned out too complex of a matter to make a simple statement about (Representative 1 & Representative 2, personal communication, April 21, 2020). The VIG was well-aware of the societal and political expectation for them to "touch upon the sector's transparency and the -perhaps perceived- excessive pricing" (Representative 1, personal communication, April 21, 2020). They were also aware of the fact that providing a code without such statements would probably give rise to criticism. For, "a code of conduct drafted by the sector itself will always be criticized, and will never fully live up to the expectations of the public" (Representative 1, personal communication, April 21, 2020). Due to the fact that the VIG wanted to publish the code nonetheless, yet saw no option of including pricing policy, they decided for the code to be a growth model rather than something definitive and made it available to the public without the inclusion of the sector's pricing policy (Representative 1 & Representative 2, personal communication, April 21, 2020).

Presently, the VIG is looking into whether a statement on pricing policy is possible still, and whether it should be included in a code of conduct at all. Representative 2 argued: "We would love to state in the code that the association and all its members distance themselves from excessive pricing. However, this is evidently already the case since excessive pricing is against the law. Nobody approves of *abuse of dominant position*[12]. Yet, the VIG cannot determine, prior to the assessment of the ACM, whether that is the case or not. That is a significant dilemma" (Representative 2, personal communication, April 21, 2020). Next to that, Representative 1 points out that pricing policy is indirectly covered by other statements made

[12] Abuse of dominant position/misbruik machtspositie is a legal term for a company that takes advantage of its dominant economic position to exclude competition or exploit suppliers or customers ("Misbruik van economische machtspositie," Rijksoverheid).

in the code regarding CSR and the VIG's dedication to the availability of medicines (Representative 1, personal communication, April 21, 2020). Thus, does it even *need* to be mentioned explicitly in the code?

Even though the VIG stated in the interview that there was a primary intention to investigate the possibility of including a premise on pricing policy in the code, the interviewees were unable to pinpoint a certain moment in time where that plan appeared no longer feasible (Representative 1 & Representative 2, personal communication, April 21, 2020). Subsequently, the interview moved on to the topic of transparency.

#### 5.2.2 Transparency

There is a societal and political desire for the pharmaceutical industry to ascertain the public that prices such as 1,9 million euros per dose of a needed medicine for a rare disease (M. Canoy, personal communication, April 14, 2020), or the Leadiant case, will no longer occur. According to the VIG, this is not possible due to the four reasons set out in the previous paragraph. In addition, there is also a pressing desire -or rather- demand from the Dutch government for the industry to be transparent about its production costs (such as the costs invested in R&D and marketing for example), so the consumer will at least know what he/she is paying for (Beverdam, 2019). Yet, this is also not a possibility according to the VIG. For, "what is transparency?" (Representative 2, personal communication, April 21, 2020), asks Representative 2; "An answer to that question which is frequently given is: "*cost-plus pricing!"*. However, it is well-nigh impossible to determine the production costs of one specific medicine. Especially considering the fact that the production companies are producing drugs for the entire world, determining the production costs for just one particular medicine in one particular country is an impossible task. Then there are also people that suggest creating a format that companies could use to demonstrate that they are being transparent. This is, however, not allowed as it leads to price agreements" (Representative 2, personal communication, April 21, 2020).

On top of that, Representative 2 refers to the international implications it would have if the Netherlands were to achieve a "system of true transparency… that could have enormous international effects" (Representative 2, personal communication, April 21, 2020). This is due to the fact that one country looks at the average maximum price of a certain number of other countries, in order to establish its own maximum price. For example, the Netherlands determines its maximum price by taking the average maximum price of Belgium, France,

Germany (will be replaced by Norway soon), and England. “Looking at the number of such ‘reference-pricing systems’, the price of the Netherlands would affect 200 other countries… Hence, such decisions can only be made on an international level” (Representative 2, personal communication, April 21, 2020).

### 5.3 Discussion of research results

It is evident that there is a big contrast between the experts on the one hand, and the VIG on the other. While the experts have various ideas for the VIG to address pricing policy in its code of conduct -if this would have been what the association wanted-, the VIG provides a somewhat scattered set of reasons as to why it did not mention pricing policy in the code. On the one hand the association argues that it is neither the association’s ‘place’ to address its members’ pricing policy in a code of conduct, nor is it necessary because non-excessive pricing is already inherent in both the code and the law which the sector is supposed to uphold. On the other hand, the VIG argues that while the sector was certainly willing to address the matter, this was legally not possible. Thus, the reasons provided by the VIG are both internal as well as external.

