UHASSELT

KNOWLEDGE IN ACTION

Faculteit Bedrijfseconomische Wetenschappen

master in de toegepaste economische wetenschappen

Masterthesis

Determinants of lobbying success at the EU level: research within the pharmaceutical industry

Lorenzo Caldarella

Scriptie ingediend tot het behalen van de graad van master in de toegepaste economische wetenschappen

PROMOTOR :

Prof. dr. Wim MARNEFFE

BEGELEIDER :

Mevrouw Diana-Maria DANCIU

2021
2022

UHASSELT

KNOWLEDGE IN ACTION

www.uhasselt.be
Universiteit Hasselt
Campus Hasselt:
Martelarenlaan 42 | 3500 Hasselt
Campus Diepenbeek:
Agoralaan Gebouw D | 3590 Diepenbeek

UHASSELT

KNOWLEDGE IN ACTION

Faculteit Bedrijfseconomische Wetenschappen

master in de toegepaste economische wetenschappen

Masterthesis

Determinants of lobbying success at the EU level: research within the pharmaceutical industry

Lorenzo Caldarella

Scriptie ingediend tot het behalen van de graad van master in de toegepaste economische wetenschappen

PROMOTOR :

Prof. dr. Wim MARNEFFE

BEGELEIDER :

Mevrouw Diana-Maria DANCIU

Preface

Deze thesis vormt het sluitstuk van mijn masterjaar aan de Universiteit Hasselt in de Toegepaste Economische Wetenschappen met als specialisaties beleidsmanagement en finance. Het schrijven van deze thesis was een intensief proces vol uitdagingen waarin in ongelofelijk veel heb geleerd, zowel over de farmaceutische lobby op EU niveau, alsook over mezelf. Desalniettemin was dit geen eenzame bedoening, en zijn er enkele personen die een ongelofelijk belangrijke rol hebben gespeeld, en zonder dewelke ik deze prestatie nooit zou hebben kunnen verrichten.

Ten eerste wens ik Prof. dr. Wim Marneffe en mijn begeleidster drs. Diana Danciu hartelijk te bedanken voor al hun steun en waardevolle feedback gedurende het schrijven van deze thesis.

Vervolgens wens ik elke respondent die participeerde in de interviews hartelijk te bedanken voor zowel hun kostbare tijd, alsook hun waardevolle inbreng. Hoewel wegens anonimiteit het niet mogelijk is om deze personen bij naam te noemen, wens ik ze toch op een manier te vermelden in dit onderzoek.

Natuurlijk kunnen mijn ouders niet mankeren aan deze lijst. Gedurende dit hele proces zijn zij een constante bron van aanmoediging geweest, en hebben ze me uitgedaagd om elke dag alles te geven. Hoewel het niet altijd even makkelijk was, hoop ik toch dat ik hun verwachtingen heb kunnen overstijgen.

Ten slotte wens ik ook mijn vriendin hartelijk te bedanken. Dag in dag uit heeft ze me gemotiveerd om door te zetten. Met haar onuitputtelijke bron van geduld en onvoorwaardelijke steun was zij mijn lichtpunt tijdens de moeilijkere periodes van dit proces. Zonder haar was het niet gelukt om deze thesis te voltooien.

Aan eenieder die dit onderzoek leest: veel leesplezier toegewenst!

Lorenzo Caldarella
Genk, augustus 2022

Summary

Probleemstelling

Deze thesis tracht te achterhalen welke determinanten een belangrijke rol spelen in het behalen van *lobbyingsucces* op Europees niveau, meer specifiek gericht op de farmaceutische industrie. Zowel de Europese Unie als de farmaceutische industrie zijn namelijk belangrijke spelers geweest tijdens de COVID-19 crisis, hetgeen de relevantie van dit onderwerp duidt. Tijdens de COVID-19 crisis kwam de relatie tussen beide ter sprake, maar het blijkt nog steeds onduidelijk op welke manier lobbying succes behaald wordt. Wetenschappelijk onderzoek toont aan dat voornamelijk drie Europese instituties "targets" zijn voor *lobbying*-activiteiten: de Europese Commissie, het Europees Parlement en de Raad van de Europese Unie. Bronnen omschrijven bijvoorbeeld financiële middelen en coalitievorming als factoren voor *lobbyingsucces* van diverse organisaties en industrieën. Echter tracht dit onderzoek te achterhalen welke determinanten specifiek van toepassing zijn op de farmaceutische industrie. Zo poogt deze thesis een antwoord te bieden op volgende onderzoeksvraag: "Welke determinanten verklaren *lobbyingsucces* van de farmaceutische industrie op Europees niveau?". Met het doel deze vraag te beantwoorden, wordt zowel een uitvoerige literatuurstudie alsook een empirisch onderzoek gehanteerd. Hierbij werden er 7 respondenten geïnterviewd, elk actief in belangenbehartiging van de farmaceutische industrie op EU niveau.

Resultaten

Deel 1 van de literatuurstudie wijst uit dat er significante verschillen zijn tussen de instituties en hoe toegang verkregen kan worden. Zo wordt de Europese Commissie gekenmerkt door haar technische karakter, terwijl het Parlement en de Raad vooral politiek in aard zijn. Ook werd duidelijk dat het systeem van Europese belangenvertegenwoordiging niet te categoriseren valt onder strikt 1 theorie, maar verschillende aspecten van verschillende theorieën incorporeert in haar systeem. Relevante theorieën zijn onder meer pluralisme, neo-corporatisme, associatieve democratie, exchange theorie en *resource dependency* theorie. Zo wordt toegang verkregen tot de Europese instellingen door een *exchange* van bronnen, en kunnen deze instellingen hierdoor (theoretisch gezien) beter functioneren, waardoor een *dependency* ontstaat. Verder concurreren belangenorganisaties vrij in de EU arena voor hun eigenbelang (pluralisme), maar worden organisaties die tekort hebben aan middelen gesubsidieerd zodat hun belang ook vertegenwoordigd wordt (associatieve democratie). Dit geheel leidt tot een uniek kaderwerk waarbinnen belangenbehartiging geïnterpreteerd dient te worden.

Het tweede deel van de literatuurstudie heeft uitgewezen dat determinanten kunnen worden onderverdeeld in 3 categorieën, namelijk institutionele determinanten, 'issue'-specifieke determinanten en determinanten gelinkt aan de karakteristieken van de belangenorganisatie. Onder institutionele determinanten wordt expliciet democratische verantwoording van de instelling vernoemd. Hier werd bevonden dat hoe minder democratisch *accountable* een instelling is, des te meer er naar belangenorganisaties geluisterd wordt. Issue-specifieke determinanten includeren coalitievorming, saillantie, conflictniveau, omvang en complexiteit van het probleem in kwestie. Coalitievorming blijkt het belangrijkste en meest impactvolle te zijn, vooral in het geval dat de organisatie toebehoord aan een diverse coalitie die relatief gezien groter is dan de oppositie. Saillantie heeft betrekking op hoe belangrijk een bepaald dossier is, hoeveel aandacht dat het

ontvangt van allerlei partijen. In het algemeen zorgt een stijgende saillantie voor minder lobbying succes in het geval van belangenorganisaties die business vertegenwoordigen. Vervolgens zorgen een grote complexiteit, weinig conflict en kleine omvang voor een verhoogde kans op lobbying succes. Ten slotte behoren tot de categorie organisatie-gerelateerde determinanten: financiële middelen, informatieoverdracht en groepstype. Hierbij sprak de literatuur zichzelf geregeld tegen, waardoor geen overtuigende conclusie gevormd kon worden.

Het empirisch deel van deze thesis bracht 9 determinanten voort, die zowel gelijkenissen met degene geïdentificeerd in de literatuurstudie vertonen alsook belangrijke verschillen. Onder de categorie institutionele determinanten vallen: institutionele verschillen, toegang tot beleidsmakers en institutionele bevoegdheden. Meer specifiek blijkt dat de Commissie vooral benaderd dient te worden op een collectieve manier en dat bepaalde politieke fracties in het Parlement minder bereid zijn de belangen van de farmaceutische industrie te horen dan anderen. De graad van toegang tot de Raad hangt dan weer af van nationale factoren. Toegang viel te verkrijgen via zowel officiële gelegenheden, dan wel onofficiële gelegenheden, waaronder vooral evenementen waar leden van het EP worden uitgenodigd. Verder zorgt de fragmentatie van het farmaceutisch beleid tussen het nationaal en Europees niveau voor een bijkomende moeilijkheid. Vervolgens werden coalitievorming en oppositie onder de tweede categorie gebracht. De farmaceutische industrie blijkt samen te werken met een diverse groep andere stakeholders, hetgeen coalitievorming in de hand werkt. De oppositie blijkt dan weer gefragmenteerd en substantieel minder financiële middelen te beschikken als de farmaceutische industrie. Toebehorende tot de organisatie-specifieke karakteristieken vielen middelen, reputatie en eenheid van de sector als determinanten van lobby succes. Reputatie bleek het grootste zwaktepunt van de farmaceutische industrie te zijn. Aan de andere kant, blijken ze te beschikken over een substantiële hoeveelheid middelen, al dan niet financieel alsook op gebied van gespecialiseerde informatie. Ten slotte bleek de farmaceutische sector niet zo eengemaakt te zijn als vaak wordt verondersteld, hoewel interne variatie mogelijk is. Zo is er binnen de innovatieve farmaceutische sector naar verluidt een goede samenwerking, maar zijn de innovatieve en generieke farmaceutische industrie vaak tegengesteld aan elkaar.

Relevantie van het onderzoek

Dit onderzoek draagt bij tot de bestaande literatuur betreffende *lobbying* in het algemeen alsook door de farmaceutische industrie op Europees niveau. Zo wordt er een systematisch overzicht geboden van de belangrijkste determinanten van lobbying succes op EU niveau in het algemeen, en wordt deze ook getoetst bij de farmaceutische industrie. Bijkomend werden er door middel van de interviews enkele nieuwe determinanten geïdentificeerd. Ook tracht dit onderzoek bij te dragen aan de kennis van het algehele publiek, door zich toe te spitsen op een veelbesproken onderwerp waar veel misconcepties over bestaan.

Kritische beschouwing

Een eerste beperking van het onderzoek heeft betrekking op het empirisch onderzoek. Vanwege het specifiek profiel van de respondenten bleek het een uitdaging om een talrijke respons te ontvangen. Bijgevolg nam een steekproef 7 personen deel aan het onderzoek, uit een *pool* van 70 gecontacteerden. Dat heeft tot gevolg dat de resultaten mogelijk niet gegeneraliseerd kunnen

worden tot de hele farmaceutische industrie. Verder bleek het ook niet mogelijk om relevante beleidsmakers op Europees niveau te interviewen, ondanks talloze pogingen tot contact. Hierdoor kon hun potentieel waardevol perspectief niet opgenomen worden in het onderzoek. Dat biedt echter wel een opportuniteit tot verder academisch onderzoek. Verder, ondanks er enkele determinanten bepaald werden die *lobbyingsucces* verklaren, werd echter niet ondervonden hoe groot hun individuele effect werkelijk is. Indien methodologisch en praktisch haalbaar, zou dit wederom een opportuniteit tot vervolgonderzoek bieden opdat die effecten statistisch onderzocht kunnen worden.

Table of contents

1. Problem definition

1.1 Theoretical and practical relevance

The recent COVID19 crisis in the past years illustrated clearly how important healthcare is for Europe. Two of the main players in the fight against this virus were the pharmaceutical industry and the European Union itself. The former succeeded in developing, producing and distributing a new vaccine in a very short time that was considered instrumental in the fight against COVID-19 (Ball, 2020; IFPMA, 2021). The European Union assisted by creating a more flexible legislative framework in which this rapid succession was possible and by coordinating European action so that this new technology could reach European citizens as quickly and efficiently as possible (European Commission, 2020). Nevertheless, the pharmaceutical industry is not always regarded in such a positive manner (Pharmaceutical Technology, 2020). Issues such as access to medicines and pricing can cause conflicts between the industry and civil society groups (Health Action International, 2022; Patients for affordable drugs, 2021).

Like many other industries, the pharmaceutical industry as a stakeholder tries to influence the EU via lobbying. Although it takes on a variety of meanings (Anastasiadis, 2006) and no consensus is found on one definition (Mayer, 2008; Zibold, 2013), lobbying can broadly be understood as "all activities aimed at influencing the decision-making and policy formulation process by special interests" (Zibold, 2013). However, lobbying has gained a negative connotation with the general population over the years, and is often associated with dubious practices such as back-room meetings with little transparency and favouritism (Mayer, 2008). Nevertheless, it still concerns a legitimate activity necessary for democratic decision-making, given that input from multiple different stakeholders in a particular policy domain are taken into account when drafting new legislation in order to ensure a legitimate and effective output (Greenwood, 2019).

Three key EU institutions are involved in its legislative process, thus forming the main "targets" for lobbying action. These institutions are the European Commission, the Council of Europe and the European Parliament. The European legislative process, very abbreviated, proceeds as follows: The European Commission takes legislative initiatives. Subsequently, both the European Parliament as well as the Council of the European Union debate on these initiatives and may propose amendments if necessary. Finally, when both institutions agree on a common text, the legislation is adopted. As this legislation often overrides national legislation, the continuing process of European integration is leading to an ever-increasing influence of the European level on the domestic level (Schendelen, 2013).

The pharmaceutical industry lobby in Europe is composed of a myriad of pharmaceutical companies, trade associations, consultancies employed by the former two and NGO's funded by pharmaceutical companies. Active in different policy domains, the industry pursues issues such as patent and intellectual property rights, investments in R&D, approval and access to medicines (Tansey, 2015). (In)Famous for its big expenditure, according to a rapport made by Corporate Europe Observatory, this group spends an estimated 36 million euro per year on lobbying the EU. A significant portion of this budget is assigned for the lobbyists that are employed, whom are no less than 290 excluding

lobbyists working for hired consultancies (Corporate Europe Observatory, 2021). Important to keep in mind is that, while it is important for pharmaceutical parties to be transparent in order to maintain legitimacy in the European arena, expenditure numbers are self-reported and thus, can also be underreported as insinuated by (Corporate Europe Observatory, 2021). To put these numbers in perspective, public health civil society organisations reported a combined lobbying budget of 6.8 million euros in 2021, which amounts to 20% of the industry budget according to a 2015 report. Additionally, public health civil society organisations employed just about 3.5 times less lobbyists than the pharmaceutical industry (Tansey, 2015). Furthermore, the pharmaceutical industry is said to allegedly have "privileged access" to the European Commission, which is related to the amount of meetings individual pharmaceutical companies as well as trade groups enjoy having with policy-makers from this institution, combined with their presence in expert groups in order to influence public policy (Tansey, 2015).

Academic research on the subject of lobbying covers a variety of different issues, such as coalition building between different parties and the study of the European legislative institutions and their functioning. Yet, research is mainly centred around explaining factors influencing lobbying success (Klüver, 2011; Mahoney, 2007; Stevens & De Bruycker, 2020). Determinants of lobbying success include institutional, issue-specific and organisation specific factors (Mahoney, 2007). However, most of the time only a "macro" perspective is taken into account, where conclusions are based on the group level such as business interests or NGO's as a whole (Dür et al., 2015). While corporate lobbying is a very prevalent subject, it can be assumed that an internal variation is present. This could be attributed to the kind of business at hand and individual/industry expenditure, the level of complexity and/of the relevant policy domains, and EU competencies, which ultimately determines the amount of impact a particular legislation can have.

Given the relevance, importance and peculiarity of the pharmaceutical industry, this research paper attempts to determine which determinants are relevant in explaining pharmaceutical industry lobbying success. Provided academic research mainly makes its conclusions on the group level, this research papers examines which determinants are especially relevant for this specific industry. In order to achieve a comprehensive answer on this matter, a review of the relevant literature is first provided, in order to provide the necessary foundations upon which the empirical research will be built.

1.2 Research objective and central research question

The purpose of this study is to provide an analysis of the lobbying determinants relevant in the pharmaceutical industry lobbying success at the EU level. This includes a brief description of the political arena which is the EU, followed by an introduction to the pharmaceutical industry in Europe. Next, an extensive literature review on the determinants of lobbying success will be presented, in order to lay a thorough foundation on which the empirical research is built. This second part of the master's thesis will be centred specifically around answering the central research question, which is the following:

"Which determinants explain pharmaceutical industry lobbying success in EU decision-making?"

2. Methodology

2.1 Literature review

The literature review consists of three sections. The first section provides a brief introduction to the European legislative institutions, namely the European Commission, the European Parliament and the Council of the European Union, and describes several relevant and unique aspects of each related to lobbying. The next chapter revolves around providing a theoretical approach to interest representation, more specifically to the way it is organised. These theories will additionally be briefly applied to the EU system. These two sections serve to develop a (theoretical) framework in which the following section ought to be interpreted. The third chapter revolves around the determinants of lobbying success. More specifically, it gives a general overview of the most important determinants found in literature and will form the basis for the empirical study.

In order to obtain the necessary literature , several means will be employed, such as search engines, books, databases and scientific journals. Uhasselt library, Google Scholar and EBSCOhost will serve as primary search engines for collecting relevant literature. Additionally, official websites of the European Union can also be consulted when needed.

The following search terms have been used to find sources:

Table 1

EU decision-making	Pluralism lobbying
EU lobbying	Corporatism lobbying
Lobbying the EU	Lobbying success
Lobbying the European Union	Coalition building
Lobbying strategies	Salience
Business lobbying	Information lobbying

2.2 Empirical research

2.2.1 Data collection

Provided the research is of a qualitative nature, data will be collected through one-on-one interviews with relevant respondents. More specifically, the interviews are set up in a semi-structured manner in order to maximise the conversational flexibility needed. Lobbying can at times be quite a complex subject to thoroughly explain, justifying the need for this flexibility. Furthermore, it provides the opportunity to further expand upon unexpected but valuable answers of the interviewee if needed in order to gain more in-depth insights. Invitations will be sent via email to the relevant parties. Moreover, every interview will take place virtually via Google meet and have a projected duration of 30 minutes to 45 minutes. This choice was made with the objective to make the threshold of participation as low as possible for potential respondents, both in terms of time and organisation.

The sample envisioned for the interviews consists of two different target groups. One the one hand, it consists of profiles active in interest representation from the supply side. More specifically, this includes profiles active in public affairs on the European level working for pharmaceutical interests

such as individual pharmaceutical companies, pharmaceutical trade associations and consultancies employed by the aforementioned two. The other group consists of profiles from EU institutions whom are the "target" of the aforementioned groups activities. More specifically, this includes members of the European Commission bureaucracy active in relevant DG's for the pharmaceutical interests, such as DG SANTE, DG COMP, DG TRADE and DG RTD. Additionally, members of the European Parliament are also included in the second group, more specifically MEP's pertaining to relevant committees and their personal assistants. No members from the Council of the European Union are included, given the reported difficulty in gaining access to them. The reasoning behind the decision to interview both groups lies in the fact that their mutual interaction is what constitutes interest representation and public affairs on the European level, with a focus for the pharmaceutical sector. Given the specificity of the aforementioned sample, it is evident that a selective sampling method will be used to gather participants. Judgement sampling relies on the judgement of the researcher to determine what constitutes a representative sample.

The final sample consists solely of profiles from the supply side, with no one from the institutions themselves. After many attempts at contacting policy-makers through various means such as email and phone calls, they either were not available at that time or refuted to participate. The people that did participate in the interviews each chose to remain anonymous due to various reasons. Consequentially, all names, mentions of their proper or other companies and personal information that can lead to their identity have been removed from the transcripts of the interviews and replaced with 'x'. In total there are 7 profiles from the supply side that were interviewed. Each had various years of experience in lobbying, ranging from two years at minimum to 15-20 years. While some were still only associates, others had the seniority to become a director. Two profiles came from two different trade organisations, one related to the innovative pharmaceutical industry, while the other was specialised in biotechnology. One respondent worked for a lobbying consultancy bureau, while another respondent was active in an NGO concerning public health. The other three were attached to individual multi-national pharmaceutical companies active in the innovative pharmaceutical sector.

The following table shows the predefined questionnaire for the interviews. The questions will be posed in chronological order. However, deviation is possible if the respondent provides information related to other questions and improves the flow of conversation. Due to the semi-structured nature of the interview, additional, more in-depth questions not included in the pre-defined questionnaire may be posed if the respondent shares information that is considered potentially valuable for the research.

Table 2

Profile: Public affairs	**Questions**
Introductory questions	Could you briefly introduce yourself, your job and the organization you represent?
Part one: the legislative process & European institutions	Could you please explain the general advocacy process to me? -Which main activities does advocacy entail?

	How would you describe the relationship between policy-makers and lobbyists/interest groups on the EU level? -How does your organisation gain access to these policymakers? -Which are the primary challenges in dealing with these policymakers?
	Is there a difference in advocacy approach between the different legislative institutions? -Who is approached when advocating these institutitions and why? (not names per se, but titles such as the head of unit for example)
Part two: the pharmaceutical sector	How would you describe the position and influence of the pharmaceutical lobby in the European political arena and why? -What would you say are the primary strengths and weaknesses of the pharmaceutical lobby? -What distinguishes the pharmaceutical lobby from other industries in terms of lobbying success? What is this industries unique advantage at the EU level?
	In which policy domains is the pharmaceutical mainly active and what goals does it pursue? -Which topics are the most important for the pharmaceutical industry? -Which factors would you say explain pharmaceutical advocacy success in these domains?
	Which factors would you say explain pharmaceutical advocacy success?
	Do pharmaceutical interests often act in unison/coalition or is it more a fragmented lobby/industry?
	Does your organisation/the pharmaceutical lobby prefer to lobby alone or collectively? Could you please explain the reasoning behind your answer?

Part three: coalition building	Does the pharmaceutical lobby often engage in coalition building? -If yes, which factors are considered/decisive when engaging in a coalition? -If not, what would be the reason for this? -What are, in your opinion, the primary benefits and costs of engaging in a coalition?
	Does the pharmaceutical industry have sustainable strategic alliances with other interest groups/sectors that you know of? -Which sectors and why?
	What about strategic alliances between pharmaceutical companies? Do they often work together politically as a 'block' and is the competition only economic or is there also a great deal of competition on the political/PA level?
	Are there certain interests that frequently oppose the pharmaceutical lobby? -What is the cause of this? -Is the composition of the opposition constant or is it issue/theme specific? -In what way do they counterlobby?

2.2.2 Data analysis

The data analysis process follows a systematic approach. First and foremost, after conducting the interviews each of them is transcribed in order to obtain a raw dataset. Afterwards, the relevant paragraphs are selected and copied into Microsoft Excel, where each will be given three specific codes. Firstly, open encoding is applied. This entails labelling each paragraph according to their respective content in such a way that they can be distinguished. Often specific wording from the paragraph itself is used in this stage. Subsequently, axial encoding is applied. This is done by grouping several paragraphs and bringing them under one label or theme. This encoding is more abstract than the first one, and is done in order to increase the comparability of statements among the respondents. In this specific case, the axial codes that are given are identified determinants of lobbying success. Lastly, selective encoding is applied. Here, paragraphs grouped in axial encoding are assigned according to the category which they fall under an attempt to give a conclusive answer. Following is the coding tree that was followed in order to become the proper encoding.

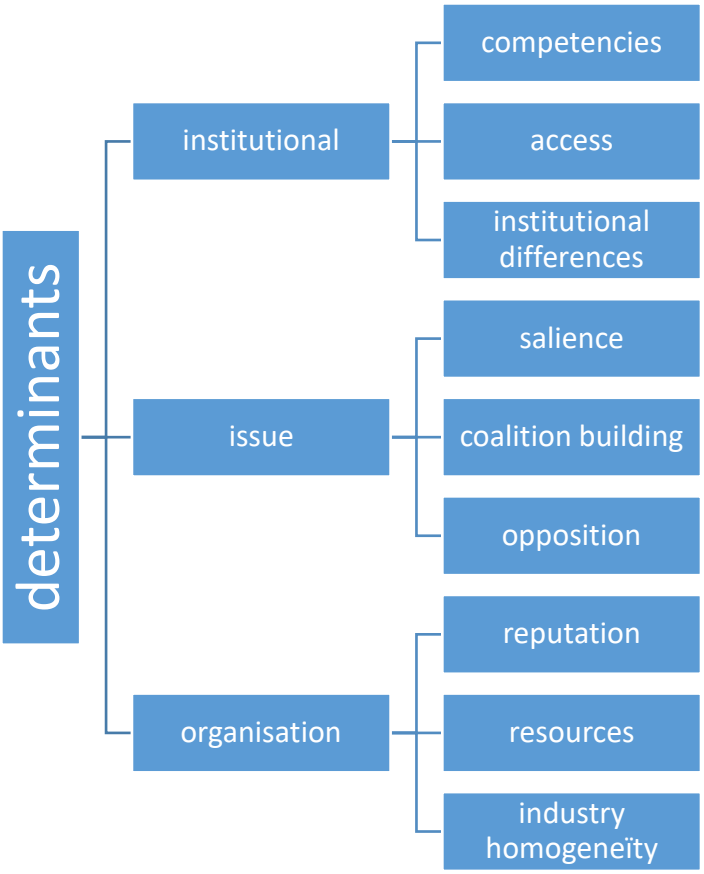

Figure 1. Coding tree

3. Literature review

Chapter 1: the European institutions

The following section of the literature review will consist of a brief introduction and overview to the EU legislative process and the institutions involved. Given the institutional complexities and peculiarities of the European level compared to the national level, this section will serve as a foundation to better understand the rest of the master thesis considering it is a recurring subject. Furthermore, it will highlight the difference between different lobbying arena's, given that certain findings may be true at the European level but maybe not in e.g. Washington (Dialer & Richter, 2018)

3.1.1 Ordinary Legislative Procedure

The Legislative content produced in the European Union can be separated into three categories, described from the top of the hierarchy of norms to bottom. The first category is referred to as 'Primary law' and concerns all treaties that regulate the behemoth that is EU bureaucracy, such as relevant procedures, institutional authorities et cetera. The second category is dubbed 'Secondary law' and concerns all legislation applicable to the member states. This includes 'direct' legislation such as regulations and decrees, as well as 'indirect' legislations such as directives, where national governments of member states have more room to determine the content themselves. These two categories are referred to as legislative acts and are drawn up in accordance with either the Special Legislative Procedure (SLP) for primary law, or the Ordinary Legislative procedure (OLP) for secondary law (European Commission, n.d; Schendelen, 2013). Given the subject and goal of this master's thesis, only the legislative procedures concerning secondary law will be described.

3.1.1.1 Formal procedure

The Ordinary legislative procedure (OLP) is the principal legislative procedure by which new secondary legislation is formed. Formerly referred to as the co-decision procedure pre-Lisbon Treaty, three European institutions are involved in this procedure (Schendelen, 2013). The European Commission has the right to initiative and draws up a proposal on new legislation. Hereafter, this draft gets passed on to both the European Parliament and the Council. These institutions have the authority to accept and reject this new proposal, but also to make amendments as they see fit. Yet for legislation to be adopted, both institutions need to agree on the same text, otherwise the legislation will be rejected. To allow for amendments to be incorporated and compromises to be found, the act is voted on in a series of three readings or stages, with a sub stage involving a special committee before the third reading. (Bauerschmidt, 2021; Coen & Richardson, 2009; DG IPOL & LEGI, 2019)

3.1.1.2 Trilogues

However, the formal procedure can take up 2 or 3 years, especially if agreement is reached only after the third reading (DG IPOL & LEGI, 2019). Therefore, more flexible practices have been established alongside it, such as trilogue meetings. Trilogues are informal meetings behind closed doors, where the EP and Council try to form an early agreement about the legislative proposal from the EC with the aim to speed up the legislative process and make it more flexible (Bauerschmidt, 2021). Trilogues are also called Tripartite meetings as the EC also participates, albeit only as a mediator to stimulate compromises (DG IPOL & LEGI, 2019). Furthermore, all three institutions are

represented by only a few key individuals. For example, the EC sends its relevant DG and other experts in the field of the legislation, the EP sends its rapporteur and shadow rapporteurs and finally, the Council sends an ambassador from the member state holding the presidency at that time and the chair of the relevant working party/parties (Bauerschmidt, 2021). Furthermore, the first meeting takes place as soon as both institutions have made their positions clear regarding the EC legislative proposal. Additional Trilogue meetings will take place before the second and third reading if no agreement has been reached at the first reading (Guéguen, 2019).

3.1.2 The European Commission

The first institution to be addressed in the OLP is the European Commission (EC). Led by the Commission president and its College of 27 Commissioners, they are assisted by a bureaucracy of no less than 33 policy departments referred to as Directorates-Generals, excluding other departments such as General services and Executive agencies (DG IPOL & LEGI, 2019; Schendelen, 2013). In charge of the first stage of the legislative process, the EC is arguably considered the most influential and impactful institution by virtue of being the only institution with the right to initiate legislation (Coen & Richardson, 2009). This primary responsibility includes a multitude of other activities, such as conceiving a new legislative idea and drafting up a valid proposal, but also actively consulting with stakeholders (Schendelen, 2013).

Before the EC effectively starts a legislative process, there needs to be a legislative impulse. This can be brought about by internal stakeholders, such as the policy-making departments of the EC itself, the EP or the Council, but also from external stakeholders, such as trade associations and groups of socially engaged NGOs (Coen & Richardson, 2009). Given the myriad of problems the EC is confronted with, combined with its resource constraints, agenda-setting becomes an additional but necessary activity in order to choose which issue to prioritise, or even handle at all. Simultaneously, this also implies a gatekeeping role of the Commission: including certain issues on the EC agenda means excluding other issues, which results in no legislative process being initiated.

