

LONDON
SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



LSHTM Research Online

Vasilescu, CL; (2018) Quantitative Text Analysis: Uses and Application in the Institutional Policy Process at EU level. DrPH thesis, London School of Hygiene & Tropical Medicine. DOI: <https://doi.org/10.17037/PUBS.04648949>

Downloaded from: <https://researchonline.lshtm.ac.uk/id/eprint/4648949/>

DOI: <https://doi.org/10.17037/PUBS.04648949>

Usage Guidelines:

Please refer to usage guidelines at <https://researchonline.lshtm.ac.uk/policies.html> or alternatively contact researchonline@lshtm.ac.uk.

Available under license. To note, 3rd party material is not necessarily covered under this license: <http://creativecommons.org/licenses/by-nc-nd/3.0/>

<https://researchonline.lshtm.ac.uk>

LONDON
SCHOOL *of*
HYGIENE
& TROPICAL
MEDICINE



Quantitative Text Analysis:
Uses and Application in the Institutional
Policy Process at EU level

CORINA LIGIA VASILESCU

Thesis submitted in accordance with the requirements for the degree of
Doctor of Public Health of the

University of London

JULY 2018

Department of Health Services Research and Policy

Faculty of Public Health and Policy

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

Funding Details: Partially Funded (up to 25%) by my employer

Supervisor: Martin McKee

Advisory Committee: Aaron Reeves

The views expressed should not be constructed as representing the views of my employer – past, present or future.

I, Corina Ligia Vasilescu, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Acknowledgements: This work was inspired by Prof. Martin McKee who offered leadership, good humour, advice and patience throughout this doctoral commitment. I am sincerely grateful for all of his pedagogical stamina, intelligence of action and for his outstanding mentorship. I wish to thank Prof. Aaron Reeves of LSE and Dr. Michel Pletschette of University of Munich for providing me with support and access to different angles of analysis throughout the drafting life of this thesis. All the staff members whom I approached at LSHTM were generous in giving me their time and in sharing their knowledge with me; I am indebted to all the professors, all the colleagues I learned from over the years and of course to my family and friends who stood by me throughout the five years of self-discovery and research. Without you – nothing.

“Never doubt that a small group of thoughtful, committed citizens can change the world; indeed, it’s the only thing that ever has.”

~ Margaret Mead

Abstract

Institutional policy processes (whether pre-legislative, legislative, post-legislative or administrative) in the European Union (EU) are probably among the most commonly misrepresented and misunderstood processes in Europe. The relationship between institutional actors and the general public, (mis-) informed and influenced by media outlets, is often hindered by high levels of distrust and by barriers to communication.

One issue that has attracted considerable concern has been the role of vested interests, represented by large teams of lobbyists, in the development of legislation and regulations. This has led some to characterise the EU as having been captured by “big business”, to the detriment of Europe’s citizens. Yet while there is extensive circumstantial evidence of the ability of these interests to exert influence, for example through meetings with key decision-makers, and in a few cases from the inclusion of specific features in legislation (or a failure to legislate), it is more difficult to quantify such influence.

One approach that has been considered to offer potential in this regard is quantitative text analysis (QTA). This refers to the application of one or more methods for drawing statistical inferences from text samples. In contrast, qualitative text analysis methods are comparatively more inductive, non-statistical and exploratory. QTA has been used to show a progressive shift away from language used in public health submissions on EU tobacco legislation towards that used by the industry.

This study begins with the premise that industry, and especially multinational corporations, and possibly other stakeholder groupings (e.g. trade organizations, industry front groups) use particular vocabulary, evidence, position-taking and semantic shifts to influence the policy process. Business case language and economic perspectives dominate over a narrative featuring public health or ethical concerns. The study then explores the scope to use QTA as a tool to “interrogate” the subject (the text submitted to a public consultation), to examine and assess the content of public consultation documents and to evaluate the policy position of stakeholders as well as their evolution. Finally, it asks whether a more sophisticated package of tools, including QTA of policy briefs, mission statements or policy papers, can complement traditional methods such as stakeholder analysis to provide a more robust

assessment that can protect public institutions against misuse and misrepresentation of scientific evidence in public consultations.

I do this by investigating the experience of public consultations in influencing the evidence base for institutional policy-making in the field of health, aiming to identify who stands to benefit from public consultations and whether they achieve an advantage. I propose that QTA could help to foster a dialogue between groups weakly or rarely represented in public health consultations and institutional knowledge systems, and focus attention on the role of public consultations in challenging power hierarchies between public health activists, industry professionals and regulatory affairs practitioners as risk managers.

I undertake QTA in three separate health-related case studies in which some variant of public consultation took place.

This study looks at:

- a) the experience of public consultation applied to a draft scientific opinion by the European Food Safety Authority (on the chemical compound acrylamide),
- b) the process of consultation on the findings of an externally commissioned study on pharmaceutical pricing policy in Europe and
- c) the draft text sequence of an important piece of EU legislation as it progressed through the co-decision procedure, the application of rights of patients in cross-border healthcare, i.e. Directive 2011/24/EU.

Table of Contents

Abstract	4
Table of Contents	6
Chapter 1. The corporate determinants of health, and why they matter	12
The “commercial determinants” of health and health inequity	12
Tactics used by corporations	14
Power elites and health	24
Defining the narrative.....	24
Setting the rules.....	25
Chapter 2. Why is the European Union a target for corporations?	27
The European Institutions.....	27
EU Decision-making.....	30
The Better Regulation Policy.....	33
Tactics employed by corporations: range of methods used to study their influence...43	
What constitutes good or bad lobbying.....	46
Conclusions.....	47
Chapter 3. Corporate influence – what do we know?.....	49
Quantitative Text Analysis	50
Chapter 4. The research question, conceptual framework, and methods	58
Dialogical Theory, Framing Research and Discourse Analysis.....	58
Dialogism	59
Discourse Analysis: Interpretive Policy Analysis (IPA) and Framing Research.....	59
Further conceptual frameworks for analysing political discourse.....	61
Democratising choice and policy literacy	61
Research questions.....	62
Aims and objectives.....	64

Choice of methods	65
Alternative methods not selected for use	67
Transformation applied.....	68
Rationale for selection of case studies?.....	69
The case studies.....	70
Pharmaceutical pricing	70
Acrylamide.....	70
Cross-border Healthcare Directive (Directive 2011/24/EU)	71
Case studies considered but rejected.....	72
What are the expected outcomes of the research?	73
Chapter 5. Pharmaceutical Policy and Healthcare Systems.....	74
The issue	74
The regulatory environment.....	75
Current developments.....	77
Policy options	78
The decision being discussed.....	78
The consultation.....	80
Participation in the stakeholder consultation	82
The Martin-Vanberg Transformation	87
The production of the Guide.....	87
Results.....	88
Main Issues and Limitations Identified with EPR and Differential Pricing	88
Nature of Comments Received	89
Transparency	90
Possible Improvements	91
Parallel Trade and Differential Pricing.....	91

Summary of the positions of industry, governments and the public health community	93
STATA and Jfreq analyses	93
Changes between the draft and final report	96
Plotting stakeholder positions based on MV scores to improve stakeholder analysis	99
Chapter 6. Acrylamide.....	103
The issue	103
The regulatory process	103
The documents.....	104
Analysis.....	105
The Margin-of-Exposure Model	107
Results from Jfreq and comparative reading via corpus analysis	111
Results from the STATA analysis	112
Chapter 7. The Directive on Patients' Rights in Cross-border Healthcare	119
The issue	119
Regulatory environment and the decision being discussed	120
Actors.....	122
Context.....	122
The consultation.....	123
Methods	124
Results.....	124
Results from Jfreq and comparative reading.....	130
Results from STATA.....	135
Chapter 8. Discussion.....	140
Limitations of the case studies and of the thesis	140
Pharmaceutical pricing models.....	143

Cross-border Healthcare Directive case study	144
Acrylamide case study.....	146
Overview	148
Chapter 9. Conclusions	150
What this study adds to the research to date – the “ <i>differentia specifica</i> ”	150
Implications for policy and research: Production of a Manual and beyond.....	151
Avenues for further research.....	152
Appendix 1. Supplementary material from Chapter 5	159
Section A. Full STATA results and sensitivity analysis.....	159
Section B. Glossary of terminology.....	161
Section C. Stakeholder analysis.....	162
Appendix 2. Supplementary material from Chapter 6	165
Section D. Sensitivity Analysis for all texts under the Martin-Vanberg Transformation.....	166
Section E. Stakeholder Analysis Acrylamide Case Study Submissions.....	167
Appendix 3: Supplementary material from Chapter 7.....	170
Section F. Stakeholder Analysis Directive Case Study	170
Appendix 4: A Manual for Quantitative Text Analysis in Policy Development.....	173
References.....	182

List of figures

Figure 2-1 The Ordinary Legislative Procedure (the Co-decision procedure)	32
Figure 2-2 The 'average' timeline of an impact assessment	35
Figure 3-1 Categories of stakeholder	53
Figure 3-2 Steps in a stakeholder analysis	53
Figure 5-1 Stakeholder consultation in the pharmaceutical pricing case study	81
Figure 5-2 Plotting stakeholder positions based on MV scores	100
Figure 5-3 Plotting stakeholder positions based on MV scores (summary measure)...	101
Figure 6-1 Stakeholder position based on MV scores and their confidence intervals ...	116
Figure 6-2 Stakeholder position based on MV scores and their confidence intervals (summary measures).....	117
Figure 7-1 Stakeholder text position based on MV scores & their confidence intervals	138
Figure 7-2 Stakeholder text position based on MV scores and their confidence intervals (summary measures).....	139

List of tables

Table 1-1	“What Public Health Practitioners Need to Know About Unhealthy Industry Tactics”	15
Table 2-1	Sections of the EU Transparency Register	40
Table 3-1	Software used to undertake Quantitative Textual Analysis	55
Table 3-2	Software used to undertake Qualitative Textual Analysis	56
Table 5-1	Stakeholder review process – overview of participation and submissions	83
Table 5-2	Format of submission by stakeholder group and cluster	86
Table 5-3	Comparative Analysis of Scores of Stakeholder clusters	94
Table 5-4	Comparative Analysis of the Review Report and its Executive Summaries	97
Table 6-1	Overview of all textual submissions by stakeholder & neutral texts	109
Table 6-2	Comparative Analysis of Scores of Stakeholder clusters	113
Table 6-3	Comparative Analysis of the Draft and Final Scientific Opinion compared to the industry and public health texts	114
Table 7-1	Overview of all submissions by stakeholder with critical control points identified	127
Table 7-2	Comparative Analysis of Scores of Stakeholder clusters without Test Texts	132
Table 7-3	Comparative Analysis of the Draft and Final Directive text	137

List of boxes

Box 5-1	Institutional structures in the field of pharmaceutical policy in the EU	76
Box 6-1	Textual changes between draft and final versions of the abstracts of EFSA’s Scientific Opinion on Acrylamide, 2015	112
Box 7-1	Textual changes between draft and final versions of the original Commission Directive proposal	133

Chapter 1. The corporate determinants of health, and why they matter

There is growing interest in what have been termed the **corporate determinants of health**. This interest builds on findings from research in a number of initially disparate fields, including the environment, working conditions, chemical safety, and marketing of a variety of products that impact directly on health, such as tobacco, alcohol, and energy dense foods. Those working in each of these fields have recognised that the political economy of corporate interests may influence the greater public good (Wiist, 2010). There is a growing concern that **powerful economic interests** play a major role in shaping the environment in which health-related decisions are made, whether by individuals, in their purchasing choices, habits or socially acceptable practices, or by public authorities, in their decisions about measures such as marketing authorisations, taxation or regulation.

The overconsumption of tobacco, sugar, fat and salt is engendering a rising prevalence of major chronic diseases, spiralling health care costs and declining population health and productivity (Millar, 2013). Marketing products that are damaging to health and the environment, at prices that do not account for these damaging effects, often targeting consumers that are ill-informed and susceptible (e.g., children or socio-economically vulnerable groups such as those with low education) is contributing to negative externalities (e.g. further poverty, pollution or climate change). It furthermore contributes to rising **health inequities** (Millar, 2013). The latter translate into further socio-economic inequalities perpetuated through generations as health, education and economic productivity are intrinsically inter-related (Onarheim et al., 2016).

The “commercial determinants” of health and health inequity

These developments reflect a growing concentration of power in the hands of multinational corporations, many with annual turnovers far in excess of all but the richest countries. Globally, higher intake of unhealthy foods correlates strongly with higher tobacco and alcohol sales, providing evidence that trade liberalisation and other policies promoted by these

corporations benefit industries producing different unhealthy commodities (Stuckler et al., 2012). Moreover, the activities of these corporations are one crucial component of the **'commercial determinants'** of health, which, in broad terms, describe the economic and political institutions that structure the production, distribution, and sale of unhealthy commodities (Kickbusch et al., 2016).

From the earliest days of what would now be called epidemiology it was clear that some people enjoyed much better health than others and that these inter-group gaps were related to the circumstances in which they were born and lived their lives (Marmot et al., 2008). In other words, people were placed in positions in a stratification system because of the circumstances in which they were born. Health inequality is acted out through various mechanisms – one of them being the ways in which corporate power is deployed, for example via marketing of health-damaging products. I start from the premise that industries producing tobacco, alcohol and energy-dense foods, in shaping the **'commercial determinants'** of health, contribute to the proliferation of health inequalities, to the detriment of a better health-informed, more meritocratic society. Health inequalities deserve further scrutiny beyond this brief mention here, not least via the examination of the root causes of ill health. Presently, health inequality as a phenomenon could benefit from further investigation into the paucity of evidence connecting health-related habits to lifestyle choices and social class transmission through the generations.

This introductory chapter covers different points of interpretation of the role of industry and notes its influence on health policy. It equally serves as a reference chapter for the rest of the thesis discussing the implications of this role, and particularly those aspects of the role involved in the interplay with public policy affecting health, with the ultimate goal of reducing health inequalities.

