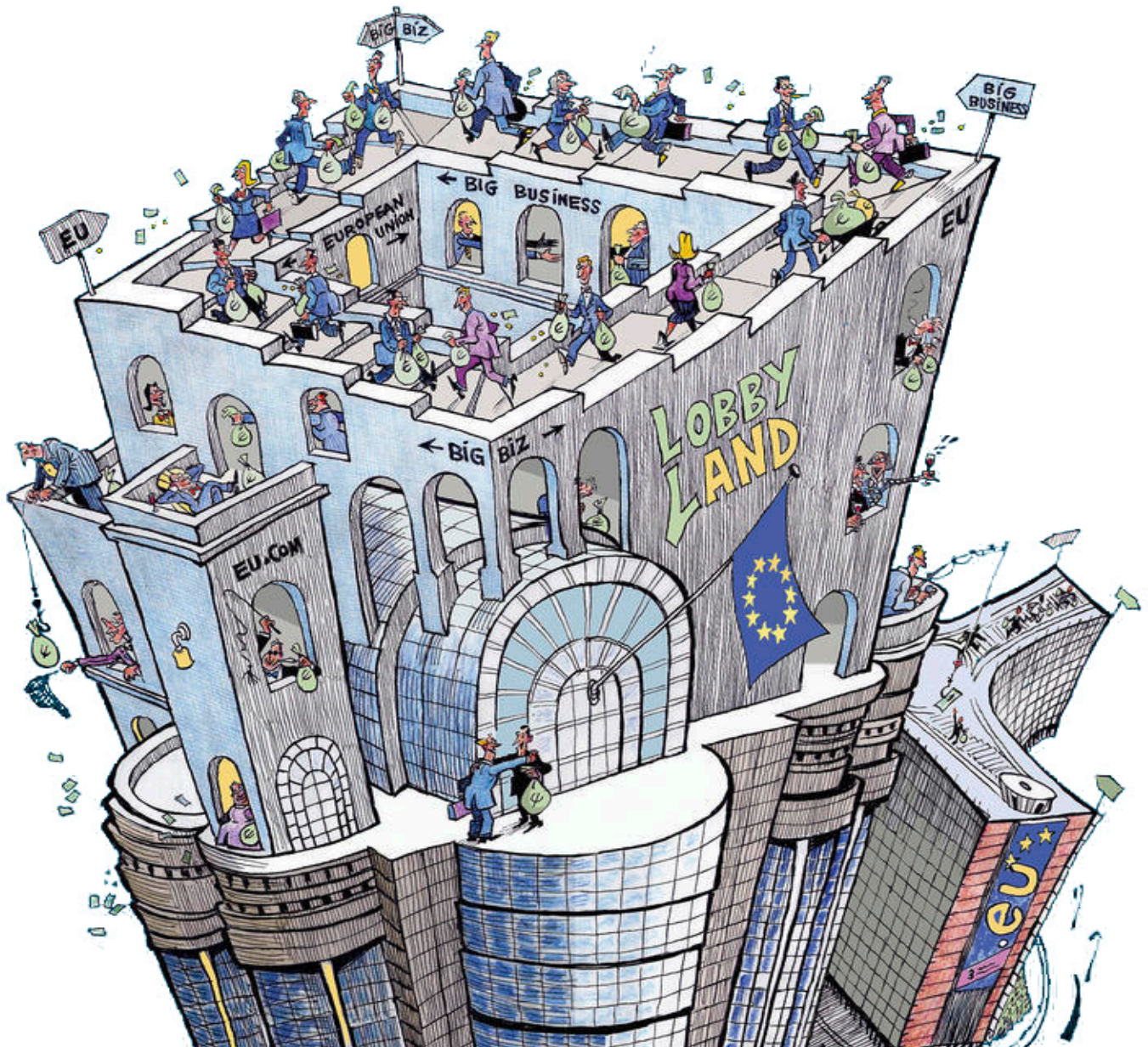


The Democratic Value of Lobby Influence in the European Union Policy Process

The case of pharmaceutical companies and the amendment of
Directive 2001/83/EC

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Abstract

This thesis examines the extent to which lobbyists bring democratic value to the policy-formulation and decision-making stages of the EU policy process. It is examined through a single case study of the amendment of Directive 2001/83/EC.

By adopting an actor-centered institutionalism perspective and through theoretical discussion on Robert Keohane, Fritz Scharpf and Pieter Bouwen, this thesis builds on the understanding of democracy as an institutional arrangement. It thus investigates lobbyists and the resources that constitute lobby influence, as a product of the demand by the EU institutions. The resources are defined as citizen support and economic power. The democratic value of lobby influence is related to the standard of representativeness, meaning that the lobbyists who influence the most in the specific parts of the policy process have to represent a broad array of citizens and societal actors. If influence is biased in favour of lobbyists with economic power as opposed to lobbyists with citizen support, then lobbyists do not bring democratic value to the EU policy process.

By looking into empirical data the lobbyists exerting most influence are found and their interests located. Influence is measured through the preference attainment method and a coding of interests. The empirical data derives from online public consultations regarding the case as well as from a comparison of the preliminary consultation draft, the policy proposal and the final legislative act.

The empirical analysis indicates that the lobbyists gaining most influence are the ones representing associations. Since it is associations with citizen support who exert most influence as opposed to individual companies with economic power, it is concluded that the lobbyists exerting most influence have representativeness. As representativeness reflects democratic value, the lobbyists influencing have democratic value. Lastly since all three EU institutions favoured trading influence with citizen support as opposed to economic power, it is concluded that lobbyists to a very large extent bring democratic value to the EU policy process.

Key words: Lobby, EU policy process, Influence, Democratic value, actor-centered institutionalism

Words: 19,804

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1 Introduction

When a policy is being made it commences with an issue being put on the political agenda. Once a decision has been made to address a specific issue, it is necessary for the European Commission¹ to formulate a proposal for action. Hereafter if the European Parliament (EP) and the Council of the European Union² decides on a policy decision, under co-decision, then the policy must be put into effect (Young 2010, p. 46). This description of the different steps in the policy cycle refers to the roles of the formal institutions in the policy process. However, the policy of the European Union (EU) is a result of strategic interaction among several or many policy actors, these also include informal, yet privileged participants such as lobbyists, and these will be subject to scrutiny in this thesis.

1.1 Problem Area

Interest groups and lobbyists

It is assumed that almost 20.000 separate interests and 26.000 interest organisations are represented in Brussels (Wind et al. 2012, p. 130). The organised interests give input to the EU's political system, and a lot of them are crucial for the output actually being implemented in the national political processes (Ibid). Where the term interest group has a positive connotation, the term lobbyist has more negative connotation (Eising et al 2010, p. 191; Kristensen 2007, p. 11). Discussions concerning lobbying in the EU are often based on negative assumptions and some would even say prejudice (Kristensen 2007). Reality, however, is that we do not actually know that much about the work and influence of the lobbyists in the EU since it is not up for public display. A mandatory lobby register would allow for direct control with lobbyists. However, though not explicitly stated in such register, this thesis aims to evaluate lobby influence using theory and a case.

In the following investigation, the term lobbyists will be used instead of interest groups, and specifically corporate lobbyists since it is a topic subject to a lot of mistrust from the citizens of the EU (Eurobarometer 2013). This mistrust is

¹ Hereafter referred to as the Commission

² Hereafter referred to as the Council

entitled if EU policy is systematically biased in favour of some lobby groups with certain resources such as corporate lobbyists with substantial economic resources (access goods), as opposed to other lobbyists with different resources such as citizen support. If this is the case the democratic legitimacy of policy outcomes is seriously undermined (Klüver 2013; Bouwen 2004).

The pharmaceutical lobby

One kind of corporate lobbyists that has been very criticised are those of the pharmaceutical industry. Europe's pharmaceutical industry is essential because it employs around 700,000 people and stands for 17% of Europe's investments in research and development. Recently, the industry represented 10% of the EU's gross domestic product (EurActiv 2014). According to statistics of the EU Transparency Register, the spending on lobbying activities by the pharmaceutical industry in the EU exceeds 40 million € a year (PMR 2015). Without an obligatory EU Transparency Register however, it is estimated that the expenditures would amount to the level of approx. 90 million € in total (Ibid). This makes the pharmaceutical industry and its lobbyists a very interesting case, wanting to study lobby group influence in the EU.

The credibility of the pharmaceutical industry was seriously harmed after the great case of *AstraZeneca* (Commission 2005). In the case the Anglo-Swedish group AstraZeneca was fined 60 million € by the Commission for misusing the patent system and the procedures for marketing pharmaceuticals to block market entry for generic competitors to its ulcer drug Losec (Ibid). The mistrust surrounding the pharmaceutical industry after *AstraZeneca* is a product of a pharmaceutical company's misuse of EU law after implementation, but it does not tell us anything general about the act of pharmaceutical lobby groups in the policy-making process. Therefore this thesis investigates if the general mistrust in the pharmaceutical industry and its lobby groups has ground in reality. The misuse of the procedures for marketing pharmaceuticals in *AstraZeneca* was a breach of Directive 65/65 later replaced by Directive 2001/83/EC on falsified medicines. This thesis looks into the single case of the amendment of Directive 2001/83/EC concluded after *AstraZeneca*. This is done in order to tease out if the final outcome of the amendment was in fact in favour of the lobbyists from large pharmaceutical companies with large economic resources but with less citizen support. Or if the influence was more equally divided between different kinds of lobbyists with different resources representing a substantial amount of citizens, and thus had democratic value in the EU policy-making process as envisioned by the Commission.

Coping with the democratic deficit

Throughout the history of the EU, the EP has been given more and more

competencies. This has been done in order to create a higher level of democratic credibility, but the discussion of a democratic deficit in the EU is only getting more prominent (Graziano & Vink 2006, p. 161). Furthermore the Commission white paper on governance proposed ‘better *involvement*’ of civil society such as lobbyists by reason of efficient and democratic governance. The Commission launched the European Governance Whitepaper in 2001 as a result of growing EU scepticism. The White Paper proposed the opening of the policy-making process in order to get more people and organisations and thus interests involved in the EU policy-making process (COM OJ 2001, p. 2). In other words, the Commission argued that interests such as the ones represented by lobbyists have a positive influence on EU policy input as a mean to compensate for an otherwise representational deficit. But the question remains, if this is the case in reality? The Commission’s argument thus becomes a hypothesis worth testing and this leads me to the research question of this thesis:

To what extent do lobbyists bring democratic value to the EU policy process in the policy formulation and decision making stages?

The above is the puzzle, and what this thesis aims to investigate in the case of the amendment of Directive 2001/83/EC.

1.2 Purpose and Contribution

The aim of the thesis is to explore the question of democracy in relation to the role of lobbyists. Democracy was not the most salient discussion point during the creation of the EU; public support towards the EU integration process assumed democracy to be implicit through the national representatives in the Council, something often referred to as ‘permissive consensus’ (Hix and Høylund 2011, p. 107). With continued integration, however, the idea of democratic legitimacy has gained potency in the public debate; if the EP is in fact the only democratically constituted European institution, can one then speak of democracy in the EU? And should the EU be measured according to traditional standards of democracy, or is it to be expected that direct democratic rule is impossible in a state of states? The term ‘democratic deficit’ is used to describe this debate, the main point of critique being that the EU is in fact deficient in democracy (Ladrech, 2010, p. 85). With the ever-expanding nature of the EU, the elitist institutional architecture is increasingly being scrutinized. To many it seems ironic that a supranational entity consisting of democratic states – some of which were among the first democracies in the world – should function in a highly technocratic way. Currently, the EU is a central agenda-setting institution, shaping the future of Europe and the member states, having a large influence on numerous areas of policy making (Bache et al. 2011, p. 353). It is also an institution with little direct contact to the citizens, although it has a major direct effect on the livelihood of member state nationals.

Furthermore it is an institution, which is often treated as though it is ‘far away’ and too complex to grasp, being at the same time hard to compare to a normal polity, with which people are otherwise somewhat familiar (Moravcsik 2008, p. 333). This thesis does not want to discuss whether there is a democratic deficit or not, however, it aims to discuss and analyze if the Commission’s idea in order to cope with a possible democratic deficit is consistent with reality.

As such, this study is quite narrow in focus, as it only evolves around one specific case and only in relation to the pharmaceutical lobby. Nevertheless the overall focus on lobbyists’ role in relation to democratic value is highly relevant to European Affairs, and takes part in academic debate surrounding lobby influence.

The analysis is build on vast literature of interest group influence, power and democracy, however though I acknowledge the sui generis nature of the EU in relation to democratic theory, it is not treated as such theoretically. The focus is on democracy as an institutional arrangement and theory by Fritz Scharpf, Robert Keohane and Pieter Bouwen. The ambition thus becomes to identify the lobbyists with access to the policy processes that influence the policy process, and analyse the resources that constitute their influence. Their resources and thus influence is a product of the demand by the EU institutions, and these will be held up against a deduced standard of democratic value: representativeness in relation to equality.