When an issue is deemed important enough to handle, the legislative process officially starts. The first phase hereof is referred to as the drafting phase. Here, the specialized DG's are tasked with drafting up a legislative proposal that will subsequently be presented to the other two legislative institutions for approval (Schendelen, 2013). Owing to the technical nature of its activities, a substantial amount of information resources are required in order to draft a qualitative proposal. However, resource constraint make it so that these needs cannot be completely met internally, "forcing" the EC to look externally for supplementary information (Bouwen, 2002; Bouwen, 2004). Thus, consultation procedures and opportunities are put into place in order to gain stakeholder input. These consultations are open to every party, be it corporate interests, citizen groups or national governments. Consultation methods include the forming of ad hoc expert groups of industry specialists but also online consultation meetings open to everyone (Schendelen, 2013; Greenwood, 2019). Furthermore, the consultation procedures of 'open dialogue' to be followed by the commission are comprehensively laid down in Treaties in order to facilitate and ensure a conversation with a broad range of societal actors and stakeholders (Coen & Richardson, 2009). However, these consultations opportunities are limited in time (Coen & Richardson, 2009) and every official interaction between the EC and stakeholders is accounted for and made public in order to ensure

transparency (Greenwood, 2019). Additionally, these consultation opportunities serve multiple purposes at once.

Firstly, it aims to compensate for the so-called "democratic deficit" the EU reputation suffers from. Given the supranational nature of the EU and its institutions, it is often posed that there is a lack of connection between the institutions and its people. By having extensive contacts with stakeholder organisations, also referred to as 'civil society', the EC attempts to use these contacts as a proxy for public opinion, thus trying to make decision-making more 'democratic' (Greenwood, 2019). Secondly, these opportunities can be viewed as exchanges for both the EC as well as stakeholders. In these consultations, stakeholders present political and/or technical information to policy-makers in order to influence the drafting phase in a way that benefits their particular policy goal in the situation at hand. Given that these organisations are more than often experts in their fields, the EC bureaucracy gains an additional supply of information useful to take into consideration while producing the legislative draft (Bouwen, 2004; Coen & Richardson, 2009; Dialer & Richter, 2018). Thirdly, the EC can use consultation opportunities in order to identify potential allies that supports its agenda. For example, if the European commission wants to introduce a certain policy, it can appeal to "friendly" interest groups to legitimize the need for the policy. This entails that the commission will enter into alliances with various interest groups to achieve certain goals of the European institutions themselves (Greenwood, 2019). Lastly, the pursuit of greater legislative legitimacy. Combining public opinion by proxy with politico-technical information from civil society and the EC's own policy information, the EC seeks both 'input' as well as 'output' legitimacy for its legislation (Coen & Richardson, 2009; Greenwood, 2019). The goal is to obtain a vast amount of information coming from different perspectives in order to draft a legislative proposal of high quality while at the same time ensuring societal support for its content.

3.1.3 European Parliament

In the following phase of the legislative process, the draft proposed by the European Commission gets passed to both the European Parliament and Council of the European Union, who scrutinize and have the authority to reject, accept or make amendments to the proposal at hand (Bauerschmidt, 2021; DG IPOL & LEGI, 2019; Dialer & Richter, 2018).

The European Parliament is currently populated by 705 Members of Parliament (MEP), each appertaining to one of 7 European political parties (European Parliament, n.d. ; Schendelen, 2013). The EP can furthermore be divided organisationally into two working units: the specialised committees and the plenary assembly. There are 28 Parliamentary committees in total, of which their composition reflects the political situation in the EP as a whole. Each committee is furthermore specialised in a specific policy domain, such as foreign affairs or employment (European Parliament, n.d.). As previously mentioned, the legislative proposal drafted up by the European Commission firstly gets forwarded to the relevant committee(s) during its first reading, where a position hereon is r eached. Afterwards, this position gets passed to the plenary assembly and adopted/rejected as the official position of the EP in relation to the legislative proposal (Coen & Richardson, 2009).

When lobbying the EU, it can be quite costly to monitor and influence the greater part of its MEPs. However, certain Members of Parliament (MEPs) are assigned specific roles and enjoy a greater

influence on the legislative process than others, making them preferred lobbying targets (Coen & Richardson, 2009). Among those, the rapporteur enjoys the most influence. For every new dossier, a rapporteur belonging to the responsible committee is appointed. Tasked with leading a dossier trough the Parliamentary (committee) phase of the decision-making process, they are responsible for preparing a draft report about the legislation at hand (DG IPOL & LEGI, 2019). This includes being the first MEP to review the proposal at hand, but also being the first MEP to propose amendments (Dionigi, 2018). Additional to the appointment of a rapporteur, 'shadow rapporteurs' also are of interests. Given that party politics are well and alive in the EP, the rapporteur unavoidably belongs to a certain front. To compensate for this, other parties appoint a committee member of their own political party to be shadow rapporteurs. They are tasked with both closely following the rapporteur and general progress of the dossier, as well as proposing amendment coming from their own political party (Dionigi, 2018).

Unlike the EC and the Council of the European Union, the EP is the only institution where its officials are directly chosen by universal suffrage, legitimising its decision-making authority by attempting to fill up the perceived democratic deficit of EU decision-making (Schendelen, 2013). Where interest groups fail to persuade the Commission on the course of action, they can try their success in the EP, which possibly has more favourable institutional features than the EC. Or, in the opposing case, interest groups may try to hinder their success being annulled by counter-lobbying efforts (Dionigi, 2018). However, the political nature of the EP can result in varying degrees of access for different types of interests. For example, certain civil society organisation may have more access to left-leaning parties instead of right-leaning parties, while the opposite may be true for business interests (Coen & Richardson, 2009).

Elaborating further on the institutional aspects of the EP, literature suggests that the EP has an extensive workload and most MEPs are not experts in the subject at hand, resulting in a number of consequences concerning lobbying. To make qualitative informed decisions, qualitative information about the subject at hand is required, which can be provided by specialised interest groups. In contrast with the EC, most MEPs do not have technical expertise on the matter under discussion, which makes them especially dependent on the information offered by the interest groups for compensation. Additionally, volume and content overload place a significant constraint on MEPs, thus making them overly reliant on interest groups (Dionigi, 2018). Furthermore, contrary to consultation procedures in the EC drafting phase, consultation is not (as heavily) regulated in the EP. Where the EC is required to consult widely with various organisations of different interests, the only principle stipulated in Parliament's rules of procedure, it is that MEPs are prohibited to receive a mandate or be bound by instructions issued by interest groups. Consequently, MEPs are not required to consult widely on the issues at hand and can favour certain interests above others if wanted (Dionigi, 2018). Additionally, in contrast with the EC, party-politics are well and alive in Parliament with the grand majority of MEPs belonging to one of the 7 official parties. Consequentially, the amount of lobbying success certain interest groups can achieve depends on which political coalition has the majority in the EP.

3.1.4 Council of the European Union

The third key institution in the legislative process is the Council of the European Union. While it gets frequently confused with the European Council, their authorities and composition illustrate a clear difference. Where the European Council is mainly concerned with long-term strategic EU affairs and composed of the heads of state of the various member states, the Council of the European Union handles more day-to-day affairs concerning legislation and has a bigger volume and variety in its composition (Coen & Richardson, 2009).

As a co-legislator, the Council of the European Union has the authority to adopt proposed legislation in coordination with the European Parliament. The main difference between the Parliament and Council is transparency and access. Where the first organisation can be dubbed an 'open institution' in relation to its admissibility of interest group input, the Council has a reputation of being less approachable for European level lobbying interests than the European Commission and Parliament. While the latter two welcome external interest groups with open arms an actively include them in the legislative process, the Council is known to be less transparent and keeps matter more private and internal, frequently literally behind closed doors (Coen & Richardson, 2009)

The Council is composed of three hierarchical layers. Described from bottom upward, these are the working parties, preparatory bodies and the council of ministers (DG IPOL & LEGI, 2019).

When legislative proposals reach the Council, they are presented to the specialised working parties at the bottom of the hierarchy and make their way up to the council of ministers. Literature indicates that a substantial and important part of the work done in the council is actually done on this lower level. The explanation behind this claim rests on the decision-making authority of this 'lower' bureaucratic body, rendering it some sort of filter for important issues. When legislation is being debated on in the working parties, officials try to form an agreement on most issues before passing it to the preparatory bodies. Meeting up on a weekly basis, these bodies attempt to form an agreement on the remaining issues. Any potential unresolved issues are discussed on the level of the council of ministers. On the other hand, if all other issues are already agreed upon, the position taken by both the preparatory bodies and working parties is formally adopted by the council of ministers (Coen & Richardson, 2009). This illustrates that issues where a consensus is already found, and are consequentially in a later 'sub-phase', are more difficult to influence, highlighting the importance of early lobbying.

In order to distinguish between already agreed upon legislation and legislation yet to be agreed upon, the council employs a system where it differentiates between 'A & B type legislation', with the already agreed upon legislation belonging to the A type and the rest to the B type legislation (Coen & Richardson, 2009). Furthermore, this system attempts to reduce the workload of the already overburdened ministers, whom meet relatively infrequently given the issues they are to vote upon. Consequentially, it would be futile for interest groups to lobby the council of ministers on A type legislation , further emphasizing the importance of working parties. Still, it can be quite difficult to assess in which category the legislation will fall, and thus proves another difficulty in lobbying the Council.

The Council 'itself', often referred to as the Council of ministers, is composed of a myriad of national ministers and official national representatives. Consequently, the composition of the council of ministers is determined by national elections. Furthermore, this layer of the institution has 10 specific configurations in which its meets according to the legislation at hand (General Sceretariat for the Council of the European Union, 2020). For example, if the subject of the legislative proposal falls under the policy domain 'foreign affairs', all ministers of foreign affairs of each member state are invited to the meeting. In contrast with the European Commission where the 'European interest' dominates and officials act in a manner above national politics and borders, ministers in the Council have a tendency to characterize themselves as (in)direct representatives of their own country and prioritise national interests. Literature even indicates that the Council (of ministers) is the place where national interests are actively integrated in the European project, with ministers functioning as the 'middleman' between domestic (interest) groups and the European Union (Coen & Richardson, 2009). Furthermore, the type of information needed by ministers differ from the type of information required by the EC. Here, The Council requires primarily political information about support or objections on the national level concerning the legislation at hand instead of technical expertise (Bouwen, 2002). This implies that the Council of ministers can be seen as a national channel to influence European decision-making. Nevertheless, ministers are often overburdened due to their dual responsibilities, resulting in great reliance on preparatory bodies to handle the bulk of decision-making, lessening both the workload and influence of this layer.

Officially, there are three ways of voting in the Council: unanimity, simple majority and qualified majority voting (Coen & Richardson, 2009). Which method applies depends on the subject and is stipulated in the relevant treaty. Nevertheless, it is estimated that in 70% of the cases QMV applies, while the remaining 30% of the cases employ unanimity (Coen & Richardson, 2009). In reality, the Council seldom votes, and in rare cases that it does consensus/unanimity voting is applied even though treaties would stipulate employing QMV. Consequentially, one could argue that ministers have an unofficial veto right, resulting in lobbying interests only having to gain lobbying success with one minister. Subsequently, powerful domestic interests could take advantage of the domestic political situation to influence the minister active in the council and thus, albeit indirectly, veto a certain legislation.

Chapter 2: Theories of interest representation

In this section, a non-exhaustive list of theories regarding stakeholder-government relationships will be discussed and applied to an EU framework in order to lay the groundwork for the second part of the literature study. After all, determinants of lobbying success are contingent on which system of interest representation is applicable. Given that this master's thesis is only focused on the EU and its unique system of interest representation, it is unsure whether its findings can be generalised to other systems.

Literature about theories regarding government-stakeholder relationship can be put into two categories. On the one hand, certain theories explain the dynamic of the relationships between stakeholders and policy-makers. The theories which could be identified as belonging to this category are resource exchange theory and resource dependency theory. On the other hand, certain theories try to explain the framework of the system of how interest representation is organised. Traditionally, pluralism and neo-corporatism would be considered the prime theories describing the way a system of interest representation is organised. However it is important to note that they are archetypes of relationships and that in practice multiple characteristics from multiple theories can be displayed. Furthermore, the respective theories can be placed on a spectrum, ranging from a "free-market" perspective to a more centralised and integrated view on lobbying relations, with the pluralist view being the most prevalent theory of the former, and the corporatist view of the latter. Additionally, two more theories will be shortly discussed, being elitism and associative democracy.

3.2.1 Resource dependence & exchange theory

When trying to explain why policy-makers and lobbyists interact with each other, literature most often seems to refer to resource dependence theory and exchange theory as an underlying framework. Resource dependence theory argues that organisations are often unable to function wholly self-sufficiently and require the remaining resources from external sources in their environment. This results in an interdependence between organisations, hence the name of the theory (Bouwen, 2002; Bouwen, 2004; Coen & Richardson, 2009). Next, exchange theory states that the interaction between policy-makers and interest organisations is mutually beneficial and based on an exchange of desired resources for both parties (Bouwen, 2004). Resources can take different forms and differ for both parties. On the one hand, resources of interest organisations include relevant technical expertise as well as information about political support in order to increase the input as well as output legitimacy of the legislative proposal. On the other hand, the institutional side can grant interest organisations with privileged access to the policy process and timely information about the start and progress of a legislative initiative (Berkhout, 2013). Applied to the EC the logic is as follows: the bureaucratic part of the European Commission is tasked with drawing up a detailed legislative proposal, requiring in-depth technical information. In the cases that the legislative proposal impacts a certain interest substantially enough, they will try to gain access to influence the proposal to their benefit. One such way is by supplying the information that is needed to the EC. Furthermore, the above explanation suggests that the more and valuable resources an interest group disposes of, the more influence/access it has to the policy-making process (Coen & Richardson, 2009).

3.2.2 Neo-corporatism & Elitism

Interest representation in a Neo-corporatist system is characterised by a high level of institutional integration, collective decision-making and centralisation. Neo-corporatist systems are often associated to tripartite arrangements between capital, labour and government (Burns & Carson, 2003). Interest group formation is highly segmented per societal group, and furthermore limited by the state. Instead, certain selected interest organisation have been given a monopoly by the state to represent a certain constituency, for which membership is mandatory. As a result of this segmentation and limitation, interest organisations are broad and can have internally differing interests, leading to members having to compromise in their position in order for a collective position to manifest (Streeck & Kenworthy, 2005). Collective position are needed because policy-making in neo-corporatist systems take place on the macro level between for instance 'market and state' (Burns & Carson, 2003). Additionally, given that interest organisations are institutionalised under this system, they theoretically enjoy a greater say in policy-making and implementation because of the integration in de policy-process (Salgado, 2013). Nevertheless, excessive state influence and control over the corporations themselves has its downsides. The most important criticism concerns the autonomy of these organisations, which is severely limited resulting in the exclusion of certain voices and full articulation of every interest (Dialer & Richter, 2019; Salgado, 2013). Additionally, Burns and Carson (2003) indicate that this system does not work substantially well in times of rapidly changing environments due to its inflexible nature.

Another theory of interest representation is Elitism. At the core of this theory lies the assumption that groups of elites have a disproportionate influence on public policy by virtue of their wealth and power, which gets augmented to even higher levels when they form coalitions (Dialer & Richter, 2019). Accordingly, most public officials, lobbyists, businesspeople come from the same socio-economic background, namely at least upper middle class and have enjoyed above average education (Godwin et al., 2012). It is argued that as a result, the policy-making process is biased and "lower" socio-economic groups are underrepresented while "higher" socio-economic groups enjoy exceptional benefits. Furthermore, under this system of representation interest groups are not granted public funding, solely due to the fact that they expect other and arguably better benefits in the form of permits and regulations. Additionally, based on the assumption that an above-average socio-economic group of elites hold crucial positions in governments as well as interest organizations, it is clear that interest organizations enjoy full autonomy under this system, given that this same group of elites control the whole system. This causes issues regarding representativeness of all factions present in a society, especially in a democratic one (Dialer & Richter, 2019).

3.2.3 (Neo-) Pluralism

By far the most popular and preferred theory utilised to explain interest group-government relationship in the western hemisphere, is (neo-)pluralism. This theory is de facto a political application of the theory of free market competition (Godwin et al., 2012; Laboutková et al., 2020). Unlike neo-corporatism, stakeholders are free to create their own interest organisations according to their needs, retaining full autonomy without being confronted by state intervention (Burns & Carson, 2003; Streeck & Kenworthy, 2005). This leads to the formation of many organisations and groups which are generally more specialised but also fragmented than under neo-corporatism.

Consequentially, a system of competitive interest representation characterised by high flexibility, openness and uncertainty is set up. Given that every individual has a peculiar set of interests, they will be at least represented by one of these organisations. If this is not the case, then the individual could, although theoretically, mobilise along with a group of people to form an interest group themselves. Consequently another group can be mobilised whose interests are in contrast with the aforementioned one. This process is repeated until an equilibrium is reached that all sides of a specific issue can compromise on and where social benefits are maximised. As a result of this process, influence is dispersed and difficult to consolidate under one particular interest (Godwin et al., 2012; Laboutková et al., 2020).

Fully in line with free market competition, the role of the government is much more limited here. Its primary concern revolves around setting up a legal framework that maximises transparency and competitiveness between organisations (Burns & Carson, 2003; Dialer & Richter, 2019). Ideally, the government in question should act as an impartial judge, deliberating every side of a political issue and making the most rational choice about which one to implement in their public policy. Nevertheless, the government most frequently also has a stance about the issue at hand, and thus must combine its role as a judge and participant itself (Laboutková et al., 2020). Furthermore, interest representation is not subsidised as it is assumed that everyone can either align of mobilise themselves an organisation fit for this purpose (Dialer & Richter, 2019).

However, important nuances must be added to this explanation. Also in line with free market competition, resources, both politically and financially, play an important role in this system (Burns & Carson, 2003). Unlike neo-corporatism, where interest groups are institutionalised and have access to state resources, the state is much less interventionist under pluralism and generally does not subsidise interest organisations (Dialer & Richter, 2019). Consequentially, there can be a great disparity in resources between interest organisations. this can lead to certain interests being underrepresented or not represented at all in this system, while resource-rich organisations can substantially influence legislation in to their benefit (Burns & Carson, 2003). When taken to the extreme, this can lead to a form of elitism, called elite pluralism (Eising, 2007)

3.2.4 Associative democracy

Three concepts stand at the core of this theory, being "equality, democracy and citizen participation" (Cohen & Rogers, 2001). Like pluralism, the system of associative democracy grants a high level of access and freedom to interest organisations who compete for influence in a system of fragmented influence and checks and balances. However, in accordance with its ideal of equality, associative democracy acknowledges that resource constraint can lead to some interests being underrepresented and a certain amount of distributive fairness is needed so that anyone who wants can get access to the policy-making process. To compensate for this, the role of government actively intervenes to stimulate the forming of organised groups representing interests that were previously excluded. For example, under this system the government at hand grants subsidies to the interest organisations, (Salgado, 2013). Another example of this would be the government subsiding and consulting citizen groups concerning climate and environment in a political arena where polluting industrial interests dominate. Nevertheless, funding is not unconditional and interest groups are to meet certain criteria regarding autonomy and representativeness to continue to enjoy these benefits (Rogers & Cohen,

2001; Salgado, 2013). Important to note is that although the government actively helps interests that would be underrepresented in a pluralistic framework, these interest groups don't enjoy the extensive benefits that would be enjoyed under a neo-corporatist system, for example an active role in implementation of public policy, yet are also to be monitored by public authorities (Dialer & Richter, 2019).

Like all systems, associative democracy also has its cons. Given that a substantial portion of citizen groups and NGO's could not exist without government funding, it could be argued that their advice and expertise may falsely be more in line with the government agenda than there is social support, fearing they will suffer repercussions if they go against the government. In doing so, the government can effectively instrumentalize these organisations and manufacture support for their policies, also called constituency building. Furthermore, it is also clear that while a myriad of organisations are funded, the choosing of who to fund can also be biased for several reasons, including the aforementioned constituency building (Dialer & Richter, 2019).

Although this theory is rather briefly explained considering the limits of the thesis, it can be concluded that it best fits the EU stakeholder-government relationships combined with exchange theory. Interest groups are free to pursue their proper goals as stipulated in the theory of Pluralism, which aligns with the theory of Associative Democracy. Additionally, the EU greatly supports the funding and creation of formal groups to represent excluded interests. While skeptics insinuate that the Commission is guilty of constituency building, judging from the critical stances of many NGO's about EU policy it may well be argued that systematic instrumentalization of these organizations does not occur on an EU level (Dialer & Richter, 2019).

3.2.5 Stakeholder-government relationships in an EU context

When applied to the EU system of policy-making, various sources conclude that there is not just one solitary theory that applies to this system (Burns & Carson, 2003). Instead, it displays some characteristics of each system. Firstly, the theories of neo-corporatism and elitism. While these are arguable the least applicable to interest representation on the EU level. Firstly, (Neo-)corporatism is too centralised and highly structured to be applicable to the EU, which is characterised by its fragmentation of influence and autonomy of interest groups (Dialer & Richter, 2019). Furthermore, the system of EU interest representation is generally much more open than defined under Neo-corporatism, combined with a much more specialized and differentiated type of governance. However, in many policy-domains the collective EU interest takes precedence on special interests, and some policy-domains on the EU level remain relatively closed, such as agriculture and pharmaceuticals (Burns & Carson, 2003). Secondly, while some organisations certainly have more influence on the policy-making process, the theory of Elitism does not hold on several accounts. To keep it concise, only two examples will be given. Firstly, it is does not account for the abundance of financial support granted to NGO's representing groups of society that would otherwise, without the subsidisation, not be heard by policymakers , such as for the poor and homeless. Secondly, procedures to be followed by the European Commission include the obligation to wide consultation with various factions of society in preparation of drawing up new legislation, ensuring a myriad of voices be heard (Dialer & Richter, 2019). If the EU functioned under the Elitist paradigm, the two aforementioned phenomena surely would not exist.

Thirdly, the theory of pluralism is often applied to an EU context due to a number of reasons. Thus, interest organisations enjoy a high degree of autonomy and access under the EU system, and may all compete for influence in the relevant institutions. Additionally, policymakers, especially the European Commission, consult a wide range of interests before taking legislative initiatives, making for a diversified and flexible decision-making machine. However, the EU system is not strictly pluralist. Firstly, similar to the findings of public choice theory, the government does not make purely rational choices and can be found to quite often put their own benefits above societies (Laboutková et al., 2020). Secondly, it recognises that there can be a substantial disparity in the amount of resources certain interest groups possess, resulting in over- and underrepresentation of certain faction and, consequently, bringing about an equilibrium that does not maximise social benefits (Laboutková et al., 2020). To correct for this, various citizen groups and NGO's benefit of government subsidies and explicit consultation in relevant matters, emphasizing the three core values of associative democracy.

Chapter 3: lobbying success and its determinants

The following section briefly covers lobbying success and includes an extensive review of literature concerning the determinants of success. These determinants will serve as an inspiration for the questionnaire in the empirical section of the thesis, while at the same time being a comparison base for the answers provided by the interviewees.

3.3.1 Lobbying success

When certain interest groups are involved in a policy issue, they first of all make their personal policy preference known to the European Commission through a position paper. According to research by Dür et al. (2015), these positions can be placed on a unidimensional scale in relation to each other. In the example given by Mahoney (2007), it is about emission standards, where industry is at one end of the spectrum (no emission standards), environmental groups are at the other end (more emission standards than proposed by the commission) and the commission and the parliament are in between. However, depending on the issue, the EU institutions may also be closer to one side or the other. Consequentially, different groups engage in lobbying efforts in order to shift the position of both institutions more to their side of the spectrum, hoping that the final decision is close to their policy preference (Dür et al., 2015). This method of measuring lobbying success is referred to as "the preference attainment method", where final policy output is compared to initial policy preferences in order to make out which organisations are successful (Klüver, 2011).

Yet, when does one group truly win? For example, successful lobbying efforts of industry interests could result in less severe restrictions, but restrictions nonetheless. Meanwhile, the environmental group did not realise more severe restrictions, but at least they succeeded a little. This example tries to illustrate two facts. Firstly, what is considered lobby success is heavily dependent on the context of the issue at hand and the interest organisation's policy preference. Secondly, European policy-making most often tries to seek compromises between all parties involved. Taking into account these two perspectives, it becomes clear that lobbying success also lies on a spectrum, and that partial lobby success where a compromise is found between the different parties involved is more common than a "winner-takes-all" scenario. In this case, three different scenarios are thus possible: the interest groups fully attains its objective, the interest groups partially attains its objective and lastly, the interest groups attains none of its objective (Mahoney, 2007).

3.3.2 Determinants of lobbying success

The relevant literature on the subject indicates a myriad of determinants of lobbying success, which Mahoney (2007) groups into three broadly defined categories. The first category consists of institutional determinants: characteristics of the EU decision-making institutions that have an impact on lobbying influence and success. Secondly, the issue context of a specific dossier has been identified as an important determinant. Thirdly, advocate characteristics also play an important role (Mahoney, 2007; Klüver, 2013; Rasmussen, 2015). Furthermore, it is important to point out that the interplay of all the following determinants is found to be important for lobbying success. Thus, a single determinant is insufficient in wholly explaining lobbying success. (Mahoney, 2007) Yet some determinants have a stronger influence than others. Additionally, the determinants are not categorised in strictly separated classes, but influence each other, either strengthening or weakening each other.

3.3.2.1 Institutional characteristics

3.3.2.1.1 Democratic accountability

Mahoney (2007) identified the democratic accountability of a decision-making institution as an important determinant of lobbying success. Democratic accountability is viewed as the level of dependency an institution has to its broader public. More specifically: are its members elected by direct popular vote or chosen through other means? For example, the political leadership of the European Commission is elected by the European Parliament and Council of the EU while its bureaucracy is fully unelected, making them little democratically accountable. Meanwhile, MEPs of the European Parliament are voted in by direct elections and thus, more dependent on the public for their position and re-election (Hanegraaff & Berkhout, 2018) However, it is important to nuance that in reality, MEPs are also dependent on their national party leadership and not solely the broader public. (Mahoney, 2007) Nevertheless, the European Parliament is still more democratically accountable than the European Commission.

Following the theory of associative democracy, it is assumed that interest organisations in the aggregate represent all of the broader public's interests. (Dialer & Richter, 2019) Building on this assumption, Mahoney (2007) hypothesizes that the more democratically accountable an institution is, the more responsive its members will be to organised interests, as they are considered a proxy for the broader public of which they are dependent on. Yet results of the research indicate that the opposite is true: policymakers are more responsive to interest organisation when they are less democratically accountable (Mahoney 2007). In cases where the EU listens to multiple parties, compromises can be made so that everyone gains a little and thus, theoretically, a larger proportion of the population is satisfied (Mahoney, 2007).

3.3.2.2 Issue characteristics

In recent years, research has been more focused on these determinants than before and uncovered that issue characteristics play a significant role in lobbying success, even more so than institutional determinants (Klüver, 2011; Mahoney, 2007). Five characteristics can be distinguished in this group in order of importance, being coalition (building), salience, issue scope, issue complexity and level of conflict. Depending on the configuration of these determinants, they can either prove a decisive benefit for the interest organisation, but also an obstacle preventing lobbying success (Klüver, 2011; Mahoney, 2007).

3.3.2.2.1 Coalition building

First and foremost, it is important to emphasise that lobbying is a collective process (Klüver 2011 ; Klüver, 2013). While some issues attract only one type of lobbying interest, and some do not attract any at all, others attract a myriad of interest organisations striving to see their individual policy preferences realised. As a consequence, different camps emerge with similar policy preferences pulling the legislation to their preferred sides. Thus, lobbying does not take place in a vacuum, but rather in a complex, plural environment with corresponding and opposing interests (Klüver, 2011). Furthermore, coalition building is found to be one of the most prevalent and effective lobbying strategies used in influencing policy (Beyers & De Bruycker, 2017; Newmark & Nownes, 2019).

Before determinants concerning coalitions are discussed, it is important to clarify what a coalition is. While some literature defines a coalition as "a deliberate and strategic cooperation among organized interests that defend the same political position" (Beyers & De Bruycker, 2017), some research papers assume a broader definition of the word and remove the cooperation section, so that only "a group of organisations with common goals" is left (Klüver 2011). This nuance is important in the interpretation of empirical results and will be specified if needed.

Firstly, Klüver (2011) identified the relative size of the lobbying coalition an organisation belongs to as an important determinant of lobbying success. In this paper, coalition is used in the broad sense, not implying cooperation between organisations but only that they have similar policy preferences. More specifically, the bigger the coalition the organisation at hand belongs to, relative to the size of the opposing coalition on the same issue, the greater the probability of lobbying success for the organisation at hand (Klüver, 2011). A possible explanation hereof can be found in (Klüver, 2013). This paper argues that the reason bigger coalitions gain more success is because of the larger aggregate supply of resources the camp disposes of. More specifically, the higher the relative information supply, citizen support and economic power, the more improved the probability of lobbying success (Klüver, 2013). To emphasise further, the absolute size of the lobbying coalition is of no importance, only the size of the coalition in relation to the opposing coalition is identified as influencing lobbying success.

Additional to the relative size, the composition of a coalition also has an effect on lobbying success (Beyers & De Bruycker, 2017). More specifically, lobbying success is increased when a coalition is composed of a broad collection of diverse interests. Additional to relative size, the composition is also found to have an effect on lobbying success. More specifically, lobbying success is increased when a coalition is composed of a broad collection of diverse interests than a homogenous coalition (Beyers & De Bruycker, 2017). An explanation for this phenomenon is rooted in pluralist theory. When a coalition is diverse rather than homogenous, theoretically speaking they would represent a broader portion of the general population, signalling the political validity of the coalition. Thus, in a democratic and pluralist context, policy-makers would be more inclined to listen to the more diverse coalition, augmenting their chances of lobbying success (Junk, 2019).

However, Junk (2019) argues that the benefits of diversity are not constant, but contingent on the salience of the issue at hand. More specifically, diverse coalitions have a higher probability of lobbying success when issues are highly salient. When issues are not highly salient though, homogenous coalition, regardless of group type, seem to gain more lobbying success than diverse ones (Junk, 2019). This is attributed to the political consequences that are faced in low vs highly salient issues. In highly salient issues, the public is involved and negative perspectives of policy-makers could result in losing credibility and their chance at re-election, while issues low in salience do not bear such consequences (Junk, 2019). Important to note is that Junk (2019) examined coalitions were individual organisations were closely working together, and not merely related by the same lobbying objective.