Tactics used by corporations

The tobacco, food, and alcohol industries stand opposed, in many instances, to the aims of the public health community, and in too many instances industry has been able to slow (and in some cases even stop) action on non-communicable diseases. Crucially, corporations use a wide range of tactics to tilt the playing field in their favour: most notably, corporations such as tobacco companies use philanthropic contributions and public relations strategically to gain political influence (Tesler and Malone, 2008). Detailed research to identify charitable causes deemed attractive to elected officials helped various lobbies and industries to target their charitable contributions and thus exert leverage to achieve their legislative objectives. Business alliances and multinational corporations fund industry front groups that pose as consumer or patient groups or think tanks and use names that seem bland and supportive of public health, free choice, pluralism, etc. (e.g. the Center for Media and Democracy) (Wiist, 2010). Corporate Social Responsibility measures also divert attention away from enforceable standards and compliance with laws.

The influence of industry spreading through research networks is also noteworthy. Manipulation of scientific research and information is now widely employed by industry, and it can translate into undue influence on universities – for example, via partnerships with corporations to fund an institute bestowing university-conducted confidential research and the rights to license the research results (Wiist, 2010). Another common tactic entails funding studies which, by design, will fail to detect a significant effect of a public health measure (e.g. standardised packaging) on smoking prevalence (Lavery et al., 2014, Diethelm and McKee, 2014) or supporting studies where the power to detect an effect is low.

Since the tactics discussed above have recently received considerable attention in the literature, a number of comprehensive and robust taxonomies of schemes employed by vested interest groups exist. I have used a recent paper categorising and listing unhealthy industry tactics (Moodie, 2017b) as the backbone of other influential work I reviewed as part

of my literature review, in a quest to showcase the wealth and depth of tactics unveiled as at work in policy-making, fully documented in specialist literature. Table 1 illustrates tactics assembled by Rob Moodie, drawing on a summary from the following sources: Oreskes and Conway’s “Merchants of Doubt” (Oreskes and Conway, 2010), Wiist’s “The Corporate Playbook, Health, and Democracy: The Snack Food and Beverage Industry’s Tactics in Context” (Wiist, 2011) and Freudenberg’s “Lethal but Legal” (Freudenberg, 2014), supported by further examples identified by the author.

Table 1-1 “What Public Health Practitioners Need to Know About Unhealthy Industry Tactics”

<p>1. Attack legitimate science</p>	<p>1.1 Accuse science of deception or uncertainty, calling it “junk science” or “bad science”, claiming manipulation to fulfil political aims.</p>	<p>Seeding doubt has previously been labelled as a “denialist technique”; first popularised by the American Hoofnagle brothers, it involves the use of rhetorical arguments to give the appearance of legitimate and unresolved debate about matters generally considered to be settled. The term can be traced to people who deny the existence of the Holocaust, but it has been applied much more widely (McKee and Diethelm, 2010). More specifically, this tactic has been labelled “identification of conspiracies”: denialists argue that scientific consensus arises not as a result of independent researchers converging on the same view but instead because researchers have engaged in a complex and secretive conspiracy. They are misusing the peer review process to suppress dissent rather than fulfil its legitimate role of excluding</p>
-------------------------------------	--	---

		work that is devoid of evidence or logical thought (McKee and Diethelm, 2010).
	1.2 Insist that there are many causes to a problem and that addressing just one of them will have minimal impact.	Undermining the case for public health action has been equally labelled as “denialism”; for instance, the tobacco industry maintained for many years that it was unaware of research about the toxic effects of smoking, especially passive smoking (Diethelm et al., 2005).
	1.3 Exaggerate the uncertainty in any scientific endeavour to undermine the status of established corpora of scientific knowledge.	The tobacco, energy, arms and chemical industries work to make sure debate is kept alive by developing false dichotomies (Moodie, 2017a).
	1.4 Use corporate-funded studies.	Well documented in the past (Diethelm and McKee, 2014) and also focusing on stroke-related alcohol consumption (McCambridge and Hartwell, 2015a). Also, a working paper at the University of Zurich evaluating plain packaging on smoking prevalence of minors in Australia, unsurprisingly used data and methods that would fail to detect any expected effect. (Diethelm et al., 2005).

<p>2. Attack and intimidate the scientists</p>	<p>2.1 Seed doubt by attacking the authenticity and integrity of the author.</p>	<p>A classic tactic is the naming of environmentalists as “watermelons” (green on the outside and red on the inside) to transfer fear and hate of communism on the environmentalist movement (Moodie, 2017a).</p>
	<p>2.2 Infiltrate scientific groups and monitor exponents.</p>	<p>The tobacco industry introduced serious bias that probably influenced scientific and public opinion in Germany, based on network analysis of the industry’s links to scientific establishments; science was distorted in five ways: suppression, dilution, distraction, concealment and manipulation (Grüning et al., 2006).</p>
	<p>2.3 Create enough doubt to forestall litigation and regulation.</p>	<p>One common tactic is to always demand more proof. Another is to flood public officials with freedom of information requests based on unlimited legal resources (Collin and Hill, 2013).</p>
	<p>2.4 Promote self-regulation and voluntary codes</p>	<p>Companies present themselves as socially responsible actors, at pains to stress their commitment to tackling alcohol-related harm – many highlighting measures they had taken or programs they had endorsed to this end (Hawkins and Holden, 2013).</p>
<p>3. Create arms-length front organisations</p>	<p>3.1 Create front groups or run projects through them (“information</p>	<p>“Information laundering” is a term used to describe how “alternative science” is “cleansed”, just as money is, to create the impression that the claims being put forward were scientific (Moodie, 2017a).</p>

	laundrying”), especially law firms that can avoid scrutiny because of “attorney-client privilege”	The “attorney-client privilege” has been recently quoted in the press in relation to lobbying opportunities in Brussels (Wermke, 2017).
	3.2 Create research institutes or think tanks that can create their own scientific studies (and publish findings selectively)	Coca-Cola evidence: a group that was set up to promote debate about “energy balance” in an effort to combat obesity closed down after it was found that its funder, Coca-Cola, had a hand in some of its decision making (Kmietowicz, 2015b). Further evidence of selective publication (Lexchin et al., 2003), in that research funded by drug companies was more likely to have outcomes that favour the sponsor’s product than research funded by other sources. Explanations include the selection of an inappropriate comparator to the product being investigated and publication bias (Lexchin et al., 2003).
4. Manufacture false debate and insist on balance	4.1 Create a controversy and instil distortion of truth	For instance, by insisting that alcohol advertising helps consumers choose between brands (Petticrew et al., 2017b).
	4.2 Divert attention from harm, focusing on CSR, or on	Scepticism about reliance on CSR programmes to achieve social policy objectives extends far beyond tobacco control (Collin, 2012). Confirmed by

	other issues as the problem	literature on community alcohol partnerships (Petticrew et al., 2017a). The limits of CSR were discussed at length in a dedicated paper (Fooks et al., 2013).
5. Frame key issues in highly creative ways	5.1 No need to look for a solution (problem too complex)	Insisting that the problem is in and of itself very complex and so cannot have a simple solution (Moodie, 2017a).
	5.2 Invoke time: premature to suggest remedies	Denialists highlight any scientific disagreement (whether real or imagined) as evidence that the entire topic is contested, and argue that it is thus premature to take action – also known as “manufacture of doubt” (McKee, 2010).
	5.3 Insist technology will obviate need for regulation	Assuring the public that technological advances will obviate the need for regulation, insisting that the marketplace is the only way to solve the problem (Moodie, 2017a).
	5.4 Invoke personal or parental responsibility: no need for a nanny state	The central “Stop Out of Control Drinking” Diageo funded “responsible drinking” campaign in Ireland (Diageo being an alcohol producer) employed a narrative around “attitudes, motivations, and behaviours” and the involvement of psychologists has strong resonances with the tobacco industry “sociological program,” which recruited behavioural scientists to develop a tobacco industry narrative around individual

		smokers' motivations (Petticrew et al., 2016). Similarly, other studies stress individual responsibility and risk management – with “responsible drinking” as an industry-affiliated term (Maani Hessari and Petticrew, 2017).
	5.5 Use colourful imagery	The controversial “Out of control” drinking campaign in Ireland – a focus on culture, peers and the family (Petticrew et al., 2016).
	5.6 Use scaremongering (fear factor) as a tool for change of policy.	Many invoke the power of fear to drive nonsensical policies (Moodie, 2017a).
	5.7 De-escalate: diminish the severity of the problem or admit that it is a serious one, but not a life-threatening one	Other methods of misrepresentation include using “red herrings” (deliberate attempts to divert attention from what is important), or building “straw men” (misrepresentation of an opposing view so as to make it easier to attack) (McKee, 2010). Also, use excluded middle fallacies (in which the “correct” answer is presented as one of two extremes, with no middle way). Thus, passive smoking causes either multiple forms of cancer or none, and as it can be shown not to cause some it must, it is argued, cause none (McKee, 2010).
	5.8 Use flattering comparators:	Also, the use of false analogies (for example, because both a watch and the universe are extremely complex, the universe must have

	the problem is serious, but less severe than other problems that should receive priority	been made by some cosmic watchmaker) (McKee, 2010).
	5.9 Cost to fix the problem too high, benefits of the problem have not been considered and other options await	Across the last century, major tobacco companies successfully embedded the cigarette into nearly every aspect and arena of culture, worldwide, in order to keep smoking “normal” and its promotion acceptable (Wiist, 2010).
	5.10 Harness the power of language: be sure to use certain language, in the face of uncertain language on the other side	Use pejorative language repeatedly e.g. “overregulation”, “nanny state”, “excessive regulation”, “unnecessary red tape” (Moodie, 2017a).
6. Finance industry disinformation campaigns	6.1 Fund such by using novel techniques (co-opt celebrities, sympathetic expert	“Message force multipliers” are expert witnesses paid by the industries they represent (Moodie, 2017a).

	witnesses, sponsor conferences challenging scientific consensus and align with other issues e.g. anti- tax groups).	
7. Influence the political agenda	7.1 Donate to political parties across the political spectrum	SABMiller engaged the influential think-tank Demos to produce reports on binge drinking, which were heavily promoted among policy makers at key stages during the development of the UK government's 2012 alcohol strategy – this was an effort to marginalise peer-reviewed literature (Hawkins and McCambridge, 2014).
	7.2 Mobilise representatives from unhealthy industries around the policy table, for standard setting or guideline development	In using fake experts, the tobacco industry coined the term “Whitecoats” for those scientists who were willing to advance its policies regardless of the growing scientific evidence on the harms of smoking (McKee, 2010).
	7.3 Invest in paid lobbyists.	The creation of front organisations, kept at arms' length from the mother company – e.g. via prestigious public relations agencies (e.g. Hill and Knowlton) and via legal firms

		who avoid scrutiny through the client-attorney privilege, discussed above (Moodie, 2017a).
	7.4 Make “friends” in important and influential government roles (by targeting their advisers, recruits or senior officials leaving office).	The Center for Responsive Politics ‘s Revolving Door project intends to identify professionals whose career trajectory has taken them from Capitol Hill, the White House and Cabinet offices to K Street, and vice versa. Its database is the most comprehensive source to help the citizens learn who’s who in the Washington influence industry (Wiist, 2010).
	7.5 Aim to reduce government budgets for regulatory, scientific or policy activities against the corporate interest.	The industry engages in covert intelligence activities aimed at undermining public health, which it refers to as “the anti-tobacco industry”, continuously testing the limits of the law (Wiist, 2010).

Table 1-1 documents in detail a taxonomy of unhealthy industry strategies to dominate the regulatory playing field, to the detriment of the average consumer. At the same time, the tactics listed, echoed in specialist literature via dedicated case studies or further investigations, serve well the policy need for transparency. They thus identify tactics and sub-techniques that are ripe for future scrutiny, preparing the ground for a system of checks and

balances that may counter such distortion or untruth and level the playing field for more effective regulatory measures. The non-direct dominance and confrontation tactics employed by various industries are more and more uncovered via the field of *corporatology*, the study of harmful industries. In the budding field of *corporatology*, framing issues are key in that industry-affiliated terms, such as “*responsible drinking*”, become strategically ambiguous, not clearly defined with relation to any particular level of alcohol consumption, and hence allowing for multiple interpretations (Maani Hessari and Petticrew, 2017). We now move to discuss power elites (who create and shape meaning in interpretation), their discourse and its health implications.

Power elites and health

The relationship between power and health is complex, consisting of vectors of constructs and systems of power that produce inequities at multiple levels. Analysing the influence of transnational power elites across different, albeit linked dimensions, is essential to better grasp the operationalization of power in shaping global health. Power elites often advocate for a diminishing role of the state via less progressive taxation yet simultaneously for an increase in its role as a source of state subsidies to them, such as access to basic science research undertaken in government facilities or research funding, and a protector of their intellectual property rights. Thus, they contribute to a skewed, contradictory, self-centred approach that fails to improve society beyond the status quo.

This thesis will look explicitly at the role of power elites, the contradictions of the concepts and positions they espouse and what can be done practically to give a voice to the unheard and power to the powerless.

Defining the narrative

Language is central to expressing political opinion. However, this is both an advantage and a challenge: mass communication has created powerful platforms that have become the vehicle for an impressive volume of text underpinning narratives in current use. At the same time, ownership of mass media has long been a source of power (such as the case of Rupert Murdoch, the Media Mogul). Power elites have the ability to frame the dominant narratives

of the moment on the determinants of health – for example, whether obesity, diabetes, heart disease, COPD, or cholesterol levels linked to food intake and other health-related behaviours are framed as issues pertaining to individual choices or societal characteristics anchored in the community (Johnson-Cartee, 2005). They also directly influence these determinants through their marketing activities, their expert advice to consumers or other actors as well as how people work, go about their lives and seek pleasure (such as whether alcohol use, substance abuse and tobacco are acceptable social norms). Power elites can influence people's belief construct on how society should examine habits and handle interactions with their most pressing health threats, using the discourse that they choose.