In order to guide this research, the following sub-question will be answered:

SQ: *Do the EU institutions favour lobbyists with a specific set of resources?*

Overall, this thesis will contribute to the literature and the field of European Affairs by offering an empirical analysis of lobby influence and its possible democratic value in the EU policy process. In end be, if the EP and other possible democracy facilitators such as the involvement of civil society and lobbyists is not able to create democracy in the functioning of the EU, it will all mean that the future of millions of European citizens is in fact in the hands of a mystified technocratic institution. It is therefore not only very relevant to examine the democratic value of lobbyists in the EU policy process - it is highly necessary. In the following section concepts related to the research question and sub question will be defined

1.3 Concepts

1.3.1 Lobbyists, interest groups and civil society

According to Princen and Lelieveldt “*a lobbyist is an individual engaged in attempts to influence governmental decision-making on behalf of an interest groups*”(Princen et al. 2011, p. 129). An interest group is a group of people that share certain preference regarding outcomes of governmental decision-making;

they organize in order to influence the outcomes (Ibid). The Commission gathers interest groups under the definition of civil society (COM OJ 2001), this, however, could be misleading, since it could mean that all the interests and the will of citizens; individuals and organizations are always represented. The term lobbyists and the definition proposed above is therefore used in this thesis. Furthermore lobbyists are divided into three categories: The ones representing Associations; Companies and National authorities.

1.3.2 Democratic value

How we define democracy is always subject to a lot of conflicting perceptions. This will be discussed in more detail in the chapter on theory, however the democratic value of lobbyists in the EU policy process in this thesis is related to the representativeness and equality of the lobbyists involved. The quality of lobby involvement is less democratic if the lobbyists exerting most influence in negotiations do not have representativeness and represent a broad array of societal actors.

1.3.3 Resources

This thesis investigates if the EU institutions favour lobbyists with specific resources. The term “resources” is related to Pieter Bouwen’s theory on access-goods. The EU institutions demand certain access goods from the lobbyists in return of influence; the EU policy process thus becomes a bargaining game between private and public actors. Instead of using the term access goods, these will be defined as resources, since I define them as citizen support and economic power. The chapter on theory will elaborate further on this.

1.3.4 Influence and power

Influence in this thesis will be defined as power. Influence can be measured when A gets B to do something B otherwise would not have done, i.e. A changes the behaviour of B (Dahl 1957 in Lukes 2005, p. 16). Influence is further evaluated from the preference attainment method; this will be described in more detail in the chapter on methodology. The lobbyists exerting most influence in the policy process are seen as the ones having most power. I argue that the EU institutions define the distribution of power in the EU, however it becomes interesting to investigate how democratic this distribution of power actually is.

1.4 Previous research

Previous research has aimed at explaining influence in policy processes. Nelson Polsby for instance argues that *“identifying who prevails in decision-making seems the best way to determine which individuals and groups have more power in social life, because direct conflict between actors presents a situation most closely approximating an experimental test of their capabilities to affect outcomes”* (Polsby in Lukes 2005, p. 16). This thesis aims to do the same, however where previous researchers have looked at the concept of influence in relation to access, in this thesis the *actual* influence is researched.

1.4.1 Method

Influence in its broadest form is understood as an actor’s ability to shape a decision in line with his/her preferences, or, in other words, *‘a causal relation between the preferences of an actor regarding an outcome and the outcome itself’* (Dür 2008, p. 561). Measuring the influence of lobbyists in the EU policy process, however, has proven rather difficult. These difficulties mean that only few studies have attempted to measure lobby influence (Ibid, p. 560). Andreas Dür explains distinct problems that hamper the measurement of influence: Two of them are the existence of different channels of influence, and the occurrence of counteractive lobbying (Ibid, p. 561). Inspired by Heike Klüver this thesis assesses lobbyists’ degree of preference attainment throughout the decision-making and policy-formulation stages of the policy process. In the preference attainment method, the outcomes of political processes are compared with the ideal point of actors (Ibid, p. 566). The idea is that the distance between an outcome and the ideal point of an actor reflects the influence of this actor. Klüver further tries to control for the resources behind the actors, affecting their bargaining power and moving outcomes closer to the actor’s ideal point (Ibid.). In this way one gets around the problems as explained by Dür (Ibid, p. 561): The different channels of influence otherwise hard to cover, *are* covered since the preference attainment method enables the measurement of the influence, since influence should by definition be observed in the policy outcome (Klüver 2013, p. 62). Second the occurrence of counteractive lobbying is taken into consideration since the method is only used to display the lobbyists who actually get their interests through, this does not mean that the “losers” lacked influence, but simply that another lobby group maybe with a specific set of resources and thus bargaining power gained more influence.

The agenda setting stage in the EU policy process is left out of scope in this thesis, this poses a limitation according to Bachrach and Baratz since they present another view on power and influence, in which they include the fact that power is also exercised when *“A creates or reinforce social and political values and institutional settings that limit the scope of political process to public consideration of only those issue which are comparatively equal to the interests of*

A” (Barach and Baratz in Lukes 2005, p. 20). The agenda setting stage would thus be where some issues are organized into politics, while others are organized out, the latter is referred to as “*nondecision-making*”(Ibid). Nevertheless this is almost impossible to measure, since this kind of lobbying is hidden from public display, and thus it has been left out of scope.

Robert Dahl’s method is quite similar to the method used in this study since he determines for each decision, which participants had initiated alternatives that were finally adopted (Lukes 2005, p. 17). These actions were then tabulated as individual “successes” or “defeats”. By this pluralistic approach, just like this research, an attempt was made to study specific outcomes in order to determine who prevails in decision-making (Ibid.). Robert Dahl argues that identifying “*who prevails in decision-making seems the best way to determine which individuals and groups have more power in social life, because direct conflict between actors presents a situation most closely approximating an experimental test of their capacities to affect outcomes*” (Dahl 1963 in Lukes 2005, p. 18). Conflict is meant as a conflict of preferences, and interests are to be understood as policy preference (Ibid). Though I acknowledge that interest might be unarticulated or unobservable and people might actually be mistaken about or unaware of their own interests, a feasible way to study power and influence in this thesis involves a focus on outspoken behaviour in the making of decisions on issues over which there is an observable conflict of interests, seen as express policy preferences, revealed by political participation (Lukes 2005, p. 19). The focus in this research as well as Dahl’s is thus on observable behaviour and from this influence and power is measured.

1.4.2 Theory

In relation to the chosen theoretical framework of rational institutionalism, Fritz Scharpf explains how “*...Social phenomena are to be explained as the outcome of interactions among intentional actors – individual, collective, or corporate actors, that is – but that these interactions are structured, and the outcomes shaped, by the characteristics of the institutional settings within which they occur.*” (Scharpf 1998, p. 1). In this sense, just as elite-pluralists would argue, I agree that the EU as an institution limits the access to the policy process.

Theorists of Elite-pluralism explain how elite-pluralism happens because the policy-process, despite claimed intentions of broader consultation, remains dominated by big commercial interests (Greenwood 2007). It is assumed that more than 70 % of EU interests representations with access to the Commission are trade- and commercial interest (Wind 2012, p. 132). However where the access to EU institutions and policy processes is displayed as mostly open to commercial interests, another question is if access equals influence. This thesis evaluates the lobbyists gaining influence in the policy formulation and decision-making process and discovers what constitutes the “winners” of negotiations in the case chosen in

terms of their influential resources. The so-called elite-pluralistic access argument thus becomes less important in relation to this research, as long as the lobbyists, who actually engage *and* influence in the policy process, represent the interests of a substantial amount of citizens, and if the policy input from lobbyists is in fact divided between lobbyists representing different kinds of societal interests. In other words, this thesis does not aim to research whether lobbyists are “good or bad”, but simply if the institutional framework they are being part of in my case facilitates good democratic quality, as argued by the Commission.

In relation to the discussion on democracy, Dimitris Chrysochoou distinguishes between two forms of democratic deficit, these being the socio-psychological and the institutional. The two aspects are connected and take its point of departure in Arblaster and Scharpf (Chrysochoou 2010, p. 379). Arblaster stresses the importance of the demos, and that it is not only the people, but also an idea of a political community of shared values and identities (Arblaster 1987 in Chrysochoou 2010, p. 379). However, the Socio-psychological perspective is left out of account in this thesis because I agree with Robert Keohane and Ruth Grant in that there is a general absence of a well-defined global or European public, as well as a European demos³ on a transnational level in contrast to the demos one talks about in a domestic democracy (Keohane et al. 2005, p. 6). In other words *“States, subunits of states, multinational firms, and NGOs were all created without any act of authorization at all or without having been authorized to act by any set of entities even remotely representative of the EU population as a whole.”* (Ibid.). In the EU it can therefore be argued there is a lack of a ‘civic we-ness’, which is a sense of common identity amongst Europeans and vital in the creation of a European demos. In this case, the demos would be a transnational one where the citizens share an active interest in policy making and are able to direct their democratic claims and rights via central institutions (Chrysochoou, 2010, p. 382). But since there is no demos in the EU to provide the EU with legitimacy, at least not even remotely close to the ones in the nation states, and since this thesis aims to investigate lobby groups, who act beyond nation states, it would be unwise to consider the socio-psychological aspect in terms of the EU’s democracy. This is because it is a concept one can argue is mostly connected to the nation state. The focus will thus be on democracy as an institutional arrangement.

³ A lack of Demos means that the people of the nation-states do not have a feeling of a common European identity

2 Theory

In the first part of this chapter, I introduce the theoretical framework of actor-centered institutionalism to guide my analysis insofar as to understand the function of an institution like the EU and the actions of the actors herein. I further introduce Bouwen's theory on access-goods, from this I am able to answer the question: What kind of influential resources could constitute a lobbyist having more influence than another in the policy-formulation and decision making stages in the EU policy process? However, not if one kind of resource is favoured more than others by the EU institutions? This question will be answered in the analytical chapter in order to conclude on the democratic value of the inclusion of lobbyists in the EU policy process. In the second part of the chapter, I undertake a normative theoretical discussion on the concept of democracy. The question: What determines democratic value? And the sub question: What constitutes a good quality of democracy in terms of equality and representativeness? Will be answered. I shall use the discussion in order to conclude on a final standard of democratic value, necessary for me to establish in order to evaluate the democratic potential of Lobby group participation in the EU policy process, while at the same time grasp the manifold nature of the concept of democracy.

2.1 The role of institutions

The point of departure is in Fritz W. Scharpf's Actor-Centered Institutionalism in Policy Research and its key components in relation to this research. Scharpf labels the framework that has shaped his research Actor-Centered institutionalism. By this, he recognizes the importance of combining actor-centered and institution-centered approaches in an integrated framework (Scharpf 1998, p. 36). The theory guiding this research is deduced from Pieter Bouwen's theory on access goods, but actor-centered institutionalism is the overall framework and starting point for analysis; access goods theory is thus a component of the framework. The theory guides the search for the explanations to who succeeds in getting their interests through in the EU policy process. I further use theory by Robert Keohane. Keohane agrees with Scharpf to a large extent, in that rational-choice and institutionalism are equally important when considering international organizations or international regimes, however, Keohane's theory is only considered to argue in favour of the importance of international institutions in world politics; a position necessary to adopt in this research in order to create a rigid framework for the research and specific focus (Keohane 1984, p. 63). But it

is questioned whether institutions such as the EU always make mutually beneficial agreements for a number of diverse citizens and the lobbyists, who represent them.

Regimes such as the EU facilitate the making of substantive agreements by providing a framework of rules, norms, principles and procedures for negotiations (Keohane 1984, p.110). International regimes help to make the expectations of governments consistent with one another; these procedures help actors to overcome barriers to agreement. Regimes are thus developed because actors in world politics believe that with such arrangements they will be able to make mutually beneficial agreements that would otherwise be almost impossible to attain and this is why regimes are thought necessary (ibid, p. 108).

With his actor-centered institutionalism Scharpf integrates rational choice and structuralisms or institutionalist paradigms, which are being treated as mutually exclusive in the confrontation between economic and sociological theories (Scharpf 1998, p. 36). This fusion of paradigms, he argues, creates a better “goodness of fit” between theoretical perspectives and observed reality of political interaction, driven by “...*the interactive strategies of purposive actors operating within institutional settings that, at the same time, enable and constrain these strategies.*” (Ibid.). Actors will respond differently to external threats, constraints, and opportunities because they may differ in perception and preferences but also because they interact in a specific institutional setting (ibid, p. 37). It thus becomes interesting to investigate the role of the institutions in shaping the outcome of negotiations in the amendment of Directive 2001/83/EC.