3.2.2.2 Salience

Additionally, the saliency of an issue is found to be a crucial determinant in lobbying behaviour and success (Dialer & Richter, 2019). Salience refers to the importance and attention given to a specific

issue by different stakeholders (Klüver, 2011). To be more specific, three types of salience can be distinguished: public, media an organisational salience (Beyers & De Bruycker, 2017). Public salience refers to the degree in which the public finds an issue important, while media salience refers to the attention media allocates to the issue at hand. Lastly, organisational salience indicates the importance stakeholders/the constituency of the interest organisation allocates to the policy issue. Important to note is that in numerous cases, not all three types of salience are present at the same time (Beyers & De Bruycker, 2017).

Salience in general is found to be inversely related to the lobbying success of an individual lobbying organisation active on the EU level (Mahoney, 2007). The main reasoning behind this lies in the fact that salient issues attract a more and broader collection of interests, each with their own policy-preferences (Klüver, 2011; Mahoney 2007). Given that EU policy-makers favour compromises instead of a "winner-takes-all" system such as in the US, Mahoney (2007) claims that policy-makers will take into account a broader range of advice, thus diminishing the amount of lobbying success an individual organisation will likely achieve regardless of the scope of the issue at hand.

However, Klüver (2007) argues that the effect of salience is not constant, but contingent on the relative size of the lobbying coalition the organisation pertains to in regard to a specific issue. Coalition in this context refers to the group of interest organisations with the same policy goal/preference, and not strictly closely cooperating organisations (Klüver, 2011). Empirical research by Klüver (2007) finds that increased salience results in increased lobbying success, albeit partially, for the organisation pertaining to the relatively bigger coalition. The opposite is also implied, namely that increased salience leads to decreased lobbying success when the organisation belongs to the relatively smaller coalition.

Furthermore, increasing salience has been utilised as a valid outside lobbying strategy by certain advocates such as citizen groups. This strategy aims to increase public interest and visibility in the hope that the general public will be opposed to the political opponent's view while supporting its own side (Mahoney, 2007). This seems especially effective against business interests, who are reported to have less success on more salient issues (Stevens & De Bruycker, 2019). However, based on the described effect mentioned before, in doing so they will most likely decrease their own lobbying success as well (Mahoney, 2007).

3.2.2.3 Issue scope, level of conflict & issue complexity

Furthermore, the scope of the issue at hand also is found to play a role in lobbying success. For example, an issue can be niche, sector-wide, cross-sectoral and even system-wide. The larger the scope of the issue, implying that a large number of interests and even the general public are interested/affected in/by the issue, the less likely a single interest organisation is in attaining lobbying success (Mahoney, 2007).

Nevertheless, these findings are to be nuanced by also taking into account the level of conflict between the interest organisations at hand, which has also been indicated to be a determinant of lobbying success (Mahoney, 2007). As mentioned before, lobbying is often a collective effort, meaning that different interests can be active on a single issue (Klüver, 2011). If these interests are strongly opposed to each other, the level of conflict of the issue is high and will affect lobbying

success in a negative manner. On the contrary, if an interest organisation encounters no opposing interests on a specific issue, lobbying success is significantly increased (Mahoney, 2007). Stevens & De Bruycker (2019) also conclude that more competitors on an issue lead to less individual lobby success. Furthermore, Mahoney (2007) finds that if an interest organisations is active on an issue with multiple other organisations, each having their own perspectives but not in direct opposition to each other, all organisations have an increased chance of lobbying success, albeit partially. Additionally, Newmark & Nownes (2019) find that when level of conflict is high, interest groups are more inclined to form coalitions in order to increase their probability of attaining any lobbying success.

Lastly, issue complexity is identified as a determinant in lobbying success. Complexity refers to how difficult a problem is to analyse and solve (Klüver, 2011). When complexity is high, policy-makers seek out external expert information in order to make optimized policy choices. This is done by consulting with specialist interest organisations, who get access to the policy-making process by providing this information, as explained before. However, when issue complexity is low, policy-makers may not need this information, consequentially limiting access for interest organisations (Klüver, 2011). Thus, Klüver (2011) infers that higher complexity issues make policy-makers more dependent on interest organisations, consequentially increasing the latter's' probability of lobbying success. Issues with low complexity levels on the other hand, make policy-makers less reliant on interest organisations, thus decreasing their probability of lobbying success (Klüver, 2011).

3.3.2.3 Advocate characteristics

Lastly, certain characteristics of the interest organisations itself can play a role in achieving lobbying success. Mahoney (2007) distinguishes between 3 determinants, including information supplied, financial resources and group type.

3.3.2.3.1 Information supply

Information is considered a crucial part in lobbying (Flöhte, 2019). Literature agrees that information is one of the primary exchange goods interest organisations utilise to gain access to legislative institutions and policy-makers and to subsequently influence them (Dialer & Richter, 2019; Hanegraaff & Berkhout, 2018). An explanation for this phenomenon can be found in resource exchange and resources dependency theory, stating that a government institution is not self-sufficient. Consequentially, it needs resources from its environment in order to keep functioning (Hanegraaff & Berkhout, 2018; Klüver, 2013; Stevens & De Bruycker, 2020).

Applied to an EU context, this means the following: policy-makers, specifically members of the Commission, have the objective of drafting qualitative legislation. This requires information regarding the relevant policy area and may include technical in-depth information, but also information regarding societal support among relevant stakeholders. Given, inter alia, the scarce resources available to the Commission, the latter often does not have this information at its disposal. However, interest groups do have this information by virtue of their own research or through their constituency. Yet, this does not mean that it is automatically available to the EC. As a result, interest groups are consulted in order to get access to this information, simultaneously allowing interest groups to gain access to the policy-makers in return (Flöhte, 2019; Klüver, 2013; Stevens & De Bruycker, 2020).

Two types of information can be distinguished: expert information and information about public opinion. The former includes technical details, studies about the effectiveness of the policy, legal and economic analysis, etc. The latter includes preferences of the general public, preferences of the constituency of the interest organisation, moral arguments, etc. (Hanegraaff & Berkhout, 2018; Flöhte, 2019). Research finds that some interest groups only provide expert information, while others only supply political information. Additionally, certain interests provide a mix of both types. Nevertheless, expert information is found to be provided more than information about public preference (Flöhte, 2019). A possible explanation might be that expert information is more often than not in private hands, while public preferences may be more open access, giving the provider of the first higher leverage to gain access (Flöhte, 2019). Various research assumes that lobbying success of business interests can be explained by this informational advantage given that they are specialised in their own domain and possess highly in-depth expert information (Dür et al., 2015; Flöhte, 2019; Klüver, 2013). On the other hand, information about public opinion regarding certain policies are more often supplied by citizen groups and NGO's, who generally are not considered as wealthy and lack the thorough expertise that business has (Flöhte, 2019).

Conclusively, the type of information provided is found to play an important role in determining lobbying success. More specifically, supplying solely expert information seems to have a positive effect on lobbying success, while supplying solely political information has a negative effect on lobbying success. Additionally, when a mix of information is supplied, expert information is still given more priority and seen as more effective (Flöhte, 2019).

3.3.2.3.2 Financial resources

Mahoney (2007) argues that groups who dispose of an abundance of financial resources are able to engage more in activities necessary to effectively lobby on a broader scale. For example, they can monitor more issues at the same time, engage in different tactics, etc. Most importantly, research argues that financial resources have an impact on the amount of expert information a group can provide, which has been found to be an important determinant in lobbying success. (Stevens & De Bruycker, 2020). Measuring the financial resources an organisation truly disposes of is often done by utilising staff size as a proxy (Mahoney, 2007). Moreover, Stevens & De Bruycker (2019) find that staff size can be indicative of lobbying success, where organisations disposing of greater staff sizes enjoy higher probabilities of lobbying success than organisations with a smaller amount of staff. Additionally, business interests are often referred to as particularly wealthy in various literature, while citizen initiatives and NGO are often said to lack the necessary funding to operate on the same level (Dür et al., 2015). While business interests are certainly wealthy, citizen initiatives are provided subsidies in order to maintain a certain level of professional activity, so that they may be effective in lobbying, in line with the associative democracy system of interest representation as mentioned before.

Stevens & De Bruycker (2020) also mention various studies that identify financial resources of an organisation as a determinant of lobbying success, a conclusion that is also reached in its research. Furthermore, Stevens & De Bruycker (2020) expand on these studies and argue that the effect of financial resources is not static but influenced by certain conditions. More specifically, the effect of media salience. Generally speaking, financially wealthy groups enjoyed higher lobbying success than

less endowed groups. However, this seems to be contingent on the level of media salience concerning the issue at hand. More specifically, the difference in lobbying success between well-endowed and less-endowed groups is highest when media salience is low, while this difference dissipates when media salience is high (Stevens & De Bruycker, 2020). This can be explained by the fact that an increased media salience can lead to the public to becoming involved, which implies an increase in public salience. In this way, policy makers, especially in democratic decision making environments, are put under pressure to listen to the general public. Thus, certain legislation may not be implemented when the public eye is watching, which would have been implemented if the process had taken place 'behind the scenes' (Stevens & De Bruycker, 2020).

While intuitively it makes sense to designate financial resources as a determinant of lobbying success, and more specifically to explain business lobbying success, research is inconclusive. While some papers indicate that financial resources play a substantial role such as mentioned above, others fail to find a causal relationship between the two (Dialer & Richter, 2019; Klüver, 2007; Klüver, 2013; Mahoney, 2007).

3.3.2.3.3 Group type

Furthermore, group type and constituency are also indicated as determinants. (Mahoney, 2007) There are several group types active in the European lobbying arena, each representing a different constituency. For example, trade associations represent business interests while NGO's or citizen groups represent the general public. Additional organisations include research institutions, regional and national governments, think tanks, law firms and consultancies. (Mayrhofer, 2014). However, the focus primarily lies on business and citizen groups, excluding other categories.

The struggle between NGOs and business interests is sometimes compared to 'David vs Goliath' in literature, referring to the abundance of resources and influence available to business interests. (Dialer & Richter, 2019). Klüver (2011) points out that it has often been hypothesized that interest groups representing diffuse interests, such as NGO's and citizens initiatives, have less success than organisations representing concentrated interests, such as for example trade associations concerning pharmaceutical companies. However, Mahoney (2007) expects that citizen groups are more successful than business organisations in a democratic context. However, reality is more nuanced as evidence for this is conflicting and inconclusive: some conclude that diffuse interests have more success while others claim the supremacy of concentrated interests (Klüver, 2007; Klüver, 2013).

However, Dür Et al. (2015) still argue that group type is a key variable in determining lobbying success. It is argued that business dominance is not as far-reaching as is often assumed, and even goes as far as to claim that non-business are especially successful in current EU politics. This is attributed to institutional working of both the EP and EC. The argument given by Dür et al. (2015) proposes that in order for the Commission to remain relevant, influential, legitimate, and to furthermore expand their competencies, a certain legislative output is needed. This legislative output mostly takes the form of regulatory policies, often on business domains. In these cases, business interests advocate mostly to retain the status quo, and are thus lobbying defensively against the EC. Thus, the EC turns to non-business interests in order to signal societal support for these policies. The latter are often engaged in advocacy concerning domains such as environmental, consumer, health and labour interests and traditionally considered to be in opposition to business interests and in

favour of more regulation. (Dür et al., 2015) Additionally, the European Parliament is also most often involved in the decision-making process. As previously explained, voting patterns of MEPs are substantially influenced by the need for re-election and thus, theoretically speaking, MEPs will vote in favour of issues garnering much societal support. Additionally, issues with a high level of conflict between different group types give rise to a higher probability of lobbying success for citizen groups in EU policy-making. (Dür et al., 2015)

Yet business interest are not always unsuccessful. Various research indicate that these interest are particularly successful in "quiet" politics, characterised by a low level of conflict (Dür et al., 2015) When an issue has a high level of conflict, business interests seem to lose their competitive advantage (Dür et al., 2015). Adding to this, Stevens & De Bruycker (2019) find that salience, particularly media salience, is an important determinant of business lobbying success. More specifically, when media salience is high, business seems to lose its edge as policymakers are put under pressure by getting the general public involved (Stevens & De Bruycker, 2019). Furthermore, the level of business unity is also identified as impacting business lobbying success. More specifically, business is especially effective when acting in unison/speaking with one voice. On the other hand, when internally fragmented as a group/industry, business lobbies are less effective (Rasmussen, 2015). Additionally, the farther the policy-preference of business interests in relation to the policy-preference of the EC, the lower the probability of lobbying success (Dür et al., 2015). Lastly, business interests also seem to do better when issues are highly complex and require much technical expertise (Dialer & Richter, 2019).

4. Empirical results

4.1 Institutional determinants

4.1.1 Institutional differences

Institutional differences between the lobbying venues were mentioned most often when asked about institutional determinants. More specifically, differences between the European Parliament and the European Commission were emphasised, while the Council of the European Union was not mentioned; possible reasons will be discussed in the following chapter.

The main difference between the EP and EC that was mentioned most frequently by respondents was the political nature of the EP in contrast with the EC, characterised by its technical nature (R1, R3). Consequentially, this brings about a number of implications. Due to the political nature of the EP, certain political factions may respond better or worse to certain interests. As indicated by the interviews, the political faction the MEP appertains to can be an indication of receptivity to the pharmaceutical interests (R7). While some MEP's are more than eager to listen to the interests of the pharmaceutical lobby, it was also clearly stated that a part of the EP does not even want to meet with, let alone listen to the pharmaceutical interests (R4). More specifically, it was mentioned that generally speaking right-leaning parties are more receptive than left-leaning parties (R3). This was attributed to the fact that right-leaning parties are generally more pro-free market (R1), while left-leaning parties find more solace in the public sphere (R4). However, a respondent also indicated that sometimes, receptivity can vary from MEP to MEP regardless of political orientation (R1, R7), but more if they have a background in healthcare or not (R5). While another respondent indicated having a good communication across many of the political factions (R1).

Secondly, another consequence of a difference in nature between the two institutions concerns the sort of message that is sent in order to advocate for the pharmaceutical industry. Logically speaking, due to the technical nature of its activities the EC is approached more with expert information, while MEP's and its assistants are served more with political messages (R1). Lastly, another difference concerns the EC. Reported as having an industry perspective in mind, they are to consult with many stakeholders in order to draft legislation (R3). Several respondents indicated the impartial and objective nature of the EC (R3), and highlighted the fact that the EC is more receptive to collective action rather than individual action (R4). As was said in an interview, the EC is actually reluctant in meeting with a company individually, thus making collective action via trade associations and diverse coalitions especially effective in getting across a message given they take a sectoral perspective (R4).

4.1.2 Institutional access

When talking about access, differences were also noted between the European Commission and Parliament. In short, some indicated that getting access to the EC happened mainly during official consultation opportunities that are registered as well as open to every interested stakeholder (R1, R2, R6, R7). Another respondent indicated that in order to get access to the different layers of the Commission, a certain level of seniority is needed (R1). For example, only the director-general and president of the board of directors from EFPIA have access to the political leadership of the European Commission, while lower level lobbyists may have access to different layers of the bureaucracy (R1).

Another respondent indicated that it was even quasi impossible to meet the top political leadership of the EC (R3). This clearly highlights the greater access trade associations enjoy as opposed to particular interests. Additionally, a respondent mentioned that it is not only the interest organisations that contact the EC, but it can also be the other way around (R7). Furthermore, it can also be deduced that expert information plays an important role in gaining access. One respondent indicated that a key ask without data is just communication and not lobbying (R2). However, it was stated that the official consultation opportunities are limited in time, making early lobbying and timing crucial in effectively lobbying (R3, R5).

Additionally, it was indicated that some people are more relevant and influential in some dossiers than others. The principal stakeholder in the EC is reported to be DG SANTE, specifically unit D5, along with DG RTD and DG GROW (R1, R3). Important within these DG's are the heads of unit of those units in charge of the relevant dossier you want to influence (R3). It was furthermore highlighted that it is especially important to cultivate good relationships with officials within these departments, as Commission officials are more challenging to engage with (R3).

However, gaining access in Parliament is different from the Commission. One respondent indicated that generally speaking, MEPs are more accessible than members of the EC, while another one mentioned that MEP's are quite busy. Additionally, it was reported that not only MEP's are contacted, but also their entourage of assistants and advisors. Contact can be made in various ways, such as a simple email or call on the phone (R3, R5). Some respondents clearly indicated the importance of informal meeting opportunities, such as events (R1, R3, R6). These events are often organised by NGO's or patient organisations working, while the pharmaceutical industry sponsors them (R3). MEP and their assistants are invited to such events as keynote speakers, where they can signal their involvement in public health to their constituency. Afterwards, lobbyists can converse with them about subjects such as reimbursement frameworks and access to medicines (R3). In this way, they can raise their profile with their constituents (R1, R3), while lobbyists get informal access to policymakers. Furthermore, there are also some people and groups in the EP that are lobbied more than others. To put a number on it, one respondent indicated that there are generally speaking 10 to 15 MEP's that are particularly in the picture in a certain dossier, as you can see who is more knowledgeable than others in a certain dossier (R5) . For instance, respondents indicated having contact with the rapporteur of a dossier they are interested in, along with key MEP's and chairs from the ENVI, the ITRA and EMPL committees (R3, R4). Stakeholder mapping seems especially important in the ENVI committee, given the broad range of policy issues they cover (R4). Additionally, it was mentioned that MEP's have very little time due to a busy agenda (R5). Thus, their advisors and assistants are also important stakeholders to target, given that they assist the MEP's in their everyday activities (R1, R5)

Lastly and shortly, gaining access to the Council depends more on the foothold the interest organisation has in the national sphere. For example, if the organisation has a lot of production and investment in a certain country, relevant officials of those countries will want to listen more (R4). Overall, the Council is reported to be the most difficult institution in comparison with the EC and EP to gain access to (R7).

4.1.3 Institutional competencies

It is repeatedly mentioned that pharmaceutical legislation is peculiar and it is important to know it. This is attributed to the public healthcare system within the European Union, where a significant part of the competences lie on the national level, and boundaries on the European level are said to be poorly defined (R2). Given the healthcare system in Europe, member states and regions pay the price for the pharmaceutical products (R4). These so-called "public payers" are different from private consumers, making for an additional peculiarity in this policy-domain (R2, R4). Legislation is thus clearly split between European and national, and this is an important distinction is knowing what is possible at EU level (R2). One respondent indicated that this resulted in clear fragmentation within the pharmaceutical sector, due to the fact that the European level has to reconcile 27 national positions (R5). Furthermore, another respondent indicated that the boundaries of what constitutes pharmaceutical legislation is very unclear, and indicated that the "division" of legislation between the EU level and the national level fluctuates (R2). Certain periods the EU gains more competencies, while other periods competencies are transferred back to the national level (R2). Another respondent indicated that now, member states are pushing more and more issues to the Commission, continuing the cycle (R6). Lastly, the pharmaceutical sector is said to have less access and freedom compared to certain other industries due to the nature of pharmacological products. This reportedly makes for an additional difficulty (R2).

4.2 Issue-specific determinants

4.2.1 Coalition building

When questioned about coalition building, almost every respondent indicated having diverse collaborative relationships with multiple parties in order to add weight to their policy-preferences and indicate wide support (R2, R3, R4, R7), as diversity of a coalition was also mentioned to be a beneficial factor (R6). Firstly, among these collaborative relationships, memberships to trade associations will also be included. It was repeatedly stated that EFPIA is by far the most important trade association at European level for the (innovative) pharmaceutical industry (R4, R5, R6). Boasting a broad membership base of 39 companies and 36 national associations, EFPIA is active on most issues concerning pharmaceutical policy, such as access to medicine, regulatory policy and drug development policy (R1), but also intellectual property, environmental concerns etc. (R5). Generally speaking, a certain part of lobbying is driven purposefully trough the trade associations, while the rest is supplemented with individual lobbying (R2, R5, R6). While not very diverse, the benefit of trade associations would be that they indicate industry preferences, preferred among for example the technocratic EC (R4). In this way, trade associations also serve to resolve conflicts between its members internally in order to stimulate unity (R5, R6). One respondent indicated that different big pharmaceutical companies are also very often associated and members of several trade associations (R5). Additionally, the different trade associations , such as MEDtech Europe, EuropaBio and EUcope for example, also seem to have a good cooperation with each other, as indicated by one respondent (R1). This makes for a very interconnected industry.

Other respondents indicated having coalitions with patient organisations, on the national as well as EU level (R3, R4, R5, R6). Given that they are the people that the (innovative) pharmaceutical industry is trying to serve, they are great coalition partner in order to have your voice heard (R4).

However, this does not mean that all patient groups are equally willing to work together with the industry. As one respondent pointed out, certain patient groups are more willing than others. In addition, multi-stakeholder platforms can also be established, another respondent pointed out (R3). For example, events are organised in the name of one of the patient organisations and sponsored by the innovative industry, as mentioned before (R3). Other organisations mentioned where the innovative pharmaceutical industry pointed out to have a coalition with or be a member of said organisations include chambers of commerce, think thanks, research institutions, consumer organisations, payer organisations and sometimes civil society NGO's (R2, R3, R5, R6). However, one respondent indicated that coalition building is not always an easy feat, and while not a structural issue certain lobbyists themselves can stand in the way of forming an effective coalition (R3).

4.2.2 Opposition

However, the (innovative) pharmaceutical industry also has its fair share of opposition. While a respondent indicated that it was not structural, patient groups can sometimes even join the opposition, especially in the case of going against the innovative industry (R3). Other opposing groups predominantly seem to include civil society NGO's, think tanks and academia (R1), but also public payers and environmental groups, albeit for different reasons, such as access to medicines and sustainable production processes (R3, R7). One respondent even specified that primarily organisations considered left-leaning in the political sphere are generally speaking against the (innovative) pharmaceutical industry (R3)

The respondent that worked for a public concern NGO indicated that they are mostly on the opposing side to the innovative pharmaceutical industry (R7). Nevertheless, it was emphasised that cooperation can be possible on certain issues, further indicating that the issue context plays a predominant role in lobbying on the EU level (R7). They also indicated that opposing the innovative pharmaceutical industry is a very difficult feat due to several reasons. One such reason they indicated is because of the immense financial resources the innovative pharmaceutical industry disposes of. This in stark contrast with the public health NGO's, who apparently have great uncertainty concerning funding (R7). Additionally, the innovative industry seem to be a group of a few companies, meaning they can easily reconcile their positions with each other claimed the respondent. NGO's in the health space on the other hand, had difficulty uniting. This is attributed to the fact that there are many more small NGO's, and that certain of these NGO's are even on the pharmaceutical industry's payroll, making it difficult to form an united front (R7).

When asked about the success of this opposition, reactions were mixed. Certain respondents were absolutely sure that the opposition could not compete against the pharmaceutical industry (R3), while others were just as sure that they are an opposition that must not be underestimated, and that with a clear message and good reputation they too can have lobbying success (R6). Some opinions were more balanced though (R1, R4) and indicated that NGO's currently also have a substantial amount of staff and resources (R6).

4.2.3 Salience

Only one respondent explicitly mentioned raising awareness in order to place the policy-issue higher on the external agenda and ensuring that the position of their company becomes the industry voice (R2). There were no further conclusions to be made about salience.

4.3 Organisation/group-specific determinants

4.3.1 Resources

Although not always clear and explicit, it could be deducted that resources have an important place within lobbying. To specify, resources can take different forms. A first form that some respondents indicated, is expert information. this can be generated internally by the company itself, but studies can also be commissioned externally (R2). Trade associations are also instrumental in generating its own data as well as reconciling data from its members (R2). This data can be used to gain access to policymakers in the EC and is instrumental in order to substantiate one's own ask and are necessary in order to have an impact and your voice heard (R2). Considering the technical nature of the policy-domain concerning pharmaceuticals, the pharmaceutical industry has an abundance of expert information at its disposal which can be used for gaining access as well as substantiating key asks (R2, R3)

A second, and arguably the most important resource, is financial resources (R3). From data generation to monitoring to networking, each of these activities are necessary to conduct an effective lobby and requires staff that need to be paid. Also, it is often the pharmaceutical companies that sponsor many events, which also requires financial resources. However, when respondents were asked about this, the answers were varied. Two respondents indicated that the pharmaceutical lobby has substantial (financial) resources at its disposal, and that this certainly has a relevant effect on their lobbying (R3). Other respondents presented a more nuanced picture, arguing that the nature of their policy domain is so specially regulated that they have no choice but to spend so much to be effective and that similar, highly regulated industries have comparable expenditures (R4).

Nevertheless, the pharmaceutical industry has very high earnings (R3) and have footholds in several European regions (R2), meaning they bring high-skilled jobs concerning innovation, production and investments with them (R1, R4). Consequentially, combined with the resources they have, they can also exercise this economic leverage in, for example the Council of the European Union, given that they represent more the national perspective (R4).

4.3.2 Industry unity

An apparently frequent misconception outsiders have is the amount of unity and homogeneity within the pharmaceutical industry (R2, R3). There are a few different sectors within the pharmaceutical industry, each with their own business model (R6, R7). Sectors include for example the innovative industry, the generic industry, the biosimilar industry and medical devices industry (R2, R4, R5, R6). Two respondent indicated that there is good unity and collaboration within the innovative sector (R1, R7), given that they are a small amount of companies thus making it easier to unify their policy-preferences (R7). However, another respondent indicated that while they may be small in number, competition is always there because another company could be working on a similar innovation (R4). One respondent indicated that there is also less unity within the generic pharmaceutical sector, but

no reason was given why this was the case (R6). However, the two sectors were indicated to be most antagonist to each other (R2, R4, R6) even though this can be issue dependent (R2). The reason for this opposition lies in their respective business models. The innovative sector is mainly concerned with R&D and innovation to bring out new pharmaceutical products. Of course, intellectual property and patents play an important role in this. The generics industry, on the other hand, is mainly concerned with the production of off-patent pharmaceutical products. Consequentially, the generics would prefer shorter patent periods, while the innovative industry would like to keep the duration as long as possible. In this situation, they could be considered natural opponents (R4).

4.3.3 Reputation

When asked about the primary weakness of the pharmaceutical lobby on the EU level, reputation was mentioned most often (R3, R4, R6). As mentioned before, reputation is important in gaining access to policy-makers, given that relationships on the EU level are highly based on trust (R6). As seen in the European Parliament, reputation can also have a negative effect (R4). Considering the fact that the pharmaceutical industry is often seen as highly homogenous and high in unity, the misdeeds of one company would be attributed to the whole sector, even if other companies have had nothing to do with it (R6). However, two respondents also indicated that the reputation of the pharmaceutical industry has improved over time and COVID even had a positive effect, given that the industry could show its service and value to the world (R1, R2). Additionally, the reputation of the lobbyist himself is also an important aspect (R2). Lastly, another respondent indicated that public opinion and trust from the general public are also important aspects and not only trust from policy-makers (R1).

5. Discussion

The empirical results make it clear that there are certain parallels with the literature study, but also important differences. As for the similarities, there was an abundance of literature on coalition building being an important determinant for lobbying success, particularly the relative size and diversity of the coalition, which was in parallel with the empirical findings. The benefits of diversity in a particular coalition being contingent on issue salience however, was not addressed in the interviews.

Furthermore, while the literature about financial resources being a determinant of lobbying success was rather inconclusive, the empirical evidence indicated that it was rather important in the context of the pharmaceutical industry. This is evidenced for example by the finding that the pharmaceutical lobby is the one funding certain NGO's and patient groups, and sponsoring certain coalitions, with coalitions already being considered an important determinant of lobbying success on the EU level. Given the importance of financial resources, this has important implications for the pharmaceutical opposition. It was repeatedly mentioned that there still is a wide gap financially, regardless of the funding by the European Union. Furthermore, it was repeatedly indicated that a substantial amount of organisations are dependent on the pharmaceutical industry for funding, raising questions about their autonomy. Expert information as a resource however, was found to be crucial in the literature. Nevertheless, evidence from the interviews were mixed. While it was mentioned that every good lobby is based on evidence and data, some others placed more emphasis on financial resources.

Moreover, the results from the interviews clearly indicated that the pharmaceutical industry is not as homogenous as one might think, going against the monolithic assumption that is often made about this industry. However, trade associations clearly have an important place within pharmaceutical lobbying, in line with findings mentioned in the literature study. Conclusions about the opposition were mixed in the empirical section, but in this case, the pharmaceutical industry seems to be more impactful than its opposition. This is principally related to the disparity in resources and difficulty in coalition building, two determinants found to be impactful in achieving lobbying success.

Institutional differences, access and institutional competencies were remarkable differences. Although institutional differences were briefly described in chapter 1 of the literature study, they were not explicitly stated as a determinant of lobbying success. Access is also a widely studied subject in literature and was also mentioned in the first two chapters of the literature study, but was not explicitly included as a determinant. However, it is important to mention that only official access through consultation meetings were mentioned in the literature. The fact that events and unofficial occasions and meetings are used to gain access, however, has important implications for lobbying. This can mainly bring about an unequal level of access between the pharmaceutical interests and its opposition, considering that the pharmaceutical industry has substantially more financial resources to spend on such matters. Nevertheless, no conclusive statement can be made about this, requiring further research in order to do so.

Additionally, competencies were not included in the literature study as determinant given that no literature about the policy-domain that is pharmaceuticals themselves was included.

Moreover, issue scope, level of conflict and issue complexity were not mentioned at all in the interviews.

Additionally, while issue salience is an extensively studied subject in literature, no respondent mentioned it as a determinant. A possible explanation for this could be found in the questionnaire, where no explicit questions about these determinants were included. On the other hand, when asked about the important things in a legislative process or a weakness of the pharmaceutical interest, no lobbyist indicated high public salience as a determinant. However, reputation was often mentioned as a negative determinant, for which it could be deduced that the negative image of the pharmaceutical interest has a detrimental effect on issues with high salience.