Setting the rules

Power elites can influence regulatory bodies by placing their advisors on committees or by creating revolving doors that enable officials to move into lucrative consultancies or front groups (e.g. research institutes) or public affairs consultancies, for example once they have retired. They capture elected officials in office, who vote for the interests of their elite funders (Gilens and Page, 2014). Power elites also shape health decisions through their tremendous influence on how and where decisions are made and the creation of mechanisms that ensure that they will survive and prosper. They deploy their research methods and concrete, technical expertise to define global standards, exemplified by the manner in which the tobacco industry set the standards for measuring the constituents of cigarette smoke, including design of the machines used for this purpose or the predominance of corporate-minded scientists representing agri-food industries at the Codex Alimentarius meetings.

Last but not least, the purpose of the thesis is not to simply add to the literature on the behaviour of corporations that have stakes in public health policy but to develop a tool to understand the positions of the different forces, public and private, better. In this perspective, decision-making is improved and actors help the playing field to evolve, rendering manners of engagement more equitable and more transparent.

This section began by noting that the activities of Multinational Corporations are subject to the influence of health policies in a number of ways. These include legislative and regulatory measures, such as bans or restrictions on marketing or use of certain products and imposition

of technical standards, some of which may be linked or incorporated into trade deals, creating what have been termed “non-tariff barriers to trade”. The next chapters will then show how corporations have a strong interest in influencing these policies, given the potential to impact on their growth and profitability. This can involve arguing for such measures to operate on a voluntary rather than a statutory basis, linking conditionalities or shaping the technical aspects of the legislation and regulation. It can also include seeking to shape public and political opinion about the legitimacy of taking any government action at all, such as the tobacco industry’s opposition to smoking bans. This is important because many corporations are now larger, economically, than many states and the larger a corporation’s revenue and the greater the regulatory pressures placed on it, the greater will be its political activity (Hansen et al, 2004). In this way, this Chapter has set the scene for the rest of the thesis.

The next chapter will look concretely at how structures and processes for decision-making offer opportunities for influence to be exerted. I will then revisit table 1-1 to delve deeper into what is currently known about how industries have exerted influence in the field of health and how this corporate influence has been studied previously. Thereafter, the methods and research question chapter will take centre stage, followed by the results of the three case studies, their conclusions and corresponding discussion.

Chapter 2. Why is the European Union a target for corporations?

The European Union is a prime target for transnational corporations because of the size of its market (circa 500 million people) and because its policies have wide-ranging effects, either direct (regulations) or following their transposition into national law (directives). Thus, to take two examples, within the European single market, the EU has competency for marketing authorisations for nearly all foodstuffs and pharmaceuticals, both areas of great commercial interest to major corporations, but also with substantial implications for human health.

This section will describe the key European institutions as set out in the Treaty of Lisbon (the European Commission, the European Parliament and the Council of Ministers) and show why they represent targets for corporate influence. It will describe how these institutions operate, setting out the stages in the Ordinary Legislative Procedure, the standard procedure for passing legislation applicable in the EU. This will show how amendments introduced by the European Parliament and the positions of the Member States expressed in the Council debates offer opportunities for influence from various interest groups to be exerted. This section will give the reader a solid grounding in the EU legislative process and the scope to influence it, thus providing context for the remainder of the thesis.

The European Institutions

Before considering the influence of corporations at a European level it is necessary to introduce the European institutions, those bodies responsible for policy, legislation, and regulation. Their roles have evolved over time but are governed by the most recent European Treaty, which, at the time of writing, is that signed at Lisbon on 13 December 2007 by the heads of state and government of the then 27 EU Member States (Croatia only joined the EU in July 2013), and entering into force on 1 December 2009. The Lisbon Treaty sought to ensure that the functioning of the European Union reflected changes following the two waves of enlargement which had taken place since 2004 and which increased the number of EU Member States from 15 to 27. The Lisbon Treaty was drafted as a replacement for the Constitutional Treaty, which was rejected by French and Dutch voters in referenda in 2005.

The Treaty of Lisbon recognises the following entities as fully-fledged institutions:

- **The European Council**, made up of the Heads of State or of Government of the EU and the President of the European Commission, meeting at least twice a year, setting the overall direction for the European Union; it does not normally adopt legal acts formally binding the Member States but issues declarations containing guidelines for future Community actions (Moussis, 2007).
- **The Council of Ministers (the Council)**, composed of a representative of each Member State at ministerial level, authorised to commit the government of that Member State. In practice, the Council of Ministers meets in ten different formations (also called configurations), each addressing a particular area. Thus, health issues will be discussed by the EPSCO Council (Employment, Social Policy, Health and Consumer Affairs Council), comprising health ministers from the Member States. Working groups comprising national experts and health attachés prepare meetings of the EPSCO Council, which are usually at Ministerial level. The preparatory work for the EPSCO configuration is done via five working groups specialising in health, social questions and food safety: the Pharmaceuticals and Medical Devices Council Working Group, the Working Party on Social Questions, the Working Party on Public Health, the Senior Working Party on Public Health and the Working Party on Foodstuffs (Council of the European Union, 2017).
- **The European Parliament (EP)**, consisting of 751 members elected by direct universal suffrage, allocated broadly in proportion to a Member State's population (e.g. following the accession of Croatia to the EU, Germany has 96 seats and the UK has 73 seats); the EP has legislative, political, supervisory, and budgetary functions.
- **The European Commission**, composed of the College of Commissioners (1 per Member State) and the Commission services, composed of multinational departments of civil servants, is the institution that has the right to initiate proposals for Community decision-making (this right is however not exclusive, since The Treaty of Lisbon gives citizens the possibility to influence the initiatives of the Commission, under certain conditions). The Commission is also the guardian of the Treaties and of all the Community's legislation. Therefore, it has the task of ensuring that the Member States fulfil their obligations and appropriately apply the provisions of the Treaties and of secondary legislation. For this, it has investigative power and can refer a Member State to the European Court of Justice if it considers that there is a case of infringement of Community legislation (Moussis, 2007).

- **The Court of Justice of the European Union** (actually a number of bodies but usually referred to as its main constituent, the European Court of Justice), seated in Luxembourg, is responsible for providing a coherent and uniform interpretation of European law, and for ensuring that Community law is observed in a uniform manner. The Court plays an important role in the European process by clarifying ambiguous legal provisions, which are sometimes the result of pressure to reach agreement between law-makers with various national interests (Moussis, 2007).

Beyond these institutions, the Lisbon Treaty recognises the status of “advisory bodies” to the **Economic and Social Committee** and to the **Committee of the Regions**. Other entities such as the **European Central Bank** and the **Court of Auditors** are also recognised as “other institutions and advisory bodies”, yet their role does not grant them the status of a fully-fledged institution (Moussis, 2007).

Some national politicians have criticised what they see as the “democratic deficit in the EU”. For example, they argue that Members of the European Parliament are remote from their constituents and they portray the EU policy and legislative process, involving the Council, the European Parliament and the Commission as lacking legitimacy (McKee et al., 2010). Many of these arguments are based on misunderstandings or, in some cases repeated misrepresentations. However, sustained by hostile media, in some countries these arguments have been used by some politicians to undermine the legitimacy of the European institutions. There is, however, a debate about the most appropriate level at which to take action, with differing views about whether a problem can most effectively be addressed at a European or national level. This has given rise to the principle of subsidiarity, where decisions are taken at the lowest level commensurate with their ability to address the issue in question. In addition, even where there are shared problems in some areas, the diversity of national contexts has made it especially difficult to create binding European legislation. This is especially true in the area of social policy where, although there are many common principles, there are also many differences of detail in the way that Member States organise their social protection and health systems. Thus, Tamara Hervey argues that a response to the problem of “social Europe” has been new forms of governance, i.e. a range of processes and practices that have a norm-setting or regulatory dimension but do not operate primarily or at all through the conventional mechanisms of command-and-control-type legal institutions (Letsas and

O'Connell, 2011). Command-and-control responses are considered problematic since the treaties restrict the competence of the European institutions in areas such as health services. However, the interface between health services and other areas that are fully within the competence of the European institutions, such as the single market and, in particular, free movement of goods, such as pharmaceuticals, and services, such as some providers of healthcare, is often unclear or contested. This previously led to several cases where the European Court of Justice has had to resolve uncertainties, such as those affecting patient mobility, in those cases arising from lack of clarity in the legislation, although these particular issues have since been clarified in a directive on cross-border healthcare. Therefore, the binding nature of EU internal market law and gaps in equally binding EU social law have led to new governance processes, such as the Open Method of Coordination (OMC). The OMC is used in the social security field, via the regular meetings of the Administrative Commission, made up of at least one specialist representative per Member State and the European Commission discussing bilaterally and multilaterally the entitlements and reimbursements in the field of social security. The ongoing review of the Social Security Regulations, Regulations (EC) No 883/2004 and their implementing acts, within the context of the Labour Mobility Package, is testimony to how social questions (e.g. invalidity pensions, posting of workers and family benefits regulation) remain a thorny issue. The Labour Mobility Package is to be adopted by 2019.

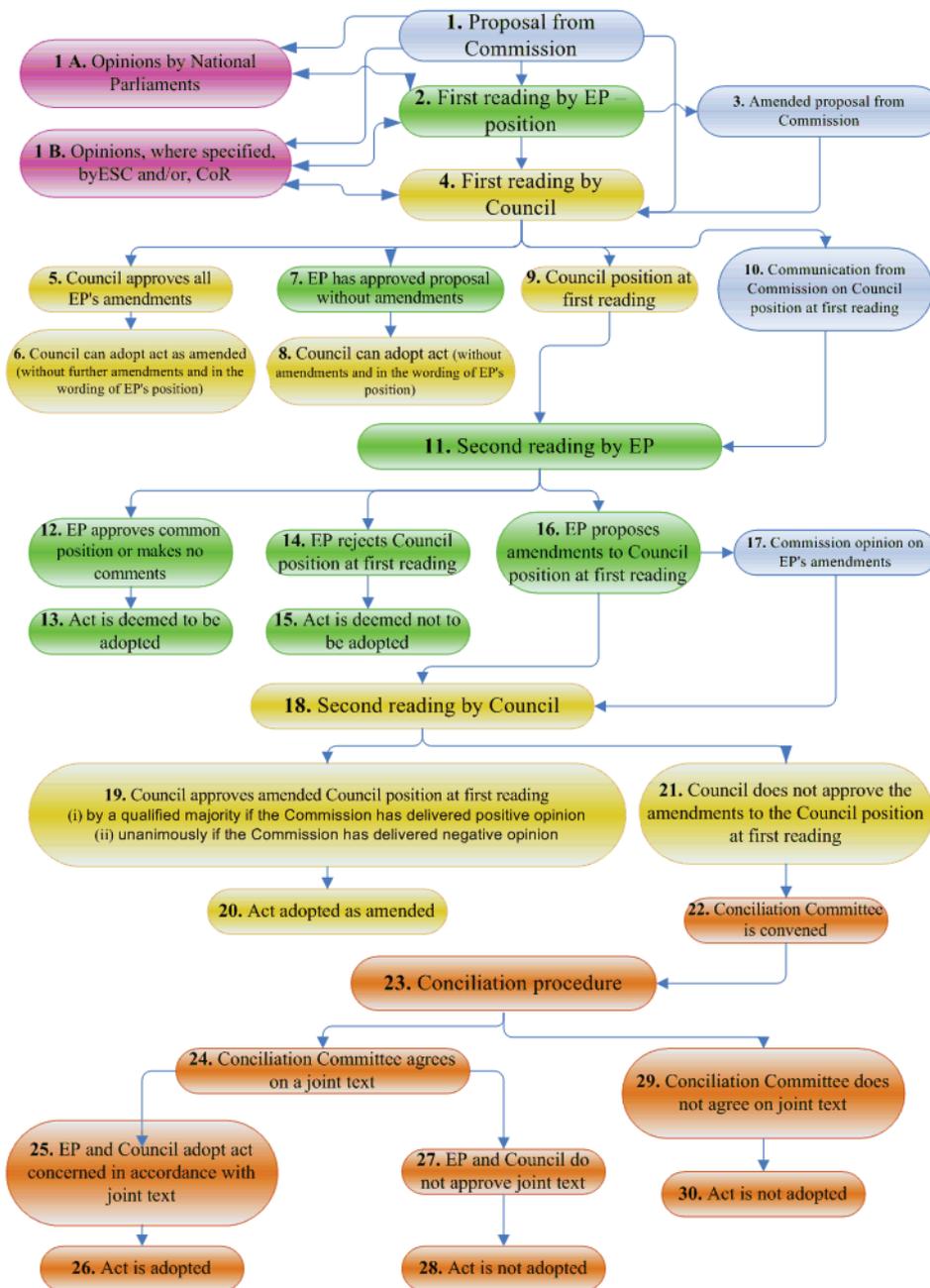
EU Decision-making

The co-decision procedure, the EU's standard decision-making procedure, is known as 'Ordinary Legislative Procedure'. In a seminal paper on the subject, David Bostock argued that *"co-decision is a complex procedure whose unwritten rules and behavioural norms have developed, are still developing and are not easy quickly to grasp"* (Bostock, 2002). Moreover, he notoriously quipped: *"if all EU negotiation is a dark mystery, legislative co-decision is a blacker shade of dark"* (Bostock, 2002). The great majority of co-decision files fall within the remit of policies dealing with the Internal Market, e.g. Transport, Energy, Environment, Research, Consumer Protection, Culture, Education and Health and Food Safety.