Yet, the answers of the experts provided valuable alternatives which the VIG could have used without jeopardizing being in breach of any kind of cartel or competition laws. Other than the legal arguments, however, there is also something to say for the other set of reasons the VIG provided. For example, it is striking that the VIG deems it unnecessary to comment on its pricing policy in the code while it does not deem it unnecessary to mention a wide array of ethical statements that are also already implicit in the law (W. Bannenberg, personal communication, April 28, 2020), or that should at least be self-evident. To stick with the aforementioned example of the primary sentence of the code: “Our behavior is open, responsible and in coherence with the best interests of patients and with that of the general public health”, the production and creation of medicines should clearly be in the best interests of the patients and the public health, what else does one make medicines for? It is also rather noticeable that the VIG does not feel like it is the association’s ‘place’ to address pricing policy in the code. If it is the association’s place to address all other aspects of its members’ socially responsible behavior, why then is the pricing policy not one of them?

Aforementioned considerations aside, in the interview the VIG stated that, ideally, the code would have included a premise such as: “The association and all its members distance themselves from excessive pricing” (Representative 2, personal communication, April 21,

2020). However, Representative 2 stated that the VIG cannot determine, prior to the assessment of ACM, whether something is an excessive price or not. Meaning that as long as the ACM does not determine that a certain behavior is legally forbidden, it is automatically justified (S.[13], personal communication, April 28, 2020). Yet, if a shoplifter is not caught while shoplifting, that person is still a thief. Naturally, non-sanctioned behavior does not equal socially -or morally- responsible behavior. "It is precisely this 'escape clause' that the VIG should have eliminated by addressing pricing policy in its code of conduct" (S., personal communication, April 28, 2020). According to the VIG representatives it is doubtful whether statements regarding pricing policy belong in a code of conduct. However, by indicating what the VIG itself believes to be the limit, in any of the ways that were suggested by the experts, it would have included an ethical principle that fits a code of conduct eminently well.

On top of that, it would be impossible to determine the production price of one single drug for one single country, according to the VIG (Representative 2, personal communication, April 21, 2020). Hence, a cost-plus pricing model would not be feasible. Bannenberg grants that it is indeed difficult, yet definitely not impossible. For, even though pricing differentiation results in the asking price for the same drug being different in the Netherlands than it is in, for example: the United States, the production price for that specific drug is the same for every country. If there are any claimed differences in the production price these can be explained by, for example: medical sales representatives. "These are, however, marketing costs, not production costs" (W. Bannenberg, personal communication, April 28, 2020). What is more, Bannenbergs statement is supported by research conducted by Carin Uyl, who looked into the possibility of a cost-plus pricing model for the pricing policy of cancer drugs (Uyl-De Groot & Löwenberg, 2018).

### 5.4 Chapter conclusion

After careful analysis of the research results it can be stated that although the VIG provided various reasons as to why there was no statement regarding pricing policy included in its code of conduct, none of those reasons appear to exclude any of the possibilities suggested by the experts. Therefore, the research results show that the absence of pricing policy cannot be explained by any of the reasons provided by the VIG, neither legal nor procedural, internal or external. This means that it was not impossible for the association to include a statement regarding pricing policy, yet it did not want to make a statement as such. Hence, the sole

[13] S. is a lawyer. He was consulted regarding the legal discussion within this thesis. Our communication was confidential and could not be used in the thesis with the exception of certain remarks.

remaining explanation to the absence of pricing policy in the VIG code of conduct is one that is already established within the existing body of literature. Namely, that the VIG code of conduct is a document drafted with the purpose of preventing (further) external regulation, improving the corporate image and enhancing stakeholder approval. Not by providing actual answers/solutions to the criticism the sector has been receiving regarding its pricing policy, but by papering over the cracks.

Looking at the theoretical framework of this study and the already established connections to the VIG code, the research results present an anticipated consequence to the neo-liberal manifestations of globalization and the idealism of capitalism that is inherent to that. It seems that, following the lines of previous research conducted by Lexchin & Kawachi, the code 'ticks all the boxes' of an ineffective code of conduct. Taken together with the fact that the research results have provided no other reason to believe otherwise, it appears that the VIG code of conduct is an exemplary case of that which Blühdorn refers to as symbolic politics. The research has demonstrated that the general body of the code can be defined as inadequate to address the issues at hand. This is due to both the absence of pricing policy as well as the fact that it contains the four characteristics of an ineffective code of conduct. Hence, the code seems to be a strategic instrument "geared towards generating false impressions under the cover of which political elites may pursue their own agendas" (Blühdorn, 2007).