6. Conclusion

6.1 General conclusions

This master thesis sought to explain the factors that make the pharmaceutical industry successful at the European level. The literature review began by providing a brief overview of the relevant institutions and their role in the lobbying arena that is the European Union, followed by a theoretical approach to the relationship between stakeholders and policy-makers. This section of the literature review aimed to provide a frame of reference in which the determinants of lobbying success should be interpreted, as different institutional settings could produce different results. It concluded that all three legislative institutions, namely the European Commission, the European Parliament and the Council of the European Union, each have their own characteristics, making for a different lobbying approach. The European Commission has the right to initiate legislation and is in charge of drafting up a legislative proposal. This requires an abundance of technical information which it cannot generate internally and must complimentarily seek externally, thus validating exchange and resource dependency theory. Generally speaking, the Commission has a more sectoral approach, making collective lobbying important in this institution. The European Parliament and Council of the European Union however, are more political and less technical. Furthermore, the EP is much more accessible in comparison to the Council. When combined with the knowledge from the empirical section, it becomes clear that MEP's and their assistants are generally most accessible, even in an unofficial context. Ministers from the Council however, are more accessible when the particular interest organisation has an (economic) stake in their country of origin.

The second part of the literature review focused on determinants of lobbying success identified at the European level. Three categories of determinants can be distinguished, namely institutional determinants, issue-specific determinants and characteristics of the lobbying group/organisation itself. The main institutional determinant identified in the literature was the amount of democratic accountability, where it was argued that the more accountable an organisations is, the more it will listen to interest organisations given they are a proxy for the voice of the constituency they represent. Issue-specific determinants were found to be the main explainer of lobbying success. The three determinants that were found to be most important in this category are in order of importance: coalition building, issue salience and finally level of conflict, issue complexity and scope. Literature indicates that the relatively bigger and more diverse a coalition is, the higher the probability of lobbying success. Salience however can have a different effect depending on several aspects. Firstly, it can have a positive effect on lobbying success if the interest organisation belongs to the relatively bigger coalition. Secondly, increased salience is reported to diminish lobbying success of business interests. Furthermore, level of conflict and scope seem to have a negative effect while level of complexity of the issue at hand seems to have a positive relation to lobbying success. Finally, the following determinants were identified in the last category: information supply, financial resources and group type. The type of information that is supplied and valuable on the EU level depends on the institution. Where the EC favours expert information, political information is supplied more to the EP and Council. Nevertheless, research about financial resources and group type are rather inconclusive.

The empirical research sought to uncover which determinants are of importance for lobbying success specifically for the pharmaceutical industry through interviews with individuals working in the sector. The aim was to identify possible new determinants, as well as to compare the named determinants with the those identified in the literature review. The results obtained from the interview were classified in the same way in the three categories identified in the literature study. Determinants relating to the institutional context concerned institutional differences between the EC, EP and Council, access to policymakers and, finally, the distribution of competences between the national and European levels. A curious finding was that certain parts of the EP are not willing to consult with the pharmaceutical industry, predominantly left-wing parties. Thus, the political climate of the moment can also have an impact of pharmaceutical lobbying success, although indirectly. Furthermore, unofficial meeting opportunities seem to be of great importance, while literature only mentions the official consultation opportunities. Concerning the division of competencies between the national and European level, it is hypothesized that if more competencies are brought to the European level, the pharmaceutical industry would have more lobbying success due to less fragmentation. However, additional research would be needed to substantiate this claim. Next, mainly two issue-related determinants were identified, namely coalition building and opposition. It is clear that the pharmaceutical industry is well connected with a diverse set of stakeholders, making coalition formation especially effective. However, opposition to the pharmaceutical industry seems to be in a sub-optimal state due to less resources and difficulties in coalition building. Finally, three determinants of the last category, namely organisation and group-specific determinants were identified, namely reputation, resources and industry unity. Reputation seems to be the biggest weakness of the pharmaceutical industry, and has clear effects in the EP. The pharmaceutical industry is also often viewed as a monolithic force, which is often also not the case. However, they dispose of a substantial amount of resources, clearly having a positive impact on lobbying.

6.2 Limitations & recommendations for further research

However, there are several limitations to this study. Firstly, a number of limitations were identified that apply to the empirical section of the thesis, more specifically concerning the respondents. Due to the specific profiles of the respondents, it was difficult to reach them due to their busy schedules. Of the 80 respondents contacted, only 7 respondents participated, which is too small a number to draw systematic conclusions. In addition, despite repeated attempts to contact policymakers, no policy-maker accepted the invitation, which means that their perspective was not included in the study. Hence, a suggestion for future research is to obtain this perspective and to compare it with this research, as well as to be able to form more representative conclusions by interviewing more parties.

Finally, this thesis only examined which determinants could explain pharmaceutical lobbying success on the EU level. However, it was not determined to what extent each determinant would influence lobbying success. If methodologically feasible and with regard to obtaining data, a future study could be set up with the aim of performing a regression analysis on the determinants found. In this way, the effect of an individual determinant on lobbying success could be determined. Nevertheless, lobbying success is already a difficult concept to determine due to the many contextual factors. In addition, the lobbying process can be very uncertain, with seemingly advantaged parties failing to

achieve the desired policies. Combined with the amount and kind of data that would be needed, it is hypothesized that it would be methodologically difficult to actually perform such a study.

7. Bibliography

Anastasiadis, S. (2006). Understanding corporate lobbying on its own terms (1479–5124). Royal Holloway, University of London. Retrieved from https://www.researchgate.net/publication/228749627_Understanding_Corporate_Lobbying_on_its_Own_Terms

Ball, P. (2020, 18 December). *The lightning-fast quest for COVID vaccines — and what it means for other diseases*. Nature. Retrieved 6 July 2022, from https://www.nature.com/articles/d41586-020-03626-1?error=cookies_not_supported&code=d9bc0b5c-5937-4797-a428-0bff0b98c8ed

Bauerschmidt, J. (2021). The basic principles of the European Union's ordinary legislative procedure. ERA Forum, 22(2), 211–229. https://doi.org/10.1007/s12027-021-00671-9

Berkhout, J. (2013). Why interest organizations do what they do: Assessing the explanatory potential of 'exchange' approaches. Interest Groups & Advocacy, 2(2), 227-250. https://doi.org/10.1057/iga.2013.6

Beyers, J. & De Bruycker, I. (2017). Lobbying Makes (Strange) Bedfellows: Explaining the Formation and Composition of Lobbying Coalitions in EU Legislative Politics. Political Studies, 66(4), 959–984. https://doi.org/10.1177/0032321717728408

Bouwen, P. (2002a). A comparative study of business lobbying in the european parliament, the european commission and the council of ministers: 02/7. (). Cologne: Max-Planck-Institut für Gesellschaftsforschung/ Max Planck Institute for the Study of Societies. Retrieved from ProQuest Central Retrieved from https://www.proquest.com/reports/comparative-study-business-lobbying-european/docview/1002707770/se-2

Bouwen, P. (2002b). Corporate lobbying in the European Union: the logic of access. Journal of European Public Policy, 9(3), 365–390. https://doi.org/10.1080/13501760210138796

Bouwen, P. (2004). Exchanging access goods for access: A comparative study of business lobbying in the European Union institutions. European Journal of Political Research, 43(3), 337–369. https://doi.org/10.1111/j.1475-6765.2004.00157.x

Broscheid, A., & Coen, D (2007). Lobbying activity and fora creation in the EU: empirically exploring the nature of the policy good. Journal of European Public Policy, 14(3), 346–365. doi:10.1080/13501760701243749

Burns, T. R., & Carson, M. (2003). European union, neo-corporatist, and pluralist governance arrangements: Lobbing and policy-making patterns in a comparative perspective. Sociologia, (42) Retrieved from https://www.proquest.com/scholarly-journals/european-union-neo-corporatist-pluralist/docview/1152160803/se-2

Coen, D., & Richardson, J. (2009). Lobbying the European Union: Institutions, Actors, and Issues (1ste editie). Oxford University Press. https://ebookcentral-proquest-com.bib-proxy.uhasselt.be/lib/ubhasselt/detail.action?docID=472159&pq-origsite=summon#

Cohen, J., & Rogers, J. (1992). Secondary Associations and Democratic Governance. Politics Society, 20(4), 393–472. https://doi.org/10.1177/0032329292020004003

Corporate Europe Observatory. (2021). *Big Pharma's lobbying firepower in Brussels: at least €36 million a year (and likely far more)*. Author. Retrieved from https://corporateeurope.org/en/2021/05/big-pharmas-lobbying-firepower-brussels-least-eu36-million-year-and-likely-far-more

DG IPOL & LEGI. (2019, November). Handbook on the Ordinary Legislative Procedure. Legislative Affairs Unit. https://www.europarl.europa.eu/olp/en/ordinary-legislative-procedure/handbook-on-the-ordinary-legislative-procedure

Dialer, D., & Richter, M. (2019). Lobbying in the European Union: Strategies, Dynamics and Trends (1st ed. 2019 ed.). Springer. https://doi.org/10.1007/978-3-319-98800-9

Dionigi, M. K. (2018). Lobbying in the European Parliament: Who Tips the Scales? In D. Dialer & M. Richter (Eds.), Lobbying in the European Union: Strategies, Dynamics & Trends (1st ed. 2019 ed., pp. 133–147). Springer. https://doi.org/10.1007/978-3-319-98800-9_10

Dür, A., & Bernhagen, P., & Marshall, D. (2015). Interest Group Success in the European Union: When (and Why) Does Business Lose?. Comparative Political Studies, 48(8), 951–983. doi:10.1177/0010414014565890

Eising, R. (2007). The access of business interests to EU institutions: towards élite pluralism? Journal of European Public Policy, 14(3), 384–403. https://doi.org/10.1080/13501760701243772

European Commission. (2020, 4 October). *Timeline of EU action*. European Commission - European Commission. Retrieved 6 July 2022, from https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/timeline-eu-action_en

European Commission. (n.d.). Types of EU law. European Commission - European Commission. https://ec.europa.eu/info/law/law-making-process/types-eu-law_en

European Parliament. (n.d.). European Parliament: members, bodies and activities. Europarl.Europa.Eu. Retrieved August 11, 2022, from https://www.europarl.europa.eu/portal/en

Flöthe, L. (2019). Technocratic or democratic interest representation? how different types of information affect lobbying success. Interest Groups & Advocacy, 8(2), 165-183. doi:https://doi.org/10.1057/s41309-019-00051-2

General Secretariat for the Council of the European Union. (2020, October 6). Council configurations. European Council. Retrieved August 11, 2022, from https://www.consilium.europa.eu/en/council-eu/configurations/

Godwin, E., Ainsworth, S. H., & Godwin, K. (2012). Lobbying and Policymaking (1ste ed.). SAGE Publications. https://doi.org/10.4135/9781483349336

Greenwood, J. (2019). Interest Representation in the EU: An Open and Structured Dialogue? In D. Dialer & M. Richter (Eds.), Lobbying in the European Union (1st ed. 2019 ed., pp. 21–31). Springer. https://doi.org/10.1007/978-3-319-98800-9_2

Guéguen, D. (2019). Reshaping European Lobbying: How to Be One Step Ahead. In D. Dialer & M. Richter (Eds.), Lobbying in the European Union: Strategies, Dynamics & Trends (1st ed 2019 ed, pp. 93–102). Springer. https://doi.org/10.1007/978-3-319-98800-9_7

Hanegraaff, M. & Berkhout, J. (2018). More business as usual? Explaining business bias across issues and institutions in the European Union. Journal of European Public Policy, (), 1–20. doi:10.1080/13501763.2018.1492006

Health Action International. (2022, 17 July). *HAI statement on the outcome of TRIPS negotiations at WTO MC12* [Press release]. Retrieved from https://haiweb.org/publication/hai-statement-on-the-outcome-of-trips-negotiations-at-wto-mc12/

IFPMA. (2021, 16 December). *11 billion COVID-19 vaccines produced in 2021 has resulted in the biggest immunization campaign in human history and 2022 will require more and better vaccine redistribution and innovation*. Retrieved 6 July 2022, from https://www.ifpma.org/resource-centre/11-billion-covid-19-vaccines-produced-in-2021-has-resulted-in-the-biggest-immunization-campaign-in-human-history-and-2022-will-require-more-and-better-vaccine-redistribution-and-innovation/

Klüver H. (2011). The contextual nature of lobbying: Explaining lobbying success in the European Union. European Union Politics. 2011;12(4):483-506. doi:10.1177/1465116511413163

Klüver, H. (2013). Lobbying as a collective enterprise: winners and losers of policy formulation in the European Union. Journal of European Public Policy, 20(1), 59–76. doi:10.1080/13501763.2012.699661

Laboutková, Š., & Imral, V., & Vymětal, P. (2020). Transparent Lobbying and Democracy (1st ed. 2020 ed.). Palgrave Macmillan. https://doi.org/10.1007/978-3-030-36044-3

Mahoney, C. (2007). Lobbying Success in the United States and the European Union. Journal of Public Policy, 27(1), 35–. doi:10.1017/s0143814x07000608

Mayer, L. H. (2008). What is this "lobbying" that we are so worried about? *Yale Law & Policy Review*, *26*(2), 485–566. https://doi.org/10.2307/40239700

Newmark, A. J., & Nownes, A. J. (2019). Lobbying Conflict, Competition, and Working in Coalitions. Social Science Quarterly, 100(4), 1284–1296. https://doi.org/10.1111/ssqu.12644

Patients for affordable drugs. (2021). *Big Pharma's big lie: the truth about innovation & drug prices*. Author. Retrieved from https://patientsforaffordabledrugs.org/2021/02/03/innovation-report/

Pharmaceutical Technology. (2020, 31 January). *The biggest ever pharmaceutical lawsuits*. Retrieved from 6 July 2022, from https://www.pharmaceutical-technology.com/analysis/biggest-pharmaceutical-lawsuits/

Rasmussen, M. K. (2015). The Battle for Influence: The Politics of Business Lobbying in the European Parliament. JCMS: Journal of Common Market Studies, 53(2), 365–382. doi:10.1111/jcms.12156

Salgado, R. S. (2013). Rebalancing Interest Representation? Associative Democracy and EU Funding of Civil Society Organizations. JCMS: Journal of Common Market Studies, 52(2), 337–353. https://doi.org/10.1111/jcms.12092

Schendelen, R. V. (2013). *The Art of Lobbying the EU: More Machiavelli in Brussels (revised edition)* (Revised ed.). Retrieved from https://ebookcentral-proquest-com.bib-proxy.uhasselt.be/lib/ubhasselt/reader.action?docID=1773763&ppg=34

Stevens, F., & De Bruycker, I. (2020). Influence, affluence and media salience: Economic resources and lobbying influence in the European Union. European Union Politics. 2020;21(4):728-750. doi:10.1177/1465116520944572

Streeck, W. & Kenworthy, L. (2005). Theories and practices of neocorporatism. The handbook of political sociology: states, civil societies, and globalization, 441–460. https://nbn-resolving.org/urn:nbn:de:0168-ssoar-194994

Tansey, R. (2015, 4 September). *Policy prescriptions: the firepower of the EU pharmaceutical lobby and implications for public health*. Corporateeurope.org. Retrieved 7 June 2022, from https://corporateeurope.org/sites/default/files/20150904_bigpharma_web.pdf

Zibold, F. (2013). *Lobbying the EU institutions*. European Parliament. Retrieved from https://www.europarl.europa.eu/RegData/bibliotheque/briefing/2013/130558/LDM_BRI(2013)130558_REV1_EN.pdf

8. Appendix

Interview respondent 1

L: hello Mrs x and thank you for participating in this interview. Could you please briefly introduce yourself and the organisation you work for

R1: my name is R1, I am a (redacted) public affairs for efpia. We are a trade association working at EU level representing the pharmaceutical industry, so companies that do research and development in member states. We have 36 national associations, because we are a European federation so we are representing our national associations in interacting with Brussels institutions. We also have 39 companies that are direct members of efpia so together with our members we interact with EU institutions as well. We also represent small and medium size companies, recently more and more SMEs have joined efpia. Together with our members we advocate towards the eu institutions to create a legislative framework that really supports research and development for medicines, to make sure that our members have a predictable and stable legislative environment that allows them to bring R&D to European patients. Also to contribute to the European investor ecosystem because a significant amount of our members have manufacturing facilities across Europe, which create jobs and other opportunities. My role as public affairs director is to represent and to facilitate the interaction with EU institutions. EFPIA has different teams, some of which are focused on specific policy topics like scientific, regulatory, drug development policy, as well as on access to medicine policy. My role is that the work that my colleagues, as well as the working groups that they are leading in policy, that that work is well understood by EU policy-makers. So really building that bridge between EU institutions and the expert work. For that I reach out reactively to, for example commission representatives from the highest level as well as members of parliament representatives as well as council so really covering all main institutions. Furthermore I've been involved in public affairs for 12 years, maybe I can go ahead and speak about my past experiences?

L: Yes, please do! I'm very interested

R1: So I've really grown into the public affairs profession. I started out as an external affairs public affairs specialist, and then moved on to manager and now director for public affairs. I started in a company x, and then worked for several pharmaceutical companies also working for national institutions and then I really wanted to develop and be challenged in working with European institutions and then I took on the role with EFPIA. I also have a bit of public sector experience, I was an advisor for (redacted), so I have that inside knowledge of how institutions work. But I've always wanted to interact with policy making institutions and decision-making so I found a public affairs role just what I was looking for. I don't have a scientific degree, but I have a degree in international relations and political economy so I don't come from the medical or pharma education but that has helped me have a more objective view on policy-making in health and pharmaceutical rather than when you come from the medical field where you're very much into the topic of curing and treating disease.

L: very interesting, very interesting. Onto the next question, so I understand that advocacy is one of the core parts of EFPIA, could you please just generally and briefly explain to me the lobbying and public affairs process and steps and activities it entails.

R1: of course! So, as I've already mentioned, EFPIA is structured around working groups. So several working groups working on different policy aspects such as intellectual property framework or regulatory medicines approval framework or access to medicines, also we have a legal working group. So all these working groups are analysing the regulatory policy framework and my proposals on what could be improved or changed or rather kept as it is, they gather information such as case studies for members and put out policy papers. Next, the advocacy team comes in and looks at the policy papers and reads them from the perspective from a policy maker or politician and takes out from the policy papers the key messages that would make a difference for a politician that would really change his mind or make additional arguments on the politicians speeches. Then, having these messages we look at who are the key stakeholders, who are the key people that we should be meeting. Who are the key people in the decision-making steps and how influential they are and what kind of messages and narratives would make them connect or make them tick with our advocacy objectives. So after identifying them we reach out and send meeting request to meet bilaterally or in partnership with several organisations, think tanks, advocacy groups or organise events with policy-makers to debate the policy proposed solutions. We are an association that represent our members so we also facilitate meetings for our members to interact with policy-makers. So It's not just EFPIA that is involved but we also always have our members involved as well.

L: Okay thank you for your answer. Then, how would you describe the relationship between policy-makers and public affairs officers such as yourself?

R1: It's an interesting question and I think a very good one. I think the relationship has improved over time and- I would say developed over time- and it also depends on what type of stakeholder you're thinking about. So if I go back to my times in x , there was very little knowledge of this profession and how to interact. We did not have and do not have a lobby legislation, so legislation regulating the lobby profession, and it gets very often associated with unethical practices. But I would say since the 12 years that I started and the situation in x has improved a lot in the sense that policy-makers trust public affairs professionals a lot more than they did 12 years ago. The lobbying and advocacy instruments and activities are better understood and not seen as unethical to the same extent as they were.

L : so it's more of a mutual benefit relationship instead of the stereotypical unilateral view?

R1: I would very much say so. Of course it depends a lot on how you build your relationships as a public affairs professional and how you position yourself, but definitely policy-makers understand better what public affairs professionals can bring to the table and that it is a win-win relationship. So we bring information, we bring data, we bring arguments, we bring messages that the politicians can then read it and if they do, can speak out on. And as a public affairs activity we also give opportunities for them to speak up by inviting them to events and giving them press opportunities to really give them the opportunities to be visible in front of their electorate. So we can really be seen as partners for the policy-makers. Of course this also applies to the EU level, but rules around lobbying are much stricter. There is for example the transparency register where organisations such as EFPIA need to be registered if you lobby and where you need to be updating your information before any EU institution meets with you. So in that sense it is a more structured and more formal process but in terms of building a trustworthy relationship it is the same. They very much understand what EFPIA

can bring to the table, the fact that we assist in providing the data, we have the means and resources to conduct studies and bring evidence forward that then the Commission, the Parliament and Council can use in their decision-making. So we do have a well-deserved seat at the table, we are invited into the Commission workshops when they do the consultations on the topic of our interest for the pharma. We submit of course our proposals as well and they are received as formal info so I would say that overall the interaction is a stable one.

L : thank you for your answer, it clears up a whole lot for me! So let's talk a bit more about the Commission as it is often dubbed as a prominent lobbying target on the EU Level. Why is that and in which ways does EFPIA gain access to the Commission and are there certain people in certain DGs that have your special attention because of their position or their influence.

R1: If I understood your question correctly, you're asking why the Commission is the most lobbied institution. I would say go back to the founding Treaty of the European Union. So the Commission is the one that is putting forward proposed legislation, they are really the ones who are drafting as they have the expertise to draft the legislation that is then passed to the Parliament and Council and is negotiated. The Parliament and Council are in my view the more political institutions but the Commission is a more technical decision-maker. So I think the answer to your question is then how the European Union works and what's the role of the Commission in the legislative process. Indeed there are different people that we interact more within the Commission because of their responsibility and role in the process so for pharma it's DG SANTE d5 unit that are in charge of medicines policy so that one is one we are interacting more with. That's not to say we don't interact with other DG's as well, because pharmaceuticals also fall for example under TRADE or GROWTH because pharmaceuticals will be a source of jobs and growth in Europe. Of course there is DG RTD for research that is also an important stakeholder for us. Those are at the technical level but we also interact on the decision level as we also for example interact with the cabinet of Commissionaires so commissioner for growth, commissioner Donbrovski for trade and research so it really goes up to the highest level and we have all these stakeholders mapped out in terms of relevance and influence, but as well the needed level of seniority in order to interact with them. So, for example it is our director-general Nathalie Moll who interacts with the commissioners or president of the commission and our president of the board of directors, one of the member companies, that has the opportunity to meet for example the president of the Commission. But then we as directors within EFPIA have the level of seniority we engage with as well because we might be well aware that seniority is also important, it is important who to reach and at what level as well.

L : Again thank you for your elaborate answer, but could you elaborate a bit more on the EU Parliament as it's an important co-legislator? Is there a difference in advocating commissioners or members of the Commission and MEPs? What's the difference in lobbying both institutions?

R1: I would say that there is not a difference in how relevant we see both institutions. We see them both as relevant because as you say there is codecision. But we do approach them, try to influence them using different messages. So for the Parliament, knowing that they are political stakeholders as they are politicians we engage with them using more political messages and less technical ones because there is not technical knowledge in the Parliament among our very technical topics in pharmaceuticals but rather more were we want to see Europe going in terms of access to medicines,

meeting the needs of the patients. So the difference is in the types of messages we're using but not in the number- of course MEPs are a bigger group so there is more to meet than the Commission where there is just a handful of people to meet- but we see them as important. But not only the MEPs themselves but also their assistants who actually support them in their everyday activities. So we have repeated meetings and conversations with assistants, trying to build a partnership and collaboration.

L: I would assume there are certain people who are more important or relevant to lobby in the EP?

R1: Yes indeed! So we look at the specific files but also look at the leadership structure. So we engage with the chairs of the relevant committees as well as the political coordinators for each topic so it's not only specifically but also trying to build a relationship with the different political groups on the longer term.

L: are there certain political groups you work with more closely than others? Or some who are not so cooperative?

R1: Yes, I would say so. We look at the MEPs as a group but also as individuals so we have, I would say, some industrial groups representatives and MEPs wo are more free-market oriented who we have more communication with and we are more aligned with. As it is also such a social topic and social impact we do have a good collaboration with groups such as S&D (social democrat?) and green MEPs on the environmental side so we do engage with MEPs across political parties. A lot of our members are doing a green transition so.

L: Okay thank you for your answer. Let's talk more about the pharmaceutical industry and lobby in a competitive context. How would you describe the position and the influence of the pharmaceutical lobby and your organisation in the EU political arena relative to other influential organisations?

R1: that's a very interesting question, indeed I don't have the numbers on which industries are spending more on public affairs but what I can say is that EFPIA is well resourced and well-staffed, we have around 65 colleagues so in terms of numbers we are well placed comparable to maybe other strong associations from other sectors such as digital for example. But in terms of the numbers I recall seeing some numbers where digital companies were investing a lot more in public affairs and lobbying activities than pharma companies. So I would say we are well placed but we are not the largest spender.

L: Would you say that there is maybe an alliance between IT and pharmaceutical generally speaking?

R1: Yes, generally speaking I would say that there is a good collaboration between the pharma and medical devices – so Medtech Europe. We as EFPIA as well as Medtech Europe are partners with the EC in the innovative health initiative. So this is a European public-private partnership that is looking at developing research projects in health, financed by both EFPIA Medtech and the EC. So yes, there is increasing collaboration because of the natural connection, think of medicines being delivered to patients trough medical devices. I would say that we definitely have a good relation with other associations representing R&D and biotech companies, so EuropaBio and EUcope, so we have regular calls with them. We have regular touchpoints and we do advocacy activities together like releasing an publishing joint statements, going to meetings jointly, so there is a lot of overlap as well.

L: so to conclude on the EU level, the pharmaceutical industry acts more like a group rather than a collection of individual companies?

R1: I would say that yes there is increasing collaboration and alignment between trade associations representing the industry, so yes I would agree with that statement.

L: Yes thank you. On the note of good collaboration, which opponents and other sectors oppose the pharma lobby on the EU level and how do they counterlobby?

R1: So, in terms of the most vocal opponents that we have been seeing in recent years is an opposition from think tanks and NGOs that are working on health and access to medicines. They have been vocal against industry practices in terms of pricing medicines and putting them on the market. Also civil society groups not necessarily representing patients but rather the society. And they, of course have good access and good speaking platforms so they organise events where they challenge our business model, they put out statements. So in that sense I would say that the civil society groups are quite influential in challenging the industry and they have been getting a lot of traction, also from the WHO. WHO now has a platform to discuss access to medicines. And gathering civil society group but also academia to challenge medicine prices and that is quite visible as well. But if that will be successful in changing the legislation? It is yet to be seen.

L: I have another question but I think you have already answered it. In light of these new initiatives and such, how would you view the future of the pharmaceutical lobby? Is it possible that the pharmaceutical lobby will gain or lose influence?

R1: It is not an easy question, to anticipate the level of influence. What definitely is keeping us alert is the fact that more and more - there is a chance to challenge business interests in the general public/general opinion, and the policy-makers are looking at what the public says, if the public says that it is opposed to various industry politicians would be influenced by that. So as long as there would be a growing opposition from the general public to big business – because EFPIA represents Big Pharma, the big R&D companies – then it will be difficult for EFPIA to remain influential in advocating for a business –friendly environment.

L: So the biggest threat would be a negative public sentiment.

R1: Yes, yes. Indeed. If the general public can't trust that companies can solve societal issues or meet the needs of the population , then our industry will become less influential. There are trends and discussions how about having more public sector investment into developing medicines. Well I come from x and we had a x regime for long, doing everything but actually really doing nothing. So they were not able to meet the needs of the population although they were claiming that only a state-owned industry will work. So maybe now that the younger generations don't remember that time anymore, where there was a lot of state control. But I am quite the pro-business and pro-market person and I have this philosophy so I don't think the state will be able to develop the medicines we need and that we do need the business sector to take risk and invest and develop these medicines.

L: Would you say that it's also a growing dissatisfaction with political institutions, such as EU institutions which are often labelled as mysterious by people who aren't that interested in politics or don't work in the public sector.

R1: Yes, definitely, there is a lack of trust in institutions because they are not transparent enough and can be quite opaque. So people don't really understand how decision-making is done and what they don't understand they don't trust. On the other hand maybe with COVID and how the government reacted some of the trust would be regained.

L: Okay, so those were all my questions. It has been a pleasure interviewing you and I really learned a lot. Thank you once again very very much for your time to participate.

R1: I also really enjoyed the interview and I wish you good luck on finishing your master thesis! Have a nice day, bye bye.

L: You also, bye.

Interview respondent 2

L: Hello Mr x and thanks for participating in the interview. I would say let's jump right in, Could you please introduce yourself and describe your job?

R2: Sure, with pleasure! So, my name is x and I'm the director for EU government affairs at x, based in Brussels. I started in this position a bit more than two years ago, a bit before the pandemic. My main area of responsibility is to be the face, the representative of the company in Brussels toward the EU institutions. So I'm responsible for the x agenda in Brussels. Overall, I would say I cover all the topics, but in terms of expertise lies very much in industrial policy and covering for everything related to IP or to trade, for instance so these are the types of measures I will cover. I have more than ten years of experience in the pharmaceutical sector specifically, as a lobbyist. I have started actually – I'm a lawyer as a background education specialised in EU law, I actually studied it here in Belgium in Bruges. I started working for trade associations during lobbying for the pharmaceutical industry here and then moved to corporate law, I actually relocated out of Brussels in a global role, still in the public affairs domain, with a similar type of responsibilities I have today. I also worked for different sector, not only for the novelty industry but also for the generic pharmaceutical industry for a little while. Prior to x I also had an experience working in the public sector as an attaché for the Danish delegation in Brussels, getting directly exposed to the work that the national delegation would carry inside the Council. I was reading your questionnaire and I already started putting some thinking around some of your questions. I don't know if you would like to start in a specific order or do you have anything that you would like to ask up front?

L: I would say, let's just follow the questionnaire chronologically. I think that would make things easier. So could you please briefly explain to me the general advocacy process and what main activities it entails?

R2: So, while I was reading your questions I think you framed it, you tried to frame under the term advocacy something that I would normally frame under public affairs?

L: Yes I actually use the terms interchangeably.