As depicted graphically in Figure 2-1 below, it is the Commission that proposes new legislation, consulting interested parties such as non-governmental organisations, local

authorities and representatives of industry and civil society. Groups of experts give advice on technical issues. Citizens, businesses and organisations can participate in the consultation procedure via the website “Public consultations” (European Commission, 2017b). National parliaments can formally express their reservations if they feel that it would be better to deal with an issue at national rather than at EU level. The Commission’s proposals must then be agreed by the Council and the Parliament, proposing amendments as appropriate. If the Council and the Parliament cannot agree upon amendments, a second reading takes place. In the second reading, the Parliament and Council can again propose amendments. Parliament has the power to block the proposed legislation if it cannot agree with the Council. If the two institutions agree on amendments, the proposed legislation can be adopted. If they cannot agree, a conciliation committee tries to find a solution (EUR-LEX, 2017). Both the Council and the Parliament can block the legislative proposal at this final reading. The two readings offer ample opportunities for interest groups to influence the tone, quality and quantity of amendments introduced by Members of European Parliament. Sessions of the European Parliament and some Council sessions are broadcast live online.

Figure 2-1 The Ordinary Legislative Procedure (the Co-decision procedure)



Source: (Parliament, 2017)

From a theoretical perspective, the story of hard regulation, as depicted above, can be understood in terms of a struggle between competing civil society and corporate coalitions (Smith et al., 2015). Although one cannot rule out the possibility of industry’s genuine commitment to self-regulation for the common good, there is now overwhelming evidence that self-regulation or soft regulation discourse (as opposed to hard regulation in terms of

binding rules to be observed) should be approached critically and seen as an opportunistic tactical adaptation to policy change (Peeters and Gilmore, 2015, Knai et al., 2015, Savell et al., 2016, Martino et al., 2017). Civil society groups believe in the need for greater EU regulation to guard against social and environmental harms (including harm to health), whilst corporate advocates believe that regulation of economic actors at EU level should be as limited as possible so as to safeguard free market ideals and promote competitiveness (Smith et al., 2015).

The Better Regulation Policy

When Commission President Jean-Claude Juncker took office in 2015, he announced that he would implement a “better regulation” policy. Following many years of internal and external deliberation within the Commission and beyond it, with the evaluation community further afield, the Secretariat-General of the European Commission issued a set of guidelines that were subsequently endorsed by the College of Commissioners on how to implement a better regulation policy. A key component of this policy was the creation of a Regulatory Scrutiny Board (RSB), composed of senior European Commission officials and resource persons external to the Commission services, responsible for the quality control of impact assessments and, *inter alia*, the stakeholder consultation process. The members of the RSB are expected to adopt a challenge function, scrutinising the quality of the impact assessments and of the consultation process. Interestingly, the RSB or Impact Assessment Board does not include any representative from the Directorate-General or department responsible for health (Smith et al., 2015), nor did it do so in the past. This is notable, since sources indicate that the Board was deliberately chosen to reflect the main categories of impacts assessed as important by the European Commission (Radaelli and Meuwese, 2008). However, it has since been revealed that the tobacco industry and other corporate interests were able to exert considerable influence on the approach taken to impact assessment (Smith et al., 2010b), which now displays many of the characteristics known to favour corporate influence (Smith et al., 2010a).

The rationale for open, public stakeholder consultation and how it came about

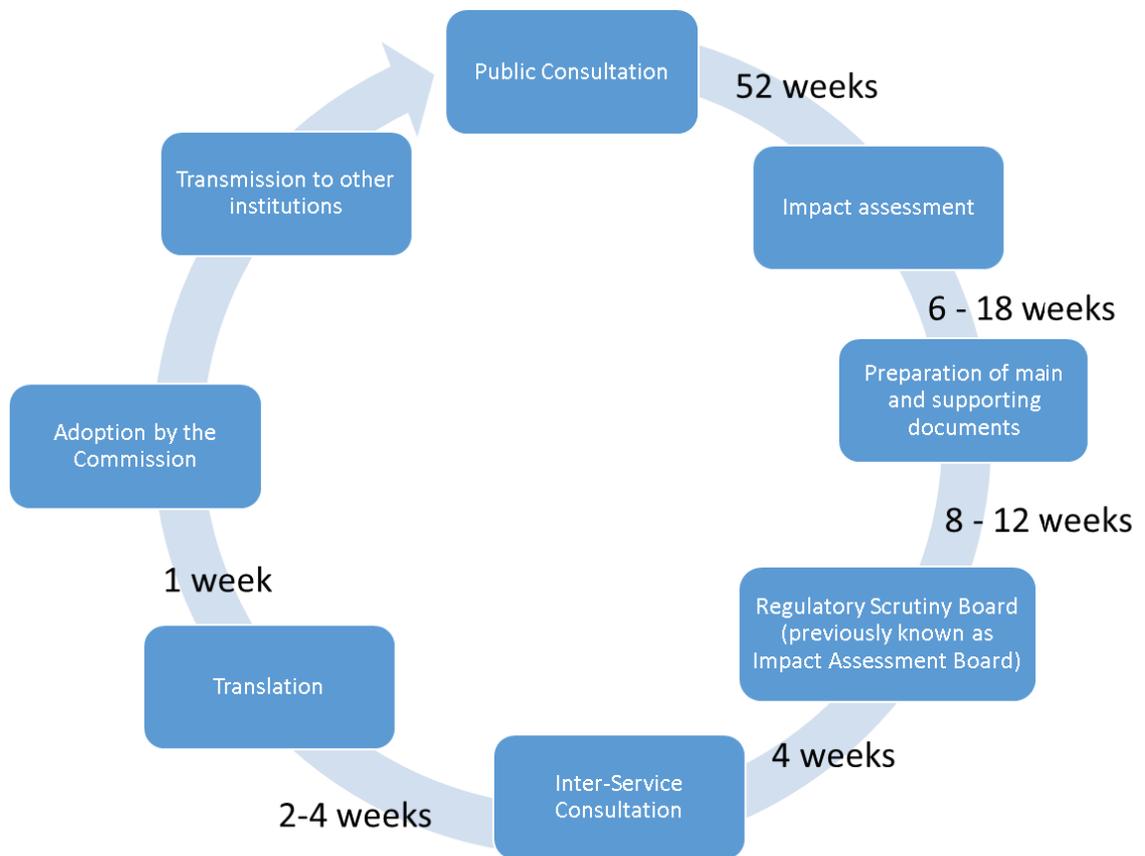
As mentioned above, the Commission holds the right of initiative (not merely politically, like the European Parliament but also practically), also known as the right to draw up proposals

for legislation and policy. Luchetta and Akse argue that, since the Commission is not directly elected and does not therefore have a broad political mandate from the people of Europe, its legitimacy relies to an important extent on the quality of its actions and the substance of its deliverables, in the shape of legislative and policy proposals (Luchetta and Akse, 2014). The impact assessment (IA) policy and corresponding process is a step in that direction, introduced around the years 2000-2005, as a Lisbon Treaty obligation for all Member States, and not merely for the EU or its main institutions.

Notwithstanding the serious concerns about its approach to impact assessment, the Commission has set itself the goal of basing all important legislative and policy decisions on sound analysis supported by the best data available. Impact assessments should collect and analyse evidence for political decision-makers, notably the College of Commissioners, on the advantages, disadvantages and trade-offs of possible policy options by assessing their potential social, economic and environmental impacts.

The 18-month preparation process for Impact Assessments is depicted graphically in Figure 2-2. An intrinsic part of the Commission's internal decision-making procedure, the duration of the IA provides external stakeholders with ample opportunities to make their involvement count.

Figure 2-2 The 'average' timeline of an impact assessment



Source: European Commission: www.ec.europa.eu

The public consultation process (further described in Appendix D) was scaled up and given more prominence following adoption of the Commission's Better Regulation Guidelines, in 2015. This was portrayed as a means to counter what the Commission argued was undue delay in the passage of proposed legislation by the European Parliament and Council, involving the passage of multiple amendments introduced during successive readings of the legislative proposals. The public consultation exercise is presented as a means by which the European Commission can understand, consider, and address stakeholder views before the final proposal is submitted to the European Parliament and to the Council. This is portrayed as offering the considerable advantage of being more efficient, increasing the quality of the regulatory output, and reducing the risk of regulatory capture by vested interests. Thus, in

the European Commission, public consultation was mainstreamed as part of the impact assessment work.

Public consultation is thus presented as a key regulatory tool to foster transparency, efficiency, effectiveness, accountability and interaction with interested members of the public (Rodrigo and Amo, 2006). Consultation is viewed as helping regulators balance opposing interests or bring into play expertise and the perspectives for alternative actions of those directly affected. It is also seen as a means to apply quality checks, identify unintended effects, assess administrative burdens and, last but not least, it can also identify synergies and contradictions between regulations from different parts of government.

Voluntary compliance can be another positive side-effect of public consultation, according to the OECD. Compliance can be enhanced by announcing regulatory changes in a timely manner and by increasing the sense of legitimacy and shared ownership that motivate affected parties to comply with them. Of course, all these arguments are based on the questionable assumption that public consultations, by virtue of their openness, reduce the potential for capture by vested interests. This is an assumption that will be tested in this thesis.

The European Commission seeks to avoid such capture, and to optimise its relations with stakeholders by applying four general principles (European Commission, 2014a):

- (1) **Participation:** consulting as widely as possible, being inclusive;
- (2) **Openness and Accountability:** rendering the consultation process and how it has affected policy-making transparent to the general public and to those involved;
- (3) **Effectiveness:** consulting at an appropriate time, when stakeholder views can still make a difference, respecting proportionality (a principle established in European law where any action must go far enough to achieve its aim but no further) and specific restraints;
- (4) **Coherence:** ensuring consistency of consultation processes across all services as well as evaluation, review, and quality control.

According to the European Commission, these principles are complemented by five Minimum Standards that all consultations must respect (European Commission, 2014a):

A. Clear content of the consultation process (**Clarity**): Consultation material including the strategy document itself should be clear, concise and include all necessary information to facilitate responses;

B. Consultation of target groups (**Targeting**): When defining the target group(s) in a consultation process, the Commission should ensure that all relevant parties have an opportunity to express their opinions and have an active voice in the process;

C. **Publication**: The Commission should organise appropriate awareness-raising publicity and adapt its communication channels to meet the needs of all target audiences. Without excluding other communication tools, (open public) consultations should be published on the internet and announced at the “single access point”;

D. Time limits for participation (**Consultation period**): The Commission should provide sufficient time for planning and responses to invitations and written contributions; 12 weeks is a minimum;

E. Acknowledgement of feedback (**Feedback**): Receipt of contributions should be acknowledged and contributions published. Publication of contributions on the “single access point” replaces a separate acknowledgment if published within 15 working days. Results of (open public) consultations should be published and displayed on websites.

There are considerable similarities between the approaches of the OECD and the European Commission, indicating synergies and mutual influence.

A critical analysis of public consultation – what works, what does not, what concerns remain
The design of this process is considered its strength. Its use of an online platform renders it publicly available, easily accessible, and convenient to monitor/follow. Also, the deadlines (minimum 3 months) are generally considered reasonable. However, there are concerns that the process may open the door to capture by vested interests during the consultation process. Coordinated lobbying and the creation of lobbying coalitions among interest groups may present the authorities with a ready-made solution (Jensen, 2015) and thus amplify the voice of powerful corporations compared to citizens’ grassroots organisations or civic purpose driven NGOs.

Further concerns relate to other aspects of transparency. Not all public consultations publish their input documents fully online – sometimes summaries drafted internally or by external consultants are the norm. Moreover, the weight given to the concerns raised is also unclear, essentially leaving this part of the process a black box. Peeters and Gilmore show that a seminal study dating back to 1999 by the Institute of Medicine in the US was pivotal in shaping tobacco industry discourse on harm reduction. Transnational tobacco companies adopted the concept “harm reduction” in response to the study, developed a CSR strategy around it and proceeded to deploy it extensively in corporate messaging (Peeters and Gilmore, 2015) to secure reputational benefits. The paper illustrates how discourse and container concepts such as “harm reduction” can be seen as opportunistic tactical adaptations to policy change rather than a genuine commitment to harm reduction. Care should be taken that vital wins hitherto secured are not undermined or reversed by efforts from the tobacco industry to inappropriately influence policy (Peeters and Gilmore, 2015).

Ultimately, the consequences of this model public consultation may only become clear in 5-10 years’ time, when there have been sufficient numbers of public consultations on sensitive subjects (e.g. endocrine disruptors, tobacco, sugar) or documents brought as evidence in litigation pursuits have seen the light of day and have been subjected to scrutiny by researchers. There are, for now, concerns that public consultations represent a new arena where interest groups can exert a specific kind of influence and engage in power games, for example by paying a think-tank to promote an agenda, establishing a front group or hiring a law-firm to draft amendments.

This thesis asks whether these types of influence can be identified using QTA, by means of case studies of recent public consultations. As such, it will contribute to the active debate on possible mitigation of remaining concerns in consultative pursuits.

The role of interest groups - A brief review of their scale and nature in Brussels

There are over 11,366 interest groups operating in Brussels currently, according to the Transparency Registry (accessed on 3 August 2017). Their estimated staff levels are in the range 15,000-30,000, according to Corporate Europe Observatory, making the EU quarter home to one of the highest concentration of lobbyists in the world (CEO, 2011). Formal membership of this registry is free of charge, yet not mandatory. Becoming a member of the

registry is a precondition for submitting valid consultations via the public consultation procedure of the European Commission.

The Code of Conduct in Annex 3 of the 2014 Inter-institutional Agreement on the Transparency Register sets out the rules for all those who register and establishes the underlying principles for standards of behaviour in all relations with the EU institutions, *inter alia* not trying to obtain information or decisions dishonestly or by use of undue pressure or inappropriate behaviour, providing complete identification whenever needed, not selling to third parties copies of EU documents obtained from the institutions and not disseminating complete or disseminating outdated or misleading information.

The EU lobby Transparency Registry is publicly available and is structured in the (sub)sections listed in Table 2-1.