2.1.1 Power

Resources can be argued to define influence and power of actors and it may be suggested that all industries will exercise economic power in an attempt to shape regulatory frameworks to their advantage (Edgar 2012, p. 296). According to Robert Dahl, power and influence almost have the same meaning and power is described as: A has the power over B to the extent that he can get B to do something that B would not otherwise do (Dahl 1957 in Luke 2005, p. 16). This statement refers to A’s capacity to the extent that he can get B to do something. Large national and multinational industries and their lobbyists may in addition be seen to have the ability to exert positive and negative sanctions on governments, if rational argument fails their purposes (Edgar 2012, p. 296). Most obviously, production or the sourcing of raw materials can be moved from one country or region to another, impacting upon local employment as well as personal income and tax revenues (Ibid.). Industry has power over government, if it can bring about a policy change that would not otherwise have happened. Equally, EU institutions have power over industry if they can prevent them from acting in a way that they otherwise would have done (Ibid.). Nevertheless the EU institutions

and the lobbyist are more interdependent and this complicates the classical notion of power.

EU policy is a result of strategic interaction among several or many policy actors, “...each with its own understanding of the nature of the problem and the feasibility of particular solutions, each with its own individual and institutional self-interest and its own normative preferences, and each with its own capabilities of action resources that may be employed to affect the outcome” (Scharpf 1998, p. 11). Scharpf argues how policy processes often involve a small number of individual and corporate actors. These actors are involved in purposeful, rational action under conditions in which the results are a joint product of their separate choices (Ibid, p. 5). In this line of thought Pieter Bouwen argues that private and public actors in the EU decision-making process become interdependent because they need resources from each other (Bouwen 2004, p. 340). The EU institutions demand certain resources crucial for their own functioning (Ibid). Bouwen calls these resources “access goods”. The private actors are responsible for the supply of the access goods, however they only gain access to an institution if that institution demands the access good provided (Ibid, p. 341). In a rational-choice theoretic line of thought one can argue that both the EU institutions and lobbyists wish to gain something from interaction. Interest groups seek influence, whereas the EU institutions require “access goods” in the form of policy-relevant information (Greenwood 2007, p. 338). It is not all lobbyists who have policy-relevant information, only those who have citizen support and economic power, the next section will elaborate on these resources.

2.1.2 Resources

This thesis concentrates on the lobbyists representing associations, companies and national associations. The difference between associations and companies is that associations are membership organizations that have individuals, companies, public institutions, or other associations as members. Companies on the other hand are corporate actors and do not have any members. Associations and companies thus have different internal structures and different functions and their pathway to survival is different (Klüver 2013, p. 26). Associations wish to ensure their survival. To do so, they strive for members because these are the main resource providers. In order to attract and retain members, they provide special services to them and seek to maximize their political influence on legislators so that the policy outcome is as close as possible to the policy preference determined by their members (Ibid.). Companies are by contrast non-membership organizations whose function is the production of goods and services, which they trade in order to make profits (Ibid.). The main resource providers for companies are customers who buy their goods and services. Companies therefore compete for customers and strive for high profits, this ensure their survival (Ibid, p. 28). Companies are only able to survive if the profits are higher than the costs they are facing. Since high profits guarantee the survival of companies, the role-specific

interest of companies is the maximization of their profitability (ibid.). Thus associations and companies both want to ensure their survival. But where associations have to attract members, who control the flow of resources, companies have to maximize their profitability (Ibid, p. 29). Associations can draw on two strategies to attract and retain members: They can maximize their political influence and they can provide services to members (Ibid.). Companies can choose from a set of three different strategies: They can acquire new customers, they can reduce costs, which are internal to their production process, or they can influence policy-making in order to bring about a more favourable regulatory environment (Ibid.). Hence, maximizing political influence is an important strategy for associations as well as companies and thus both lobby the European institutions in order to influence the policy-making process.

Their level of resources decides the bargaining power of lobby groups. It is however, not necessarily the same resources that all EU institutions want. According to Heike Klüver the Commission needs the before mentioned expert-knowledge in order to make the best policy-proposal, but both the EP and the Council's first priority can be argued to be citizen support since these two institutions are directly elected and depend on this resource for survival, it thus becomes interesting to see which resources and thus what interests of what actors prevail in negotiations (Greenwood 2007, p. 338; Klüver 2013, p. 32-39).

Both the Commission, the Council and the EP demand economic power from lobby groups in return of influence because they are responsive to concerns raised by companies that control an important economic sector; job creation and business investments than they are to interest groups that do not (Klüver 2013, p. 49). It could thus be argued that both economic resources and citizen support represent specific policy-relevant information in the sense that economic resources enables expensive know-how and expertise, and that citizen support represent a substantial number of voter-positions necessary for re-elections in the national or supranational arena. However, where a high number of represented citizens reflects a certain kind of democratic *representativeness*, economic power does not necessarily do the same. This thesis thus investigates if individual corporate lobby groups with substantial economic power influence more in the policy process than lobbyists representing associations, who represent a higher number of diverse citizens.

The discussion on theories is related to causality and the driving resources affecting the "winners" of influence in the policy-formulation and decision making stages. The driving resources are being exemplified as economic resources and citizen support. The resources are extensive and incorporate many aspects affecting the bargaining position of the lobbyists. In the choice of resources, I have been looking into previous research and theories, and have found these two factors to be the ones most important in relation to the focus on democratic representation and influence.

2.2 Democratic value

The role of democracy in a supranational relation and how to evaluate the quality of democracy in such setting is rather normative in nature, theorists disagree as to whether there is in fact a democratic deficit in the EU, and if so, to what extent and how it can be identified. Measuring the degree of democracy in the EU as whole, however, is difficult due to the complexity of the institutional infrastructure and the variation in the nature of the different institutions; the Commission, the Council and the EP are fundamentally different and intended to uphold each their areas within the functioning of the Union. Treating them as a whole would thus be an unsuccessful exercise. In general, it is difficult to measure, or even perceive, the degree of democracy or lack here of within the EU, simply due to the variety of academic approaches to the concept.

2.2.1 Democracy as an institutional arrangement

As mentioned in the section on previous research, Dimitris Chrysochoou distinguishes between two forms of democratic deficit, these being the socio-psychological and the institutional. This thesis only focuses on the institutional.

When democracy is defined as an institutional arrangement for making decisions, with the legitimacy of those resting on elections, then the institutions of democracy can be viewed as an end in itself in a democratic sense. Institutions thus become the means by which to realize democracy and the common good (Chrysochoou 2010, p. 379). Under modern (Western) conditions, legitimacy has come to rest almost exclusively on trust in institutional arrangements that are thought to ensure that governing processes are generally responsive to the preferences of the governed, this is referred to as input legitimacy, “government by the people” (Scharpf 2005, p. 1). This thesis builds on this understanding of democracy as an institutional arrangement and investigates lobbyists and the resources that constitute their influence, as a product of the demand by the EU institutions. In other words, if the institutional framework they are being part of in this case creates good democratic quality in relation to input legitimacy and the inclusion of lobbyists in the policy process.

2.3 Input legitimacy

Normative disagreement on the concept of “Democracy” remains a controversial subject in academic discussion and public debate (Schmidt et al 2004, p. 4). The concept is contested and associated with diverse ideal requirements and real-world institutions and practices (Ibid.). Democratic representation has conceptually been

linked to the state and, respectively, since the French Revolution, has been linked to the nation state. If that were all that matters, input legitimacy would be ensured by institutions maximizing either the direct participation of the governed in policy choices or the accountability of governors to the collective preferences of the governed (Scharpf 2005, p. 2). But the EU is neither a state nor a nation and consequently one has to rethink the concept of representation and ask which of the various conceptions of representation fit this very particular polity (Kohler-Koch 2010, p. 101; Piattoni 2013; Keohane et al. 2005).

Democratic representation is a crucial element in legitimate governance; however, even though the potential contribution of civil society to the democratic legitimacy of the EU is popular in academic and political discourse, one can argue it is not linked to the concept of representation (Kohler-Koch 2010, p. 101). The EU white paper on governance advocated ‘better *involvement*’ of civil society such as lobbyists by reason of efficient and democratic governance but did not relate to the wider issues of democratic legitimacy in the EU (Kohler-Koch 2010, p. 104).

In order to discuss democratic representation it becomes interesting to look at the specific functions attributed to lobbyists. Pluralists would argue that competition and coalition between big numbers of lobby groups is a predominant governance mechanism in political systems (Eising 2009, p. 1169). The EU’s political process is characterised as being very open to external interests, EU institutions can be argued to be very input-dependent in relation to the surrounding society (Börzel 2010, p. 203). Interest organisations and companies have the expertise and technical knowledge, which is crucial for especially the Commission, since the European administration is very understaffed (Wind 2012, p. 132). However, the democratic representation cannot always do this alone, but the input from functional specific interests, is very important in order for the input-flow to be as broad as possible. The access of interest groups into the political system can therefore be argued to affect the societal legitimacy of the system (Ibid.). Citizens are represented in EU policy-making by lobbyists; it is a case of representation built on the expression of preferences (Kohler-Koch 2010, p. 107).

2.3.1 Representativeness

One can argue that conceptually, governance and representation do not fit well together. This is true according to the perspectives on the division of power in the EU system (Börzel 2010; Kohler-Koch 2010, p. 104). This perspective argues that since the Commission’s competence is restricted to only initiating and executing EU policies, EU governance is mainly linked to the Commission and to the consultation of stakeholders: Stakeholders such as the ones represented by lobbyists. Furthermore since civil society and lobbyists have only a voice not a vote, democratic input legitimacy can be argued not to be at stake (Kohler-Koch 2010, p. 104). The Council and the EP (in case of co-decision), however, have

decision-making authority, and consequently only these institutions have to live up to the standards of democratic representation (Ibid.). Democracy in the EU can thus be defined as an institutional arrangement for making decisions, with the legitimacy of those resting on elections, and the EU can be viewed as an end in itself in a democratic sense (Chrysochoou, 2010, p. 379). In other words, representation is important to the Council and the EP, but governance is important in relation to the Commission. Thus, democratic representation is not an issue of concern in relation to EU governance (Kohler-Koch 2010, p. 104).

In this view, the Commission is not concerned with democratic representation; it is concerned with the *representativeness* of those who want to be consulted. '*Representativeness*' is an attribute of lobbyists; those who want to participate in policy-making have to prove that they are representative (Ibid, p. 110). Representativeness is an important issue in the Transparency Initiative and other initiatives of the Commission aimed at improving EU– civil society relations (Ibid.). Political representativeness ensures that input from the lobbyists into the political system is sufficiently representative of the political community. The most important objective of representativeness is to ensure broad public acceptance, and as a result effectiveness of the policy of democratic institutions. In other words it should be impossible for actors with substantial economic power to fast-track their influence without also being representative i.e. have citizen support. In this way one can question the theory by Heike Klüver, in that the Commission *could have* just as great an interest in the resource of citizen support as the EP and the Council. This is because citizen support equals broad public acceptance and makes it easier for the Commission proposal to go through the EP and the Council in the co-decision procedure. The scope of Heike Klüver's method will thus be expanded in the analysis to also include an evaluation of the representativeness of lobbyists exerting most influence in the analysis.

2.3.2 Equality

Another empirical question in relation to democracy concerns the democratic quality of the input process. In order to qualify as democratic, representation has to live up to the principle of equality (Kohler-Koch 2010, p. 110). Concerning the representativeness of the input process and the enacting of accountability, what actually constitutes representativeness is still highly disputed. The EU institutions, commissioned academics and Non-governmental organizations (NGOs) are quite divergent in terms of criteria (Ibid.). Most common is the insistence on membership from a minimum number of EU countries (Ibid.) (Greer et al. 2011). This thesis look into the criteria of associations' citizen support as opposed to companies' economic power in order to "measure" the state of equality in the inclusion of lobbyists into EU policy process. Economic power and citizen support was chosen because democratic representativeness also regards the plurality of societal actors involved in EU policy-making. The organizational capacity of societal interests is distributed unevenly and, due to the economic

origin of the EU, corporate lobbyists have forceful presence in Brussels (Kohler-Koch 2010, p.110). In order to redress biased representation, the Commission supports so-called 'weak interests' by providing funds and by designing consultation mechanisms that lower the threshold of access (Greenwood 2007, p. 342). Over the years the gap between economic and professional interest groups on the one side and general interest groups on the other has narrowed, but numerous case studies provide evidence that, in terms of social cleavages and territorial origin, representation is still unbalanced (Kohler-Koch 2010, p. 111; Greer et al. 2011). It is important to note that influence in itself does not equal democracy, however indicates whom the EU institutions are interested in trading influence for access goods with. The inclusion of lobbyists therefore has to be treated with caution from a normative standpoint. When evaluating the democratic value of lobby inclusion in the policy process it thus becomes important to stress that lobby participation can only enhance the democratic quality of supranational policy-making if influence is not systematically biased in favour of some interests as opposed to others constantly losing (Klüver 2013, p. 3). The necessity of a balanced presence of societal interests also means, that the lobbyists exerting most are not representative if influence is biased in favour of large companies as opposed to small, and medium-sized companies. The democratic added value thus differs in relation to the *representativeness* of the lobbyists and an overall balanced presence of societal interests (Kohler-Koch 2010, p. 107). In order to decide on the democratic potential of lobby group participation in European policy-making, an empirical assessment of lobby groups' influence and the distribution of influence among them thus become necessary.