R2: Yes because to me advocacy falls under public affairs. Public affairs really relates to me the strategic management of the overall relationship that a company may have with external stakeholders and how you interact with them. This of course relates a number of different activities such as the policy-shaping, the positioning, communication but also PR and actual lobbying/advocacy. Normally, here in Europe, we tend to use the term advocacy over lobbying because of the negative connotation associated with lobbying, while lobbying is a bit more frequently used in the US. But of course this can also cover campaigning, raising awareness activities. So there is a wide range of activities and I would say there is no strict rule, so now you would use all those types of activity along your process but it is more you that set up certain specific objectives that you set up front, how you want to be positioned on certain topics and therefore how you want to be seen by the external stakeholders and decide how you want to place them strategically in your work. So that's to me the main phase. Of course, I do know that when we think about public affairs but also advocacy specifically, we tend to refer to what is the legislative process. But I would actually take up a wider perspective because this would actually relate more to what I would call shaping the external environment which may lead ultimately, to a legislative framework where you would actually like to shape and input a certain legislation and the process because that is actually more the key element that you would think about. It's more to say how things would start normally. So, you would be the type of company- for the type of company we are we have quite a portfolio of pharmaceutical products, we have a large footprint in Europe, we have a number of diverse interests which would be from strict pharmaceutical but also digital green agenda- so it's quite wide, the spectrum of issues we would cover. The way I would say it starts more in the internal perspective, defining what your type of priorities are and see how these would be placed, defining your objective, and around that defining a clear positioning. Then you would also start monitoring the external environment, to see actually how things are moving. Because what you will normally see, there are a number of debates that would not necessarily lead to a legislative process because of course you have an external health agenda with policy priorities that has to be pursued. But what I would say is that overall, it is up to you to see what is that match based on your own priorities, where the priorities are placed on the external agenda, and then also it's about how you shape the debate. So, up front, just working on examples we could say a certain priority for me is very high, but on the external environment it's not that high. So as a public affairs/advocacy point of view I need to monitor the debate, I need to shape the environment more externally, I need to raise more awareness because this is actually a more important issue that needs to be debated. So you start exactly engaging externally, in public debates, with other stakeholders to see with who you could partner with and engaging also with policymakers to start bringing the topic on the table to really see how you could move it up to the agenda. Then the ultimate goal may be, a revision of a new piece of legislation or a new piece of law, but it can also be a policy major sometimes that can be for example a new type of guideline like some political commitment depending exactly on what you want to do because on the EU level it's also understanding exactly what type of activity you could really do because if you look at the health care space, the boundaries are not very much defined at the EU level in terms of competencies. Actually, we have seen now with the (inaudible) a different trend. Now I know I'm moving a bit from your original questions.

L: no problem at all, please keep going!

R2: Okay good. Anyhow stop me if something is not clear or you think it's not relevant or you want to know more.

L: ah yes I would like to interject for a moment. So, lobbying success really depends on the issue context, for example in one situation success can be preventing a certain piece of legislation while in the other case it can be really pushing the legislation.

R2: Yes that's basically it. I mean it's your objective that would define how you act after all, that's the starting point. It's always an internal process first in terms of setting your objective and then your overall positioning, so how you would be externally positioned. Only after that, you can start the external work. The external work normally would lead a step – for a company of our size but also for others would be – members of other associations. So actually, how to be sure that our position becomes the industry position so to shape the voicing of the industry because that is what actually would improve your weight externally. So a step-wise approach that would lead ultimately to – how you can basically increase your representation to be sure that your voice is heard and your points are taken aboard. What I was saying before, on the legislative process, if we look at bit more strictly on the process we need to start with a preliminary point. COMPETENCES. It's key at the EU level to define what you can do. When we look at healthcare, you have pharmaceutical policy which is very much industrial policy and that's very much a EU competence you know with the establishment of the EMA and the approval process of pharmaceuticals, with the free movement of goods, with incentives that are given to innovation to support there. Then you have the so strict more healthcare policy which is all about access to medicines, pricing and reimbursement of those medicines on a national level because as you're probably aware, in Europe we have a system of universal healthcare. So we have public payers - for the vast majority of medicines, all these things would be covered by your health care services on a national level, especially for the novelty pharmaceuticals. So, you have this interaction and different boundaries, but the competences are not always super clear and well defined and the more we integrate the internal market, the boundaries get very much unclear. For instance, we have seen a tendency in the late 2000's to the earlier- before the credit crunch where we have seen an expansion of EU competencies in the field of health, with many new legislation coming in but also replacing directives with new regulation which would actually set a complete different way how you would approach a certain matter at the EU level and then when the credit crunch did come in, a number of – actually we did see a different type of tendency with member states trying to regain competencies from the EU level. So actually we have seen a back and forth from the two. Now, because of COVID, we have seen a new trend coming in with more Europe. So we see and hear more frequently about moving toward a European health union and see about how we could make that happen. So we are now in a process were all our key legislative files and framework under which we have operated so far is going to be under review by the end of this year with the EC putting some proposals on the table. So that is to set the scene. So when you are in a situation like this one it is very much important to , as a company, to define clearly what would be your priorities in such a legislative environment and situation and you see exactly what are the type of data you need to support your advocacy because a good advocacy is based on data, solid and robust data. I mean at least I'm a supporter of fact-based advocacy because otherwise, if you don't substantiate your key ask with data, it would be like communication and that would not be public affairs.

L: And with data you mean expert, in-depth technical information as opposed to information about public and stakeholder preference. So really –

R2: So, it could be different ways. It could be generating your own data so you would be sure that you have the input, the company data in a certain manner so you can substantiate a certain ask, and be sure that this is done in the association work. Because there is a lot of work that has to be done in association when it comes to this type of things. That's the first one. The second thing could be commissioning studies, and that's something we could do as an association – not so much as an individual company, but certainly as an association – we will normally conduct a lot of studies in the area of our interest so we can see how the market looks like or how certain issues look like in order to substantiate some of our key asks. Then the other part of the work is about inputting the decision-maker, which normally in this phase is the EC. So, as you know, in the legislative process –ahead of the process – you would have a series of consultations – which could be public consultations, which could be hearing of stakeholders, workshops , meetings that you would set and organise – you should use that phase strategically to input your decision-makers with the right data at the right time so that you can also have your voice heard officially as well. To do these things, I think there was a point where you asked how you can be sure that you are heard-

L: specifically how you would gain access yes

R2: Exactly, so I think what you should think about at the EU level is rather , it's a matured market. I don't think we are yet at the top level as it would be in a situation like the US, but we are moving to that area and I think we are pretty advanced compared to some national situations. To operate as an organisation, you need to be registered in the EU commission transparency register , with all your financing, lobbyists, activities need to be published there. And the organisation you work with, you need to also be sure that they are registered. Every year, we run this process in the association – but also individually, to report on our activities and all the work we do. So this is the prerequisite to operate externally otherwise we cannot operate. Every interaction with an EU institution is registered, at least at commission level. EU parliamentarians have this option, if you go to the website you will see that some are reporting on the activities and some are not, they still are free to choose. Delegations – national delegations at the council level – to my knowledge, they still have this type of freedom and I am not aware of any reporting of meetings in that sense. But, of course we as a stakeholder, we bring wider interest. I mean , as (pharma company) we are an organisation with x employees and we have an important foothold in your region – meant as European union- with an important footprint so we have a wider representation. So, there is normally an interest also from the policy-makers to hear from us who are the experts in the sector. What you never should forget about is that we as a stakeholder have an interest to be heard, but the policy-makers also have an interest to hear from us because we are the subject matter expert and we are those who can provide the information on how the market works and why it works in a certain manner. Of course, you as a public institution have the responsibility so ensure that all stakeholders are heard and that all the voices are taken aboard. But we as a private one, we are those who have to be sure that we are heard and it's up to us that if we do a good job that we do it structured in the right way so that we are heard the way we want to be heard and understood the way we want to be understood.

L: Very good, I think you answered a few questions all at once there. So I would say let's move on a bit: how would you describe the position and the influence of the pharmaceutical lobby in the EU political arena.

R2: So, well, when we look at pharmaceutical – when people think of the pharmaceutical industry, normally it comes with a number of misconceptions and myths that need to be demystified. Of course there have been issues and scandals in the past decades, but if you look overall: we are one of the highest regulated sectors and I think, compared to that time, if we look how fast we have moved so far it's impressive.

L: Excuse me, but would that also explain why the pharmaceutical lobby is so present and has such a high expenditure compared to some other groups, just because this sector is so highly regulated?

R2: Yes, this indeed plays an enormous important role in that. Of course, the increasing competencies of the EU plays also another extra role in that. And because of the high, strong interaction with public payers that we have because of the system it is very important for a company that wants to play properly in the market, that it is capable of interacting with those people in the market. So you really need to have experts who know how to speak to governments because otherwise- you can not have a situation where you have people who have purely commercial experience interacting with those people because that would lead to problems because you would not speak the same language. While other sectors who normally operate on the private market, for example cars and foods, all of these things would entail private consumer money. So, it interests other kind of players. When it comes to pharmaceuticals, it would probably involve more public money and that's why it changes in that sense. And you would see that the type of access of stakeholders compared to other sectors is completely different in the sense that you would not have the same type of freedom that you would enjoy if you work as a lobbyist for the food industries or other industries. So those types of industries have a wider access to stakeholders compared to pharmaceuticals. So in that sense, it is quite a different game. Then of course, we need to look in more detail at the pharmaceutical industry, which is not as homogenous as you would think. First of all, we have different sectors that are represented. You have the novelty pharmaceuticals, that I work with, which are those who bring new medicines to the market, called originator medicines and also patented medicines. Then you have the off-patent medicines, which is the generics, and then you also have the biosimilar market. And then you have the consumer medicines or off-the-counter, because you have a lot of medicines which are out of pocket of the patients that can access them freely without a prescription. So in that sense, it is quite a wide sector the pharmaceutical industry. When it comes to weight and reputation and everything, I would say, personally, I think the reputation of this industry has improved a lot in the past decades at least and I think COVID helped to show the good of this industry. One element that has to be taken into account is that because we are looked as an homogenous category, normally individual company behaviours which may raise several questions would negatively affect the whole category and that's the situation that we are in, while being honest, in my experience working for different companies already, I can tell you that companies are different. Of course there are similarities, the business is same for everybody, but you can see the difference between companies when you are internally active, while that is not always evident from the outside.

L: And going further from what you have said, you explained the different categories and would you say that the pharmaceutical industry often acts in unison or is there more a fragmented industry in terms of lobbying. So you also said that you would make the position of your company the industry position, do you often succeed or?

R2: I would say it depends on the issue. There are some issues that could be a bit more divisive, others certainly would be easy to reach consensus. It depends very much on the specificity, I mean many of us are competitors so there can be divergent interests so it's – and we may operate in the same therapeutic area so it's quite complicated in that sense –

L: excuse me for interrupting you, so also in the public affairs sphere , you would say that there is competition between pharmaceutical interests.

R2: yes, because normally you would have big – the wider industry position under which everybody operates, but then you as a company may have some specificity that you may want to still push forward. OF course, that would still fit the larger position, it's not something that would go against , but you want to be sure that those points are taken on board too as individual company to get those points in. This is about your own network, your own presentation that you have built as a company as an expert on a certain matter, so to be sure that what you bring to the table is heard while others may actually try to do the same, so then it is a race. But you cannot always measure, you always see it at the end so it's a bit difficult.

L: and would you say that is also issue dependent? Meaning that issues that are more sector-wide for the pharmaceutical industry, that it unites more in comparison with industries that are very niche?

R2: I would say normally, the more we get into the detail of something, the more we start seeing differences. When we are in a phase when we are waiting for new legislation to come in, we have some key general industry asks where every company defined its own position, we may have a few divergences but we are more or less there. When the actual legislation is then put on the table, then you would see the actual law- what each line and word would say – and then you can assess what would impact you. And sometimes, you may have a more or less positive affect on you, individual company because of your own exposure. So there are some measures that could affect – I don't know, the orphan medicines for the sector. Clearly, companies who have a portfolio of products which would for example be focussed on rare diseases, would be higher affected than companies like us and have probably a more clear interest there. So if being an expert company in that space would also qualify you as an expert, as somebody I would like to hear the voice of- a company who is investing in rare diseases rather than other companies. In that sense it varies lot. In the same sense I would say it applies to associations. Associations tend to aggregate the positions at industry level, but to do so they also need the expertise. So it's up to you as a company to be sure that you provide the right expertise at the right time to those who are committed to come to the meeting to contribute and provide inputs to the generation of the data to give strategic advice, etc. And the more you do it, the more you position yourself, so you build your reputation, you build your position based on your commitment so the more you give, the more you would get, which is quite important because – and the earlier you start, the more you would get because if you come at the very last when it is almost pretty defined you would have very limited chances to shape that position. So it's important

that you go in the beginning. And you would see that for some prioritised issue somebody would like to take the reporter sheet so "I'm happy to volunteer to draft the first paper" and you would be the responsible for the drafting of the paper, and then everybody would have to comment on what you are putting in. So you see, there are a number of things that you can do, but it always come to "building your reputation", building your profile so that you can actually gain more.

L: so you would say that reputation plays a substantial part in achieving any lobbying success.

R2: yes, yes, reputation is key. Also as an individual. Now I work for x but tomorrow I could work for another company – I already worked for other companies- my network of stakeholders that I built around it, it is related to me. So it's very much important that you, as an internal public affairs expert, you are in an active position and never in a passive position so that you can challenge the business internally in a way "no way this is not gonna fly I'm not going to put this thing externally, it is not robust enough, it is not good enough, it's not the right moment". But you need to challenge it internally because in the end it is you who spent your own credibility outside and if you mess with the trust or credibility of the policy-makers, it would be very difficult to regain afterwards. So you would normally not have a proper second chance, so it's important that you get it right because those people would actually count on your expertise.

L: okay a lot to take in thank you for your in depth-answer

R2: and don't forget also you need to know the environment you operate in. I'm one of the people interfacing with public stakeholders, but others would do the same so there is a lot of noise around so it's also to be sure that you are spotted in the mass. And then I would say that when you interact with those, that people speak to each other. It can come very easily that if you speak inside the parliament, council or commission that those people would interact with each other so if you would give diverse information they would spot it immediately so it's very much important – that's why I would say credibility and reputation are key and what you give has to be substantiated properly otherwise it could turn out against you rather quickly.

L: good. Going further along those lines, does the pharmaceutical industry have sustainable strategic alliances with other industries and within the pharmaceutical sector itself.

R2: so we are members of certain organisations, which could be trade associations but also for instance chambers of commerce – such as AMCHAM – we are member of think tanks like friends of Europe and EPC, or the industry of Europe round table. So we are members of different associations. Every year internally, we run a process of reviewing all those memberships and to see what value they bring to us and to see if it's value for money and whether we should continue or discontinue the membership se we run an assessment of the associations compared to our priorities and then we decide. We also work with public consultants, we normally work with patients associations as well – there of course it is heavily regulated so we have a strict policy on how we interact – in general we have a strict policy of how we interact with all the stakeholders, so there is a policy that regulates internally how we would interact with policy-makers, with government officials, inside trade associations and patients organisations. So for everything there is an internal policy that we follow so we operate in a strict framework internally as a company. For patients organisations there are several rules but normally how we would operate is that we try to build alliences or coalitions around

common interests and agenda. So we would be very conscious whether we are asked for specific funding or a project or something like that so we prefer to be issue driven. So if we have a common interest on something we can do something together otherwise difficult.

L: So coalitions are really issue-specific in this case?

R2: Yes normally so, but then of course you have the more structured with the trade associations.

L: would you say that there are certain interests that systematically oppose the pharmaceutical industry on the EU level?

R2: If I look at innovative pharmaceuticals, no I do not think there is something that would oppose regularly. If we look at a sector – it always depends on the issue – but of course you know, between the innovative and generic market there can always be some tensions as well because of course we claim that they can harm – that certain policy can harm innovation, they claim that certain policies delay generics entry, so it's always a difficult one there, but we also tend to operate in a coalition with them so there are some issues were we are in partnership, but we also have issues that are highly divisive so – but again, I can not really give a strict answer on that one sorry.

L: would you say there is a possible reason for the fact that you do not encounter much cross-sectoral opposition in pharmaceutical policy? Because of the highly technical nature of the policy domain?

R2: When you say cross-sector, you mean outside of the pharmaceutical, correct?

L: yes, indeed

R2: yes, because I think a lot of specificity –

L: because it requires such a high level of expertise to be effective?

R2: yes, but it is also think about, you probably also heard a lot of the green agenda. So this affects us, we are active as well but of course in a completely different manner. So for example for the production of pharmaceuticals we use a range of components that could be risky for the environment , but either in terms of quality or emission or – because it is the only way we have to produce the medicine, that also puts divergent interest into contrast between health and environment. So it is also something that has to be balanced compared to other industry sectors. So there are sometimes specificity that would apply to our sector. In terms of the horizontal policy that could affect us in an even manner, at the moment I see very few. Because food is completely differently regulated, other industry sectors like cars have normally complete different issues and would relate more to standards, while already our standards are super super high , it is more about – and nobody calls for lowering those standards, we can keep calling for higher standards – but Europe has one of the highest standards together with the US. But for us would be very much about what type of policy would support innovation. One of the key issue of our industry is that Europe has been food decades a hub for research and innovation and we are losing ground to other regions. Already three decades ago, one of two medicines was discovered in Europe. Now it is 1/5 of all medicines and if you see there is an enormous decline in investment in research compared to the US market – okay but there we already lost the race – but we are also losing ground to other regions, for instance China who is investing a lot in pharmalogical innovation. So we do have a big issue there to wake EU policymakers

up and say "look we need you to invest more in R&D" because we may risk being in a situation where we would be dependent on innovation from other regions. Today, if you look at COVID, we have been an important provider for the solutions , not only in terms of discovering but also in terms of transporting – Europe was the largest exporter of vaccines in the area. But tomorrow – and the efficacy of what we have been able to produce is not comparable to China has developed yet – but if that race continues and we are not keeping the pace, we might end up in a situation where the solution could end up from the other party.

L: so the policy domain of innovation is really a possible future threat that you envision.

R2: yes, for us innovation issues are quite key for us in Europe. It is very important that Europe remains an innovation hub for research and of course this entails a complete ecosystem that covers from everything. Not only taxation or incentives , IP, but it would also relate to skills, access to data , a possibility to run a public to private partnership – or even a private to private partnership. So all these types of things will be extremely important for the future of innovation in Europe.

L: Back to coalition building and the theoretical aspects of it, what are in your opinion the benefits and costs in engaging in a formal coalition with other parties.

R2: the benefit is that you would expand your representation – you would increase your voice externally – but you would also diversify your energies. So it's also a good way to split the work to optimise resources. When it comes to the costs of course you need to compromise on certain things, that's why it comes back to the original point of having a very clear position with clear red lines and priorities because you need to know your negotiating mandate.

L: would you say that generally speaking, the position of x – how would you describe the position of x in relation to the position of the EC on certain issues, given that the EC often supports more regulatory policies and regulations, while industry is most often completely against it. How would you rate what I just said, is it as broad as I claimed or is it frequently more close to each other?

R2: I would certainly not frame it in this way because probably what you are talking about is to put up barriers, because normally in regulation depending on how this is framed I could actually unnecessarily hinder some activities. In terms of objectives we have quite an alignment to make sure that we can reinforce the innovation hub to increase access throughout member states, all those things are there. It is normally more about how you would get there that could sometimes rise some questions and of course everyone brings their own point. What I think is important to keep in mind from a legislative point of view is that we operate in a sector which is heavily involved with science and science can evolve and it can evolve pretty fast. So it's important that you have some framework that has the ability to keep the pace of science. One of the concerns we sometimes may have is that if something is put in a strict legislation and is too rigid, it might be outdated in a few years and is not able to capture what is new. That's why sometimes we would actually prefer no legislative instrument, like scientific guidelines and such, that would help to adapt quickly to something that could change. Imagine now what happened with COVID: one of the things that has been proven to be extremely helpful is the possibility for the EMA to start the rolling reviews that could actually accelerate the regulatory approval process while maintaining the same level of standards. This proved to be an excellent tool. Now we have a discussion in how to make a wider use of those type

of instruments to accelerate the approval of more drugs or to conduct inspections in site in a faster manner also using virtual tools rather than only physical tools. There are also a number of discussions about how to steer innovation to where it is more needed: such as discussion on unmet medical needs , on how we can be sure we generate innovation in an area where we did not have that yet. Of course there are a number of discussion about the definition what we mean with that and how do we want to mean it. Are you going to put a category into legislation? That could prove to be an issue because what could be a need today might not be a need tomorrow. So it's not more about the use of legislative tool vs not legislative tool, it's more about the efficacy of a proper tool to achieve the intended objective. Also do not forget that the EU legislative process works different likely than how it works for the national. You will normally have the commission which can normally work to put forth a proposal and might come out with an idea. But this idea can be completely rejected by the parliament and council when it is out there. So it's also about how to be sure that we remain focussed in the scope and the objective we want to achieve because some ideas may pop up. Imagine now they're going to review the full framework, I expect to have so many new and creative ideas from the parliament and council so hopefully let's see how it comes out.

L: Okay thank you, Mr x! We went through all the questions. Thank you very much for your time and in-depth answers, I really learned a lot today and it was very pleasant to interview you.

R2: I'm happy to help! Feel free to email me if you still need something or if something is not clear!

L: I will surely do so, thank you and have a good day!

R2: you too, bye bye

Interview respondent 3

L: Hello x, how are you?

R3: Hello Lorenzo! I am so sorry I'm late, I just had a thousand things to do at work today and my mind is all over the place! I'm good thank you, how are you?

L: Not a problem at all, I understand that you have a very busy schedule! I really appreciate you making some time for me today!

R3: I'm very glad to help don't worry

L: Okay good so let's dive right into it! So x , let's say could you please briefly introduce yourself, the job you do and the organisation you work for.

R3: So, currently I'm working for x public affairs. I joined two months ago in the position of consultant on the EU health team. I work with quite a propriety of clients, I'm working right now with six clients, at the moment. All very big pharmaceutical companies focussing on things as rare diseases, vaccines, etc. So the companies are all very different themselves, bigger and smaller. It is quite a heterogeneous portfolio of our clients and what we do. Then about me: before – and that's my main professional experience –I work as a health policy consultant at x for a bit over two years at the national level. And there I also worked with really big companies – oncology, cardiovascular, respiratory and so forth. All the big companies. Generics as well.

L: Okay great! So next question: what does lobbying and advocacy entail, what main activities does your job as a consultant include.

R3: I will try to tailor my answer to you. Lobbying focussing at the EU level? Because at the national level I think it is slightly different.

L: Yes indeed, it is so obvious for me that I forgot to specify

R3: First, and this is the basis of public affairs, is monitoring of the main political and legislative process and stuff – they have big updates. Monitoring can be very broad. So we report from the very political abstract updates that are relevant for our clients , to very technical things such as for example revision of the legislation on the LDH, very technical. And we assess the issues, we draft an analysis on them and we share with the clients key highlights – key short alerts – in an email that you can read in five minutes, because you know clients are very busy and don't have time. Secondly is the direct lobbying. So when you want your position/an issue on the public agenda, for example right now a company we are working for wants to position health at work on the EU agenda. So putting their own priorities at the top of the EU agenda trough lobbying. That's the goal of the engagement and lobbying.

L: And how is that done specifically?

R3: We develop, first of all a narrative, very abstract. You need to have a position on the issue that comes from the abstract point to the "that's why you need to buy our product"

L: So, the rumoured policy papers?

R3: Yes indeed exactly. So you first need your narrative, your storyline, your idea, and after you need an comprehensive engagement strategy saying we are going to go and we are going to meet in the Parliament the rapporteur of the health at work directive. In the commission the people working with osha, on health and safety in the cabinet of the relevant commissioner. And we are going to go back to the parliament and meet with key MEP's that are in the ENVI committee and ITRA committee as well. And in the Council we are going to talk with key attachés that are relevant that are in COREPER 1. So this is the idea of a comprehensive strategy. This goes for every single client company and issue and engagement goes like that. So it's really important to identify key MEP's that are involved in the issue you want to lobby on. For example, the ENVI committee is the most important one, but it is not the only one. But also you have some cases where you have the ITR committee because in the end it is the pharmaceutical industry involved. EMPL for example is also involved in some cases, I'm thinking health at work. Also, sponsoring MEP's and inviting them to events is also important and all of that generates policy momentum. So, the engagement it has two ways right, direct and indirect. Lobbying is direct when you meet with an MEP and say "hey, right now, the Parliament is working on, for example the revision of the pharma strategy, we want you – okey we don't say it like this, we do present an argument, but okey the conclusion is that's why it is extremely important that there will be specific mentions in the wording of the report of the Parliament". And for that you need to use MEP's, socialist, liberal etc need to propose amendments including this one we propose, that call for for example novel payment models that will facilitate access to rare diseases, more innovation, etc. So this is how it goes for direct lobbying in a specific

policy file. And then there is the more indirect lobbying when you don't want a specific thing, which of course you want but you want in this case to position your cause, key issues and consequently yourself in the policy arena. This indirect lobbying involves also other things, for example events – which I think is a key thing – and it's not going to be an event sponsored by x or done by x or x, it's going to be a patient organisation or an NGO or an umbrella organisation – might be x as well.

L: for positioning purposes, no?

R3: exactly, sure sure. And then you know like it's going to be the event of the x forum focussing on rare diseases – and the x forum is the one that is going to invite MEP whoever that will talk about the importance of creating value assessment, pricing and reimbursement frameworks so that accessibility is improved so people in Europe can have access to medicines for rare diseases, and of course companies can sell them at the enormous price that they cost – or that at least they say they cost. But it is the patient's forum that invites the MEP but in the end you will see the logo of the pharmaceutical company there.

L: so it's more for framing purposes really?

R3: so it's complementary, and you want it to be because it is not lobbying – lobbying is not only about creating relationships between the industry and policymakers, but also about cultivating them. And that's what is difficult about public affairs. Because another file will come, and you need a really good relationship with the people that are relevant and that you need in for example DG SANTE – our key stakeholder in the Commission, but also DG RTD and GROW. You really want to create longstanding relationships with particularly MEP's, but mainly with commission officials because they are more difficult to approach than MEPs and it is more challenging to engage with them.

L: would you say that it is because lobbying regulations are more strict for the Commission than the Parliament?

R3: No, I would not say there is. Honestly, in my very little experience, I don't think that's the case. Honestly a really good point. But I think it is because they are civil servants, they are technical people. What I mean engaging with the Commission is – the top political level, forget about that, absolutely impossible, not happening – but a company we work with say let's meet maybe someone from TRADE and GROW so let's meet Donbrovski – but the agendas of the Commissioners are extremely busy , they are only available and accessible for high level events, and therefore we told them no way, we are not even going to ask for the meeting – because that's what we do as consultants, we draft the email the invitation and send them and take care of the follow up and call to the cabinet and say to the secretary – and this happens for the MEPs, we call their APA's ,their assistants and ask if they saw the email we sent. But in that case, I would say no way. At the commission level, what could be interesting would be meeting with someone within their cabinets – so Donbrovski has five or six advisors within , the commissioners teams are available online its public information, so you take a look there and we see which one is focussed on health, so let's meet with them, but no way with a commissioner. So in the commission you want to meet with the heads of unit of those units in charge of the policy that is relevant for you – and we as lobbyists are to figure out which units are holding the proverbial pen who are in charge of the given file we want to influence.

L: okay very good thank you for your answer. The next question is about a whole other thing though, so do you view lobbying and public affairs as different things or would you say the terms are interchangeable?

R3: I think they are the same, because technically I mean you can make the difference because public affairs also includes public relations which is more communications and stakeholder engagement that is not only limited to political stakeholder engagement, so there is the difference. But I believe they are considered the same is because the word- the specific term public affairs – I'm going to put it in other terms: any position in Linkedin that you see that is related to public affairs , is a lobbyist. Sure, some cou-

L: So it's more a question about labelling?

R3: Absolutely, so of course there is this technical nuance that can be made between them- which I think is correct – but in reality they can be considered the same. If it would be my thesis I would remark that difference – but I would also highlight that in the end a lobbyist would never call himself a lobbyist. But if you search public affairs lead/consultant etc. you will find a million profiles on Linkedin. This applies for every sector, not only the pharma sector.

L: Okay great answer, I would say let's move on to the next question: how would you describe the relationship between policy-makers and lobbyists on the EU level.

R3: Very natural, that's the first and foremost feature, and I think it also relates to again all sectors not only pharma, because – we're mainly thinking about MEP's here right? Or not necessarily?

L: no we're focussing on the whole EU policy sphere so Commission, Parliament and Council.

R3: okay good but still I think it applies to everyone, even attachés for examples who are diplomats/civil servants it still applies, but I think mainly for the Parliament. It is a very natural relationship because Brussels and the parliament is a venue where lobbying has been here from day 1, all companies NGO's, civil society organisations, industry associations have very extensive relationships with policy-makers, so I think they are very much used to it. That's the main difference, that they are extremely used to it and it is natural.

L: so it's like a good collaboration?

R3: I would not define it as collaboration. Some MEPs, I'm thinking for example the pro-industry MEPs from for example the EPP, these are the most pro-industry MEPs, but renew Europe as well. With them it is indeed collaboration because when you go and have a meeting with them, for example x, rapporteur of the pharma strategy, is very welcoming for the industry's input. And it is like this for every single file where it's the case that you have pro-industry MEP's , they are super happy to hear you and say "hey, send me the list of bullet points and I will see what I can do to include them. So with pro-industry MEPs there is collaboration, but in very general terms, I mean that the relationship is natural and normalised in the sense that – you know when you think about lobbying is extremely dark, mysterious, try to influence, calling someone, closed meeting in the back of the restaurants.

L: so really stereotypical?

R3: Absolutely, and of course there is a lot of that , really a lot and at the national level it is even worse. But it is – MEP's have their agenda's full of meetings with the industry, but also with patient groups and NGO's for example.

L: And what would you say do these policy-makers have to gain in accepting- literature mentions that a primary way that lobbyists gain access by providing information to policy-makers , both technical and political information

R3: that is indeed correct

L: would you say that us the only way?