Table 2-1 Sections of the EU Transparency Register

Section	Name of category	Total	Breakdown per subsections
I	Professional consultancies/law firms/self-employed consultants	1,328	-Professional consultancies 769 -Law firms 141 -Self-employed consultants 418
II	In-house lobbyists and trade/business/professional associations	5,618	-Companies & groups 2,113 -Trade and business associations 2,326 -Trade unions and professional associations 852 -Other organisations 327
III	Non-governmental organisations, platforms and networks and similar	2,975	No further breakdown
IV	Think tanks, research and academic institution	852	-Think tanks and research institutions 542 -Academic institutions 310

V	Organisations representing churches and religious communities	50	No further breakdown
VI	Organisations representing local, regional and municipal authorities, other public or mixed entities, etc.	543	-Regional structures 120 -Other sub-national public authorities 96 -Transnational associations and networks of public regional or other sub-national authorities 81 -Other public or mixed entities, created by law whose purpose is to act in the public interest 246
		$\Sigma=11\ 366$	

We will now turn to a public consultation’s individual components, the stakeholder contributions in the guise of “formal text submissions” or “policy positions/papers”.

A brief review of evidence on how interest groups operate – Role of “Formal text submissions” and “policy papers” in the political process

The preceding sections have described how the European institutions have responded to pressure for more formalized preparatory processes in the legislative process, including explicit frameworks, procedures, and instruments. These developments have also played out in many other settings, both in national governments and international organisations. As a consequence, formal text submissions have been gaining in importance in a variety of fields of policy-making (see appendix C). Authorities responsible for analysing these submissions need to undertake a robust analysis to make sense of their content as well as their intent. The

UK government's website features more than 3,100 public consultations. The existence, and availability of this wealth of material, including larger volumes dealing with highly technical guidelines, has been seen as offering potential for the use of innovative approaches to research, and in particular, text mining techniques or machine-based text analytics. This approach has been applied to submissions on the topic of standardised packaging on the EU Tobacco Products Directive (Costa et al., 2014). Costa et al applied quantitative text analysis to evaluate the impact of tobacco industry pressure on EU policy-making and to expose the role of vested interests in the process. The analysis demonstrated the presence of textual shifts, so that, at the Commission stage, proposals for plain packaging and limitations on point of sale displays were removed. At the Parliament and Council stage of the legislative adoption process, the size of pictorial health warnings was reduced from 75% to 65% of carton size (Costa et al., 2014). By using Word scores estimated using the statistical software package STATA, Costa et al. concluded that, compared with traditional hand-coding methods, automated content analysis offers an objective quantification of policy positions. The underlying assumption is, however, that each actor's ideology is expressed through word choice.

Incidentally, even though the directive was amended in ways that were desired by the tobacco industry, the pressure to weaken it further continues. Very recently, Poland, supported by Romania, challenged the prohibition of menthol cigarettes (Case C-358/14) before the European Court of Justice in Luxembourg. On 4 May 2016, the Court ruled that it confirms the validity of the provisions of the Tobacco Products Directive and, in a linked case by a UK company, that the special rules applicable to electronic cigarettes do not infringe the principle of subsidiarity.

As in any public policy debate, health policy-making can only benefit from vigilance by the organisations in charge of running the public consultation. However, if massive intrusions and misleading, obstructive submissions can be identified (Stuckler et al., 2016), a question that lies at the heart of the present thesis, there is a need for improved ways to understand the political positioning of stakeholders and where their policy priorities/interest lie, as well as offering a means to grasp better their margin of manoeuvre. For these reasons, it is possible that automated text analysis could help to understand stakeholder responses.

A more fundamental question relates to whether publication or public reporting of contributions/ submissions to a public consultation (as required by the European Commission) in general improves the quality of the submissions *ex-ante*, as stakeholders dedicate more time and effort to reflect what to focus attention on before submitting their contribution. Some studies have indeed suggested that incentives which pursue quality improvements through “professional reputation mechanisms” can be stronger than financial incentives (Rechel et al., 2016).

Public opinion polls, surveys and speeches, election campaign manifestos and slogans are all vehicles of modern political communication that inherently rely on careful word choices and well thought-out semantics. It has already been demonstrated that greater ambiguity can help parties as they move to the centre, but it could hurt them as they move to the extremes (Lo et al., 2014).

Given the growing importance of qualitative assessment of policy-related texts in many fields of politics, the challenge is how to understand the best argument that wins the case and how to examine the architecture of the case – especially, how arguments are stacked, diffused or intertwined. This approach could strongly influence health policy-making in ways that polls and survey data currently already do.

What is known about how the industry has exerted influence in the fields of health and food safety in the European Union?

Tactics employed by corporations: range of methods used to study their influence

Much is known already (beyond Table 1-1) about the numerous and varied political tactics employed by corporations and other interest groups to effect influence on health policy and democratic processes, tactics that would favour the bottom line over the greater good. The larger a corporation’s revenue and the greater the regulatory pressures placed on it, the greater will be the corporation’s political activity (Hansen et al., 2004).

Alliances

A trend among corporations is to partner up with NGOs bestowing staff and programme budgets on them, thus avoiding confrontations (Wiist, 2010). Corporations such as tobacco companies use philanthropic contributions and public relations strategically to gain political influence (Tesler and Malone, 2008). Detailed research to identify charitable causes deemed attractive to elected officials helped them to target their philanthropic contributions and thus exert leverage to achieve their legislative objectives. Corporations and business alliances create or fund industry front groups that pose as consumer or patient groups or think tanks and use names that seem bland and supportive of public health, free choice, pluralism and so on (e.g. the Center for Media and Democracy) (Wiist, 2010). Without disclosing their affiliation or funding, such front groups seek to undermine scientific findings, most notably on global climate change and tobacco control (McKee and Diethelm, 2010).

Corporate Social Responsibility Agendas

The term “Corporate Social Responsibility” is now recognised as often being highly misleading. Frequently, it is used to divert attention away from enforceable standards and compliance with laws. To exemplify this, Peeters and Gilmore study the emergence and rise to prominence of the concept of “harm reduction” and its connection to CSR agendas of major tobacco companies. Simultaneous with the public health community’s emergent interest in tobacco harm reduction, transnational tobacco companies’ corporate social responsibility (CSR) agenda was increasing in prominence and Peeters and Gilmore’s findings suggest they were mutually reinforcing (Peeters and Gilmore, 2015). Their research shows that the CSR agenda emerged once evidence from US lawsuits began to damage the tobacco industry’s reputation seriously, signalling a pledge by industry to rebuild its lost reputation, improve its credibility and re-establish dialogue with public policy officials.

Misusing research

Manipulation of scientific research and information is another tactic at hand, which can include exerting corporate influence on universities – for example, via partnerships with corporations to fund an institute bestowing university-conducted confidential research and the rights to license the research results (Wiist, 2010). Much of the evidence on industry supported manipulation of research comes from the field of tobacco control, such as the

major program by Philip Morris to create uncertainty about the harmful effects of second-hand smoke (Diethelm et al., 2005) and, more recently, its work to distort the evidence on the effectiveness of standardised packaging in Australia to reduce smoking prevalence (Lavery et al., 2014, Diethelm and McKee, 2014). Earlier examples include the long-standing industry funding for a number of eminent and highly influential epidemiologists and public health specialists in Germany (Gruning et al., 2006), an issue that cannot be ignored when seeking to understand the persistent opposition by successive German Governments to effective tobacco control. However, these tactics are not confined to the tobacco industry, with evidence that the alcohol industry has adopted similar approaches (McCambridge and Hartwell, 2015b) and, more recently, revelations about the Coca-Cola company and its support for researchers seeking to divert attention away from the contribution of soft drink consumption to obesity (Kmietowicz, 2015a).

Safeguards in place: Internal Ethics Guidelines and OLAF

The European Commission does have a strict internal policy on ethics and reporting and foregoing gifts or diplomatic gestures. The internal ethics guidelines have been further tightened in 2016 following increased surveillance of irregular incidents – all gifts above a modest threshold, including invitations to conferences and events have to be declared and returned or donated to selected charities. Circumspection is also widely accepted as a value to be nurtured in newcomers to the job and young civil service recruits.

The same cannot necessarily be said about the other institutions, except perhaps for the existence of the watchdog the European Anti-Fraud Office (OLAF). The watchdog can be contacted anonymously and works in all of the 24 European languages. OLAF investigates fraud against the EU budget, corruption, and serious misconduct within the European institutions, and develops anti-fraud policy. It publishes a yearly report available on its website, where it investigates a wide range of wrongdoings from embezzlement, fraudulent claims and misconduct in public procurement procedures, to customs fraud, although even it is not without criticism. For example, the Supervisory Committee (SC), a body of four independent experts charged with the task of monitoring the quality of OLAF's activities, issued a relatively critical opinion of a high-profile investigation carried out in 2012: the so-called Dalli-gate case (McKee et al., 2012).

The former Commissioner for Health and Consumer Policy, John Dalli, was forced to resign in October 2012 by Commission President, José Manuel Barroso, after an associate was accused of asking for €60 million from Swedish Match, the main producer of Swedish snus, in return for Dalli's help in amending European tobacco regulations (Wikipedia, 2017). John Dalli had allegedly wanted the OLAF report on his case to be published, with the latter eventually being leaked to the press via a Maltese newspaper. On 7 October 2014, a French public television station aired a two-hour report entitled "Tobacco Industry: the grand Manipulation". In this feature, the journalists investigated documents they acquired from Philip Morris showing that the tobacco lobby had planned a strategy to target Dalli for his drive to push through a tobacco products Directive. Corporate Europe Observatory (CEO), a platform aiming to unveil corporate lobby influence in Brussels, published online in July 2014 both the Supervisory Committee's analysis of the OLAF investigation of Dalli and the letter to CEO about the release of this opinion. The opinion of the Supervisory Committee points to the short timeframe which was given to OLAF to check the legality of the allegations and to carry out the assessment of the incoming information: *"Apart from OLAF verification of the existence of the persons/companies whose names figured in the complaint, the SC has not found any trace of any other check made or any other additional information gathered by OLAF with regard to the allegations and their credibility, as it is foreseen in Article 5(4) of the OLAF Instructions to Staff on Investigative Procedures (ISIP) relating to OLAF's obligation to evaluate the accuracy, the reliability and the supporting evidence of the incoming information"*(CEO, 2014)¹.

What constitutes good or bad lobbying

Daniel Guéguen, co-founder of the first European school of lobbying (1992) and author of several books and guides on the subject, describes "a good lobbyist" as someone who delivers

¹ It should be noted, however, that even now, many questions remain unanswered about this case. Indeed, the mystery has deepened following the broadcast of a television programme made by two Danish journalists who initially were approached by Dalli CAMILLERI, I. 2017. *New film claims John Dalli unsuccessfully tried to obtain info about alleged conspiracy against him* [Online]. Times of Malta. Available: <https://www.timesofmalta.com/articles/view/20170727/local/new-film-claims-john-dalli-unsuccessfully-tried-to-obtain-info-about.654229> [Accessed 6th August 2017].

solutions, or more precisely, a facilitator. Notably, at first and second reading stages, Members of European Parliament often introduce amendments drawing closely on interest group data and argumentation. Guéguen offers expertise and explains technical aspects of the dossier, looking to forge a European consensus at the heart of the association he represents. Where he disputes elements of a proposal, his criticisms are measured, justified and his counter-proposals are technically and financially credible. In his role, he pushes for a solution, always maintaining his credibility.

By manner of contrast, a “bad lobbyist” complicates the problem even further, lacking technical skill and being of no particular interest to MEPs or officials. He may be seen to act systematically in a defensive or negative manner. His case is made up of technically suspect building blocks and solutions which are financially untenable. Therefore, he is around, but rarely welcome (Guéguen, 2007).

Major pitfalls in achieving successful lobbying/interest group representation include sloppy, dilettante coordination and ignorance of cost-saving opportunities/inefficiencies, lack of attention to detail and lack of expertise on decision-making procedures (e.g. comitology or co-decision, impact assessment and evaluation, etc).

The Corporate EU Observatory (CEO), a member of the EU lobby Transparency Register, takes on the mission, mandate and motives of lobbyists but is a lobbyist in itself; it is a research and campaign group endeavouring to expose the undue influence of corporations and their lobby groups in EU decision-making. CEO is registered as a not-for-profit foundation under Dutch law at the Amsterdam Chamber of Commerce. In its latest online report *“Thinking allowed? How think tanks facilitate corporate lobbying”*, CEO challenges the guidelines of the Transparency Register and the categorisation contained therein and argues how corporate interest masquerade as think tanks. As think tanks represent approximately 5% of the registered lobbyists in the Transparency Register, it is not surprising that their private agendas are not purely academic.

Conclusions

This section began by explaining the main institutions in the EU legislative process and then argued why the EU is a major target for industry interest, with a focus on how its structures and processes offer opportunities for influence to be exerted. The section offered a critical

analysis of how public consultation works, existing concerns, and what could be improved for the future. A brief review of the scale and nature of interest groups currently operating in Brussels provided a quantitative overview of those active in health and food safety. Finally, I explain how interest groups operate employing various tactics to strengthen their influence in the policy process and what constitutes a good or a bad lobbying agent.

Chapter 3. Corporate influence – what do we know?

Language is central to expressing political opinion. However, this is both an advantage and a challenge: mass communication has created powerful platforms that have become the vehicle for an impressive volume of text that scholars can no longer analyse individually, leading to an interest in automated text analysis, be it qualitative or quantitative.

The benefits and shortcoming of using text-mining techniques for the analysis of large-scale consultations submitted via the Internet have been discussed in various papers (Bicquelet and Weale, 2011). Bicquelet and Weale look at automated text analysis in a specific case, i.e. a public consultation organised by the National Institutes for Health and Clinical Excellence (NICE) in 2008 on “end of life medicines”. They argue that large-scale e-consultations are still in their formative years and experience teething issues. Some of the precautions they identify to minimise ethical issues are: consultation organisers should inform respondents about the presence of analysts/ researchers among those reading responses and obtaining their consent for the types of methods used to analyse the opinions expressed. However, by analogy with research using social media as a data source, there is a strong argument that these have been placed voluntarily in the public domain by their authors. A requirement to obtain permission before analysing publicly available text could equally apply to articles in newspapers or scientific journals, something that most would view as inappropriate. Second, techniques or coding employed should not endanger confidentiality or create potential harm to vulnerable groups or individuals. Finally, to enhance the validity and meaningfulness of their findings, researchers should usually employ a methodology that blends quantitative and qualitative analyses.