2.4 Conclusion to theory

In the first part of this chapter, I introduced my theoretical framework of actor-centered institutionalism. According to this theory policy processes involve purposeful rational actors. Institutions such as the EU, however, facilitate the making of substantive agreements by providing a framework of rules, norms, principles and procedures for negotiations. Actors in world politics believe that such arrangements will produce mutually beneficial agreements, and thus institutions become necessary. However this thesis questions whether institutions always make beneficial agreements for a number of diverse citizens and the lobbyists who represent them.

Pieter Bouwen and his theory on access-goods argues that public and private actors in the EU decision-making process are interdependent because they need resources from each other, lobbyists seek influence whereas institutions require access goods. It is argued that because of their reliance on election, citizen support is important for the EU institutions. Furthermore economic power is also of importance, since lobbyists having these resources control economic sectors, job

creation and business investments. I thus end up arguing that citizen support and economic power are influential resources which could constitute a lobbyist having more influence than another in the policy-formulation and decision making stages of the EU policy process.

The second part of this chapter have concluded on a final standard to determine democracy in relation to the democratic value of Lobby groups participating in the EU policy process. Democracy in this study is defined as an institutional arrangement: The lobbyists exerting most influence and the quality of their democratic value are seen as products of what is demanded by the EU institutions. The EU is an institution, not a state, and should therefore neither be perceived as such. In terms of democratic representation only the Council and the EP have decision-making authority (in the case of co-decision), and only these have to live up to the standards of democratic representation. The Commission on the other hand only has the power of initiating and executing policies. Governance and not representation is thus linked to the Commission and the consultation of stakeholders such as lobbyists. The democratic value of lobbyists in the EU policy process is thus linked to the question of *representativeness*. The specific functions attributed lobbyists is to represent the different interests and views and to bring knowledge and experience of citizens into the policymaking process, the question of equal chance to influence for different kinds of lobbyists is therefore also important. A good quality of democracy in terms of the democratic added value of lobbyists thus differs in relation to the overall balanced presence of societal interests i.e. the democratic representativeness and equality of the lobbyists.

In order to create an overview for the reader, the road to the analysis has been summed up in figure 2.1 on the next page.

Figure 2.1 Step-by-step figure of the theoretical arguments leading to analysis

| | |
|----------|---|
| RQ | <p>To what extent do lobbyists bring democratic value to the EU policy process in the policy formulation and decision making stages?</p> |
| AIM | <p>Testing Commission hypothesis: Interests such as the ones represented by lobbyists have a positive influence on EU policy input as a mean to compensate for an otherwise representational deficit.</p> |
| THEORY | <p>Overall theoretical framework: Actor-centered institutionalism. EP, Council and Commission provide a framework of rules, norms, principles and procedures for negotiations. They demand resources in the form of citizen support and economic power from the lobbyists in trade for influence in the policy process.</p> <p>Democracy is thus defined as an institutional arrangement: Institutions become the means by which to realize democracy and the common good. The resources that constitute the lobbyists exerting most influence is a product of the demand by the EU institutions</p> <p>When the lobbyists exerting influence have representativeness in relation to equality: All societal actors should have a chance of influencing and influence should not be systematically biased in favour of interests with economic power as opposed to others with citizen support constantly losing.</p> |
| ANALYSIS | <p>What constituted the actors exerting most influence in the case of the amendment of Directive 2001/83/EC? This answers the question of the lobbyists the institutions favours the most in relation to trading resources for influence with, and decides if the lobbyists exerting influence bring democratic value to the EU policy process.</p> |

3 Methodology

This section presents the methodological choices and considerations pertaining to the analysis. First it reflects on the single case study method applied and the theoretical framework, before focusing in particular on the chosen method of coding for interests.

3.1 Strategy of analysis

This thesis is a single case study. The case chosen is a critical case as it will allow for testing and a better understanding of the circumstances and processes in which the Commission's hypothesis - that the inclusion of lobby groups foster input legitimacy - will or will not hold (Bryman 2008, p. 55). The case is the amendment of the Directive 2001/83/EC. The criteria for selection was that it is a case of the EU policy process in the area of pharmaceuticals, for which citizens of the EU are very sceptical and mistrusting. Furthermore it is a case of the amendment of a Directive: a general binding legislation and thus the value of the issue is important. It is also a case subject to the co-decision procedure and thus allows for considerable lobbying activities (Commission 2007, p. 10). Lastly a policy proposal was selected for which the Commission had carried out online consultations; otherwise it would not have been possible to find the specific interests of the actors involved.

Working with one case study provides high internal validity and is well suited for generating new hypotheses and checking rival theories (Bryman 2008, p. 55). The level of abstraction is, however low and thus generalizability and the replicability of the findings is limited (Ibid.). This is because the findings create a multitude of hypotheses and are characterized by contradictory findings (Ibid.). It is therefore important to note that the aim is not to identify typical cases or to generalize, but to choose a case of importance, and to test it in relation to the Commission's hypothesis.

In the first part of my chapter on theory I deduct some resources, from Fritz Scharpf and Robert Keohanes theory, that could be of importance in the constitution of lobbyists gaining most influence. A rational-institutionalist view on the role of institutions is thus adopted. According to this view institutions matter and they decide the rules actors such as lobbyists have to follow. Pieter Bouwen's theory on access goods was further used. In Bouwen's theory the EU demands access goods from the lobbyists in return of influence in negotiations.

By using Pieter Bouwen's theory on access goods, a deductive method was applied, deducing two resources of importance from his theory. Citizen support and economic power was found to be of importance in the constitution of lobbyists having more influence than others in the policy-formulation and decision making stages of the EU policy process. Heike Klüver also conclude these resources as being of substantial importance, and they become subject to empirical scrutiny in the analysis. The importance of the two resources will be analyzed by holding these up against empirical findings in order to conclude if lobbyists with one specific resource exert more influence than others and thus if the lobbyists exerting most influence bring democratic value to the policy process.

The chosen theoretical framework consists of different theories. The different theoretical approaches are applied in relation to democracy in the EU in order to answer the problem formulation. The purpose of the second part of the theoretical chapter was therefore to theorize on a standard for evaluating the democratic value of the inclusion of lobbyists in the EU policy process. Furthermore I wish to test and possibly develop Heike Klüver argument that the Commission is more interested in economic power than citizen support, since this institution is not directly elected. I do this by defining democratic value in relation to representativeness, and I argue that citizen support could also be of interest to the Commission. This is because representativeness and citizen support equals broad public acceptance and makes it easier for the Commission proposal to go through the EP and the Council in the co-decision procedure. In this way the theoretical ambition of this thesis is to use existing theory, test it and possibly develop it.

The following sections will in depth describe the method for analysis.

3.2 Coding who influences

In order to look into possible changes between the outcome and the ideal point of the lobbyists involved in the EU policy-making process, the method of coding is used. For the coding, the policy proposal concerning better protection against falsified medicine and thus the amendment of Directive 2001/83/EC was chosen. Working with qualitative data is much more abstract than quantitative data, as there is no specific rule regarding how one deals with the data. Numbers can easily be arranged and placed into systems, whereas it is more complex with words and statements (Bryman 2008, p. 538). Coding indicates that data are broken down into component parts and it hereby links the data to our ideas (Ibid, p. 542). By use of coding, the content of a qualitative text is categorized in order to analyze systematically. This means that when a text or a statement is read, I label sentences of the texts that are relevant to a given proposal and systematize the otherwise less systematic empiric data into numbers. A label in this study will thus occur every time an actor is displaying an interest. Once all texts have been coded, they are re-read and re-coded in relation to what has been learned through

the first coding and, finally, the coded interests are compared. To code each time an interest is displayed reduce the chance of bias. In the end the coded interests are placed in an excel sheet, giving each proposed article, and the interests connected to this, a specific color in order to create an overview.

As an example the pharmaceutical company Pfizer wrote that *“If the use of tamper evident packaging by manufacturers is to be an effective security measure, it is obvious that medicines packs must not be opened at any point in the distribution chain, save by the end-user (hospital or healthcare professional or the patient). The current practice whereby intermediate traders open packs for re-packaging for other markets in course of parallel trade destroys any tamper evident packaging and frequently other security features applied to them by the manufacturer”*. This is a clear display of interest in relation to the ban of repackaging proposed by the Commission in article 4.1.3 of the preliminary consultation draft. Consequently it is marked in turquoise, as it display an interest regarding article 4.1.3. In the same way, as seen in Appendix I on the following Compact Disc (CD), interest displayed in relation to the proposed article 4.1.4 of the preliminary consultation draft is coloured army green and so forth.

Influence is measured in the policy formulation and decision-making stages of the policy process, by looking into public consultations with the Commission. Empirical material is used in the form of public consultation material available on the Commission webpage. From the policy positions from interest group consultation submissions, interests will be extracted by virtue of coding and compared with the Commission's preliminary consultation draft, the Commission's final policy proposal, and the final legislative act adopted by the Council and the EP. The thesis only studies lobbyists representing associations, companies and national public authorities. This is due to the fact that previous studies have found that associations and companies are the most active lobbying actors at the European level and that they contribute to the biggest groups participating in online consultations (Klüver 2013, p. 105). National authorities will be analyzed in order to look at policy positions of member states, which is of importance to the Council and the EP.

The Commission launched a public online consultation, which ran from 11 March 2008 and was open to anyone interested in this issue. The amendment was seen as highly important and the Commission received 123 contributions from stakeholders (COM, 2008). However only 50 submissions are analysed. This has been done since interests have to be displayed in relation to specific parts of the preliminary consultation draft in order to say which lobbyists influenced. Policy position submissions, which only state if the sender is for or against the whole proposal and which do not give any fruitful criticism have thus been excluded as they do not display any specific interests, furthermore individual's submissions have not been considered, since I only study companies, associations and national associations. Lastly three submissions have been excluded due to language barriers in German and French. In the following section the plan of coding is

presented.

3.2.1 Coding for interests

Though Klüver has inspired this thesis, she measures influence through the method of word-count, but as mentioned previously in this chapter, in this thesis hand coding is used. This does not only allow me to find the lobbyists exerting most influence, but it also gives me a chance to look into what the different actors' interests are. The different categories of interests are highly relevant determining the bargaining position of each actor. It is however important to consider the limitations of the chosen method, as there can be some difficulties with the qualitative method. Since the main intention is not to generalize on a basis of many respondents, the data is highly based on interpretations (Saldaña 2013, p. 4). There is no checklist as to how one identifies the most relevant interests, so my personal assumptions will automatically play a role. By doing several rounds of coding however the chance of bias is minimized.

The goal was to code for specific interests, however this is sometimes very difficult. This is because actors are not always either in agreement with a proposal or against, and it has thus been my exercise to decide what their expressions mean. Two examples are given below:

The company *Aegate* wrote in response to the proposal of a Centrally accessible record (Part 4.1.4 of the proposed Directive) that “*An obligatory approach to trace the movement and ownership (pedigree) of a medicinal product is an idealistic solution, not one that is practical in the near term.*” I chose to read the sentence as against the proposed 4.1.4. However, it is not clear here and directly stated that they are directly negative towards the proposal, and on one hand they state that it is an “*idealistic solution*” however on the other hand they state that it is “not practical”. Here as a scholar, I had to make my own clear distinction of what I describe as being against the specific part of the directive. As a coding is never black and white, a specific evaluation criterion had to be developed for being mostly pro or against part 4.1.1. of the Directive. In this line of thought even though *Aegate* think that it is an idealistic solution, they are against a proposal according to its practicality. If *Aegate* did not value economic consideration as related to practicality and effectiveness above patient safety measures, they would have been positive towards an extra measure. Another example of the difficulties of coding is given below:

The Association of the European Self-Medication Industry (AESGP) wrote in response to the proposal of a Centrally accessible record (category 4. Part 4.1.4 of the proposed Directive) that “*Although AESGP does not deny the value of such a proposal in theory, it is not immediately clear how the implementation of such a system would work in practice*”. *AESGP* does not clearly state whether they are positive or negative towards the proposal, and thus they were marked as neutral.