R3: No, definitely not. I'm thinking so many things. I think many times, MEPs in particular want to position themselves and acquire visibility in a particular issue. So they really want to have- you know industry organises a million events, they want to be invited as speakers. And you know, so their ultimate goal and objective is not only receiving the input and knowledge, but also them as politicians they want to acquire visibility, popularity and recognition as key opinion leaders on, in this case, health. Could be any topic and also super specific, for example oncology or social related care, etc. So when you think of oncology, you think of their face. And to do that it is quite… it's not their main objective of course, but it is one of the main benefits that they obtain in having relationships with the industry. And I think that applies mainly for the pro-industry ones. The anti-industry – for example in the COVID committee you have some MEP's in favour of an IP waiver, which is a really key issue for the industry right now, they don't care about that. But the pro-industry one's , for sure. And this mainly applies for the EPP and RENEW Europe. Some socialists as well, who are also collaborative , but mainly the first two. They are so happy that such a powerful industry provides them with a platform, a venue and microphone, that's also another factor. Again, those are not the only ones.

L: okay amazing, so would you say there is a difference in lobbying approach and strategy between the different legislative institutions? For example between the Parliament and Commission?

R3: Definitely. The parliament is much more political, the commission is purely technical. For that reason it is much more difficult to engage with technical people, technocrats, than politician. I think the tone of the engagement is very different. Convincing in a meeting an MEP is difficult, convincing an expert is even more difficult. Because the MEP in the end he knows that you are there because you want him to vote in favour or include an amendment that is in your interests.

L: so it's more difficult to lobby the Commission than Parliament?

R3: Yes, indeed. The commission is also much less accessible. They are very open and accessible, used to deal with all kinds of stakeholders, but they are much less accessible. Or let me nuance: not less accessible but more difficult to access than MEPs.

L: And why would you say this is? Does it concern reputation or something else.

R3: I think there is literature on the role of public servants. Their self-perception is that they are guardians of objectivity, which indeed is what they are. And they need to ensure that every one of the stakeholders voices, including the industry, are integrated. But they are there – their primary

concern is that the legislation they draft is objective and represents the general interest. And they know that you are there because you want them to draft legislation that favours your interest as industry.

L: so they are like mediators between different parties, including their own?

R3: yes exactly, they are there- the main difference is that the politician is partial and the commission official is impartial, at least in paper. In pen it is always going to be pro-industry, will regulate more the industry but will never harm its interests. That is the ultimate reason that it is more difficult to engage them. Going back very quickly to the strategy on what we do. With the MEPs it is much more easier: you can invite them to events – one of our clients is sponsoring a campaign to promote an issue on the agenda, and for that reason we funded a multi-stakeholder platform to launch a policy call to action for better policy and more funds, which will be signed by multiple MEP's: we will share it with different MEPs and ask them to sign. By an initiative sponsored by an NGO, a multi stakeholder organisation and association.

L: sorry to interrupt, but in this multi-stakeholder organisation for example, how is it composed? You mentioned NGO's, you mentioned-

R3: multi-stakeholder platforms are first and foremost sponsored by the industry – not always but most of the time. Because the other stakeholders need funds. So they are impulse and sponsored by the industry. But they have many people, also sectoral partners, patient groups, medical societies, they have other organisations that are involved in the issue. And most if not all times they are done- it's not x "launching an initiative", it's – for example the x alliance is sponsored by different companies, amongst which also trade associations. Then you have the events- this is the most typical- following the logic this call to action maybe launched trough an event and you're going to invite the MEP to the event. Then also sponsoring a campaign. We are working with a client for flu vaccines, so we encourage an MEP to take the flu vaccine, make a picture and post it on twitter – digital communication is also very important to shape the policy conversation – and put our hashtag. So you have those kind of initiatives but also for example we give one grant a year for a researcher on a specific subject, and ask the MEP to be the keynote speaker and to hand over the prize. But all these things, you cannot do that with commission officials. I mean you can invite them to events, and they go absolutely, but they present what the commission is working for and might answer questions of the audience. So commission officials you have events, but these kind of round tables, and then you have the classic meetings where you go and present what you want.

L: Okay great, two follow up questions on that. Firstly, you say that the commission officials are more difficult to access for outside organisations, are Parliamentarians sometimes used to approach commission officials?

R3: No no no, you really have to think they are civil servants, they're totally different categories. They are people involved in drafting extremely technical texts. MEPs will never approach them for steering a particular policy.

L: Then about the multi-stakeholder platform, do you find that a multistakeholder approach has better chances of success than an approach only done by strictly pharma companies?

R3: uhm, thank god my managers are not here because they would devour me. It is indeed issue dependent, and the issue is not only on the particular topic, but on WHO is there, which companies are a part of the multi-stakeholder platform and also on how hot the issue is on the policy agenda. For example last year everyone was talking about oncology, all companies were there, they create a multistakeholder coalition and invest in it to steer it. So in that case it might be – that multistakeholder might become a strong weapon and instrument for advocacy that might be very useful for the companies in order to continue their own things, because both are complementary – a company never gives up on their individual lobbying – but we develop the multi-stakeholder platform because it is usefull now. In other cases it is not really useful, it is difficult. And sometimes companies that are part of the platform quit because other companies are there. It's like a friendship group in the end. So "normally I go have a beer with you on Friday, but this guy is also coming talking about x and I don't want to go" so it makes it difficult for the two companies to chat.

L: So is it more difficult for pharmaceutical companies to build coalitions with other parties that are not pure pharmaceutical companies such as NGO's and civil society.

R3: No, not particulary. I can develop in a minute. What I meant is for example last week there was a meeting for x between different stakeholders and companies? And most companies agreed that x must do this, but there was this other company being difficult. That's why I say that it's more like a group of friends where sometimes you all agree where to have dinner, but there is one that says they don't. That's really the case and what I meant, I said it's not only dependent on the issue, it also depends on who is there. Because sometimes that company has a particular interest – you know we all share a common cause – but one, two or maybe a minority of them have a particular issue that makes it difficult to reach a consensus with the wider group and therefore makes the collective action more difficult or not as useful and effective.

L: to maybe elaborate on that: is it that these companies that are more difficult to work with on a specific issue, are they – is it dependent on a specific niche they work in such as generics or rare diseases?

R3: no, I think that's very ad-hoc situation dependent. So it's not a structural issue but it really depends. Sometimes it's company a sometimes is company b. also I think it's important to mention a specific thing that is extremely minor but I think is important: sometimes the people representing the company, make it difficult. Sometimes the fact that the head of policy or director is not cooperative makes it very difficult for the others to unify. So it's really as simple as that so it's not always the company but the person who works for them that can be the problem. The human factor many times makes it very difficult and is key in lobbying as well, as unsophisticated as it sounds. I would not say it's the main cause, it's a tiny element but nonetheless I would say it should be remarked. Sometimes this is the case. So it's not the fact that one of six of the representatives of the organisation is uncooperative – it's not that it's going to paralyze lobbying and coalition building, it's not going to be the cause of the ineffectiveness of the lobbying instrument, but it makes it difficult.

L: Okay amazing, such as simple thing can be easily overlooked. Would you say that it's also the case that there is a difference between an in-house lobbyist attached at a single company and a consultant such as you

R3: yes absolutely that's the case

L: interesting for further research I would say , the effectiveness of both types of lobbyists.

R3: yes because they contact us because they don't have the capacity. And what we offer is our contacts, the experience of having done this for years, the expertise, not only networking capacity. It's a tricky question. The lobbyist as a person can influence lobbying ofcourse just – if you are a shark in Brussels that has such a long list of contacts.

L: Then what would you say are determinants of a good, effective lobbyist? So contact list, networking ability?

R3: for sure being comprehensive and not forgetting anyone in the institutions and the institutions themselves as well. The timing is very important so that you begin lobbying early on time, because in my opinion agenda-setting is the most important part of lobbying. So if the wording is included in the inception phase of a file, you're in. as opposed to proposing amendments in the very end of the process, it's going to be very difficult to include this. And also good combination of direct lobbying , meeting key policymakers with key policy asks, and indirect lobbying to cultivate the relationship between the industry and policy makers trough event, trough calls to action , PR campaigns, etc.

L: So, let's move on to the next question, how would you describe the position and influence of the pharmaceutical industry and why?

R3: In terms of industry, pharma has an extremely big influence , extremely big. They are an industry with insane and huge revenues.

L: so, resources, financial resources play a big part in lobbying success?

R3: Yes, I do think so because you're talking about companies who made billions in profits last years. Trillions in dollars in assets industrywide and there are many companies right. So, just look at the position papers of EFPIA, it's a company and industry that has loads of jobs and a huge economic impact. The topic is also human health, human wellbeing and it's really a distinctive feature that they have. In comparison with other industries and interests, human wellbeing is such an important topic , no other sector has such an impact on citizens as this sector. All combined gives them a unique position for lobbying. They are extremely strong and have a very high level of access and have a very strong position in Brussels.

L: quick question, you mention EFPIA association a lot, would you say that the pharma lobbies more collectively via trade organisations such as EFPIA or more individually.

R3: 50/50 , but not complementary but more in a parallel sense. There are very specific things that are done through EFPIA and x for example. For example with the COVID committee, so x says they have a meeting with the chair of the covid committee. By next week, every one in x should send us one or two pages with your key policy asks. So they aggregate everything and prepare the industry position. But your position – so let's say you have 4 priorities, some of them are unique for you as a company. All companies have some positions they share and some which are really specific for themselves for which they have to lobby themselves. But when you aggregate your position with the

others your position is going to be deluted of course, that's why you have your own lobbying. But it is not like one or the other, it is like both.

L: So, what would you say are the primary strengths and weaknesses of the pharma industry?

R3: so, strengths I already mentioned incredible resources, access, expert information. But expert information I would not exaggerate it so much. It is an asset, but the resources and access really are more influential and important.

L: really? Because literature really emphasizes expert information as opposed to resources as important.

R3: I'm not saying otherwise, but I would say resources are more important. So nothing else on the strengths , but on the weaknesses I think they have a really – I mean engagement is very easy but can also be challenging- because they have a huge reputational issue. Especially some companies such as x when they bought x for example. Companies focussing on rare diseases that want – they put extremely high prices to their products, such as companies selling gene therapy. One therapy for one person can cost 2 million euro. Really mad. Also check the case x. That's the most known one.

L: so reputation is the primary weakness?

R3: yes, indeed. And maybe I would say more for some companies instead of others. Because yeah, some want to make as much money as possible from human diseases. So like why don't some companies want to liberate their licences for their IP patents so we can produce vaccines in Congo? At least for one year so we can vaccinate the entire Congo? Vaccines? No, because they have the patent and don't want to liberate it. And they can do it , but it comes with a cost.

L: Does the pharma have strategic alliances with other industries cross-sectorally?

R3: were you thinking of any in particular?

L: maybe the chemical industry?

R3: I mean I was going to answer yes very sure, but I can't come up with an example.

L: maybe we can move on to another question first and revisit this one later?

R3: yes of course!

L: okay so, does the pharma industry really have good aliances and coalitions within the health sector

R3: yes indeed, with patients groups, civil society etc. It depends on the sector though, I think cancer patient groups are very active and engage a lot with the industry. I think other patient groups engage less with the industry. Also, it depends on the company: there are companies that don't have a relation at all with the industry, because they don't want to or because they find it difficult for example. Also, others that love the patient group and want to engage with them etc. but that's really the minority, but overall I would think there is a lot of relationships.

L: would you say that the pharmaceutical industry frequently, or more frequently lobbies together in a coalition with other parties or more on themselves individually.

R3: I think this goes back to the question of the multistakeholder one. But I think nowadays there is more collective lobbying than –

L: a good industry unity then?

R3: yes indeed there is, but a remark is the complementarity of individual and collective lobbying.

L: are there certain specific interests or groups that frequently oppose the pharma?

R3: yes by far, who doesn't? Sometimes you have their own patient groups, especially in the case of rare diseases, where companies put such big prices that governments would not pay and thus block access to these treatments. For the rest I think the opposition can be really issue-specific. I don't think its structural in terms of patients groups. But NGO's, environmental groups and such calling for fair pricing and such then it can be structurally. Also all left-wing organisations that are opposed. Greenpeace and such. I think there is an angle with environmental groups and pharma.

L: and would you say that these groups are successful in counterlobbying the pharma?

R3: No, and I go back to the power and strength of the industry.

L: okay , those were all the questions, thank you very much for your time, you have been a huge help!

R3: no problem I was very happy to help! If there is something you still want to know feel free to email me!

L: okay great thank you, good evening.

R3: bye bye

Interview respondent 4

L: Hello Mr x , how are you today?

R4: I'm very good thank you , and you?

L: great thanks for asking, and thank you once again for making some time for me and participating in this interview today

R4: with please!

L: so, let's maybe start with a brief introduction, could you please introduce yourself, the job that you do, and what role you have in the organisation

R4: Sure. So my name is x, I work for x. Concretely I work in vaccines policy at the EU level. So basically from the EU policy hub we have here in Brussels we try to make the bridge between global strategies and priorities, as our headquarters is in the US as we are a US company, and then translate that into EU decision-making and of course also make the link with country colleagues both for national priorities and also especially for EU policy. So, taking care of vaccines policy, concretely we

have a couple of collaborations with health organisations because for our company some vaccines such as the x one, the x one, that is being uptaken in ten to 15 years depending on the member state, then we have a strong collaboration with the health organisations because it is important that all these messages concerning vaccination are understood by youth. Therefore we have a collaboration with x, a youth specific health NGO here in Brussels with global presence. With them we built a coalition together with other sponsors like x or x. With this coalition what we try is, we advocate for taking into account youth's perspectives when it comes to vaccination, of course especially we're thinking x vaccination when it comes to my company but not only this one. The idea is to have webinars, to also have some policy-makers introduced in the coalition, as is the case with some MEPs. So I'm kind of taking the lead on that part of that collaboration we have at the EU level, but then I'm also supporting the team with many other priorities, for example at the moment everything about the European health data space is quite important, so we have a big project running on the importance of data systems when it comes to vaccination because at the moment some countries, especially in Eastern Europe, do not have a very powerful system when it comes to tracking vaccination and therefore you don't really have a visual on where you stand in terms of vaccination coverage rates, so how many people got the vaccine in the cohort that is targeted. For instance, there was a good example with covid. You might have seen in the ECDC, the European Center for Disease Control, that they built some kind of COVID19 vaccine tracker where you can kind of see live the vaccination coverage rate for COVID in different countries. So that is what we are advocating for in all vaccine preventable diseases. But it is absolutely not the case. Actually, databases are national and sometimes the delays are about two years, so right now you are about the start to see the impact of COVID in these databases and for instances in some other countries, like Sweden or Denmark, they have a very powerful data system where actually you have these vaccination coverage rate updated every six months. So you can see how fragmented everything is so that is a big file I'm working on at the moment. Then of course we're very busy with the pharmaceutical legislation review that will be happening potentially towards the end of this year but probably early next year. I'm then supporting the team with many other files but conclusively, x coalition, datasystems and also a third pillar I'm really working on is the EU funding. So basically all these EU funding opportunities we have trough the recovery and resilience facility, all these post-covid19 recovery funds at EU level that were made available for countries and now also for EU health program, for so the say the "EU budget for health" I'm monitoring these kinds of opportunities and making the link with our country colleagues so they can reach their stakeholder because none of these funds are available for our industry, but to at least make sure that they are aware of these opportunities and then they can make the link at the national level with potential stakeholders that might be interested. So that's a really- in a nutshell everything I do in terms of policy files, and then of course I'm – as you may understand we are a very big company so there's a lot of internal work when it comes to coordination between country level and regional level and also making the link with global colleagues so a lot of my work also goes into internal matters. So that's a very broad overview

L: okay great answer, I've got a few follow-up questions already on the things you just told but they will come later on in the interview. So, the next question really concerns terminology, and – how do you view lobbying and public affairs? Do u view them as interchangeable terms of are there very specific differences between them.

R4: okay so here comes my personal opinion, no company one. But I will say that they are perfectly exchangeable but the problem is that lobbying in most countries, but also in the general public is perceived as bad influence- It's not really the most the best word for- it will link almost everyone with the image of this big companies influencing or almost bribing politicians – which is absolutely not the case, at least as far as I have seen. And of course, eventually if people would really understand what lobbying is, you could exchange them but of course it's not the same to say that "I'm an advocate" or "I'm a lobbyist" that's – it's really in the sense of nuances when it comes to terminology, it think it's perfectly exchangeable and the problem is that as we try to run away from this lobbying word that is kind of mentally perceived wrongly by the general public, then we are looking for many euphemisms. For example public affairs, for instance in my company everything that has to do with lobbying is labelled "public policy, then even we are the policy department so we really are trying to look for many other words – in other companies they call it government affairs so you can see the big nuances that this implies but I will say they are interchangeable.

L: Great. Now, about the advocacy process, which phases- what do you find most important in the advocacy process and what do you find also most influential.

R4: so, as a company, of course and this is not always the case at the national level and that is because especially in small member states – when a big company like us has a big presence in a small country, for instance Belgium or the Netherlands, then you have of course many things to leverage in terms of employment, investments, factories, so you are a privileged interlocutor by the government. When you come to the EU level, of course if we go by our own to the Commission, they are going to meet us but we're just one company and they always try to have the overall view on the sector, and the sector within all countries. So I think when it comes to advocacy what is most important at EU level is coalition building to have- of course it is very much important for us to have as a company a really important position in the trade association, in this case EFPIA but specifically for us as vaccines manufacturers x. So it's really important for us to be active in these forums and to even try to lead the path in these associations. And then of course, and it also happens at the national level to build coalitions with patients organisations, with patients advocates because that will always bring an added value and of course it will not be perceived the same way by a public decision-maker to meet as a company then to meet as a company together with the patients. And actually it's the patients together with their families which are always the best advocates for your products because they are the ones that need these innovations, in some cases they are the ones that really need these innovations as fast as possible because as you know, when it comes to pharmaceutical innovation, and of course again this changes a lot between northern Europe, Eastern Europe, Southern Europe, but there are important delays when it comes to access. So, some medical products, for instance for cancer or for other very sad and hard diseases for the patients and their families, they take 6 years between being approved by the EMA, so that science says that they are effective and safe and so on, there is a six years delay to access in some Eastern European countries. So this coalition building around patients is really powerful when it comes to advocacy. So I would say at EU level, there of course are many nuances compared to country level, it's coalition building and the trade organisations. I think that is more or less the two ways we advocate. And of course you can always meet a particular MEP, a particular decision-maker as a company, but overall, the strategy is centred around these two bases.

L: okay great, I think you answered a few questions at once there, so they might resurface in a few minutes and maybe then you can elaborate a bit more. So, next question is really about the policy-makers and how would you describe the relationship between someone such as you and policy-makers at the EU level? And more importantly, how is access gained to these policy-makers.

R4: so I want to say that at the EU level, there are very important differences between the three institutions. So when meeting policy-makers from the Council, it is a very different story that meeting the Commission and then meeting the Parliament. So I would say in the Parliament, generally of course, we are the pharma sector, as you might guess some parties are not really keen on meeting us and they actually even look forward to at least water down our business model. So, given that there is just some part of the Parliament that is eager to meet us, I would say that in general, policy-makers from the Parliament are not always familiar with the pharmaceutical sector. You also have to take into account that the ENVI committee is the one handling health issues and health legislation and it is a really broad committee in terms of numbers of MEPs – it is the largest – but also in terms of what they do: you have environment, so all these big legislative files on the Green Deal? Carbon neutral and so on , but then you also have health issues which are very specific and quite technical and many times policy-makers are not experts in the field, so they aren't doctors or don't have a sound background on health policy and therefore they are kind of welcoming to meet the industry – usually more the trade association because it is a broader representation than just our company, but we are also meeting MEPs on a bilateral basis several times on many different topics. And I would say they are more or less welcoming but when it comes to the Council it is a different story, there you have to find the right way in the sense of which member state do you want to target, usually the one holding the presidency, and also you have to take into account our presence in the country. So if it is a country in which we have a very large footprint In terms of factories, investments, employment, it is easier generally speaking to meet them, otherwise it gets a bit more complicated. Then from the Commission: we don't really meet the Commission bilaterally, it is quite exceptional compared to the Parliament especially, but I would say that generally, if we do that, we do it through the trade association. I mean, commission officials are really reluctant to meet specific companies from the pharmaceutical sector bilaterally , but kind of welcoming to the trade associations because they always have to have the wider scope.

L: okay great, very condensed informative answer. On to the next question about the pharmaceutical sector itself. How would you describe the position and influence of the pharmaceutical lobby on EU decision-making. So I know it's a big question so maybe it's better to split it in two: what would you say are the primary strength of the pharmaceutical sector on the EU level.

R4: so, before jumping into that I think it is important to differentiate the different aspects of the pharmaceutical sector because it is so wide. So you have generics which are a completely different business model and antagonic to what we do. Of course, medical technologies and medical machines, what's called medical devices, are completely different as well. So when it comes to innovative medical products, that's the innovative pharmaceutical industry, the strength is – it is always complex, and it is a big question to be answered only by me, but I would say that of course we have universal healthcare and we are seeing some decreases and increases on some diseases, so for example on cancer you might have seen the Europe's beating cancer plan that was recently published

by the Commission. So we can see that cancer, by 2050, is going to be the main cause of death in the European Union, even more than car accidents and tobacco but even more than strokes and things like that. So we have to make sure that we have the best innovation, treatments, the most efficacious ones, the ones that are curing the best for the patients so not only they are curing them, but also giving them good quality of life once they survive, which is also highlighted in the Commission plan. So, we as an industry are the innovators. So, of course you might change the incentives, you might have a lot of generics flooding into the market and prices will really decrease, but te problem is in ten years, there will be no one in the EU developing innovations to treat these new diseases and trends. So I think the COVID vaccine was complicated, but I think it was a good in the sense that it showed that without the innovative industry, there is no developing of new medical products and treatments that will meet what is called unmet medical needs. So I would say that's the main strength, and then the second strength, more concerning the societal impact, so to say, of our sector. Of course it is very complex, but pharmaceutical sector, higher salaries, it is a really large investment industry – in the sense that if a company is building a R&D centre in a member state, that will cost several billion euros and bring high quality employment, higher salaries and actually with qualified workers so I think that's also the strength. So generally, even if the general public thinks we don't have the best reputation as the pharmaceutical industry, for pragmatic policy-makers they really see the added value of having a strong pharmaceutical sector in a country because then it enables more innovation and there will be innovation centres, there will be universities also benefitting from that so I would say those are the two strengths. First, that we (innovative sector) meet unmet medical needs – and society is really asking for that and it would be difficult for a policy-maker to explain that "we will be paying less, but in ten years new cancers won't be cured – that's impossible in our system. And secondly, the high added value industry we are.

L: okay great. Now to go on about that, so the pharmaceutical lobby is often perceived and infamous for spending a lot on public affairs on the EU level; Would you say that it is- would you say this gives the pharmaceutical lobby an advantage in this arena or would you say it is more of a necessary evil because of the unique domain that is pharmaceutical policy.

R4: I would say it is a mix of those. So on one side I would tend to disagree that we as the pharmaceutical lobby are investing a lot of money on policy or lobbying. Because then, even if we are doing so, especially at the EU level but also at the national level, there are still a lot of barriers and problems. For instance, I would separate what is called policy or government affairs or lobbying, and then what is called market access. So the fact that when your product is market approved, it gets to be reimbursed on the market and then you start making money on it. So even if we spend a lot of money and resources on policy and lobbying, there still are a lot of delays and price discussions and really hard negotiations with countries or what is called "payers" – so the public health authorities from different countries or regions. So I would not say that even if we spend a lot of money that we are that effective because then, it is a whole other story when it comes to market access and you have to understand that we are really interested in having the right policy framework because it is a very complex sector. For example you need the right framework on investments for R&D , you have to make sure that you have the (unintelligible) system when it comes to research centres and qualified workers so it's really really complex – because of course then policy makers have to understand the complexities of manufacturing so as an example x COVID vaccine has more than

180, almost 200 ingredients made in I think 19 different factories in at least three continents. So you can guess how complicated, complex and fragile as well the supply lines are on the production lines of vaccines but also- with vaccines, it is even more complex than with general products. I would say that of course, we are spending a lot of money, we are really powerful on terms of resources on national level, but I would not say that it is really much more than other highly regulated sectors such as energy and such.

L: sorry to interrupt you x, so you would say that because the pharmaceutical sector is so highly regulated and public payers are involved, that such big amounts are necessary to be effective in general, not more effective than other highly regulated policy areas per se?

R4: Of course. I would say so. First I would say that we are spending a lot of resources because as a sector, we are very big and due to the system built in Europe and the world, it is driven by multinational Big pharmaceutical companies such as mine, x , x and so on. But then, the thing is that this is because the system is built in such a way that we have so much to lose and also so much to win trough policy-making or advocacy that we are spending so many resources on that. But if you compare it to for example the energy sector, I wouldn't say that much more – at least, you have to take into account that when it comes to EU level the challenge is that the EU is setting the main framework- in most cases approval of medicines- it also has the EMA, so more on the approval one and overviewing competences. But competences are after all in the countries, and in some cases even the regions and they are the ones paying the bill so to say- the EU is not buying medical products so to say. So we might – even if we spend a lot of resources at the EU level, the thing is after all that competences are not at the EU level while in some other sectors such as energy, the EC is really powerful, or tobacco or some others has a very powerful competency in the sector. It is kind of complex, but I would say we spend a lot of resources because we are a very big sector because the system is built in such a way that we are needed in the recipe of universal healthcare and at the same time also being so big – contracts are for so high volumes with countries, there really is a high added value for us as companies. So if you shape more or less the policy framework in the right way, the added value is massive. Therefore, you might invest a lot in resources but what you might win afterwards in terms of economic impact, which is always complex to measure in lobbying, is a lot of added value.

L: So really, high risk-high return?

R4: I would say so. I mean, the highest risk because we are probably the only big sector in which the public sector is the one paying the bill. So, our buyers are states, regions and it's not a consumer after all because of the system of universal healthcare that we have built.

L: Okay great answer, thank you very much. So what would you say then are/is the primary weakness/weaknesses of the pharmaceutical lobby on the EU level.

R4: first of all, our reputation. If the general public is not perceiving us as what we are, being innovators and really investing a lot of money on treatments – just a couple of figures here: on average at the EU level it takes 5 billion euros and 13 years to develop a medical product from the initial idea in a lab and then selling it or having it approved. So you can guess that holding this big investment for such a long time – and actually the success rate is quite low – it really implies that

we are investing a lot of money. But people are not always perceiving that, they are perceiving us as big, greedy companies making money out of people's health. Of course, there have been in the past many bad practices by the sector, and therefore I think our main weakness is our reputation as a sector. And I would say that is it because it is really difficult as you can advocate with policy-makers – but because of that reputation part of the policy-makers, especially in the Parliament, don't want to meet you, then the EC is not eager to bilaterally meet an individual company. So, our main challenge and our main weakness at the same time is to explain what we do, and that it gets understood and that we overcome this lack in reputation we have. And also the fact that, if you come as a company on your own, you will be perceived as having a commercial interest and that of course is closing many doors. That's why for us coalition building and the trade association is very important.

L: Okay, great. So, you mentioned there are different branches within the pharmaceutical sector itself. Would you say there is kind of a competition on the EU public affairs level between them?

R4: Of course. So, first of all we have competition even if it's within the sector, for us the innovative pharmaceutical industry, we have competitors everywhere. Even if there aren't so many, for example 10 to 15 to 20 big pharmaceutical companies working worldwide that are developing innovations, the fact is that we have competition always. So if you are developing a new product or vaccine on Dengue or whatever, you always have someone else, be it x or x, but always someone else is developing a similar product, then we have competition in these areas. But I will say in general the sector of innovation, we are really antagonic to generics. So basically generics is the one that patents are over, they take over the recipe and they do it, so to say, "cheaper". Of course, it's very complex because most of the generics come from India and China, so there's also a discussion when it comes to strategic autonomy on that. But I would say of course we have a lot of enemies in that sense and our antagonic sector within the pharma sector is generics because they have the complete opposite business model and of course they advocate as well for having low incentives such as shorter patent times so they can enter the market earlier and of course they have a very powerful message when it comes to public payers and policy-makers because they are saying "okay look, if you reduce incentives at this stage, we will enter the market and decrease prices by, I don't know, 80% and you will have a lot of this medical products. OF course, the picture is a lot more complicated on that but that's the narrative. I would say that that's that when it comes to products, commercial competition that happens in every sector between companies. And then, the main opposition by generics and also there are many – I wouldn't know how to label them, I would say social movements, activists or some part of some political families that are really against pharmaceutical companies in the sense that they want our business model to be over. They probably want to advocate for a public pharmaceutical company, then we could debate on whether this is feasible or not, probably not. I would say that that is more or less in this complex ecosystem that the pharmaceutical sector is, we have this different competition and opposition in the sector.

L: okay great,so it's really between generics and innovatives mainly.

R4: yes, when it comes to medical products. If you go to medical devices, that's a completely different story. You could simplify it like this but further than the generics there are activists and organisations that are really against us. Of course, when it comes to vaccines there is also these

anti-vaxxers movement- they actually are not pro generics but simply against vaccines. And that is also complex to fight.

L: Of course. So, maybe more on this opposition, if you could maybe elaborate on which sort of organisations they are such as NGO's, civil society in general or?

R4: that's the thing. We know that there is vaccine hesitancy, you can check the data, you can check also the internal difference. So I was checking last night the COVID19 vaccination rates and it's really amazing because you have Portugal which has 86% coverage rate and then you have Bulgaria which has 29%. It's meant to be the same market and union. And that happens with all vaccination coverage rates, you name it: measles, HPV, everywhere. So we know there is hesitancy, it's linked to many – it's very complex, multifactorial phenomenon. There are big differences between countries and this is also linked to culture and political culture and so on. So we know there's that, but it's really difficult to identify one organisations, one NGO, one person that is anti-vaxxer and is really advocating for that. It is so complex, so shady, that it is difficult to counteract because there is no one actually saying "we hate vaccines, no vaccines are safe, we don't want to vaccinate anyone". They will look for many other arguments and of course this is really shady and they have a very high presence in social media and so on.