Word-processed text analytics offer new insights and rely both on expedient machine-driven poll and survey analysis tools developed chiefly for ethnographers (for interview content analysis, such as Nvivo® or Sketch Engine for qualitative text analysis) as well as tools created for comparative literature analysis. A number of techniques from comparative linguistics and mathematical logic applied to semantics have been stimulating software developments and are awaiting further applications to aid our understanding of the evolution of the meaning of texts in fast evolving health policy debates. This approach was first used in Grounded Theory and sociological research in the 1960s, designed to improve social scientists’ capacity for

generating theory that will be relevant for their research. It draws on the constant comparative method of qualitative analysis, on clarifying and assessing comparative studies and pinpoints the potential of quantitative data handled systematically by theoretical ordering of variables in elaboration tables, that the analyst will indeed find rich terrain for discovering and generating theory (Glaser and Strauss, 2009).

Quantitative Text Analysis

This section will describe QTA in detail. It will note that it comprises a group of methods used to make statistical inferences about a population of texts. It complements qualitative methods in that it offers metrics and contributes to a theoretical basis. There are different methods and algorithms for undertaking QTA. This section will note that there are a number of gaps in the literature describing its use in studying corporate power and influence, including validation and guidelines for its applicability.

Principles of automated text analysis

Grimmer et al (Grimmer and Stewart, 2013) have suggested four principles of automated text analysis to guide scholars in their endeavour to faithfully capture political texts in their analytical processes:

1. Quantitative models are of limited use as they fail to capture sufficiently the complex nature of the data generation for texts, even for linguists. Evaluations should emphasise helping researchers to assign documents to predetermined categories, discover new and useful categorization schemes for texts, or measure theoretically relevant quantities from large collections of text.
2. Quantitative methods do not replace but rather augment human capability, as texts still need to be read in order to give a fuller understanding of the substance at hand.
3. There is no single global reference method, i.e. “best method for QTA”. What works depends on the nature of the task at hand.
4. Validation is crucial.

Roberts, in his seminal paper that addressed the question: “Which quantitative text analysis method best affords answers to what research question?”, handles the conundrum of how to draw statistical inferences about text-populations, given the data matrix of text-related variables as well as a bunch of contextual variables that may also be available (Roberts, 2000).

In other words, in encoding text blocks as networks, the coder must appreciate the fact that certain types of links are transitive (e.g. if “A triggers B” and “B triggers C”, then “A triggers C”), whilst others are not (e.g. if “A loves B” and “B loves C”, it does not necessarily follow that “A loves C”). Assumptions that certain nodes in a network are central or conducive will be void if the network does not have a causal, equivalent, affective or some other specific kind of arc. Roberts warns against the pitfalls of ignoring arc-types, as this may usher in false conclusions that nodes are linked in some “unspecified way”. Possible contextual variables can then indicate the source, message, channel, and audience associated with each text sample being analysed. Among texts with particular types of audience, source, message or channel, QTA can genuinely help answer questions such as “what themes occur”, “what semantic relations exist among occurring themes”, or “what network positions are occupied by such themes or theme relations” (Roberts, 2000). The inferences that can be drawn are left to the discretion or the imagination of the analyst.

Text submissions, policy papers and stakeholder analysis

Information and communication technologies such as the Internet have enabled a plethora of opportunities for the participation of citizens in policy-making (Bicquelet and Weale, 2011). Since the 1980s, new public management tools and the public policy reform process have created a global interest in stakeholder consultations (Rodrigo and Amo, 2006). The process is increasingly formalised and in this context, in support of its health policy-making processes, the World Health Organisation (WHO) has produced a number of guidelines and toolboxes.

The adoption of a systematic approach to consult stakeholders with the aim of drawing up major policies such as those on nutrition, diet and health by the WHO, as the UN body responsible for health policy, signals an important change imposed by the growing importance of civil society organisations in policy-making but also the need to coordinate policies among different UN organisations better. The guidelines developed not only provide a technical brief to be used within the organisation itself but also inform NGOs and other public health actors on the way to make the best use of this instrument.

In 2015, the European Commission, the executive body of the European Union that also doubles as the Guardian of the Treaties and a legislative initiator, published Better Regulation Guidelines, with the stated aim of cutting red tape and administrative burdens (European Commission, 2015a) in other words, formal requirements for impact assessments and

evaluations that must precede the creation of any new piece of legislation. In these guidelines, a major role is given to stakeholder consultation based on a formally agreed prior strategy that in turn is based on stakeholder mapping. These requirements will be dealt with *in extenso* in the next chapters.

Stakeholder mapping and analysis in WHO and its value in health policy

Based on Schmeer's methodology (WHO, 1999), stakeholder analysis develops stakeholder maps with four quadrants (Schmeer, 1999). Stakeholders are grouped into these quadrants based on their position along two axes (Varvasovszky and Brugha, 2000):

- **Position/ Interest**, along the x-axis, i.e. whether the specific stakeholder supports, opposes or is neutral with regard to a certain policy (e.g. a reform, a standardisation, a privatisation of a service) or a mandate or a mission of another actor in the policy field;
- **Power/ Influence**, along the y-axis, i.e. the stakeholder's ability to influence a certain policy or a mandate or a mission of another actor in the policy field.

The key stakeholders are those in the top right quadrant and they are deemed to have both a high level of interest in the policy/ mission/ mandate, and some level of influence over the implementation or success rate of the latter. These are the "natural" (i.e. relatively easy to reach) target audiences for the stakeholders from whose viewpoint the analysis is performed.

The groups in the bottom right quadrant are potentially interested, but their influence is limited, which in effect makes their engagement being strategically less important.

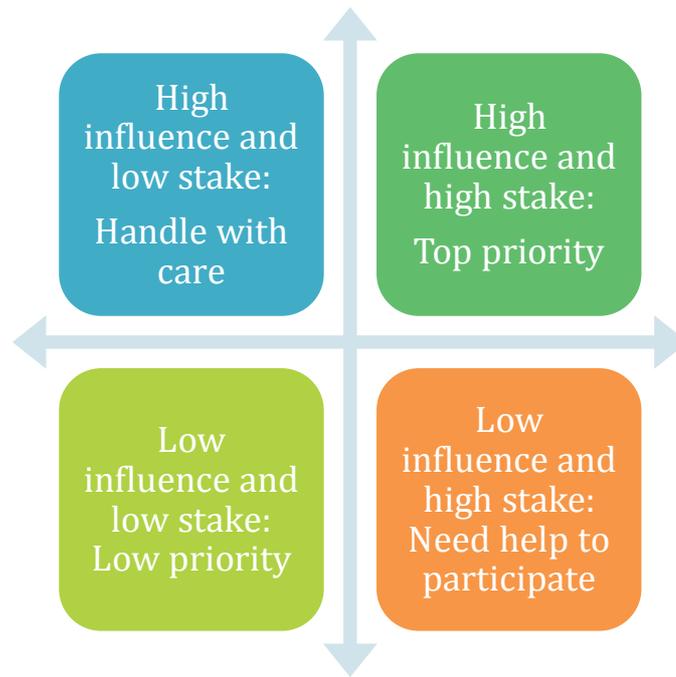
The stakeholders in the top left quadrant are of note, as their high level of influence coincides with relatively low levels of interest.

Finally, the bottom left quadrant contains the stakeholders that combine low levels of interest with a low level of influence.

Stakeholder Analysis Guidelines in the European Commission

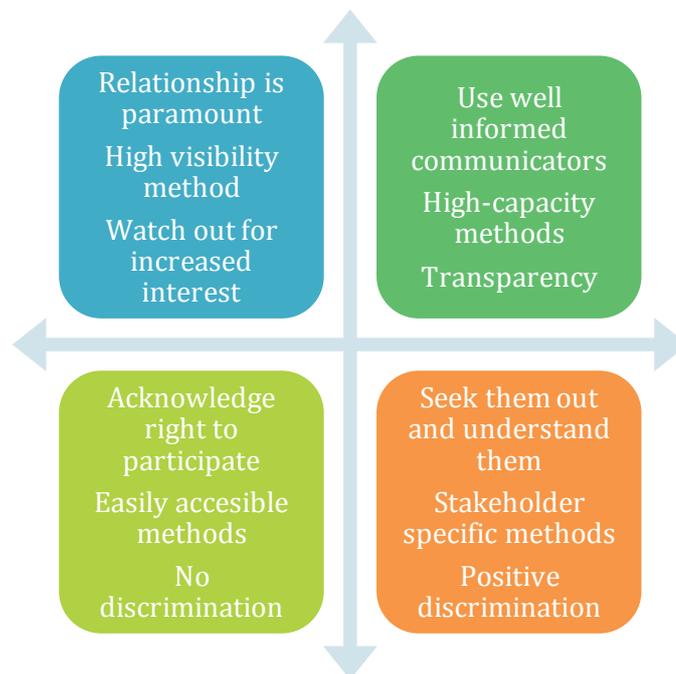
According to the guidelines, the stakeholders can be assigned to four groups (Figure 3-1).

Figure 3-1 Categories of stakeholder



For each stakeholder type, the European Commission encourages certain steps to be thought through (Figure 3-2).

Figure 3-2 Steps in a stakeholder analysis



It remains to be seen to which extent the above stakeholder engagement strategy is applied and how it can influence public consultations. One recent study (Azzopardi-Muscat et al., 2015) examined the European Semester documents by means of textual analysis, looking at the use of words related to “health”. In the European Semester, which is a function of the “Europe 2020” strategy on competitiveness, European Union Member States are subject to a system of economic monitoring and governance (Földes, 2016). In this process, the European Commission produces annual, public Country-Specific Recommendations (CSRs) (European Commission, 2017a) as tailored policy guidance to Member States to help address reform efforts, including for some countries in the area of health. By examining CSRs as a data source, Azzopardi-Muscat et al. analysed the way health systems and their sustainability were addressed over the period 2011-2014. The fact that all the CSRs for pensions and health are captured under the heading of “sustainability of public finances” and not that of employment and social policies reveals the current skewed status of the debate. Whilst the paper calls for more active involvement of health stakeholders in the process, Földes et al. recognise the role of the crisis in placing health system objectives on the EU agenda to an extent that has not previously been observed (Clemens et al., 2014), despite resistance from some Member States – i.e. some countries ignore health CSRs and others oppose the very idea of the EU making recommendations without a formal legal basis enshrined in the Treaty to do so. This raises the question of whether a formal public consultation on CSRs may be a way forward for the future, an interesting avenue worth exploring in future research.

How is QTA undertaken?

This section will elaborate on the use of QTA, showing how it allows for developing statistics and matrices using words as data. Several types of software have been used to undertake QTA, each with strengths and limitations (Table 3-1).

Table 3-1 Software used to undertake Quantitative Textual Analysis

Type of QTA/Software	Assumptions	Strengths	Weaknesses
Jfreq	Word frequency matrices built for each word in every text.	Allows the researcher to identify extremely frequently used words and gaps.	Does not compute aggregate statistics.
Wordscores in Stata, R	Reference texts are assigned by the researcher.	Well-suited for analysing texts submitted for public consultation	Results may change if reference texts change.
Wordfish in R	No need to assign reference texts.	Good if words are quite different (e.g. Left vs. Right)	Cannot run in Stata
Plagiarism Detection Software	Recognises copy-pasted text.	Good for analysing censorship and deviation from mainstream discourse.	Is not necessarily suited to all purposes.
ReadMe in R	The sample of hand-coded texts grouped into mutually exclusive categories provide enough info for the programme to extrapolate the filing system to all texts under review.	High reliability.	A categorisation tool, not an analytical tool.

How has QTA been used previously and how does this thesis add to what is already known?

As noted above, studies that combined QTA (using Wordscores) with qualitative analysis were previously used by Stuckler et al and Costa et al, as well as by Kluever to quantify industry influence in environmental issues. This study will apply this method to three case studies, selected because their characteristics are thought to pose different challenges to the use of QTA. The initial review has identified Wordscores and Jfreq as having the greatest potential in selected fields of health. However, while this thesis is focused on quantitative analyses, it must be borne in mind that, for a comprehensive analysis, these methods will be complemented by qualitative methods.

Qualitative text analysis takes three main forms: thematic, evaluative and type-building. Thematic analysis, being the most common one, is based on pinpointing, examining and recording patterns (“or themes”) within data. Themes are patterns across data sets relevant

to the research question and describing a particular phenomenon. They test how different concepts are related to one another.

Evaluative text analysis is the process of turning written data such as interview or field notes into findings. Its main purpose is evaluative and not descriptive – describing in detail a particular phenomenon, usually based on fieldwork results.

Type-building text analysis is often seen as a goal in qualitative research and it is viewed as the method to arrive at representative generalisations, oftentimes applied in quantitative research. From case summaries one can extract typologies by reducing the diversity of the categories or cases encountered.

The three methods are independent approaches that build on each other in some respects, but this should not be interpreted as a hierarchical ranking (Kuckartz, 2014). They are all category-based methods for the systematic analysis of qualitative data (Kuckartz, 2014).

There are also several software packages that can assist in these analyses, in various ways. Selected examples are shown in Table 3-2.