This shows it can be hard sometimes to judge what category the lobbyists should be subjected to. Other scholars might have read the statements differently, but as mentioned I coded the submissions several times and always subjected lobbyists to neutral when in doubt or when contrasting statements were displayed. Furthermore to avoid personal bias of interpretation Celia Stenderup, another scholar was asked to reread and reinterpret whether the interests displayed were pro, neutral or against the proposed articles. Where disagreement between her and I appeared, Celia's interpretation was always favored.

3.2.2 Operationalization

In the analysis the most debated parts of the Directive is brought up for analytical review. These are article 4.1.1, 4.1.3, 4.1.4 and article 4.1.5.

The position of the Commission in the consultation draft, the policy proposal and the final legislative act adopted by the EP and the Council are compared in order to say something about the change in opinion before and after consultation with the lobbyists and lastly the change after consultation with the EP and the Council. This is done in order to say something about the actors who align the most with the policy proposal and thus have influenced the Commission the most, and the actors who align the most with the final legislative act and thus have influenced the EP and the Council the most. However, to grasp the full picture of the winning actors, and relate this to the question of democratic representation, the different constitutions of the winning lobbyists will be studied as well.

In order to evaluate what constitutes the lobbyists exerting most influence in terms of resources, the findings from the coding will be held up against the theoretically deduced standard of democratic value, and the resources of importance to the institutions. Heike Klüver found that citizen support; economic resources and policy-relevant information are three crucial resources for the level of influence of lobbyists in the policy process of co-decision. It is however argued in the chapter on theory, that both economic resources and citizen support represent specific policy-relevant information in their own right, and the levels of these factors are thus what is aimed at looking into within the lobbyists exerting most influence.

In order to understand the lobbying success it is necessary to look at the aggregated citizen support and economic power of the group of lobbyist exerting most influence (Klüver 2014, p. 56). As mentioned in the chapter on theory, the EU institutions are subject to a wide variety of lobbyist who seeks influence in the policy process. The institutions are most likely to trade influence for resources with the lobbyists who are members of the strongest coalition, since the strongest coalition can supply them with substantial amount of resources (Ibid). What matters thus becomes the strength of the coalitions that share the same policy goal. These coalitions are not official, however they will be treated as groups

throughout the analysis, because they share the same interests.

It will be analysed if it is associations as opposed to companies that win in terms of influence. This relates to the concept of representativeness and equality since citizen representation associations have citizen support, while companies have economic power and less citizen support. Furthermore in associations, small companies have a chance to form coalitions in order to influence and this is related to the deduced standard of equality. It will therefore also be analysed if it is the big companies as opposed to the small companies that win in terms of exerting most influence.

As already discussed in the theoretical chapter, lobbyists can represent different sets of interests depending on the type of lobby or interest organisation considered. Citizen representation associations such as the International Trademark Association represents the interests of the consumers and hence the citizens. Their representation is thus based on achieving an outcome satisfactory to their members and their target groups, since these associations justify their role in the policy process by virtue of this exact representation of interests. As such, they translate the wants and needs of the broader, unorganized citizenry into single contact points and trade-in the information sorely needed to the Commission. The Commission needs this information to obtain public buy in via citizen support.

Companies on the other hand are profit-maximisers, indicating their interests will ultimately stem from their self-interest in economic development. This interest can be both regulatory or de-regulatory as some companies might benefit economically from stricter rules matching their existing internal procedures and hence equalling out the competition (e.g. companies already following a stricter packaging standard) while others might support less regulation to limit their costs. Both interests, though divergent, are founded in profit-maximisation logics and hence on representing the interest of the company only. It is important to note that the distinction between associations and companies might be simplistic, yet based on theory.

4 Case Introduction and Analysis

In the first part of this chapter, I explain why it is hard to predict what the outcome of my analysis will be, because of the paradox that lobbyists representing big pharmaceutical companies have substantial power, but that this power at the same time is very restricted. I will further introduce the case investigated and describe the amendments proposed by the Commission. In the second part of the chapter, I will begin my analysis of the empirical data gathered. First I conclude on the most debated aspects of the case in order to narrow the scope of the analysis. Hereafter I turn to the normative standard of representativeness in relation to equality deduced from the theoretical chapter. Having this in mind, an analysis of the resources of the lobbyists exerting most influence will be made. This shows what lobbyists the institutions are mostly interested in trading resources for access with and will help me answer the problem formulation: To what extent do lobbyists bring democratic value to the EU policy process in the policy formulation and decision making stages?

4.1 The power of Big Pharma

In relation to theory of rational-choice, the pharmaceutical companies want to gain something from their interaction with the EU institutions. As companies produce goods and services, they trade in order to make profits; the main resource providers for companies are thus the customers who buy their goods and services. Customers and high profits, just like in any other company, ensure the survival of the pharmaceutical industry, but the pharmaceutical companies are a special case (Edgar 2013, p. 295). This is because of four reasons: First, they face a higher degree of regulation than other businesses. Medicine is potentially dangerous if misused and thus they require extensive regulation, intended to protect the consumer and general public (Ibid). Second, pharmaceutical companies are often prohibited from selling many of their most significant products directly to the consumer. I.e. the consumers are given access to the medicine only through complex systems of gatekeepers within the health service such as prescribing physicians working within the boundaries of national law (Ibid.). Third, and maybe most important, is the fact that the consumer rarely pays either directly or in full to the pharmaceutical companies, consumption can thus not be linked to any clear way of demand (willingness or ability to pay), but instead it is linked to the notion of “need” (Ibid.). Lastly, the legal framework for patenting entails companies to have exclusive rights over the production and sales of a new product for a very limited time (Ibid.). Despite this unusual distribution and sales process,

however, there are substantial profits to gain from the pharmaceutical industry. Because of all the restrictions and regulation surrounding the specific industry of pharmaceuticals one could expect a general trust among the citizens of the EU towards the companies. Yet, the above-mentioned features of the industry also indicate the bargaining power of the pharmaceutical industry.

Because of the “need” for medicine instead of the classical definition of demand, governments as well as individuals are very dependent on the pharmaceutical companies and the specific medicine they produce, this is however also why there is substantial profit to collect in the pharmaceutical industry. Furthermore since pharmaceutical companies are prohibited from selling their products directly to the consumer, they are more prone to use lobbyism as a mean to gain profit. Regulations can thus be argued to demand that pharmaceutical companies exercise its power in a highly distinctive manner. Big pharmaceutical companies have to attempt to influence the perceived legitimacy of government health policies, through complex negotiations including physicians, media, other medical professionals as well as government agencies involved in determining medical formulary (Ibid, p. 296). But as lobbying is a costly affair, it is often only the big pharmaceutical companies known as Big Pharma, that engage in such activities.

In a classical understanding of power and influence, it can be argued that all companies will exercise economic power in an attempt to shape the regulatory frameworks to their advantage. In this line of thought, one could expect Big Pharma to be against the implementation of more regulation measures in order to cope with falsified medicine. This is because regulation measures can be rather costly and because the problem is not substantial enough to them. But instead of a classic understanding of power, Big Pharma’s power can also be argued to include communication skills.

Communication skills can be approached, turning to the significance of advertising and public affairs. As mentioned in the chapter on theory, companies’ interest is to survive, in order to survive they need to have customers, and thus they have to represent the needs of the consumers, however at the same time they wish to reduce costs. In relation to the case at hand The World Health Organization (WHO) estimates that up to 1% of medicines available in the developed world are likely to be counterfeit. Though it can be argued not to be a substantial problem, this figure increases to 10% on a global scale and it is rather dangerous since it regards medicine and it can be potentially dangerous to consume (Jones 2014). The responsibility of solving this problem lies with many actors, one of them is the pharmaceutical industry and it is of interest for them to engage in such debate since the pharmaceutical companies in recent years have seen their images dramatically eroded (Hogerzeil 2013, p. 899). Big Pharma’s public image has been damaged by aggressive patent policies that seriously hamper access to generic medicines for developing countries and by highly visible court convictions for aggressive marketing — for example, in the United States and China (Ibid.). Abuse of patent as in the case of *AstraZeneca*, and as a

consequence higher medicine costs have further hampered the public image of Big Pharma. As a reaction several of the big companies have sought guidance from health experts on improving both performance and public image (Ibid.). The European as well as the international public health community expects a responsible pharmaceutical industry. This means that it becomes hard to predict Big Pharma's strategies, and if the companies in general are actually for or against further directives to cope with falsified medicine.

Though the companies might have substantial economic power, they are also aware of their public image in relation to the consumers and the professional health community. This means that the inclusion of pharmaceutical company lobbyists can be undemocratic in terms of representativeness and a reflection of inequality between different societal actors. However, at the same time lobby influence can be of common good to the European citizens after all, and thus we come back to the assertion that this thesis does not aim to study whether lobbyists are good or bad, but simply if the inclusion of these in the policy process provides democratic legitimacy. The analysis will in more detail investigate the influence of Big Pharma lobbyists, but before this, it is necessary to introduce the case and the specific amendments proposed in relation to Directive 2001/83/EC.

4.2 The proposed amendment of Directive 2011/83/EC on falsified medicine

The point of departure for the assessment of lobby influence is the preliminary draft proposal as it marks the beginning of the legislative process and therefore sets the agenda for the legislative debate (Klüver 2013, p. 156).

As part of the pharmaceutical package, in December 2008, the Commission published a communication in which it proposed a legislative framework to protect the EU from falsified medicine and thus the amendment of Directive 2001/83/EC. The Commission called for several improvements in labelling and handling of medicinal products displayed in a preliminary consultation draft⁴.

Though it can be argued that all the proposed articles were of importance, the majority of lobbyists only brought up a handful in their policy submissions. From the coding of interests in the total fifty policy position submissions from lobbyists Diagram 4.1 on the next page was made. The graph illustrates the extent, to which a certain article was subject to lobbyism, i.e. the articles, which received the most attention. The attention received is here used as a measure for interest

⁴ The proposals are described in Appendix II on the CD.

concentration, i.e. the attention corresponds to the concentration of interests by the participants in the hearing. It was done through a calculation of the amount of lobbyists out of a total of fifty, who mention directly their interest in relation to a specific article of the policy proposal from the Commission. The chart shows how the frequency of lobby interest is highest concerning four proposed articles. These are article 4.1.3 which suggests to improve product integrity through a unique seal from the manufacturer to the retailer or wholesaler, using a risk-based approach, supported by a ban of repacking; article 4.1.4 proposing a centrally accessible record to facilitate traceability of batches throughout the distribution chain; article 4.1.5 which stipulates mass serialisation for pack-tracing and authenticity checks on a case-by-case basis; and finally article 4.1.1 which stipulates that all actors of the distribution chain should be subject to pharmaceutical legislation. These four articles and the interests expressed in relation will serve as subjects of analysis in the following sections.

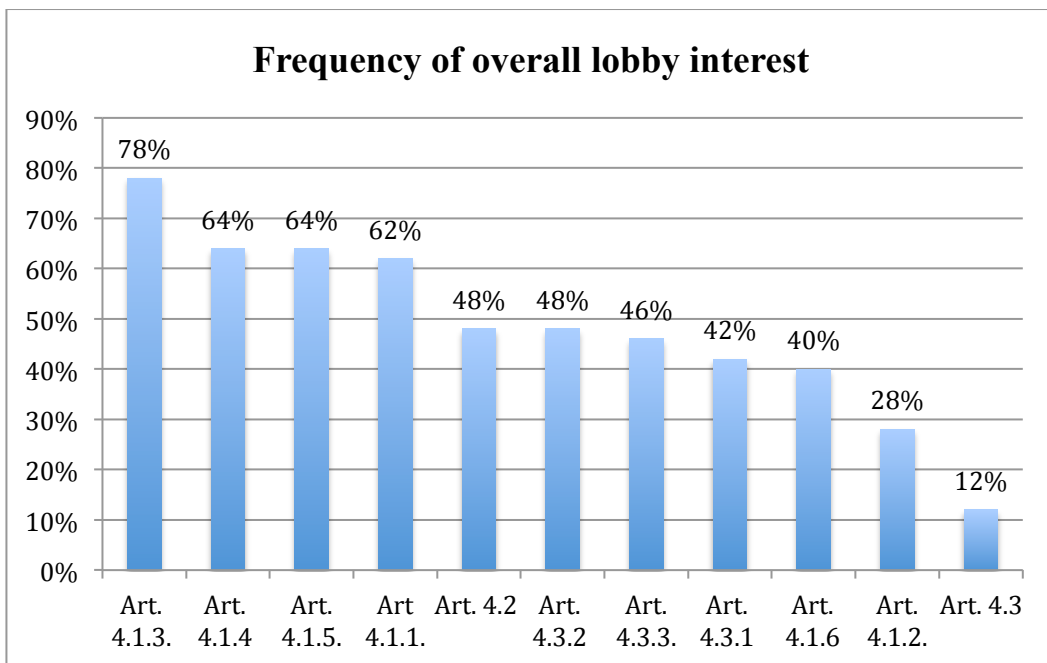


Diagram 4.1 Frequency of overall lobby interest according to specific article proposal in the preliminary consultation draft (N=50).