L: So, the identification of the opponent or opposition is really the problem?

R4: yes, that's it. It is really difficult to identify when it comes to vaccine hesitancy. So when it comes to organisations against the pharmaceutical sector, it's not that different, it's not that difficult, there are a few. But when it comes to vaccine hesitancy, it's really difficult, it could be a very tiny organisation and tiny amount of people, but it's more like, an ecosystem they form to be vaccine hesitant. But it's really difficult because otherwise you would be "this person from here, this organisation is saying this" but then we would have the scientific evidence from us and the EMA that this is not true. But, it's such a complex phenomenon that it is really difficult to identify anyone.

L: okay great, very interesting. And how would you say these anti-pharma organisations do their opposition in for example the Commission or Parliament? Which strategies do they employ?

R4: I think one of their main arguments is what is called the "double payment" and it that sense it is really a big argument around that on covid vaccines. So what they argue is that the public sector is funding some research on pharmaceutical innovation and then pharmaceutical companies are taking that knowledge and putting it into a patent and making money out of it, but then it is the public sector again paying the bill. So that is one of the main arguments in the sense that the public sector is paying twice for one thing. Of course it is not completely accurate and other factors are important like it is linked to political interests. But that is one of their main arguments. Then the second one is, as price negotiations is the most sensitive part of the business, and actually, you are actually buying to different payers. So for example in Spain or in Italy or Belgium, it is not Spain buying most of the product but the region of Valencia or region of Brussels and so on. So, as prices are so sensitive, there is no transparency at all on vaccine prices and it's part of our strategy and business model. So, another argument they are really advocating for is to make sure that we as companies are to disclose, at least partially, our R&D cost. So, if you as payer or government get a view on how much this company has invested on R&D and developing that product, you will have a

more accurate price. Of course, that's super complex because, if taken to the extreme it will be almost impossible – for example on COVID vaccination it was based on MRNA technology, it was the first vaccine produced at that scale around that technology but it has been already developed by the companies for over 15 years. So how do you assess the R&D cost linked to a particular product or platform, and what happens with exploratory R&D costs. And what happens to the fact that success rates are so low that you are actually – you might have invested 5 billion in this product, but what happens to the 20 other billions that are invested in researching other products that didn't go anywhere? So that is the second argument that they have. Mainly it is the fact that there sometimes is a link between public investment and initial developing of certain products, this argument of double paying and the other argument about disclosing costs are relevant.

L: okay, great. And, would you say these opposing parties are generally successful in their efforts?

R4: That's very difficult to assess. I think we will see that in a couple months or a year when there is the proposal of the pharmaceutical legislation review, but I would say they are successful, sometimes they are, sometimes they manage to gain amendments on some wording of policy initiative that are in their favour but they don't really make sense. I'm not really in a position to assess how successful they are or not. In the part that they are successful is because at least a part of the policy-makers in Parliament are not willing to meet us. So they are already convinced against us.

L: and that is because of the reputation you mentioned?

R4: probably, it's a mix but I would say so.

L: so, these opposing parties really use this reputation against you?

R4: of course, and they use these arguments on public funding and around R&D and high prices and how unfair it is. And of course, if you have that on the European scale , they are playing that argument in some countries. So imagine in some countries, for example in Romania the price of vaccines is not the same as in Germany but they might say that this price is too high for Romania, or this particular medical product is too expensive. And that is already some form of success because they are not receiving the whole picture but rather a part of it.

L: now really focussing on coalition building. So you mentioned that it is a very important aspect of lobbying on the EU level. Would you say that in building these coalitions, do you often work with mostly other pharmaceutical companies or is it more a multi-stakeholder approach?

R4: I would say it is pretty unusual that a single company is sponsoring a coalition. Usually, it takes a few companies. Especially when it comes to the main advocates, or I would say probably the most successful ones that are the patient advocates. These kind of patient forums are always funded by several companies. That's partially what I was saying in the beginning: as patients and their families are the main interested in having these innovations as soon as possible, they are also the best advocates. It's not the same to meet the policy-makers as a sector and say "look, I have this product, and there is this issue" because it will be received as having a commercial interest. But if it's a groups of patient advocates saying "look we as patients and families want this product to meet these needs" probably it will be more effective to reach these policy-makers. Of course, it's a big simplification

and it's much more complicated and complex than that, but this is the idea in a nutshell. And then when it comes to the sector itself to be heard as a single voice trough these trade associations is also really important at the EU level.

L: so, is there a difference in the advocacy that is done by the trade associations and companiesin general?

R4: sure, of course. When it comes to patient organisations, the message is around patients. Patients that look for treatments and needs that are not met such as rare diseases. They are actually calling for a certain framework that allows companies to have enough incentives to develop what's called "orphan drugs"', so really particular drugs and products and treatments for very rare diseases. So its quite different when it comes to trade associations that is speaking on behalf of the sector. So "we as a sector in Europe invest this much, have this many employees, we have this economic impact that's huge, we want to be heard and if possible taken into account". So it's kind of difficult because its really different dynamics.

L: does the pharmaceutical industry also have sustainable strategic alliances with other groups – you mentioned that data is very important, so maybe IT and such?

R4: Yes, sometimes but that's a rather particular – on data systems for instance, yes – you also have for instance the big data companies that also have something at stake, such as infrastructure , we are more on the outcome so what would be the impact. But I would say that alliances are issue-specific and it's based on a couple of topics. In general it's quite, - there are some broader associations that have more parties in its coalition.

L: okay great. That's all we have time for today. Javier, I want to thank you very much for your participation and for making the time for me, your answer surely will be very useful in writing my master thesis.

R4: with pleasure! If you need or want something clarified feel free to email me!

L: great I will! Thank you and have a nice day.

R4: you too, bye bye.

Interview respondent 5

L: Hello Mr x, how are you?

R5: I'm great thank you, a bit warm I must say but that's my Irish blood speaking.

L: haha, as an Italian myself I'm thriving in this weather.

R5: Yes my wife is an Italian as well and this is the first time in a year that she is kind of "warm".

L: I totally understand her. So firstly, mr x, I think it would be best to start with an introduction of yourself, who are you, what does your job entail and what does the organisation you work for do?

R5: Yes, I'm happy to do so. My name is x and I am a lawyer by background. Most of my study focussed on medical law from postgraduate onwards and then specifically research and innovation for the advancement for new science and tech and how can the legal framework and policies be

impacted mainly by societal views. I also took a stint studying bioethics. My current role – so I work for x, we are the trade association in Europe. We have two sides of the business if I can describe it like this, so one side of the business is focussed on industrial biotechnology and has to do with things such as catalysts, … yeah it's not my side of the business, but catalysts and, … essentially sustainability to bioplastics and things like this. Now the other side, my side of the business obviously, is healthcare. So we work with biopharmaceutical companies, small medium and large sized, and a number of national associations as well so, to say our counterparts in the member states at a national level. I have been working in Brussels for just over 2 and a half years more or less, so before that I did PHD research and when I was finishing that up I started a Brussels based career. I should mention last year I was a member of the European health parliament, which you probably heard of, so this was a very nice initiative basically bringing together groups of youth under the age of 35 but you have to have a bachelor's degree minimum or something, just a very nice experience kind of complementary to the day to day work I do today. It brings together youth from across Europe that have an interest in healthcare policy and basically how to shape recommendations based on what is currently the most hot topic in healthcare more or less. My day to day work looks at, essentially, how do we shape and influence the legislative and policy environment and framework on healthcare on behalf of our member companies and by extension on behalf of our national association too. I work quite a lot on – so my portfolio concerns what is called the regulatory working group and the digital working group. In the regulatory working group I work with colleagues active in regulatory policy, so working with the EMA specifically and more technical aspects of how we govern and approach the safety, efficacy an related systems and frameworks, at the EMA and also to the companies. So some of it is quite technical and some of it is more high level – let's say the systems more generally or how exactly the EMA goes about carrying about its services and functions as another stakeholder in the group of EU institutions that focus on medicine. Digital working group is quite different in that they are working on the European Health data space, so the stakeholders there are mainly the European Commission and – with increased along the process the European Parliament, the council, the permanent representatives etc. And probably in-between in my day to day I fill in the blanks with my other colleagues, so we cover – we also have specific working groups in x that work on ATMP's – so selling gene therapies – and orphan medicinal products and paediatrics products. And then we have a specific , it's not a working group as it has a slightly more limited focus – we also provide a platform in which industry, institution stakeholders, and patients can discuss things. So this is our way of basically bridging the gap between what we do on a day to day with industry members and the policy we are working on with them and the patient communities. Essentially we have good, robust discussions on hot topics and see how we align and diverge and what recommendations we can take into account. I'll stop myself there for the first couple of (unintelligible)

L: okay, thank you great introduction! So, very short question about terminology really: how do you view lobbying and public affairs? Are these two terms perfectly interchangeable for you or do you find that there are very distinct features to each term?

R5: I think that's a really good question. I think lobbying needs to be seen as an umbrella term. All the different functions, let's say public affairs, government affairs and I'll also throw in regulatory policy or regulatory intelligence because this is not always immediately thought of as a lobbying arm

but it's the more high level policy more politically focussed aspects with technical regulatory- you know going through the motions of actually applying a law to a medicine in this case, so regulatory affairs as well. For me, advocates – let's say patient advocates, NGO's, anyone that advocates on behalf of any group should also be considered a lobbyist. I've had this discussion recently with a few colleagues- not at work but just in general- anyone that is trying to shape a policy environment, a law, a way of looking at a system is lobbying in my opinion.

L: Okay, great thank you! So, once again in your opinion, what is the most important part of the advocacy process? Or the most important activity?

R5: In what sense? The process itself depends I guess, that would be my answer. I depends on your end goal, because if you see your end goal as – it depends on what your end goal is. If you want to maintain the status quo, you take a different approach. Different aspects of your advocacy campaign will reflect what you want to achieve in a status quo or maybe achieving maybe an amendment or positively trying to shape an environment- dare I say negatively shaping an environment as well although I don't think it's fair that anyone tries to negatively shape an environment, it doesn't really work.

L: Okay good, I know it's a very broad question. Do you find that lobbying for the status quo is more difficult or easier than lobbying for specific changes?

R5: I think it can be harder. I think it's an interesting one. Knowing that you have interviewed a colleague that is much more experienced in lobbying than I am, you can maybe compare across different answers. So what I have seen so far is that you will always try to maintain the status quo as your first objective until such a time where other stakeholders move along the process or the process itself changes. So you, maybe this also answers your other question, you're constantly adapting what your other strategy is as you go along. It can also depend on what time you come in to a lobbying campaign. Is it harder? I think it really depends on a lot of different factors: the mechanisms trough which you will try to achieve or maintain the status quo are not necessarily so different than those that would embroil if you seek out a change, you just will emphasize and nuance certain aspects of what you're doing.

L: okay, great. How would you describe the relationship between policy-makers and lobbyists such as yourself on the EU level. Maybe just in general and then you can mention if there are any differences between the institutions if there are any.

R5: So far I've experienced it to be a lot more collegial than people think. At the end of the day- what you see a lot on the one hand particularly in the EU bubble, people move around. It is quite often that you see one day someone is working for industry, the next day they're working in an institution of maybe in the Commission or in a more political role perhaps in the Parliament, or indeed they're in consultancy, which is always interesting because then they can be working for everyone as they have clients across the board. Or indeed they can also change and work for a patient organisation. More often than not, you have certain people that are very passionate about the job they currently have and the sector they are representing, but in my experience 90% of the time people understand that everyone has a role to play and that every stakeholder has to bring their voice and has to also listen to the others because you can't really achieve anything simply going

against the grain, it's just never going to work. When you think- it's very common to do this- very American movies and this idea of lobbying that maybe exists there in that environment, I don't really experience that myself in Europe. I find- it's not to say that if I pick up the phone to the Commission or to a MEP's assistant- they're not going to leak information to you in that sense, it just doesn't work that way. It's not to say leaks don't happen but-

L: so it's not the stereotypical view that people often have about the profession and Europe,

R5: No, indeed.

L: it's also more based on compromises instead of the winner-takes-all approach often associated with American lobbying, no?

R5: absolutely. Of course I can't comment on lobbying in the US. But the stereotypical view indeed- this idea that there has been some sort of backroom deal to achieve an amendment to a piece of legislation- I would probably say that this happens more within the political parties themselves because of their own competing interests among politicians and their careers and what the party line is. For other stakeholders I think the process here in Europe is quite a lot more transparent than people may think because at the end of the day it's very structured because we know how a file progresses from start to finish so it's kind of abvious when people are meeting with a Commission official, an MEP, a permanent rep – there's logs of it – and iven if the logs are not well kept, it's quite obvious that you're having these discussions and I think when you spend a little bit of time in any sector, everyone knows "they probably want this or that" , a lot of it is public knowledge, you read politico and other newspapers like this and they're quite well informed. I think there's no big secrets within lobbying in Europe I think.

L: okay so, following up on that question, how do certain organisations gain access to these policy-makers throughout the different institutions.

R5: Email. Simple. My experience of lobbying has also been entirely during COVID so it's a very different experience from other people you might speak to that have a longer track record of experience specifically in this field. But you know, we send an email and if needs be you ring people as well. It's always – I think we've forgotten during covid that picking up the phone to someone is a really useful tool because generally you're just ringing them and saying "hey, how are you? It's me person x from organisation Y, any chance you could look at my email?" and then they come back to you via email. It's not- what's starting now, and it's really nice to see, you get to meet people at events. When you really want to sit down and organise something you still go through official channels because everyone is looking at their calendar, you know you need to put things in agendas so – maybe you catch someone out on an evening and you take a quick beer but, 9/10 times you still want to follow up in person let's say to achieve what it is that you want to achieve.

L: okay great. And what would you say are the primary challenges in dealing with these policy-makers? Maybe first the Commission specifically and then Parliament.

R5: I think overall, and it's something we said in the beginning of the call, is time. I don't always have the time, nor do the people that I know I'm emailing, ringing and whatever – they don't necessarily have the time to familiarise themselves with exactly what it is that they're going into.

Sometime if you're lucky, you have 15 minutes, often it's not the case and you have 2-3 minutes at the start of a call when everyone is "taking their time" to join and relook at an email and remember what is it that we're talking about now and you're always juggling things. With the Commission, it depends a lot on the timing of the process. Let's take for example the revision of the pharmaceutical legislation. Of course, they're nearing the end of their own internal processes and they want to put pen to paper and let's say cross the t's and dot the I's. They don't necessarily want to hear from stakeholders at this present time. They have gone through an entire lengthy process – the door has been opened up to meeting up till now, now they need their time to finalise things and go through their internal processes. So this is normal I would say, it's a thing of timing more than it's a lack of willingness to communicate or engage with stakeholders. Generally I find when you sit in a bilateral meeting with people from the Commission, because of the nature of their work – so policy officer and up- they know what they're talking about, they're not moving between files, they're not necessarily so politically charged – the higher up you go the more that can become an issue in terms of how informed that person sitting before you is, but 9 time out of 10 in the Commission I find – maybe you speak with DG or a Commissioner and they're no longer at a very nuanced level of detail on a file and that's fine – I don't expect that of someone that is running the show so to speak. Segway into the Parliament, sometimes you see and know who is a more informed MEP than others. You know the ones that are particularly well versed on a file or a topic and who are not. You can very quickly tell in fact what is their comfort zone on a particular file. And there the challenge is more knowing how to catch their attention. With the Commission I find it's not an obligation per se, but for the sake of transparency they're very happy to meet with stakeholders because it goes in a log, there is no real issue. Whereas with MEPs – they're constantly busy! They're constantly running around and have different meetings so trying to catch the attention of an APA is how you will then get your meeting usually. Which is quite often also the case in the Commission; when the APA is well informed, that's very useful because they are obviously the one helping to keep their MEP up to date and making sure that they're on the know on what the issues are.

L: Okay good, so n Parliament, would you say there are certain political factions that are more or less responsive to pharmaceutical interests?

R5: I'd say no, probably not, but then there is always a group of 10 or 15 MEPs that you target as a lobbyist, you know, I guess across every sector there are. There are the politicians that are trying to make a name for themselves in a certain area or fields. So, usually you target the kind of three main parties and then one or two of the smaller ones, but, no I can't say that –

L: so it's really irrelevant to say or assume that?

R5: yeah, it depends more on the MEP themselves. If they have a particular profile in healthcare or any other area, that's the person that you're going to want to talk to based on what it is that you want to achieve.

L: okay great, thank you. Then how would you describe the influence and position of the pharmaceutical lobby in the European political arena? And I know it's a very big question so let's split it up into two main questions. What would you say are the primary strengths of the pharmaceutical lobby on the EU level.

R5: I think, one of the things I find interesting is, I've spent a stint working –although I don't work in that jurisdiction but I spent a stint working in more, let's say American charged lobbying. And what I always find quite interesting with my colleagues that work on the EU level in pharmaceuticals is the nuanced level of informational knowledge they have on Europe. Because it isn't fair to say when you lobby for healthcare (unintelligible) , but you only lobby in Brussels it doesn't work. You need to be able to translate quite a bit of different sources and streams of information that comes from the member states because, as it currently stands, healthcare is a national competency. So, while you level in Brussels on certain issues, what I experience is colleagues that are extremely knowledgeable of what the market impact is, how it translates and how it compares. So I guess you could say one of the big strengths for pharmaceutical lobby in Europe is their ability to compare and contrast 27 different member states – plus Switzerland as well given the fact that a lot of companies are headquartered there as well – and then let's say neighbouring markets. We sit very central on the globe when it comes to pharmaceutical lobbying because Europe is a big market but it's – you have a lot of American companies that are dominant in the market globally – so that means that you need to be knowledgeable on what the company position might be because of the US influence. You have to be knowledgeable of Europe, take it in the middle , Europe as a whole 27 markets plus the UK plus Switzerland plus whatever. And then you're always knowledgeable of what is going on in the East as well in the east and south, both geopolitically – how is it impacting you commercially- and then what does that mean for healthcare. COVID was a great example of that: we weren't just producing vaccines in Europe, for Europe. Which meant you weren't just lobbying necessarily for Europe and COVID vaccines, but you have to take in mind there are so many repercussions you have in our market than you might have in a more isolated market like the US. So I think that level of knowledge is across the pharmaceutical industry when you work with the collegeaus I work with, they are the crème de la crème in what they're doing and more often they are also doing it in multiple languages as you're working not in your first language too and this is quite an impressive thing to see and I don't know if other markets also have that amount of things they have to take into account.

L: so really a high level of integratedness?

R5: yes, exactly.

L: To really condense it into one sentence, it's really about contrasting the national level with the European level, as the national level is where the competencies lies

R5: exactly, but I'd say it's all three: its national, EU and international. Because the international level at the top often impacts and dictates on the national level perspective of what politics should be. For some reasons – people often overlook or forget the EU. So they complain about it a lot but then they don't know how it fits, whereas everyone can think of the US is doing this and china is doing this, and Ireland and Italy are somewhere in the middle, and they kind of forget we're , the EU, is just a step above. Comparing and contrasting where Europe sits with regard to the national, EU and international competencies.

L: okay great. Then what would you say is a primary weakness of the pharmaceutical lobby on the EU level?

R5: fragmentation. Because the best thing about the knowledge that I just spoke of is obviously having it, that's how you have to work. The problem and weakness of pharma in Europe is that it's completely fragmented, so it's the absolute opposite of – I guess every greatness has an equal weakness- it's because of the fact that you have to take all these minutia into account, it can become very difficult to stand your ground, when you want to make the business environment – so for pharmaceuticals, the revision of the current legislation is absolutely necessary but what it impacts on is the business environment : how do you actually do your R&D, how do you make that into a medicine and then how do you commercialise it and sell it so you can do more research and make more medicine. Deliver it to patients, well that part is obvious. Because of the fact that Europe is so fragmented and the companies are split, it's very hard to deliver sometimes a policy that is cohesive because you don't want to – you're always conscious of what are your national priorities in a given member state or in a given market, vs how much do you want the EU to do and start to achieve? Do you want more competency, don't you want more competency? It's probably more a weakness of the system than the industry because it's something the industry has to deal with.

L: if I understand correctly, fragmentation is the main weakness and it's because of the difficulty to make a uniform legislation on the EU level? So logically speaking, it would be – with the current system of public healthcare – it would be best to have a legislation as broad as possible on the EU level so that the national level can be targeted more effectively? Am I correct? I'm just trying to make sense of it all.

R5: It's a different – it is a takeaway from what I am saying but it goes into a different topic. Let's say in terms of a weakness for the pharma industry is dealing with the fragmentation in the EU market. You will always have different interests coming from- I can say it from my job, because it makes it easier to speak to companies that I haven't worked in- I will have interest for the EU level, that my national colleagues may not have or agree with, because their – because what they experience with their members is abc, what we experience with our members at the EU level is xyz, while the members are the same , but the colleagues I'm representing are different because I have eu focussed colleagues that work for the companies. Take x or x for example, they will have colleagues that work at the EU level at the top, but they will have colleagues that work at the market level as well so they will staff the national groups and they will insert their national agenda, they will say what they want to achieve in this country. Of course at the top, you have the same people working for the same company, but their focus is on the eu. So that's a bit difficult to try and bridge the gap in the company – even for my company – that sometimes causes divergences and frictions where you need to find a compromise.

L: okay great, now I understand thank you. So then, which topics are most important for the pharmaceutical industry and in which policy domains is the pharmaceutical lobby mostly active?

R5: I'm probably the wrong person to ask because with biotechnology we have a much smaller focus. I can only say by, from a more objective standpoint when you look at the likes of EFPIA, they focus on nearly everything. It ranges from IP and the pharmaceutical revision for example, but it also goes into labelling requirements and environmental concerns, SDGs and things like this because it all impacts the business environment. We are most focussed at the moment on the pharmaceutical legislation review, revision of the orphan medicinal products, we also look quite a bit at the GMO

legislation as well, and related files like blood tissues and cells- a little bit more nuanced- but the things that you always have In the back of your mind are IP and incentives because these are the two biggest buckets that first and foremost always come into my mind because you also need often the incentives that are existent within legislation – whether it is direct incentives but indirect incentives too – so directly it can be you do x you get y, but indirectly you can also just have favourable systems or priority reviews, things like this which Is indirectly an incentive to do something and then IP is always necessary because when you do the R&D it protects your products very broadly speaking. These are two areas – its probably not just for pharmaceuticals tbh – but in general from a business perspective, these are important.

L: okay, and I think it's best to move on to coalition building because I'm asking a lot of questions and we have so very little time. Do you find that the pharmaceutical lobby often acts – or let me phrase it a like this – Is the pharmaceutical lobby a lobby with high unity among its companies and associations or would you say there is a certain level of fragmentation on this level and maybe even competition between different branches of the pharmaceutical sector.

R5: good question. I think there is a healthy competition. So, we have innovative and generics trade associations, I work for an innovative trade association but I have colleagues that work in the generics trade association , then let's say staying within healthcare you have not just pharmaceuticals but then also medical devices, you have contract research organisations that have their own representation so when you look at the range of different trade associations that exist – this is one thing: at that level you see a lot of – within the different groups being generics, innovative, medical devices whatever, there's obviously competition between the trade associations themselves, first and foremost. You know I like to eat, I like to have my salary so I need to have members. When you maybe go a step down and look at the companies that are actually members of all these associations, its fair to say I think every company from medium size up, is probably a member of – let's say there's 12, there are obviously more but let's say there are 12 – they're probably a member of 4 associations. I'd say with large companies they start being a member of 8 or more associations. Because we always try to align within ourselves, even if we're within healthy competition with each other, it doesn't make sense for me and a sibling organisation to have two completely different messages on behalf of the innovative biopharmaceutical industry. Likewise across the board. And then we also work with colleagues from generics and self-care medicines as well – in my case medical devices as well – comfortably a third of my week is spent on calls with colleagues – inter association calls – that – it can be secretarial colleagues from ,I don't even know. You lose track because you see people coming in and out. We also represent the interests of our member companies. Our job is to funnel those messages and to deal with the converging and the diverging messages. For the companies themselves, that's why trade association or lobbying groups exist, that's why they pay our membership fees, so that they are not doing it all by themselves. Of course, individual companies will also do their own lobbying and are directly in competition with any number of other companies. I can definately speak for us, I can also speak for a few of the other trade associations: every single meeting we have starts with anti-trust guidelines. So, they don't come to us. when the colleagues from the member companies sit in our meetings, they're not there to talk about specific products and specific pipelines, that's taken out of the discussion. They can speak about it on the high level to inform the lobbying point, but that's removed so we don't have to deal with that. When you have

contentious or divergent viewpoints – maybe you have a trade association that has – I have had this experience personally – where I've had colleagues that worked for the pharmaceutical industry and the medical device industry, and we were one of the few trade associations where they came together. So if you're working for pharma or medical technology its easy: you develop two different positions and that's it. When you have your companies coming into one trade association and you need to comment on our file – like the health technology assessment file – it's a bit more difficult because you have to write a reaction piece, when the colleague in front of you is not able to say " now I'm with pharma, and now I'm with medical devices". So this is part of the job, it doesn't happen so often but in terms of coalition building yeah I think it's done every day. I'll stop rambling in a moment, but we also work quite a lot with not just industry, but you'll also constantly see trade associations working with the patient organisations. So we're also working a lot with patient organisations and other stakeholders such as payer organisations and traders etc. They're still stakeholders, its not to say as if – there is less alignment, that's obvious, but for example then when you go to a meeting with the Commission where we're a consortium doing a study on behalf of the Commission. When you put 200 people in a room, you have everyone. So this goes back to an earlier point that everyone moves around in Brussels and you know each other, you know you all work in the same field so. You might have divergent opinions or bring diverging messages because of what your role is, but you still always know in the back of your mind you are working for the betterment of the same healthcare systems.

L: in terms of alliances with other groups, not other companies and associations per se, you mentioned payers groups and patient organisations, are there may be other types of groups?

R5: I think one of the other part of the group of stakeholders we try to work with is the part that is focussed directly on research. So clusters, from things like this – in my experience, we're working a lot with university colleagues and such, where the research is being done and that side of how healthcare works and functions within Europe. It's equally necessary because a lot of the time they're somewhat stuck in the middle. I personally- in my role we don't work with kind of civil society organisations a lot. I have in the past worked a bit with consumer organisations too, because its- because we have less consumer products for biotechnology and pharma so. It's not a group of stakeholders that I work with, but I know colleagues in other sectors or in the public health ecosystem, they will also work with trade associations that focus on consumers or groups of consumers too, not just patients. They look at that aspect of the market as well.

L: okay great. And would you say that this level of connectedness and networking leads to more lobbying success than if this wasn't the case?

R5: I think it really depends on what you define as lobbying success. This is definitely going to be a personal comment. At the end of the day, my job is from 9-5, when I go home, I'm still a citizen, you still have – I balance my personal opinion with my professional opinion, that can vary for every person – what is successful lobbying? When I look at the entire overarching picture of how we shape law in Europe, what I see is a system that is extremely connected. So, from my personal experience I know I can sit tomorrow with someone who works in a patient organisations and we can share our views and agree or disagree. I can sit the next day with someone that sits with the insurers and we can agree or disagree, on a personal and professional level etc. And then you lobby and go to an

MEP and the Commission al that, it all comes together. I'm not saying it's a perfect system – because that is something I have done my PHD on , I don't think its always perfectly done. How, the very process by which we engage a stakeholder if we try and shape a law. Its an extremely complicated, interlinked framework that you have to work through to make sure you tick all the boxes of engaging everyone that can be impacted by our law. But, I would – and I can be quite cynical – we can try – we try in Europe, and I think that that is really a thing that makes me proud to be European and why I for example like the fact that the EU exists because I see how it works. However, my in-laws absolutely hate the EU, and I see at the personal level how it can be misconceived. But, as a system trying to bring together all the moving parts, you need to have disagreement, but to a point you actually made earlier, lobbying success is nog actually winner takes all, it's win win win, you try to make sure everyone comes to a compromise that everyone is happy with. Because otherwise, you have achieved nothing. From a pharmaceutical perspective, access is a massive debate at the moment. I mean, c'mon, people are sitting around and trying to make a narrative that pharmaceutical companies only want massive profit. Of course they want profit, they need to pay for their business! But on the other hand, if they can't sell any medicines to patients, they are not going to have any money. so it's a no brainer, we equally want to come to a compromise and find a solution so that the end piece of legislation just makes things work.

L: For the last question are there certain interests that frequently oppose the pharmaceutical lobby? More specifically, on which issues, what is the composition of the opposition, does it vary across issues or is it mostly the same?

R5: I don't know if it's a direct answer but in my current experience, but the narrative that we face a lot is about pricing. You know, "why does a one shot treatment as a medicine cost a million euros upfront? This is horrendous, the healthcare systems can't deal with this" . I mean, everyone builds their own narrative, this one is equally as flawed as the pharmaceutical industry probably saying they can't properly calculate the pricing of medicine. I mean, we can but it's just super difficult. No one believes that but it really is extremely difficult. On the other side, it's also extremely difficult to say, once you give someone a one shot treatment of a very expensive medicine, that person doesn't need doctors and other things, they're cured once and then they don't have 30 years of treatment.

L: so, really the opportunity cost of the medicine?

R5: exactly. This is something we face a lot. I think, because I've seen this in other areas for example in the GMO debate and the stigma that GMO faces. But stigma, no matter on which issue, tends to eb and flow. I think, over time when you're lobbying – it's the same thing like you're always reacting to the political environment, the societal environment, blablabla - the diverging opinions that you face also tend to eb and flow I mean something that you disagree on now, maybe ten years down the line the system has completely changed an you completely agreed with the stakeholder you were previously fighting with. I always find that interesting. If you compare two pieces of legislation ten years apart, 99% of the legislation is exactly the same and all that's changed is the name. Because what we do is we drop the name that has gathered a lot of stigma, and change it. That's the same for debates. When a debate gets a lot of stigmas around it, we move on.