Table 3-2 Software used to undertake Qualitative Textual Analysis

Type of QTA/Software	Assumptions	Strengths	Weaknesses
Corpus linguistics	The study of language, as expressed in “corpora” or samples from source texts, i.e. real-world text.	Corpus as a locus of linguistic debate via annotated samples, rather than as an exhaustive fount of knowledge.	Corpora need to be collected in the field with minimal experimental interference. This may result in data being scarce.
Nvivo	Computer software package produced by QSR International. It has been designed for qualitative researchers working with very rich text-based or with multimedia information, where deep levels of analysis on small or large volumes of data are required.	The software allows users to classify, sort and arrange information; examine relationships in the data; and combine analysis with linking, shaping, searching and modelling. The analyst can test theories, identify trends and cross-examine information in a multitude	Visualisation ranges from word clouds to charts comparing key themes, but there is room for improvement. This software needs to be downloaded.

		<p>of ways using its search engine and query functions. They can make observations in the software and build a body of evidence to support their case or project.</p> <p>Analyses social networks to discover influencers and opinion leaders.</p>	
Sketch Engine	<p>Sketch Engine processes texts of billions of words and retrieves instances of a word, a phrase or a phenomenon and presents the results in the form of Word Sketches, concordances or word lists.</p>	<p>Sketch Engine is an online service delivered via standard browsers – it does not require installation.</p>	<p>Sketch Engine supports corpora in over 80 languages. Files can be uploaded in a language that Sketch Engine does not currently support and one can search the corpus and generate wordlists or collocations but some more advanced features will not be available for languages that are not yet supported.</p>

There are other types of QTA or software available, however for the purposes of this thesis the above are the most notable ones at the time of writing: corpus linguistics, Nvivo and Sketch Engine software.

This chapter started by noting the origins of this approach in Grounded Theory and sociological research in the 1960s, it discussed the principles of automated text analysis, it then moved on to discuss the steps taken in carrying out a stakeholder analysis and finished with methods and tools best suited to undertake QTA and qualitative text analysis. The next chapter will examine the research question, the conceptual framework used and the methods employed in this thesis.

Chapter 4. The research question, conceptual framework, and methods

The thesis examines written responses to consultations on European Union policies, using QTA to analyse them. It thereby examines processes of public consultation and seeks to quantify the potential collective risk of corporate capture of such processes via individual written submissions. The research has also allowed me to develop a manual on how to calibrate Jfreq and STATA's scaling algorithm entitled Wordscores to various stakeholder texts for rapid identification of their policy positions (Appendix 4).

Public consultation is the most common regulatory tool used among OECD countries, according to research led by OECD (Rodrigo and Amo, 2006). I use QTA for three separate health-related case studies in which some variant of public consultation took place, examining who stands to benefit from public consultations and how they achieve an advantage in the process. I propose that QTA could help foster a dialogue between groups weakly or rarely represented in public health consultations and institutional knowledge systems, and focus attention on the role of public consultations in challenging power hierarchies between public health activists, industry professionals and regulatory affairs practitioners as risk managers and knowledge brokers.

I argue that QTA provides a lens through which value systems underlying contributions to public debate can be monitored, tracked, and analysed over time and across policy fields and through which anomalous, irregular, or spurious submissions to public consultations can be identified and examined. The method unveils written submissions that are partial to certain interests but not transparently so and detects contributions that are fake, duplicative, or void. The approach has the potential to optimise the mechanisms of public consultation, to render them more inclusive and to ultimately facilitate the resolution of protracted policy controversies.

Dialogical Theory, Framing Research and Discourse Analysis

What follows is a brief account of the theoretical approaches that have informed my methodology and my thinking on the nature of public consultations and whether it provides a level playing field, while reflecting wider collaborative platforms. By combining dialogical

theory with framing research and discourse analysis, I gain a more subtle understanding of public consultation processes than would be obtained through the lens of one theory alone. Before presenting the research questions, I will succinctly outline the conceptual framework and the main constructs that underpin it.

Dialogism

Dialogism recognises that the world as perceived is grounded in dialogic relations between groups and individuals, and the mutual effects that they have on each other (Bakhtin, 2010). Perspective taking and recognition allow for diversity to be discovered and are a precondition for dialogue which consists of mutual recognition (Jovchelovitch, 2007). Sandra Jovchelovitch (Jovchelovitch, 2007) mixes dialogical theory, social psychology and philosophy with a critique of self-other relations to examine encounters between different social groups. Observing and analysing variants of open public consultation as *knowledge encounters between stakeholders* (and the wider public) through a dialogical lens will help to critically analyse whose voices are heard, which positions are subsumed and whose interests are ultimately served in public consultations. Embracing the existence of a plurality of knowledge (or recognising different forms of knowledge) can shed light on how different forms of knowledge are inter-related and how communication between these forms can lead to new forms of knowing (Jovchelovitch, 2007). “Knowledge” here, constructed in communication, refers not just to the technical knowledge of biomedicine, biochemistry, economics, law, or sociology but also to social, cultural and political functions, which apply equally, leading to a plurality of knowledge, and thus informing policy.

Discourse Analysis: Interpretive Policy Analysis (IPA) and Framing Research

Along with theorists like Frank Fischer and Maarten Hajer, proponents of IPA (myself included) emphasise the importance of non-technocratic forms of policy-making that encourage greater citizen participation and deliberation (Fischer, 2000). Innovative methods to analyse the production and contestation of meaning in policy can render practices of policy formation and implementation more accountable and democratic (Glynos et al., 2009).

Such methods have been developed in parallel to framing research or framing analysis. The theoretical origin of frame analysis is widely regarded to lie with the work of Erving Goffman, a sociologist who in his pioneering work "Frame Analysis" defined interpretive frames as a principle of organisation "*which govern the subjective meaning we assign to social events*" (Goffman, 1974). In Goffman's conception, frames balance *structure* and *agency*. Overtly and covertly, they highlight the problem and the problem holder while obscuring the analyst and other aspects in order to define problems and suggest a remedial course of action. Frames are a variety of ideas, packaged as values, social problems, metaphors or arguments – their "strength" and "resonance" play a more defining role in determining the size of the effect in competitive environments than a frame's repeated usage (Koon et al., 2016). Studies of voter behaviour and public opinion formation have benefitted from the framing concept in material and meaningful ways across different academic disciplines: political psychology, behavioural economics, communication and media studies, social movements research and socio-linguistics. Moreover, recent management theory focusing on NLP (neuro-linguistic programming) has also highlighted the shared understanding that "*frames in communication*" influence "*frames in thought*" (Druckman, 2011), stressing the transformative nature of discourse. Framing therefore offers key insights into understanding the nature of political debate by providing an explanation of both structure and agency in the policy process. Some accounts even go as far as to argue that rhetoric and argumentation are the "mobilisation of bias" (Howarth, 2010).

I take the view that frames and discourse, alongside beliefs and narrative, can be labelled as "ordering devices", which explain how policy makers and stakeholders structure reality to gain a handle on practical questions, in a complex world where politicians look to their advisers for clarity, to help them overcome ambivalence (Hajer and Laws, 2006). Ambivalence (equivalent to ambiguity) is defined by Hajer and Laws as the possibility of assigning an object or an event to more than one category and is not always a problem but can also be a tool to engage with good policy work – "*what we want is not terms that avoid ambiguity, but terms that clearly reveal the strategic spots at which ambiguities necessarily arise*" (Burke, 1969). Whilst concerns with framing and reframing, dominance and intractability abound when dealing with ambiguity *in situ*, seeking stability and acting in a social world that is a

kaleidoscope of potential realities and meanings is only a natural reaction. Acknowledging and handling ambivalence is therefore essential for prudent action (Hajer and Laws, 2006).

Further conceptual frameworks for analysing political discourse

As more and more stakeholders (including industry front groups and trade organisations) seek and obtain public consultation credentials (*inter alia*, public consultation experience, feedback and results), the increased analytical and administrative burden placed on the shoulders of public consultation managers can be expected to erode the efficiency of public consultations. This has stimulated interest in new approaches (quantitative and qualitative), including text mining, to facilitate this process. However, this requires a nuanced approach: for example, alcohol pricing policy should not be seen as a simple dichotomy between public health activists on the one hand and a uniform, monolithic alcohol industry on the other (Hawkins and Holden, 2013), but between subsets within each group. This is the approach the present research adopts, for a more informed and nuanced view.

Democratising choice and policy literacy

In many OECD countries, better educated and informed citizens are taking on new roles in the development, implementation and revision of regulations and demanding more information from governments, thereby pushing for more open consultative mechanisms, with better information and more effective opportunities for participation and dialogue (Rodrigo and Amo, 2006).

It is my contention that public consultations can help to level the playing field for citizens and advocacy groups entering public debates alongside representatives of industry. However, this depends on consultations being designed and analysed in ways that offer the former equal opportunities for input into the policy-making process. Well run consultations may also improve the level of voluntary compliance, including a smoother implementation of new legislation, once agreed. Advances in information technology are enhancing the abilities of civil society groups to organise in pursuit of their goals (Rodrigo and Amo, 2006). Policy outcomes may still vary, but do so increasingly according to merit and the strength of the evidence base underlying the policy arguments put forward, rather than owing to stakeholder group background. By endowing open consultation with greater visibility, public consultation

managers (organisations, governments, or knowledge brokers) strengthen the level of policy literacy (civic educational attainment) and of policy performance in a jurisdiction. Furthermore, they may reduce both the risk of regulatory capture by well financed groups of interest or with a deep legislative knowledge (Rodrigo and Amo, 2006) and the risk of spurious or anomalous texts under the guise of credible, legitimate submissions, which have in the past been criticised for unsettling or disrupting the public consultation process (e.g. the consultation on the Natura 2000 network recognising the importance of nature conservation in a living and changing landscape where crowd-surfing was used to intercede in the consultation process and burden it with duplicated contributions). By anomalous texts I refer to submissions that are irregular, present abnormalities or deviate significantly from their immediate context, deliberately or otherwise.

Approaching this contention from the perspective of framing research, inclusiveness of consultation (not least via use of plain, accessible language and ability to dissect issues of technical complexity) alongside capacity to disseminate detailed and timely information on regulations can both provide a rationale for the emergence of open public consultations as a normative prescription and act as a plausible framing mechanism going forward. There is a further reason why anomalous submissions erode the quality of public consultations. Since public consultation credentials (dictated by previously published submissions, not by stakeholder background) send a signal to the public about stakeholder abilities, equality of opportunity becomes deeper and more meaningful, increasing the information value of the credential. In a scenario where there is a level playing field, credentials tell citizens and the public more about a stakeholder's ability to represent their interests competently and fairly than in a context where opportunities for exercising one's consultation abilities are a privilege rather than a meritocratic exercise.

Research questions

This thesis seeks to answer two questions:

- Can innovative methods of text analysis reveal patterns of interest representation in the European policy process?

- Can the various public consultation norms, constellations and mechanisms that characterise knowledge brokering help to decrease the relative disadvantage of public health advocacy groups in the policy arena?

This thesis is an effort to investigate, explain and contextualise anchors, mechanisms, and outcomes of public consultation processes. Firstly, the present research will support public consultation managers as “explorers”, inviting views and expertise on a particular public policy, mapping policy positions onto written submissions. Secondly, and perhaps more in hope than expectation, a more reflective approach in submitting input to public consultations could engender broader and deeper analysis prior to submission by the actors involved and contribute to raising the standard of responses across the board, thus enhancing the quality of the evidence-base for reinforcing, negating or qualifying the terms, the elements and the overall policy action subject to consultation.

This thesis begins with the premise that industry, and especially multinational corporations, and possibly other stakeholder groupings (e.g. trade organizations, industry front groups) use a particular vocabulary, evidence, position-taking and semantic shifts to influence the policy process. Such groups begin with many advantages. Thus, they are often forewarned that an issue will reach the policy agenda. Guéguen (Guéguen, 2007) argues that those who engage earliest in the process are best able to exert influence. Recent research from Copenhagen Business School corroborates this hypothesis – i.e. that keeping tabs on the Commission services’ Working Groups and acting before the first draft is written pays off from the perspective of the lobbyist in the long run (Jensen, 2015). The aim of the present research is to test this hypothesis further and to analyse and explain the findings obtained via QTA.

The thesis then explores the scope to use QTA as a tool to “interrogate” the subject (the text submitted to a public consultation), to examine and assess the content of public consultation documents and to evaluate the policy position of stakeholders as well as their evolution.

The primary research question aims to ascertain whether text analysis using Wordscores can reveal patterns of interest representation in the European policy process. The research aims are three-fold: first, to review research on the ways in which the food, alcohol, tobacco and pharmaceutical industries have sought to influence EU policies, including a description of their actions and its impact but, especially, the methods used to study it. Second, having identified

a gap in the available methodologies and the potential for QTA to fill it, to review its use, including its strengths and weaknesses. Third, to gain experience by applying it to three case studies purposively selected to exhibit characteristics that may influence the use and interpretation of QTA.

A series of subsequent questions arise and are developed further in the next chapter, under aims and objectives of present research.

Aims and objectives

As set out in the previous section, this thesis reviews the predominant methods for QTA in political science (including examining their strengths and limitations), to set out the rationale for selecting one method and applying it to three case studies of interest and to make practical recommendations on how QTA methods could be deployed and mainstreamed into the EU political process in the future. Public consultations becoming more and more the norm before important legislative proposals are put forward for co-decision to the European Parliament and to the Council, QTA solutions could improve efficiency and drive down costs.

The objectives are therefore two-fold:

- **Landscape analysis of political/scientific texts submitted for public consultation:** to assess the feasibility of applying different methods of textual analysis to written responses to EU consultations and determine whether they can differentiate material from different sources;
- **Detecting patterns (constellations of stakeholder mapping):** to determine whether the positions of individual texts and constellations of texts relate to the positions of the parties to a negotiation (interest representation in the policy process) and whether it is possible, quantitatively, to identify significant shifts in the content (and thus the underlying expression of interests) during the course of a consultation?

A third objective, visual analytics, i.e. developing a type of visual analytics that can help capture best the results of such a QTA was dropped at the Upgrade stage following the advice of the Examination Panel.

These objectives are further reiterated in Appendix A. The methodology for each objective is detailed below.