The analysis will now turn to an analysis of the lobbyists who influenced. These will be analysed from the deduced standards of democratic value.

4.3 Representativeness in relation to equality

As argued in the chapter on theory, the Commission is concerned with the representativeness of those who want to be consulted in the policy process. Representativeness ensures broad public acceptance. Lobbyists thus have democratic value if they represent a balanced presence of societal interests. Large

companies, as well as small and medium sized companies should have equal chance of exerting influence in the policy process, and influence should not only be a consequence of economic power.

4.3.1 The proposed ban of repacking

As mentioned previously in the chapter on previous research and in the chapter on theory, Robert Dahl argues that identifying *”who prevails in decision-making seems the best way to determine which individuals and groups have more power in social life, because direct conflict between actors presents a situation most closely approximating an experimental test of their capacities to affect outcomes”* (Dahl 1963 in Lukes 2005, p. 18). Conflict is thus important in relation to the analysis of interests of lobbyists and what kinds of lobbyists who influence. The conflict is substantial in some cases and minor in others, depending on the policy proposals discussed. Each displays a different problem, which highlights the interest of different actors.

Regarding the proposal of a ban of repackaging referred to in the proposed article 4.1.3 there is a clear division of specific lobby groups in favour and against the proposal. Diagram 4.2 below displays the percentage of national associations, associations and companies respectively, which are pro, against or neutral towards the proposal. What is interesting is that mostly lobbyists representing companies were pro the proposal (80%) and none of them were against, however several associations (31%) as well as national associations (57%) were against such proposal and expressed substantial concern regarding the proposal.

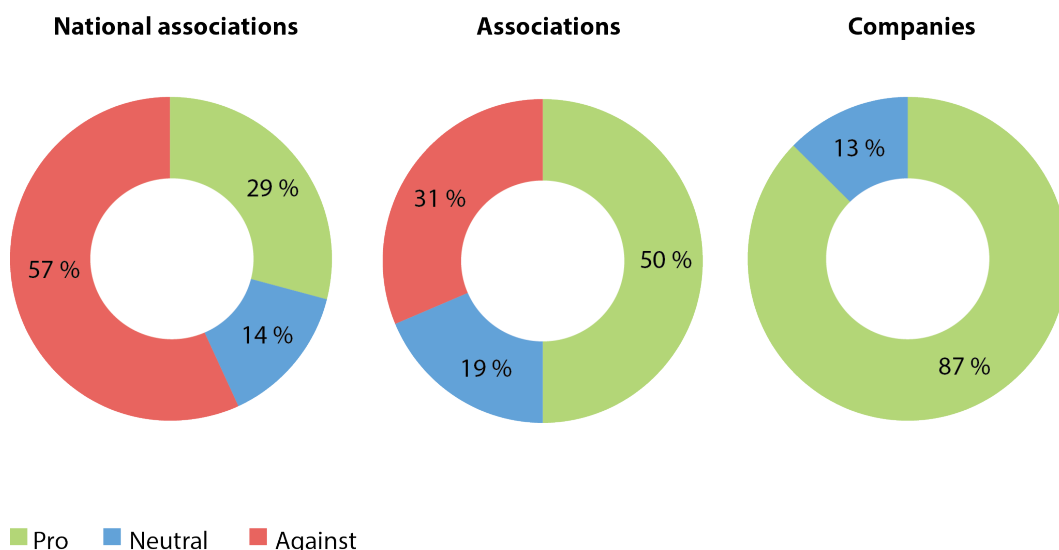


Diagram 4.2 Percentage of National Associations (N=7), Associations (N=17) and Companies (N=15) in favour, neutral or against a ban of repacking, as proposed in article 4.1.3 of the preliminary consultation draft.

The proposed ban of repacking is of special importance to parallel traders. Parallel imports are genuine goods produced under the protection of intellectual property rights (IPR), sold into one market, and then brought legally into another market without the authorization of the local IPR owner (Bicen 2014, p. 25). Throughout the EU a product might be sold at one price in one member state and at another cheaper price in another member state. This makes it attractive for wholesalers, and thus they buy products in one member state, import it into another and sell the products at a lower price. However parallel imports also take place between the EU and third countries and they can also take place regarding products that have not yet been introduced in, and imported to, a given country by the IPR owner.

Parallel import directly results in substantial losses to companies (Ibid). As an example the parallel import of pharmaceuticals was valued at one billion Euros in the United Kingdom alone (Ibid). While parallel trade has negatively impacted manufacturers, proponents of parallel trade highlight the beneficial effects for the end consumers in that the goods become accessible at inexpensive prices (Ibid). In this way especially the proposed ban of repacking in article 4.1.3 of the Commission preliminary consultation draft becomes important, since repacking is vital for parallel importers, who have to repack the pharmaceuticals imported into a new country according to the new country's specific safety feature requirements. The parallel importers are thus against the proposed measure to ban repacking. In other words, being in favor or against the ban of repacking represents divergent interests since parallel import have negative impact on the profit of companies. However, at the same time it is good for the citizens and consumers represented by associations, since parallel imported medicinal products are cheaper and thus more available to a broad array of citizens.

In the legislative proposal, the Commission retained its proposal with minor, though very important changes. In Article 1(9.2) it is directly stated that *"The safety features referred to in point (o) of Article 54 shall not be partly or fully removed or covered-up, unless the following conditions are fulfilled"*. One of these conditions is that *"The manufacturing authorisation holder complies with point (o) of Article 54 by replacing the safety feature (...) without opening the immediate packaging as defined in Art 1(23)."*(COMb 2008, p. 12). The immediate packaging defined in Art 1(23) of the previous Directive refers to the container or other form of packaging immediately in contact with the medicinal product. This definition is highly important, since it is only the outer packaging that is necessary for parallel importers to remove.

Since it was only associations and national associations that were against the proposal, it can be concluded that the associations and national associations against the proposed article 4.1.3 must have influenced the Commission the most in this case. This is further highlighted by the fact that the Commission from the beginning introduced the ban of repacking itself. In relation to theory this means that the lobbyists against the proposal got the Commission not to do something

they otherwise would have done. No consideration, however, was given to the interests of individual companies.

The associations exerting most influence in the case of article 4.1.3 were: Associations of European Self-Medication Industry (AESGP), European Association of Euro-Pharmaceutical Companies (EAEP), and International Trademark Association (INTA). AESGP is the official representation of manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe. It represents more than 2000 companies operating in the consumer healthcare sector in Europe, affiliated with AESGP directly or indirectly through the national associations. The AESGP further includes main multinational companies as well as the European small and medium-sized enterprises of the sector (AESG 2015). The second association is EAEP, who's objective is to: safeguard the free movement of medicines, as laid down in Article 28 EC, and to counteract any attempts to restrict the freedom of choice for the consumer through trading patterns in breach of Articles 81 EC Treaty & 82 EC Treaty. Furthermore it represents 70 firms in the parallel import industry from 16 countries (EAEP 2015). Lastly INTA is a global association of trademark owners and professionals dedicated to supporting trademarks and related intellectual property in order to protect consumers and to promote fair and effective commerce (INTA 2015). What these associations have in common is that they all reflect the interests of a broad array of societal actors, including small, medium-sized and big companies as well as consumers and individuals. This, however, also means that though individual companies did not directly gain influence regarding the proposed article 4.1.3, they could have done so through associations. Nevertheless since the article touch upon issues of parallel import, important to smaller and medium sized companies doing parallel importation, but very undesirable to big companies, the Commission, in this case, could be argued to favour actors with broad societal citizen support as opposed to economic power.

Regarding the proposal 4.1.3 and a ban of repackaging, there was further distinction between interests of actors with substantial economic power as opposed to actors with less. This division was between national associations from big member states as opposed to others national associations from smaller member states. To bring matters to the head, Malta Chamber of small and medium sized companies especially expressed its concern regarding article 4.1.3 and wrote: *“The only entity to benefit from this is what is generally known as the Big Pharma Lobby. Despite its many legal losses over these last 30 years, where it has lost every case in the European Court of Justice challenging Parallel Distribution, this lobby will persist in finding new ways and suborning new entities to its will in its never ending quest to stop Parallel Distribution. We are saddened that of all entities, the Commission, which is the bastion of all that is the EU, has lent its attention to this lobby's entreaties.”* (GRTU 2008 p. 5). The Polish Association of parallel importers of Medicinal products emphasised the same problem and stated *“Parallel import is an activity that is regulated by law,*

*legitimate and subject to full control. As emphasised by Zofia Ulz, it is unfair to give an impression as though this were not the case.”(SIRPL 2008, p. 3). What these associations have in common is that they are both from smaller member states with less economic power than big countries, and thus they rely on the cheaper provided pharmaceutical imports from parallel trading. On the other hand, National associations from bigger countries such as The German association *Verband forschender Arzneimittelherstell* argued in favour of the ban of repacking and stated that: “*Product integrity should be strengthened by obliging manufacturers to seal packs and traders/pharmacies to sell product only with which the manufacturer’s sealing remains intact; this combined obligation for both partners in the supply chain is crucial. Additional leaflets, labels etc., if necessary, could be taped onto the original intact box.*” (VFA 2008, p. 2).*

The Commission thus favoured the associations against the proposal, as well as the national associations from smaller member states. This shows that it is not only the lobbyists from big companies or countries with substantial economic power that always influence, and thus regarding the proposed article 4.1.3 the lobbyists exerting most influence had democratic value in terms of different societal actors having equal chance of exerting influence.

4.3.2 The proposed centrally accessible record

In relation to the proposed article 4.1.4 suggesting a centrally accessible record to facilitate traceability of batches throughout the distribution chain, Diagram 4.3 below show that the majority of both companies (50%) and national associations (75%) were in favour of such proposal. What is interesting is that only the majority of associations (38%) were against a centrally accessible record. It is, however, important to state that no actors were against the general idea of traceability.

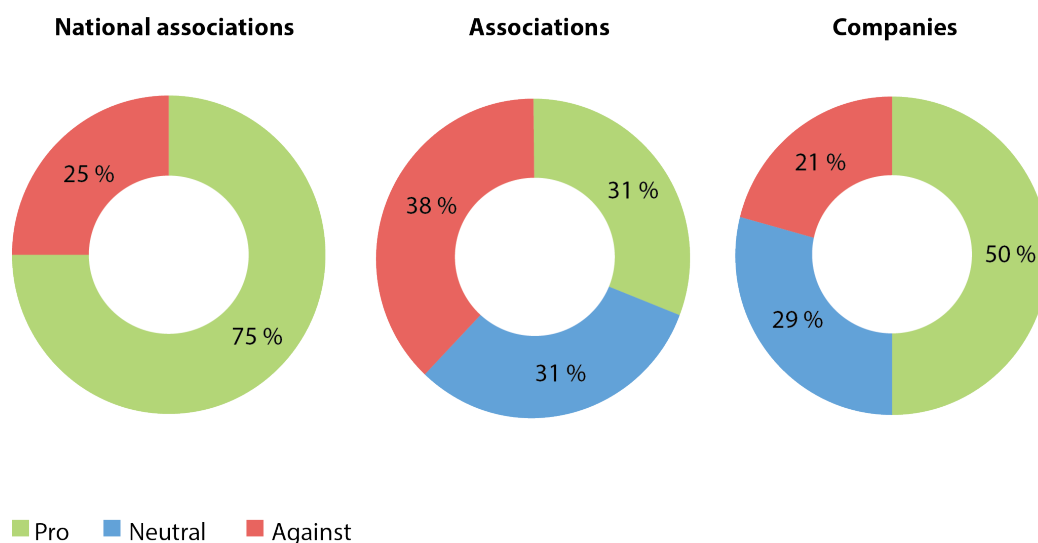


Diagram 4.3 Per cent of national associations (N=4), Associations (N=13) and Companies (N=14) in favour, neutral or against a centrally accessible record, as proposed in article 4.1.4 of the preliminary consultation draft.

In the policy proposal, the Commission included a point referred to in 4.1.4 of the preliminary consultation draft. However where the previous article proposed a centrally accessible record to facilitate traceability of batches throughout the distribution chain, the policy proposal leave out the centrally accessible record and only propose that the holders of distribution authorization “(...) *must keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products received, dispatched or traded (...)*” (COMb 2008, p. 13). The outcome was thus in the interest of the lobbyists that were against the idea of a centrally accessible record as proposed in article 4.1.4.

Since most companies were in favour of the proposal and most associations were against, it can be concluded that the Commission favoured the interests of the majority of associations. Since associations represent several individuals and several companies, the associations can be argued to have citizen support as opposed to individual companies, only having economic power, this support the representativeness of the lobbyists exerting most influence. The Commission thus favoured trading influence for citizen support in relation to the proposed article 4.1.4.