Following the lines of Bartley's theory, it is due to the neo-liberal manifestations of globalization that companies are able to create codes as such. For this construction of contemporary society grants companies the power of a magnitude that is equal to that of a political actor and are consequently in the position of determining their own rules and regulations. Indeed, this luxurious position of the ability to self-regulate, taken together with the fact that public governance hinges on corporate reputation, creates a likelihood for companies to use a code of conduct to 'greenwash' reality (Bartley, 2003). Bartley additionally argued that due to the fact that this type of regulation is privatized, it might not live up to the "democratic ideals of openness and accountability" (Bartley, 2003). Hence, a code of conduct might restore corporate images while leaving the daily affairs of the business unchanged. A seemingly unavoidable consequence in this case.

# 6 Conclusion

Various authors have argued that the exceptional societal position of the pharmaceutical industry results in a moral imperative to act in a socially responsible manner. This exceptional societal position comes from its ability to provide life-changing products: medicines. However, despite of the industry being one of the most profitable industries in the world, insufficient access to medicines remains a considerable problem. This can be explained at the hand of the industry's transformation from an industry of drug production to an investment industry. Accordingly, the pharmaceutical industry profits from a problematic system that causes an inaccessibility to essential medicines for numerous people. However, this current business model, which is demonstrated in the absence of pricing policy in the VIG code of conduct, has had its vulnerability exposed as a consequence of the current corona crisis. As it has been illustrated by multiple events during this pandemic that the pharmaceutical industry strives for profit maximization at all times. Next to that, it has become clear that the public is paying the bill of the pharma industry's business model: the health care premiums are ever-increasing due to the fact that the government has to pay excessive prices for new medicines, while not even all the medicines are included in the health care package because some are simply unaffordable.

Consequently, the initial reaction to the VIG code of conduct of those who are critical of the pharmaceutical industry was one without much surprise. It was argued that pricing policy was absent in the code because the VIG is not willing to do anything that could limit the profits of its members. While such assumptions cannot be made without careful examination of the circumstances, the research results of this thesis point in the same direction. This brings me back to my research question: *why does the VIG code of conduct not touch upon the industry's pricing policy?* In order to answer this question I argue that the VIG did not want to include the industry's pricing policy, as the code of conduct was not supposed to inspire actual change in the daily affairs of its business. It was constructed as a strategic instrument to ward off external regulation, and simultaneously restore the corporate image and enhance stakeholder approval of the VIG and its members. This is something which Bartley would refer to as *greenwashing*, and Blühdorn would refer to as *symbolic politics*. Essentially, it boils down to the same principle: the implementation of CSR standards motivated by strategic incentives of TNCs to manage and boost stakeholder impressions, rather than the benefit of the public.

In spite of the fact that it is well-established that private regulation in the form of a code of conduct is predominantly characterized by a lack of enforcement and a failure of initiating systematic change, self-regulation continues to be the preferred form of regulation for corporations on various occasions. As was the case with the VIG: while the government had

options to take up the challenges faced by the pharmaceutical industry as a result of extensive public criticism, it instead chose for private governance. As Bartley previously argued before me, it is due to the neo-liberal manifestations of globalization that matters as such are no longer perceived as governmental concerns, rather as matters of CSR for which the companies or association should take responsibility and find a fitting solution. For, the development of private governance in itself is a demonstration of global neo-liberalism, indicating the ever-increasing power of TNCs, bypassing binding and enforceable public regulation or legislation.

Conclusively, I am of good hope that this case study of the VIG code of conduct during the current corona crisis has successfully demonstrated why a neo-liberal system driven by ideals of capitalism is problematic, especially within the pharmaceutical industry. Due to the industry's importance to the public health and the previously illustrated problematic system that it operates in, *symbolic* codes of conduct that are guided by profit maximization rather than the public interest are not sustainable. Hence, there is a conflict of interest inherent to self-regulatory private certification systems within the pharmaceutical industry.

## 6.1 Limitations and need for further research

As I previously indicated, it is a possibility that my connection to organizations that have taken a critical stance towards the pharmaceutical industry on multiple occasions has limited my access to insightful data from the industry itself. Due to the fact that three out of five participants from the VIG (or representing) either withdrew or postponed their participation to the research this could have resulted in a lack of information from their side. In contrast to those participants, it should be noted that the experts that I spoke to were elaborate and open in their communication. Truth be told, these circumstances could have resulted in an overrepresentation of one side to the story. However, considering the fact that the interviewees from the VIG were invited to participate but chose otherwise, this can also be perceived as a reinforcement of my argument.

All things considered, it is safe to say that I have not been able to take an actual look behind the scenes. During the interview with the VIG representatives they were either unable or unwilling to provide me with an elaborate description of the process of the formulation of the code of conduct. Hence, I have had to rely on publicly available documents to create a timeline of the process. As a result, it is possible that this timeline does not include certain landmarks of the process.