L: okay great, thank you for the amazingly pleasant interview, I liked it a lot and I'm sure I can use your answers well in my thesis!

R5: with pleasure, I look forward to reading it!

Interview respondent 6

L: Hello Mrs X, how are you?

R6: hello, I'm good thanks and you?

L: I'm great thank you, and thank you for wanting to participate in this interview and make some time for me!

R6: my pleasure, really. I'm glad to help.

L: okay great, so I would say let's start with a brief introduction of yourself, your job and what your experiences are.

R6: yes. So my name is x. I am with x since five years in our Brussels office here in Belgium and before that I worked ten years for the generic and biosimilar trade association in Brussels. Before that I worked a year for the cosmetics federation in Brussels. I am a political scientist by training and I also have a degree of medieval history from x University.

L: okay, that's great. I would say next question concerns a bit of terminology really. Do you view a difference between lobbying and public affairs or are these two terms interchangeable for you?

R6: yes, for us it's interchangeable a s long as its responds to the same criteria of compliance.

L: so, it's not that lobbying is strictly influencing the legislative process but it can also include managing external factors and such?

R6: I think it depends. Here in brussels we are looking at European legislation, but we do also interfere with some patient associations that are engaging policy-making process, or like NGO's, consumer associations. So, it's not entirely focused on legislative stakeholders.

L: okay, great. To go onward about the advocacy process: what would you say is the most important thing it the advocacy process itself.

R6: Just maybe as an introduction, its important to know as x we have to follow very clear guidelines , such as the discussion we had on compliance for this interview. We have to stick to responsible lobbying guidelines, and those are guided by three main principles. So if you want I can explain them quickly, how we see lobbying at Novartis?

L: yes, please go on.

R6: So, the first principle is transparency, but also honesty and integrity. And that should be reflected in all the actions we take in lobbying/public affairs. Ther second principle is more around how the decision is made, so how informed it has to be. It also always has to be in the way of looking at how to extend people's life, or having a positive effect on people's life. So that's very…

L: excuse me, the connection went bad for a second, could you please repeat the last part? I heard up till' helping people live longer and such.

R6: yes, so the third principle is that, as x associate I should not attempt to improperly influence any decision by inducing lobbying stakeholders to act or not to act in violation of their official duties. And maybe I can also send you this responsible lobbying? You can also find it on our website. We are also fully trained in order to stick to these principles.

L: that would be great thank you! So, next question: how would you describe the relationship between you and your organization and other public affairs professionals and policy-makers on the European level.

R6: So, you mean us the Brussels office and internal stakeholders or external stakeholders?

L: really internal stakeholders, for example with the Commission. So what's important in keeping this relationship, how do you gain access, and things like that.

R6: okay, thanks for clarifying. I think the first element is building trust in the sense of partnership. I think a lobbying process can only be effective is there is mutual trust in the beginning. And of course, you probably know better than me that you have to be trustworthy. So you have to make sure that the data you provide, information is 100% correct. This also relates to those principles I just mentioned before that it has to be, that the information has to be given in all good faith in order to have an improvement in society.

L: so, access is primarily gained trough exchanging information or maybe some other ways.

R6: yes, so you have different ways. If you take a purely legislative process, the influence starts as soon as the information is given from stakeholders that a legislative process will start. But then you have all the consultation time before, with official opportunities for stakeholders to provide information, and that is often complimented by more bilateral discussions or discussions also via trade associations. So you have both very formal moments and then informal moments that you get via one-on-one meetings or events. So yeah, you have a more specific question on that so more about it later on.

L: yes, okay great. So, next question: how would you describe the position and the influence of the pharmaceutical industry lobby in the European political arena. So maybe it's best to split up the question in two parts. What would you say are the primary strengths and advantages the pharmaceutical industry lobby has on the European level in the political arena in and of itself, but also in comparison with maybe other lobbies cross-sectoral.

R6: Yes, good question. I think the presence of the pharmaceutical industry as a stakeholder in brussels is quite old. So there is tradition also of having a presence in the Brussels bubble. It's a topic that attracts a lot of passion I would say, and you have a lot of misrepresentation, we have a lot of awareness work to do. And I think there is quite a high demand in understanding better our business model. So yes, we are present since a long time and we are also quite important in terms of presence. I don't have the figures in my head but for instance EFPIA, the federation of innovative

medicines, is quite a big federation in Brussels, the same for the generic one that has also been here for years.

L: would you say it also relates to the specific environment that the pharmaceutical industry lobby operates in? I understand it's very technical at times, does that give rise to a bigger demand of external information from the policy-makers themselves.

R6: yes, I think it goes both ways. I think there is a lot of – there is an expectation from stakeholders to be ready and for us to provide information, but there is also a lot of resources from our sector to be present in Brussels. So I think it really goes both ways.

L: and, would you say that – I understand that the pharmaceutical industry is one of the biggest spenders in the lobbying arena. Would you say it's out of necessity? Or –

R6: I'm happy to say something there, because I think there is also a bit of misrepresentation that the pharmaceutical industry – but when you compare with other stakeholders or NGO's, you also see that they have a lot of lobbyists in their staff. So, maybe I can also send you – I think I have a slide about the pharmaceutical industry representation/NGO, I will see if I can send it to you.

L: that would be great, thank you! Everything you can send is more than welcome, the more information I have the better.

R6: And I do have some slides also on the representation and on how this job is also more and more professionalized because you have more and more scrutiny, both from institution and society, to better understand how we do things and why we are here. So I think our presence is quite balanced looking at the big milestones we are heading to. We need to be present.

L: what would you say is a primary threat/weakness of the pharmaceutical industry lobby? Something that could be worked on?

R6: yes, there is. There is this right of information, so. I mean, I'm in brussels since fifteen years and I also saw the trend of transparency increasing drastically, for the better of course. When you have meetings with Commission officials they are disclosed, and we have the transparency register that we subscribe to where we are really sticking to the guidelines and making sure that we really declare as much as we can. Of course, sometimes the numbers seem quite big but that is because we are really declaring everything and it's a process that we take extremely seriously. So, anyone can go on the website and check how much Novartis is spending. That's a very good step in that sense, it's very transparent and now I forgot your question.

L: it's okay, don't worry thank you for your answer! The question was, what is the primary weakness or threat to the pharmaceutical industry lobby in your opinion.

R6: so, for me the number one weakness is reputation. You have to understand that sometimes there is a disconnect between functions internally in the companies, so some actions or communication that we as public affairs would never do – yeah, sometimes for communications they don't need our green light and they go ahead and I think each company, they had a bit of a reputation issues at some moment and I said it in my introduction that trust is the number one element in building a relation, and when you have those types of reputational crisis, even though it could be

only allegations, the trust will fall off and then it takes a lot of time and effort and activities to make sure that the mutual trust can be restored.

L: to follow up on this, I maybe have two questions. Firstly, would you view the pharmaceutical industry lobby as homogenous and acting in unity? Secondly, would you attribute this – you mentioned reputation, yes? So , if one company gains a bad reputation for maybe a miscommunication or something else, would you say it affects the whole industry?

R6: yes, and I mean it's interesting because as x we have also in place this sense of solidarity. So not throwing other companies under the bus. So if something happens for example with vaccines with a competitor, we would not go out and speak about this competitor. But it's also a bit something natural. You know, when we came out with x therapy a few years ago, with a price that was what it was, we knew that some other companies thought that the communication was mishandled etc. So then of course it can create some tensions. But often, those tensions are then fixed at trade association level so that when the trade association goes out, they know they are equipped with the right messages and they don't convey this internal competition. And I think its also something that is good, is healthy to have a natural competition. Within the trade association we have an open discussion and we try and solve those issues internally rather than stakeholders. Because at the end of the day, like I said, if one has a bad reputation, it really can affect the whole sector so it doesn't make sense to play on that with stakeholders.

L: To go on about this, so in the public affairs domain, the pharmaceutical industry would you say, is more a fragmented industry in the sense that there is also a substantial amount of internal competition? Or would you say it's more cooperative?

R6: I think if you take the innovative pharmaceuticals, yes it's rather collaborative. If you take the off-patents sector, there is less collaboration. It also depends: if you take regulatory issues, then often you can agree, but then if you look at patent protection, more market access then yes everybody will fight a bit for its own interest.

L: So, the level of internal competition really depends on the policy domain or specific issue at hand?

R6: I do believe so. Because we have excellent example of collaboration, such as the public-private, private-private partnerships for example. We have some other ideas to work out, such as a new type of public-private partnership for instance for rare diseases. And we really are hoping that would work out. But then, if you start discussing on more specific issues, yes you have more – also different visions in what success would look like. If you are a big pharmaceutical or small biotech it's not the same. Or even like generic producers and innovatives. Sometimes it can be divergent.

L: okay great thank you for your answer. Then, next question more about coalition building. Would you say the pharmaceutical lobby often acts collectively, maybe trough EFPIA, and how would this be – an issue would be more collectively lobbied and then supplemented by individual lobbying or how can I maybe see this better?

R6: yes, I think it's a good summary. Some activities we will drive them trough EFPIA and some others we would try them as companies, so as x. Depends also a bit on what you have in your pipelines. We were the first company to come out with biosimilar in the past, such as x. Of course,

there you have to pave the way, the same with x therapy and it's really like paving the way for the other companies coming after. But then, yeah I think it really depends – it's a case by case. And as x we really do both. We also try to prioritize as much as possible to see what we have to lead trough the trade association and what we have to do on a one-on-one basis. Also, pipeline is one element but then you also have the element of the circumscription – so the constituency. Depending if you have a strong footprint in a certain company, you may have more arguments to speak directly to those stakeholders and other trade associations. Just to compliment, often also the request comes from the stakeholders because they have a particular interest in the product, or a business area or localization, supply of necessary resources, supply chain is handled there and there. So they really want to speak with the specific company that has a foothold instead of another company.

L: Great, thank you. Would you say that the pharmaceutical industry or maybe the company you work for itself has sustainable alliances and coalitions with other interest groups or maybe cross-sectoral?

R6: So, in the therapeutic area we had some coalition building on the subject of breast cancer. We handled for more brain issues, such as Alzheimer, and we are building alliances for heart-related diseases. But then, when it comes to oncology for instance, we are trying to build more cross-sectorally. It is not really what I'm working on ,as I'm working more on the therapeutic areas, but more highlighting of what a company can do in terms of diversity and inclusion for instance, more CSI issues. But the main point there is always to be very transparent: who are we and why are we doing this. The point is not hiding behind a coalition but to be stronger when we are together with other voices.

L: and this coalition, would you say it's a diverse collection of stakeholders? For example pharmaceutical companies and NGO's, and patient organizations? Or does it mainly consist of other pharmaceutical companies?

R6: so, successful coalitions are with different kinds of stakeholders because if it's just a collection of a few companies, that's often not the best scenario. The best is when you have also have the trade association on board, you have patient organizations, you have companies and from institutions themselves.

L: so really diversity of a coalition is key.

R6: yes, it is. Very important to have more than one company. Yes, as a company you can build a coalition but it's always better to have a few companies with the same interests on board.

L: maybe it's a really issue specific question, but what type of coalition gets most success: a relatively bigger coalition or a more diverse coalition?

R6: it can be diverse and targeted. In the case of the breast cancer there was an MEP that had a very specific interest in breast cancer. She was really leading: organizing events, writing OP-eds enough for the coalition to profile itself. So that works quite well.

L: great. Are there certain interests or certain organizations or types of organizations that frequently oppose the pharmaceutical industry?

R6: Of course, that's why we exist. Because often the goal is the same but then the ways how to achieve these goals differ. If you take the very simple yet complicated issue of access to treatment and medicines. If you speak to a patient organization, an NGO, a politician and us, we all want to have better access for patients. But how to get there is a different story. And we have our own vision of how the private sector can help and we have to confront this with the stakeholders views. That's quite a different , difficult exercise sometimes to understand the perspectives of the others better. Because often, we are tempted to say "ah, they don't understand, that's why they say this and that" but that isn't the case: they perfectly understand it's just that they have a different opinion. And that's also where us lobbyists come in, to explain to our expert collogues back in the headquarters what could be an alternative solution.

L: and is it generally the same organizations, in the sense of for example patient or environment organizations that constitute this opposition? Is the composition of the opposition constant throughout issues, or does it vary between issues?

R6: I think that it's more issue specific, because we might fully agree with consumer associations on for instance transparency. But then when it comes to procurement for example we would disagree, and the same geos for patient associations. They fully agree on having access and early dialogue, but then they would disagree on some other programs we are working on. It's really issue specific.

L: and how would they go about bringing this opposition? How do they counterlobby, what strategies do they use?

R6: As I explained in the beginning, you have those official moments for stakeholders to spread their views, and then unofficial. And as I said as well, they are quite well equipped. You no longer have these professional and less professional lobbies, everyone is professionalized.

L: to maybe interrupt you for a moment, because in the literature I saw mention of business interest being "all powerful" and NGO's being a bit more – David vs goliath. But you would say that is not the case?

R6: no, indeed it is not. And I think especially in brussels its also what you have to say that counts. And the reputation you have. So if you have an NGO, even smaller but with very good reputation and with very crystal clear and sharp messages, you can get trough. And I experienced it, even with the generic association where you had less resources than the innovatives, but with very clear messages and very good mapping of stakeholders with whom to speak you can actually achieve a lot.

L: and would you say that in actuality, they are quite successful in their – just generally speaking – in their efforts, or would you say that's not the case?

R6: I think they are, and I think it has greatly improved throughout the years that you have maybe a different balance of power nowadays than maybe 20 years ago.

L: so you would say that the typical view, of someone who does not know about EU public affairs, that the pharmaceutical industry is "all powerful" and NGO's are less. Would you thus say that it's evening out more?

R6: yes, and when you see the policies, legislation that are upcoming, you can clearly see it. And if you see it also who has submitted what to the public consultation, because that is all public information, it's not the easiest literature to go trough. But the Commission usually has like drafts to see who said what – we see that the balance is not what it used to be twenty years ago.

L: and this change of balance, could you maybe attribute it to – just as a suggestion- a difference in institutional factors? For example, the EU Commission wanting to improve their democratic deficit so to speak. Not to put words in your mouth though.

R6: but that's of course my own views. You have – what I see is that first of all, you have more member states, which results in the legislative process becoming more complex. The voting system is what it is, but it's more complex as well. You have a lot of pressure for member states that are pushing a lot of their issues to the Commission because they don't want to solve these problems themselves. They ask the Commission to act, and then the Commission is nudged to action. That was maybe less the case in the past. So yes, a lot of very important issues are popping up, and we also know that we can't do business as usual: things have changed, COVID came in, crisis as well. So yes, it obliges us to reflect how we are doing things and how we can improve and better stick to the reality of member states and the needs of the – that is conveyed trough the Commission, because that comes from a (unintelligible). For instance, we as x, we always try to have a kind of innovative view of how to work on access with innovative payment models etc. It's less difficult or heavy for member states to absorb those upcoming costs. But of course, that can only be done in dialogue, if you can negotiate.

L: so, it's not really a case of winner takes-all, but more about making compromises between the different parties that are active?

R6: yes, it is. And it's not the case that the pharmaceutical industry will come and impose its views, that's not the case. Otherwise we would not have a job.

L: great, thanks for clarifying. To finish: would you like to say to say something that I really need to include in my end result? Something very important that I can not overlook, such as a quote or something?

R6: yes. I think it would be interesting for you to look at those public consultations to see exactly who is saying what. Then you can also see the diversity of stakeholders, to give you a bit of a barometer of what is going to happen. Because if the people submitted their views there, you can anticipate lobbying activity later on. But, you can really see that the pharmaceutical industry has to take a step back and reflect in how we are doing business.

L: maybe another question, not so nuanced maybe, but would you say the more diverse the stakeholders, the less success the pharmaceutical industry has?

R6: it's a question of representation of course. If we would be on our own in those public consultation, I think it's very straight forward. But I don't think it's the ambition of the Commission to take on board everything that the pharmaceutical industry is proposing. And again, I think it's also a good exercise for us to think about how we are doing things and how we can always improve and stick to the needs of society.

L: okay great. Those were all my questions. Thank you very much for your great answers and cooperation and making time for me, I really appreciate your participation!

R6: glad to help you, Lorenzo! I wish you very much good luck in finishing the master's thesis.

L: thank you very much! Have a great day, bye bye.

R6: you too, bye.

Interview respondent 7

L: Hello, good morning Mrs. X; how are you doing?

R7: Hello Lorenzo, good and how are you?

L: I'm good thank you, and thank you for wanting to participate in this interview!

R7: no problem!

L: okay great, so x, could you please briefly introduce yourself and the organisation you work for? And what does your job entail?

R7: sure, Lorenzo. So, I'm x and work for the x. And I work there as a senior policy manager of healthcare delivery, which includes our access to medicines stream of work. And within that we also have – we also host an coordinate an alliance of civil society organisations, patients, consumers that is called the x and we work towards an R&D system that is focussing on public health needs and that delivers affordable medicines. Because we are looking at access to medicines and affordability of medicines, because of that we follow very closely pharmaceutical policy in our work.

L: next question is about terminology. How do you view lobbying and public affairs? Do you consider them two perfectly interchangeable terms or do you view them as having clear differences.

R7: this is my personal view but we, in the civil society world we use mostly the term advocacy rather than lobbying. But if you define lobbying as influencing policy-making, than I guess we do this type of lobbying. The difference is that we do it on behalf of the public interest, not serving particular interests. But rather the interest of civil society, citizens, public interests .that is the main difference. When you talk about public affairs, that is for me a bit of a different thing because usually it's about organisations trying to strategize and this is not the usual thing we do. But of course we all engage in public affairs, it's also the face of the work we do. But it's not a terminology that we use very often.

L: okay, great thank you. And what would you say is the most important part of the advocacy process in your personal opinion. I know it's a very broad question, but what would you consider the most important thing in achieving advocacy success so to say.

R7: let me ask a question: do you mean what is the most important requisite or requirement/conditions?

L: no really it's about activities that you do to gain lobbying success. For example, would you say that – not to put words in your mouth – that coalition building or working together is really important and instrumental in achieving lobbying success? Or something else entirely?

R7: okay, if I can give you different perspective: there is not one component, I think this is a multi-component set of activities. Because to do successful advocacy work, you need to have a good understanding of the issues, that's a first prerequisite. Then, you need to develop – and the understanding is very important because that is the area you can move. So if you want to influence policy making, in a particular context for example the EU pharmaceutical legislation revision, you need to understand what is possible within that position. What is being called by a particular legislation. Then you need to develop your own recommendations as clear as possible. So I can go into more detail if you are interested. So that's a whole set of activities there. And then you need to also communicate them, because building your advocacy is not enough, you need to reach out to the policymakers to communicate your recommendations. And of course building coalitions with other organisations that have a similar position can only help. Not only because you raise your voice stronger, but also in civil society work it's also very true that we are talking about NGO's, small organisations that often have very limited resources. So the advocacy work that we carry out is very complicated and technical, so you need resources to pull that together.

L: On that note, would you say that – if I understand correctly, your main opponents would be big pharma? To state it in an unnuanced way.

R7: well, I wouldn't put it as our big opponent. You can use the terminology, but – it's also because when you are talking to the industry, you're not only talking about one particular type of industry. I mean, in the pharmaceutical sector there are different types of industry that are represented. There are different types of business that can be developed. And sometimes it might happen that we share positions with one of those sectors. Doesn't mean that we work together but it happens. So, I wouldn't put them as opponents, but it is true that because of the nature of exclusivities in the system of pharmaceutical policy –

L: so, really innovatives?

R7: sorry?

L: so, would you say that the innovative sector within the pharmaceutical industry is really –

R7: so, we are often in opposition – or have opposite views –with the innovative industry. When it comes to the particular exclusivities. But I wouldn't put them as our opponents, because there are many other aspects to pharmaceutical policy.

L: and how would you describe the relationship between your organisation and the EU policy-makers? Maybe also in term of how does your organisation gain access to policy-makers, as a side question.

R7: sure, so my organisation – the main target of our advocacy work are EU policy makers. National policy makers sometimes, also via our national members, but it's mostly EU policy makers. So there is the relationship – it might look that we provide them with feedback and that's it, but in reality it really is a bidirectional relationship because we need to have feedback into what is the mind-set of the commission and parliament for instance. We also try to understand that. The second part of your question, could you remind me please?

L: how does your organisation gain access to EU policy-makers.

R7: okay, so x has more than twenty five years – I mean let me correct that if you can because I don't really remember it exactly. I think the way we have access is that we have a long term relationship, which is the way you build trust in the sense – they know that we are one of the biggest NGO's working in health. So that's one part of the thing. It's not that we-)re completely new to that. Now, how do we have access – we do have access in the formal ways in which we are invited for instance into consultations, or we respond to open consultation that is public, that any citizen of the EU can respond to. But we are also actively reaching out to commission officials, people in parliament and to the extent that it is possible: to member state representatives also. So you can have different ways in approaching them, and having access to them.

L: what would you say are the challenges between the three institutions. What are the differences in for example the ways of approaching the commission and parliament?

R7: definitely. I would say that with the commission, we have a very – it's an ongoing relationship. Also the commission is often preparing proposals so sometimes it's really them that are reaching out to us. And many times it's us reaching out to them so it's a very continuous and good relationship, in the sense that there is a lot of exchange of information. With the parliament, it's the same but of course with the political aspects. It depends on the views that these MEP's individually and the parties have on the different issues. So we have access to some parties and some groups more than to others, according to their political perspectives. And then on the third pillar, the council and national representatives, it's I guess the most difficult part because of course it requires- I mean we are talking about 27 different views. And we do have permanent representation in Brussels, but often times it's the most challenging and difficult policy-makers to get access to and to get – and again there is no magic formula, you need to be in relationships and have contact often times. And EPHA has done it in the past as well.

L: okay great. What would you say are the primary strengths of the pharmaceutical industry lobby on the EU level?

R7: the main positive aspects of the pharmaceutical – it's a very broad question , but if I'm going to the right direction – of course I mean in general terms the pharmaceutical industry is vital, is crucial to various – if you are talking about the innovative industry, it's to invest and to develop new medicines, vaccines, medical tools in general. If we are talking about generics, they are crucial also in bringing to the market the competitors once the IP expires and to bring competition into the market. And so on, and you can say these sectors are vital: we are talking about medicines, it's an essential type of product that is heavily regulated. But obviously, I mean at the core the industry is necessary to bring this about. Now, I think it is far more complicated than that, because the pharmaceutical R&D takes place over a very long period of time. So industry contributes a part, but not the whole. And the public puts a lot of resources into that, also academia also contributes to that. And what is difficult is to track the contribution of each and to provide a good set of incentives that then keeps the balance in the market because we are not talking about luxury goods but medicines that are needed for patients and that , if the prices go to high, it can put a big burden on healthcare systems.

L: Great. What would you then say are the primary weaknesses of this industry lobby that can negatively influence their lobbying success on the EU level.

R7: oh, I think I got the previous question wrong then. Well, if I put myself into the shoes of the people working for the innovative industry – their strengths is that they are a small set of organisation that get together and can very easily agree on common messages that they all want to push forward. That, and at the same time having enough financial resources to put together a lobbying strategy and communication strategy. These are the very big advantages they have on the subject of lobbying. I mean, if that is the correct angle on that question. So, they get together and can very easily come up with common points and they can spend lots of resources on that. And on the negative side, or disadvantages that they have, well I mean – they don't have necessarily disadvantages if I think about it. But of course the way they present – the way these policy-makers and the , let's say civil society but other organisations presenting other angles of the discussion- they know what the lobbying of the pharmaceutical sector is about to push and what are their core messages. I wouldn't say it's a disadvantages, but of course I will hope that the policy-makers are cautious about the messages that are being sent by the pharmaceutical sector as they only represent a part of the view of a particular sector and not necessarily the public good.

L: okay great, and then I would like to ask you the same question about your organisation and perspective. What are in your opinion the advantages and disadvantages of a public health civil organisation at the EU level.

R7: basically the reverse of what I said. Because for us I think the big advantage is that we are a trusted source of policy recommendations in the sense that policy-makers know that if they come to civil society organisations they will get a view that is based and aspiring to be the view of the public interest. So it might be that at some point we even share the same view with particular industry sectors, because if that coincides with the public interest that shouldn't be a problem. So we don't have vested interests, we are independent. So again our advantage is being – not having a particular conflict of interest allows us to be presented as a stakeholder that policy-makers can trust. Now, the big disadvantage is that we are scattered organisations. So, when you talk about civil society, you know that it's a very diverse group consisting of NGO's, patient organisations, consumer groups. And even the practice of how NGO's work will tell you that it's very difficult to assemble them, to collect all their opinions and then to develop a very cohesive argument. We actually work to overcome this obstacle. But I think at the very basis, I'm telling you the original disadvantage that we have is that. So in our nature, we very scattered civil society organisations working for citizens, and we have very few resources. And when I'm talking about resources, I'm talking about financial resources to sustain NGO's in an independent manner, without funding coming from other organisations with their own interests.

L: okay great, I think you answered a few questions at once there. So, the pharmaceutical industry, or better the opposition to this industry. Are there certain interests that frequently oppose the pharmaceutical industries?

R7: could you repeat please? I didn't quite catch that.

L: are they any other organisations , for example NGO's or academia, that frequently oppose the pharmaceutical industry? And is the composition of the opposition constant or issue-dependent?

R7: okay, sure. So, I guess, I mean on the side of health NGO's is very often that health NGO's working on pharmaceutical policy will be in different positions, usually in opposition to what the innovative industry is saying. Not on all issues, though. Other sectors, I mean academia sometimes but it's not only academia obviously because the very nature of academia is to be independent, so you cannot really talk about academia in a void. So, certain, scholars and people in academia can be on the same lines. But, yeah, it's difficult because veen when you talk about health NGO's, you have to differentiate because there are also many organisations – to keep anonymity – inside health NGO's you see a lot of diversity. And you do have some NGO's that work very closely to the pharmaceutical industry. Those are practically financed by industry directly. So it's not to say that all NGO's would directly oppose the views of the pharmaceutical industry.

L: would the fact that some NGO's really closely work with the pharmaceutical industry and find themselves often on the other side of the opposition to the innovative industry, would you say this makes it difficult to influence EU policy because then pharmaceutical industry has the industry position plus some NGO's while the other side only has NGO's.

R7: yes yes definitely! I mean, that's an added difficulty. But it's also that the difficulty there is due also to a certain extent on the lack of funding opportunities. So if those NGO's would be able to have independent funding, then I guess they would be more free to express their own views and to have a different contradictory – if they get money from the pharmaceutical industry then it's very difficult that they will.

L: how Is it about funding from EU institutions itself? Because, I know the commission also grants subsidies. Do these organisations also receive funding from EU institutions, and if yes, do you find that it helps in sustaining their activities or is it more a droplet on a hot plate?

R7: I mean, I can tell you also for my own institution. We have received since many years, several budget periods in the EU – we have received a formal funding that is granted to NGO's, precisely with the idea that these organisations can provide valuable feedback to policy-making and that they remain independent. There is more to it, but it's basically with that idea. But, there is a big problem with that funding because there is a lot of uncertainty. It's a long story, it was cut back at some point and it's a very important source of funding, because it's the only –apart from national funding for some health NGO's- the problem in this sector is that there is a lot of uncertainty, be it at national or EU level. Every couple of years we face the same problem: will we have funding? What type of funding? This, for instance, that I'm telling you about are called operating grants: particular funding schemes that the EU commission grants to NGO's. in the case of health, they are managed by the DG health, but there are similar grants for other consumers and other types of NGO's in other sectors. So that's pretty important, because that funding guarantees that NGO's can develop their lobbying. And lack of this funding put NGO's into other – there are only a few foundations, private donors that provide funding without restriction and keeping the independence for NGO's. So that's an added difficulty.

L: okay, thank you for clarifying. Would you say that this uncertainty in receiving funding would make some NGO's more dependent on the EU commission itself, in order to have more security in funding? So that the position of these NGO's can be seen as a reflection of the Commission position?

R7: if I understand you correctly, does the fact that you receive money from the commission would make you more prone to accept the EC position? I would say no, I'm telling you on the basis of my own organisation, we remain very critical. Also the type of funding is granted without strings, concerning the activities that you have to do. But these activities – I'll tell you a particular example of why it's not such a problem. The fact that the Commission needs to do it, needs to look at what the needs of the stakeholders are when they are putting forward proposals. And, for them it's even positive having a variety and diversity of views. I mean, if they consult and everyone agrees – it will be great if they already have an idea, but many times they are consulting because they are trying to find a solution. So, we have not witnessed this problem of having to be softer with the Commission because we are receiving funding. It's different for the parliament, and also the grants to fund the operations of health NGO's. so part of it is to feed into policy-making. Another part of it is to develop other activities. So, it's a good balance. I wanted to add on the other stakeholders or sectors that we work together with very often, is the national payers. On issues of pharmaceutical policy, prices of medicines, we tend to very often agree with the payers, national healthcare systems. Because we also look at the sustainability of those healthcare systems.

L: okay great thank you for your answer. Then, what would you say are the primary strategies used to make this opposition to certain pharmaceutical interests? What are the arguments used? Is there expert information provided or more public preference information?

R7: very often, because it's a very technical matter, I think it's mostly expert information/consultation – it sounds as if we're consulting with other people, but actually it's a mix of information that is already in-house in the NGO's. we do consult with others as needed, but it's really about evidence. Very often, it's about bringing balance into the evidence. Because evidence is a tricky war, in the sense that the pharmaceutical sector will present some evidence, data, some facts and new information. But if you look into those, it's not another angle. I mean, it's the same statistics and their interpretation might be a bit different then when it's presented by one sector. So it's mostly expert information because matters are mostly technical.

L: Okay great. Those were all my questions, thank you very much for your time and valuable answers. I'm sure they will be instrumental in writing my thesis!

R7: I'm glad to hear that, Lorenzo!

L: so thank you for the interview, and I will keep you posted when the thesis is done! Have a good day!

R7: yes, please do! Thank you and have a nice day as well.

L: bye bye.