In case of the proposed article 4.1.4, one could, however, assume a division of interests between small and medium sized companies. This is because traceability features such as pedigree and machines to read a batch can be rather costly. Smaller companies might not have the necessary funds to implement the proposed measures. However as seen in table 4.1 below, no pattern exists between big firms with substantial economic power in favour of the proposal, as opposed to small and medium sized companies against. What is interesting in the table is that the division is quite diffuse, most big companies with annual revenue above one billion are in favour of the proposal, however the biggest company Johnson & Johnson is against it, as well as the smallest company Sanofi Aventis.

| Companies against | Annual revenue 2014 | Companies in favour | Annual revenue 2014 |
|--------------------------|----------------------------|----------------------------|----------------------------|
| Amgen Inc. | 16,6 bio € *2013 | Bristol Meyers Squibb | 14,9 bio € |
| Johnson & Johnson | 69,7 bio € | First Odemand Ltd | - |
| Sanofi Aventis | 33,7 mio € | Novartis | 51,6 bio € |
| | | Pfizer | 46 bio € |
| | | Aegate | - |
| | | Reckitt Beckiser | 14 bio € |
| | | Roche | 45,7 bio € |

Table 4.1 Annual revenue of the companies in favour and against the proposed article 4.1.4 regarding a centrally accessible record

The majority of associations however, as mentioned, were against the proposal of a centrally accessible record. Such associations represent small, medium sized and big companies, as well as pharmacists and community pharmacists. It can thus be argued that the Commission favoured the interests of the majority of associations

having citizen support, however not the majority of companies with substantial economic power.

The chance of exerting influence in the policy process by different societal interests has thus proven rather equal in the cases looked into in this section, because an association represent these and because the associations have a chance to gain influence.

4.3.3 The proposed mass-serialisation feature

Article 4.1.5 suggested the possibility to trace each pack and perform authenticity checks, attained by a mass serialisation feature on the outer packaging. As seen in Diagram 4.4. below, 80 % of the national associations, 67 % of associations and 64 % of the companies were in favour of this. What is interesting in the table is thus that the vast majority of lobbyists in all the three groupings were in favour of such suggestion.

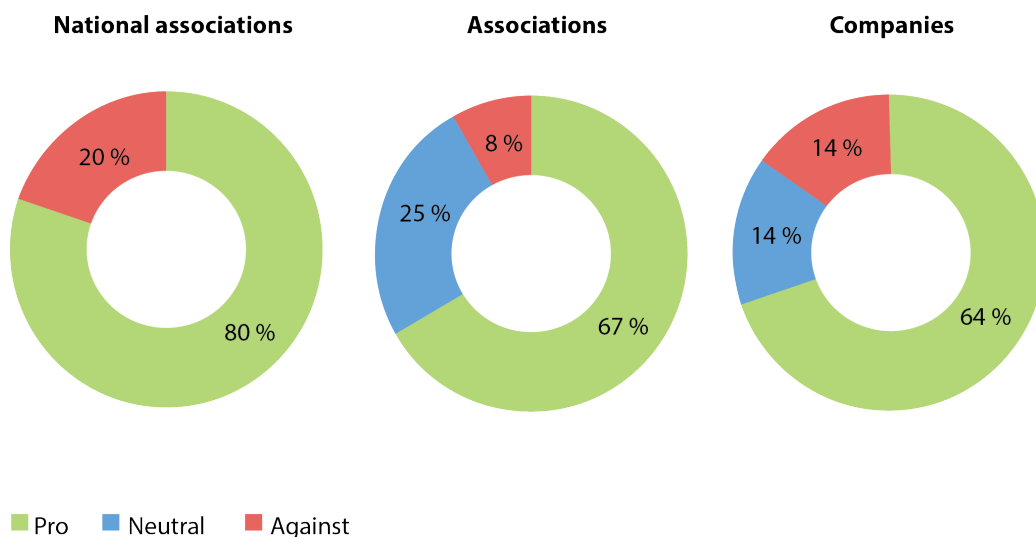


Diagram 4.4 Per cent of national associations (N=5), Associations (N=12) and Companies (N=14) in favour, neutral or against a centrally the proposed mass-serialisation feature, as proposed in article 4.1.5 of the preliminary consultation draft.

In the proposed legislation for the EP and the Council, the Commission respected the majority. Though not specifically referring to a mass-serialisation system it is stipulated that: *In Article 54, the following point (o) is added*". (o) Refers to "safety features making it possible to ascertain identification, authenticity and traceability of medicinal products (...)"(COMb 2008, p. 14). Article 54 in the amended directive refers to specific particulars that shall appear on the outer packaging of medicinal products. The Commission thus respected the interest of the majority in terms of verifying authenticity. Since the lobbyists exerting most influence regarding the proposed article 4.1.5 were the majority of both national associations, associations and companies, together they constitute

representativeness.

4.3.4 The proposal to subject all actors of the distribution chain to pharmaceutical legislation

In relation to the proposed article 4.1.1, and thus to subject all actors of the distribution chain to pharmaceutical legislation, the overall majority of the lobbyists representing different interests were also in favour of the proposal except for the national associations who split fifty-fifty between neutral and in favour. Diagram 4.4 below display how 71 % of companies, 75 % of the associations and 50 % of the national associations were in favour of the proposal. What again becomes interesting to notice is that the vast majority of both companies and associations were in favour.

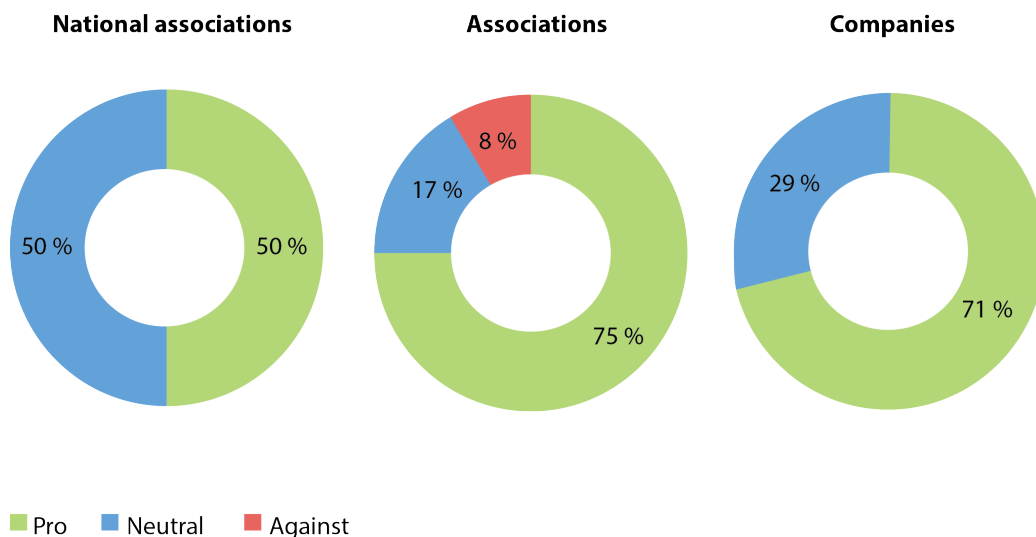


Diagram 4.5 Per cent of national associations (N=4), Associations (N=12) and Companies (N=14) in favour, neutral or against the proposal to subject all actors of the distribution chain to pharmaceutical legislation, as proposed in article 4.1.1 of the preliminary consultation draft.

The Commission respected the interests of the majority and in the final policy proposal it stated that “*In order to ensure reliability in the distribution chain, pharmaceutical legislation should address all actors in the distribution chain: this includes not only distributors who procure, hold, store, and supply products, but also persons who are involved in transactions without handling the products*” (COMb 2008, p. 18).

It can thus be concluded that the Commission followed the interests of the vast majority of lobbyists representing different lobby groups in relation to the proposed article 4.1.1. This was also the case in relation to the proposed article 4.1.5. The result thus means that since the lobbyists exerting most influence regarding the proposed article 4.1.1 were the majority of both associations and companies, together they constitute representativeness.

4.4 Democracy as an institutional arrangement

In this thesis democracy is defined as an institutional arrangement. It is therefore the institutions, i.e. the EP, the Council and the Commission, which shape the outcome of the policy process, also in terms of how democratic the outcome might be. This is because institutions decide who gets influence in the policy process and what resources they are willing to trade this influence for.

In the chapter on theory, Heike Klüver argued that both the Commission, the Council and the EP demand economic power from lobby groups in return of influence. If this was fact, it would mean that the lobbyists allowed to influence by the Commission would not bring democratic value to the EU policy process, since this would effect in only allowing lobby coalitions with economic power, to exert influence in the process. On the other hand I argued in the theoretical chapter, that the Commission could also have interest in citizen support, since it is also interested in the representativeness of the lobbyists exerting influence in the policy process. The latter turned out to be true in relation to the Commission and some of the amendments investigated. In relation to the proposed article 4.1.4, citizen support was favoured more than economic power, since the outcome was in the interest of the majority of associations, however not in the interest of the majority of companies. Citizen support was thus favoured more by the Commission than economic power, since only individual companies have substantial economic power, and because associations have citizen support. In relation to the proposed article 4.1.3, the interests of the individual companies was again not valued by the Commission, this has positive impact on the equality of a chance of different interest to exert influence, since the outcome was in favour of only associations and national associations.

In relation to article 4.15 and 4.1.1, though not directly favouring either lobbyists with citizen support or economic power in the final legislative proposal, it can be concluded that the Commission followed the interests of the vast majority of lobbyists representing many different lobby groups both associations and companies. The outcome of negotiations with the Commission was thus in favour of the majority of each of the different lobby groups and the lobbyists exerting most influence was thus representative.

4.4.1 The final legislative act

With its monopoly of legislative initiative the Commission has an important agenda-setting function: It decides the terms and conditions of any legislative debate because it is the role of Commission to design the content of a legislative proposal on which basis the other institutions bargain about the final legislative act (Klüver 2013, p. 156). This is essential since the lobbyists have to take into account the proposal just like the Commission has presented it; the Commission

premise is therefore starting point, no matter size and power of the lobbyists. Nevertheless it always has to be approved by the Council and the EP. The Commission adopted its legislative proposal in December 2008 and forwarded it to the Council and the EP, for legislative discussion under the Co-decision procedure and the decision-making stage of the policy process (COM, 2008). Interest groups enjoy multiple access points during the decision-making stage. They can establish informal and formal contacts with the Council, the EP, and the Commission to shape the final legislative act. The final legislative act can thus be seen as a result of the interests from lobbyists important for the EP and the Council to trade resources for access with. The Council and the EP approved the final legislative act after the first reading in February 2011 (EP 2011). The institutions made minor changes and the amendment was adopted with 569 votes in favour, 12 against and 7 abstentions (Ibid). The changes are analysed in the following section.

In relation to the proposed article 4.1.3 the text in the final legislative act was the same as the one proposed by the Commission. It was stipulated that *“In order for the safety features to be effective, a manufacturing authorisation holder who is not himself the original manufacturer of the medicinal product should only be permitted to remove, replace or cover those safety features under strict conditions”* (Directive 2011/62/EU (12)). Furthermore a ban of opening the immediate packaging was stressed in article 47(b) (Directive 2011/62/EU). However, not a ban of the outer packaging as the parallel traders had feared. The Council and the EP, just like the Commission did thus not favour the lobbyist with economic power in relation to article 4.1.3. In relation to the Council and the EP it is interesting that five national associations were against the proposition, which was the majority of the national associations displaying their interests on this matter in total. This of course could also have influenced the EP and Council, as the members of these institutions are directly elected on national and supranational levels. However, in relation to the proposed article 4.1.3, just like the Commission, the interests of the individual companies was not valued by the EP and the Council. This have positive impact on the equality of a chance of different interest to influence, since the outcome was in favour of only associations and national associations, but no individual companies.

The proposed article 4.1.4, however was adopted to a larger degree in the final legislative act than it had been in the policy proposal. In the final legislative act something close to a centrally accessible record was proposed, however only described indirectly as safety features that should allow *“verification of the authenticity and identification of individual packs, and provide evidence of tampering”* (Directive 2011/62/EU (11)). Furthermore it is stated that: *“Safety features for medicinal products should be harmonised within the Union in order to take account of new risk profiles (...)”* (Ibid). And that *“The unique identifier as well as corresponding repositories (...) might include commercially sensitive information”*(Ibid). To include a notion of a centrally accessible record was different from the final policy proposal by the Commission. Instead of favouring

the 38 % of associations against, what is interesting is that 50 % of companies and especially the majority of national associations (75%) were in favour. The Council and EP thus favoured the citizen support from the member states, and the economic power of companies, however it would be interesting to see whether the majority of companies would have been favoured, if they did not align with the interests of the national associations. The lobbyists exerting most influence thus had representativeness, as these were the majority of national associations. This also reflects that both lobby actors with substantial economic power, as well as lobby actors with less economic power had a chance of exerting influence, since lobbyists from small companies would have a chance of exerting influence through the national associations of their member states of origin.