The research results of this study fit the theoretical framework that was used in previous studies on similar topics. In retrospect, the study shed light on the exact elements which I expected to find at the beginning of the research. While one could argue that this is academically beneficial, the intention of the study was to uncover yet unfamiliar insights, contributing factors or arguments that would change the course of the study along the way. However, all things considered it not possible to be certain about why such things were not discovered. Either this is due to my limited access into the internal affairs of the VIG, or there are simply no novelties to uncover.

With regards to the aforementioned limitations, I believe that it would be insightful for a similar study to be conducted by a researcher with a more favorable position in relation to the VIG than myself. With a more substantial insight into the process of the formulation of the code, the research results might lead to different observations. Furthermore, it would also be insightful to see if and how the research results would differ when comparing two similar studies conducted from different positions.

# 7 Discussion and recommendation

At the hand of a case study of the VIG code of conduct, this study has shed light on a more general problem within the pharmaceutical industry. The study has illustrated that the pharmaceutical industry operates in- and benefits from a problematic, neo-liberal system. As I previously argued, the problem of the current system is found within the contrasting goals between the government and the private sector. For, the aim of the pharmaceutical industry is to maximize its profits, while that of the government is to protect the public health. However, there is another question that arises in reaction to this: is Big Pharma the one to blame? Come to think of it, how abnormal is it really for a company -which quintessentially exists in order to make a profit- to be unwilling to undertake actions that would limit its profits? Even though the pharmaceutical industry is part of the public health system, it remains a set of companies. Regardless of its powerful position in society as political actors, granted to them by the government, the pharmaceutical sector is not a government body. Hence, one could argue that it is no more than logical that the pharmaceutical industry operates from an incentive of profit maximization rather than from an ambition to serve the public good.

Bartley pointed out that privatized systems might not live up to the “democratic ideals of openness and accountability” (Bartley, 2003). Therefore, one cannot expect the same standards to be lived up to from privatized systems as of public ones. Looking at other privatized

industries reinforces Bartley's point. Take for example the fossil fuel industry which is operating from an incentive of profit maximization and is consequently polluting extensively. Another example would be the prison body in the United States, where human rights are continuously violated in an attempt to cut corners and respectively maximize profits. In spite of such examples, which demonstrate the conflict of interest between public and private and its respective detrimental consequences, the Dutch government decided to privatize the pharmaceutical industry. This decision was made because the government did not see the benefit to it remaining publicly owned as the high costs that are attached to the development of drugs were too high of a risk for the government to take. Privatizing the industry and it becoming extremely lucrative provided the sector with the incentive to take such risks in return for high profits. Yet now the government is paying excessive prices for medicines which they have ultimately funded themselves, and is simultaneously trying to make the pharmaceutical industry take its social responsibility, which has been a strenuous process to say the least.

However, the absence of pricing policy in the VIG code of conduct has proven that the government cannot expect the private sector to operate from the same ideals and ambitions as the government itself. While the concept of CSR is an admirable addition to corporate affairs, it is simply not the same as government regulation or legislation and cannot be expected to be perceived as such. More public-private collaboration is required if the government wants to prevent additional medicines becoming inaccessible in the Netherlands. Additionally, more legislation and governmental intervention is required to prevent hazardous situations to the public health. The current pandemic has also shown that the pharmaceutical industry cannot simply be left to market forces as this would lead to exclusion. Naturally this is not tolerable as public health is not a private, but a public good. Therefore, the government should take a more powerful stance to ensure the equal right to healthcare.

The priorities of the pharmaceutical industry lie in a place where neither the government nor the public wants them to be: with the money. However, the industry is perhaps wrongly taking the heat for it. It is not reasonable to expect a company to behave as a governmental body and reduce its corporate interests. Hence, the government should take a more active role in achieving the results which it requires from the pharmaceutical sector. Meaning that if the VIG publishes a code of conduct that is insufficient in the Minister's opinion, the government uses its power to intervene. It is false to suppose that one can realize a solution within the framework of the traditional order when this order is at the very root of the issue at hand. As Einstein once

said, “we cannot solve problems with the same thinking we used when we created them.” Hence, as the neo-liberal institutions of globalization are at the root of this problem, society needs to shift paradigms in order to restore a public-private balance with regards to public health. In spite of the novel principles of CSR, the responsibility of this lies not only in the hands of pharmaceutical industry, but also in those of the government.

*“The COVID-19 crisis marks a critical moment for generating the change we need. But how do we go from the neoliberal capitalist logic to something else, towards a system that is driven by the needs of the public and the health of the people?”* - (Commons Network, 2020)

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# 8 Bibliography


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