The proposed article 4.1.1 was adopted in the final legislative act in the same way as it had been in the policy proposal by the Commission. It stipulates: “*Persons procuring, holding, storing, supplying or exporting medicinal products are only entitled to pursue their activities if they meet the requirements for obtaining wholesale distribution authorisation*”. (Directive 2011/62/EU (6)). This is in line the proposed article 4.1.1. And thus the Council and the EP also favoured the majority of all the lobbyists.

The interests of the majority of both associations, national associations and companies was also respected in relation to the proposed article 4.1.5 and the possibility to trace each pack and perform authenticity checks, attained by a mass serialisation feature on the outer packaging. This was covered in Article 54 and the point (o) added, referring to “*a device allowing verification of whether the outer packaging has been tampered with*”. Though one cannot conclude anything about what resources the EP and the Council favoured, it does tell us that the lobbyists exerting most influence regarding both 4.15 and 4.1.1 had representativeness, since both the majority of associations, national associations and companies was respected in the final legislative act. Furthermore different lobbyists all had equal chance of exerting influence, since associations allow for both big and small lobby actors to influence.

4.5 Conclusion to analysis

In the first part of this chapter, I started out stressing that it was hard to predict the strategy of companies in relation to the chosen case. A realist would argue that big pharmaceutical companies are the ones who always influence the most in negotiations because of their exceptional power. The concept of power in the case of pharmaceutical companies is however restricted, because they rely on public opinion of their consumers.

Hereafter, from the policy positions submission and the coding, four articles was pointed out as being especially important to the lobbyists in relation to the

preliminary consultation draft made by the Commission. These were article 4.1.3 proposing a the ban of repackaging, article 4.1.4 proposing a centrally accessible database, article 4.1.4 proposing a feature of mass-serialisation, and lastly article 4.1.4, proposing to subject all actors of the distribution chain to pharmaceutical legislation.

An analysis of the actors exerting most influence made by a clear distinction of the interests of associations, national associations and companies followed. Concerning article 4.1.3, the outcome in the final proposal by the Commission was that the lobbyists against the proposal were favoured. Since no companies were against the proposal, none of the interests from lobbyists representing big individual companies were favoured. This means that the Commission favoured the citizen support of the associations and national associations against the proposal, but not the economic power of individual companies. Furthermore article 4.1.3 proposed measures seriously hampering small and medium sized parallel importation companies however was in the interests of big companies wanting to stop parallel import, since parallel import decreases the profit of big companies. The outcome was therefore neither in the interest of the economic power of the majority of associations representing big companies. The majority of interests of national associations and 31 % of the associations however *was* respected. This display equal chance of different actors to influence, since small companies, as well as big, and individuals would have had a chance to influence through the associations.

In regards to article 4.1.4 the majority of associations were against a centrally accessible record. The Commission did not propose a centrally accessible record and thus the outcome of negotiations in the final policy proposal was in favour of the majority of associations. The lobbyists from associations, exerting most influence thus had representativeness, since associations represent several individuals and several companies. Furthermore the lobbyists exerting most influence also displayed equality of the chance of different actors to exert most influence, since as mentioned small companies, as well as big companies and individuals can influence through associations. The Commission thus favoured the citizen support of associations as opposed to the economic power of companies concerning the proposed article 4.1.4.

In relation to the proposed article 5.1.5 on mass serialisation and 4.1.4, both the majority of associations, companies and half of the national associations were in favour, and thus the lobbyists exerting most influence had representativeness. Furthermore the lobbyists exerting most influence also represented equality in relation to a fair chance of all the different lobby actors, to gain influence when joining coalition with an association.

Lastly it was concluded that there were no substantial changes in the final legislative act as opposed to the proposal by the Commission, this suggests that the three institutions favoured the same kinds of resources, lobbyists and interests.

However where association's citizen support could be argued to be of importance to all three institutions, especially the importance of the interests of national associations could be argued to be of importance to the Council and the EP, since these institutions favoured the national associations as opposed to the associations concerning the proposed article 4.1.5.

The lobbyists exerting most influence were thus the ones representing associations. Since citizen representation associations represent the interests of the consumers and hence the citizens, they translate the wants and needs of the unorganized citizenry into single contact points, trading information needed by the EU institutions via citizen support. For the EP and the Council, citizen support represents a substantial number of voter-positions necessary for re-elections. In relation to the Commission citizen support relates to the representativeness of the lobbyists since citizen support equals broad public acceptance and makes it easier for the proposal to go through the EP and the Council in the co-decision procedure. The EU institutions thus favoured the lobbyists with citizen support, as opposed to the lobbyists with substantial economic power.

5 Conclusion

On the basis of the Commission white paper on governance, this thesis aimed to prove or disprove if ‘better *involvement*’ of civil society such as lobbyists creates efficient and democratic governance.

With rational institutionalism as a foundation, including Pieter Bouwen’s theory on access goods and Heike Klüver’s theory on EU institutions and interest groups, I created a method in order to evaluate the democratic value of lobby influence in the policy formulation and the decision-making stages of the EU policy process. In relation to democratic value I concluded that the Commission is concerned with the *representativeness* of the lobbyists who want to be consulted. Political representativeness ensures that input from the lobbyists into the political system is sufficiently representative of the political community. The most important objective of representativeness is to ensure broad public acceptance, and as a result effectiveness of the policy of democratic institutions. However, the democratic added value also differs in relation to an overall balanced presence of societal interests. The necessity of a balanced presence of societal interests means that the lobbyists exerting most influence are not representative if influence is biased in favour of some lobbyists with substantial economic power as opposed to lobbyists with citizen support. This definition of having representativeness allowed me to evaluate on the democratic value of lobbyists.

Furthermore, I have attempted to create knowledge as well as understand who the lobbyists exerting most influence were. The knowledge arrived from the methods of preference attainment and my coding and the understanding was created through my interpretation of the outcome based on the theoretical framework. It is on the basis of my choices of theory and method that I answer my research question: To what extent do lobbyists bring democratic value to the EU policy process in the policy formulation and decision making stages?

Defining lobbyists in the three different groupings of national associations, associations and companies allowed me to conclude whether the lobbyists exerting most influence had citizen support or economic power. In most cases the outcome was in favour of associations, and thus associations influenced the most. Citizen representation associations represent the interests of the consumers and hence the citizens. Their representation is based on achieving an outcome satisfactory to their members and their target groups, since these associations justify their role in the policy process by virtue of this exact representation of interests. Companies on the other hand are profit-maximisers, their interests ultimately stem from their self-interest in economic development. Since the

lobbyists who exerted most influence were associations in part of the policy proposal where there was substantial conflict, I argue that both the EP, the Council and the Commission were willing to trade influence for the resource of citizen support. I thus conclude that *lobbyists in general* add substantial democratic value to the EU policy process. It is here important to note that the mere inclusion of lobbyists in the policy process does not by itself amount to democratic value; it is, however, the EU institutions that facilitate the frame by which the possible democratic value of lobbyists can or cannot unfold. In the presented case the EU institutions demanded citizen support from the lobbyists seeking influence. Lobbyists having citizen support translate the needs of the broader unorganized citizenry, and trade-in the information sorely needed to the EU institutions. The institutions need this in order to obtain public buy via citizen support. In this way the EU institutions restricted the influence of lobbyists, so that the lobbyists had to have representativeness in order gain influence. The EU institutions in other words facilitated the right frame, so that the potential democratic value of lobby influence could unfold. As such, the Commission proposal was consistent with reality from the very beginning, in that involvement of lobbyists *can* have a positive effect on democratic governance, as a mean to compensate for an otherwise representational deficit. However, it is the institutional settings, i.e. the needs of the Commission, EP and the Council, that decide if the lobbyists' potential democratic value will be used.

Moreover, I wanted to test and possibly develop the argument by Klüver (2013) that the Commission is more interested in economic power than citizen support, since this institution is not directly elected. I did this by defining democratic value in relation to representativeness, and argued that citizen support could also be of interest to the Commission, since representativeness and citizen support equals broad public acceptance and makes it easier for the Commission proposal to go through the EP and the Council in the co-decision procedure. Nevertheless I expected that companies, because of their substantial economic power, had a possibility to fast-track their influence without proving representativeness. It thus came as a big surprise to me that my analysis showed that the lobbyists who exerted most influence in the chosen case were actually associations. Because it was associations and not the individual companies who gained influence, it can be concluded that the lobbyists who exerted most influence in the case brought democratic value to the EU policy process, since associations represent a broad array of citizens' interests. Furthermore it can be concluded that the lobbyists exerting most influence in the case *to a very large extent* brought democratic value to the policy process, since associations and their citizen support were favoured in both the policy formulation stage by the Commission and in the decision making stages by the EP and the Council.

6 Reflections

The following reflections should be seen as having two purposes. The first section provides critical reflection regarding application of this thesis' findings, the second part ignore the limitations of the thesis and provide possible further research approaches and alternative perspectives.

6.1 Critical reflection

While previous studies have largely provided a static view focusing either on the entire policy-making process or on just one stage of the policy cycle, this thesis compares interest group influence at different stages of the policy-making process. I decided to build this thesis around the policy formulation and decision making stages of the policy process, because these stages allow for comparison in relation to the method of preference attainment. Furthermore it was chosen because especially the policy formulation stage, has been argued by several to be the stage whereat lobbyists have the best chance of exerting influence (Klüver 2013, p. 156). I am however aware of the fact that had other stages of the policy process been taken into consideration, the outcome might have been different and arguably broader. Nevertheless looking into only the policy formulation and decision making stages, allows for a deeper, and arguably more thorough comparative analysis instead of a superficial analysis of more stages of the policy process. Furthermore I am aware that had another case regarding another policy area been chosen the outcome might also have been different. Nevertheless pharmaceutical policy served as an excellent case when investigating the influence of lobbyists, since the pharmaceutical industry are so criticized by the public, and because this industry make use of a substantial amount of lobbyists.

I am further aware that there are other channels for exerting influence in the policy-making process than through public consultation, however most lobbyists who try to influence the policy outcome should be covered by the analysis. This is because consultations constitute the easiest form of access. Furthermore other empirical research has shown that many diverse actors indeed participate in online consultation e.g. associations, NGO's and individual companies (Klüver 2013, p. 95).

As the analysis is based around the chosen theoretical deducted standard and resources, it is important to note which delimitations this might have. Whether the

EU is democratic or not depends on a lot of different variables. In this thesis I look at a handful, which I have deducted from the chosen theories, meaning the conclusion to the problem formulation is directly tied to the theoretical choices made. Only some aspects of democracy are researched, but I believe this is sufficient for the thesis, as it would be impossible to grasp every aspect within the page limit. However, while it is still possible to draw conclusions concerning the democratic value of lobbyists in the EU policy process it is essential to consider that the conclusion is based on the deducted standard of democratic value and the two resources. As these are deducted from some of the main theorists on the field of democracy and institutional theory, it is argued that they are significant and can answer the problem formulation albeit recognizing that generalization can be difficult, granted the conclusion is interlinked with the chosen variables. Furthermore, the result might have been different if other groupings of actors were chosen. However, as this thesis specifically looks at citizen support as a valuable and important asset of lobby groups in relation to their democratic value, the specific division of associations and companies supported the aim of analysis. What could be problematic are associations who also represent companies, as these could deceive the researcher into thinking that they represent citizens but in reality they only represent companies. Nevertheless the proposed article 4.1.3 and a ban of repacking, served proof that this was not the case of the associations exerting most influence, since the proposal was in direct conflict with the interests of big companies, as opposed to small companies using parallel import, and the citizens who gain cheaper medicinal products from parallel import.

While the replicability of the findings in this thesis might be limited due to the specific codings made, the replicability of the method and theoretical claim is what is brought to the study of lobbyists. It can be used in any other case, wanting to evaluate influence by lobbyists in the EU.

6.2 Further research

For the purpose of looking into the democratic value of lobby influence in the EU policy process and on the basis of the findings and conclusion in this thesis, it would be interesting to see if the same pattern of influence and resources is to be found regarding other policy areas. Furthermore it would be interesting to look into the agenda-setting stage and the implementation stage of the policy process as well. Since the agenda-setting stage is very much influenced by the public and media. In the implementation stages it would be interesting to compare different countries' domestic lobby groupings and investigate the lobby groups exerting most influence at this stage. Furthermore it would also be interesting to look into principal-agent theory and responsiveness of the lobbyists exerting most influence, in order to see if the lobbyists actually represent the interests of the represented.

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Table 4.1

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