Choice of methods

In choosing the methods to use in this thesis, it is first necessary to review the methods that have been developed so far for text analysis in sociological and political science – what are their limitations and how could they be improved and mainstreamed?

Wordscores is an algorithm that infers policy positions, or scores, for new documents, i.e. “*virgin texts*” on the basis of documents with known scores, i.e. “*reference texts*”. It measures positions along an axis, for example right or left wing party manifestos or press releases for or against health regulation. Based on the underlying assumption that agents with different policy positions use different wording that reflects their stance, it uses the frequency of words in each document, relative to the total number of words in a text, to generate scores for each document. *Wordfish* is another software tool that uses frequency distributions of words (Slapin and Proksch, 2008). However, no assumptions concerning reference texts are needed. This is rather more appropriate for examining left/ right party manifestos (Proksch and Slapin, 2009), where texts are quite different and use different words, rather than for public consultation processes that are the focus of our present investigation (Proksch and Slapin, 2010).

Cost is not a criterion in the selection – *Wordfish* is available free of charge and *Wordscores* is a package within the statistical analysis software STATA v14.0 or within R (the latter is also free). A further freely available method is *Jfreq*, which simply lists all the words in a number of uploaded texts and compiles a matrix of their frequencies. *Wordfish* software has been used extensively in publications by Heike Kluever (Klüver, 2011) and Sven-Oliver Proksch.

However, *Wordscores* has been evaluated as a valuable word scoring technique, arriving at largely similar estimates to independently derived position measures and producing time series of government positions with high validity (Klemmensen et al., 2007). I shall therefore use *Wordscores* rather than *Wordfish* in the three case studies at hand.

Extracting policy positions from political texts using words as data has already been employed with the Better Regulation agenda e.g. on environmental policy public consultations at EU level (Bunea, 2014) and at national level by reviewing tobacco industry submissions to the UK

government consultation on standardised packaging of tobacco products (Uluncanlar et al., 2014). Uluncanlar et al argue that stakeholder consultation provides an opportunity for highly resourced corporations to slow down, weaken or to prevent altogether public health policies. Theirs is an examination of how the industry critiqued evidence supporting Standardised Packaging, via examination of the curriculum vitae of “experts”, a cross-documentary analysis comparing references made to published sources with the original sources to confirm their veracity, an interpretative analysis to identify conceptual themes and a thematic analysis based on systematic conceptual coding (e.g. the micro-themes “misleading quoting”, “misleading interpretation” and “selective quoting” were grouped under “misleading quoting of evidence”). This paper will inform the pattern-recognition objective of the present research.

Stuckler et al. (Stuckler et al., 2016) continue this examination, by unveiling various tactics that industry employs in order to thwart effective public health intervention, to the detriment of global nutritional goals. They demonstrate how alcohol and sugar-related/ affiliated industries employ denialism (promoting doubt and undermining the case for action) as well as a complex array of tactics: a) obfuscating the relationship of sugar with health outcomes by disputing what is being measured – i.e. total or added sugar, b) setting unrealistic expectations of science, c) displacing attention to other risk factors such as physical activity and d) shifting focus on avoiding the harms associated with their product rather than measures to reduce consumption.

The approach to methodology outlined in Stuckler et al will be replicated here. I will first run a *prima facie* analysis of the texts using the program JFREQ to identify the most commonly used words and then I will select the reference texts for each case study and run them through *Wordscores* in Stata v14.0.

I endeavour to present a framework for the visual integration, comparison, and exploration of correlations in non-spatial text-mining research data (for details, see summary measures graphs in Chapter 5, 6 and 7).

Such visual representations have received considerable attention of late, not least since a nascent category of computational tools integrate data analytics with interactive visualisations, to facilitate the performance of cognitive activities involving big data, especially

textual analysis techniques. To illustrate this point, to investigate causation of a mosquito-borne outbreak, an epidemiologist can examine relationships between most frequent words in tweets (e.g. referencing parties in specific locations prior to an epidemic) and local bodies of water in a specific region (Sedig and Ola, 2014). Visual analytics thus offer an advantage by illustrating geographical, age-related or historical data trends in a way that a human mind can capture them quickly.

Alternative methods not selected for use

An alternative choice of methods for my research could have followed the path of press releases compared via **plagiarism detection software**, along the lines of studies indicating that NGOs create cultural change by relying on mainstream messages that resonate with prevailing discursive themes (Bail, 2012). I have chosen not to use this software since plagiarism detection software tends to work best for censorship/ deviation of press releases from mainstream discourse where reliance on validated text is more illustrative than in public consultations where copy-pasting is not likely to influence the end result, i.e. the consolidated document.

Secondly, the **ReadMe software package for R²** examines a set of text documents (such as speeches, blog posts, newspaper articles, judicial opinions, movie reviews, etc.), a categorization scheme chosen by the user (e.g. ordered positive to negative sentiment ratings, unordered policy topics, or any other mutually exclusive and exhaustive set of categories), and a small subset of text documents hand classified into the given categories. ReadMe software can thus report, normally within sampling error of the truth, the proportion of documents within each of the given categories among those not hand coded. ReadMe computes quantities of interest to the scientific community based on the distribution within categories but does so by skipping the more error prone intermediate step of classifying individual documents. I have chosen not to use this software since neither of the three case studies lends itself well to categorisation based on hand-coding.

² <http://gking.harvard.edu/readme>

It is however expected that the methods outlined in detail above will be sufficient and fitting to the objectives of the present research.

Transformation applied

The logic of *Wordscores* is to “score” texts mechanically (and the policy position contained in documents) based on the frequency of words, using the dictionary created from the reference texts. It is precisely the simplicity of this approach, which eliminates the need for close analysis of meaning that characterises Laver Benoit Garry’s insight in creating *Wordscores*. To compare texts, what a researcher wants to know is how the frequency of word usage in one text compares to that in another, as judged by the dictionary of words contained in the reference texts.

In analysing scores, the central issue concerns comparing virgin and reference texts. The core assumption at the heart of the LBG (Laver Benoit Garry) transformation is that the dispersion of reference and virgin texts is the same (Martin and Vanberg, 2008). Since reference texts tend to have overlapping, non-discriminating words, their word scores tend to be pulled towards the middle of the scale (Lowe, 2008). Bias will be removed to capture the correct baseline and to address the tendency for non-discriminating words to pull scores towards the middle of the distribution. *Wordscores* are then re-scaled using the Martin-Vanberg transformation³ (Martin and Vanberg, 2008), rather than Laver Benoit Garry’s transformation (Laver et al., 2003). Laver et al offer a far more complex algorithm that also rests on the unjustified assumption that the dispersion of reference and virgin texts is the same – the LBG transformation adjusts the variance of virgin text scores to equal the variance of reference scores (Martin and Vanberg, 2008). Centrist parties may become more polarised from one election to another and, in any case, the constant variance assumption is problematic. Therefore, I will use the more straightforward Martin-Vanberg transformation for my purposes.

³ Scores for each virgin text are rescaled using equation $(s_v - s_1)/(s_1 - s_2)$, where s_v stands for the raw score of each virgin text and s_1 and s_2 for the estimated scores of those virgin texts with the most extreme values.

Rationale for selection of case studies?

The rationale for the selection of case studies is outlined below. During the upgrading process it was agreed that, at most, three case studies could be undertaken in sufficient detail within the scope of a DrPH thesis. Following from this, two criteria were used to select appropriate examples. The first was the nature of the evidence that was available. This ranged from issues where the evidence was highly technical, such as that relating to product safety, even if there was debate about how the evidence should be interpreted and the weighting placed on different findings, to those where there was genuine scope for debate about the goals to be pursued, where the interests of different stakeholders in pursuit of legitimate, but differing goals might vary. A second consideration was the extent to which the decision to be reached impinged on commercial interests.

Pragmatically, the choice was limited to recent consultations for which details of responses were available. Several were considered, such as one on mHealth. However, consistent with the considerations outlined above, the final choice was narrowed down to:

- a) An examination of a narrow technical issue where the evidence was reasonably clear. This was the public consultation on the European Food Safety Authority's scientific opinion on acrylamide. It is worth pointing out that technical consultations, or public consultations on very technical texts such as on acrylamide (and many others run *inter alia* by the UK government) will have limited spectra of semantic shifts.
- b) Examination of a complex issue involving multiple stakeholders, with their own legitimate, but differing, perspectives and interests. For this, a consultation with selected stakeholders during a technical study concerning pharmaceutical product pricing was selected. The relevant study involved a complex process of negotiation with multiple and often competing agendas of key actors (institutional and non-institutional).
- c) The third is an example where there are few vested commercial interests, the EU Directive on the application of patients' rights in cross-border healthcare, where the parties are primarily governments and non-governmental organisations.

The case studies

Pharmaceutical pricing

Pharmaceutical expenditure represents an increasing share of health expenditure and has been the fastest growing cost pressure on health systems for many decades. There is a consensus that there are unintended effects from current pharmaceutical product pricing systems in the European Member States, even if views differ as to their importance. The high prices of innovative medicines have also attracted much attention lately. The European Commission, in response to Council Conclusions agreed under the Italian presidency, launched a study on enhanced cross-country coordination in the area of pharmaceutical product pricing in 2014. The interim report was shared with selected stakeholders for written consultation on August 10th 2015, in accordance with the Terms of Reference for the study. The participants belonged to one of the following three groups: representatives of the interests of consumers and patients, of public payers, and of the pharmaceutical industry. The stakeholder representatives were European associations of manufacturers, patient/consumer/ professional organisations, plus some Member State representatives/ public payers. The rationale for selecting the stakeholder group of participants followed the same approach as applied for the Working Group of the Platform “Access to Medicines in Europe” under the process on Corporate Social Responsibility in the field of pharmaceuticals. The aim of the stakeholder meeting on 17 September 2015 was to garner the views of stakeholders on the report. The case has been chosen since the issue of pharmaceutical pricing is likely to be controversial in the years to come, in particular given its inclusion in the agenda of the 2018 Austrian presidency.

Acrylamide

I ask whether and how the scientific opinion of the European Food Safety Authority (EFSA)⁴ shifted towards positions that favour the biscuit, coffee, and baking industries⁵(starch users) which are against acrylamide regulation.

⁴<http://www.efsa.europa.eu/en/consultationsclosed/call/140701>

⁵<http://www.efsa.europa.eu/en/efsajournal/pub/4104>

Acrylamide is a chemical compound/ contaminant of interest since its significance as a potentially toxic food ingredient was not understood until some 15 years ago whereas it was well known as an occupational hazard in the chemical industry. According to Jorgen Schlundt, World Health Organization (WHO) coordinator of food safety research, acrylamide probably has similar effects to heterocyclic amines which caused cancer in animal tests. However, only little was known about potential health risks in humans. Acrylamide is an obligatory by-product of heating starch and other complex polysaccharides present in many foodstuffs such as fries, potato chips, biscuits, but also soluble coffee. Its increasing occurrence is directly linked to industrial food processing. The discovery is likely to have a significant impact on the food industry as a whole: the determination of threshold levels that, under EU legislation, will need to be advertised on the food labels and even as warnings, might have a large impact on sales as well entail obligations to change the food processing technologies employed. The consultation on the scientific opinion ran between 1 July 2014 and 15 September 2014.

Cross-border Healthcare Directive (Directive 2011/24/EU)

Directive 2011/24/EU sets out the conditions under which a patient may travel to another EU country to receive safe and high quality medical care and have the cost reimbursed by their own health insurance scheme. It also encourages cooperation between national healthcare systems.

The European Treaties have given the EU a limited and clearly defined role in health policy. Article 168 of the Treaty on the Functioning of the European Union notes that Member States have responsibility for “the definition of their health policy and for the organisation and delivery of health services and medical care.” The same article also states that: “The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.” Historically, therefore, there was considered to be virtually no EU dimension to policy on the management and provision of health services. In recent years that view has changed, for a number of reasons.

Firstly, EU legislation originating from other policy areas – for example the Directive 2003/88/EC concerning certain aspects of the organisation of working time and Directive 2005/36/EC on the recognition of professional qualifications – has had significant impacts on health services.

Secondly, over a number of years, the European Court of Justice has developed the principle that healthcare was a service within the meaning of the Treaty on the Functioning of the European Union, and that the principles of the free movement of services therefore apply to health services, albeit with important safeguards.

The EU institutions and the Member States are therefore faced with a series of questions about how these principles apply to health services, and what this means in practice for health systems.

The Directive 2011/24/EU on the application of patients' rights in cross-border healthcare was the first step towards answering some of these questions. This Directive codified and clarified the jurisprudence of the Court with regard to the rights of patients to obtain and be reimbursed for healthcare received in another Member State. The Directive did not just deal with the rights to reimbursement, but also introduced a number of significant flanking measures to ensure that patients could use these rights in practice. As part of this there is now, for the first time, a minimum set of requirements which apply to all health providers and all healthcare provided within the EU. These requirements relate to transparency, information to patients, and safety and quality of care.

My intention is to examine whether and how the initial text proposed by the European Commission has been altered following the opinion of the European Parliament and the General Approach of the Council in the two readings of the co-decision procedure.

Case studies considered but rejected

The inter-related topics of eHealth and mHealth were considered but dropped from the list of case studies in this research because aligning positions for and against regulation of eHealth and mHealth at this stage appears premature and intractable as a problem (European Commission, 2011). Telemedicine is the provision of healthcare services through deployment of ICT (Bashshur et al., 2000) in situations where the health provider and the patient (or two health professionals) are not in the same location (Sood et al., 2007). Telemedicine requires the secure transmission of medical data and information through sound, text, images, video and so on needed for the prevention, diagnosis, treatment, monitoring and follow-up of a patient's illness or state of health. Data transmission can be synchronous (real-time), as in video-conferencing or telephone, or asynchronous (store-and-forward) as with imaging in

Telepathology or Teleradiology (McLean et al., 2013). Therefore, eHealth and mHealth were dropped as fields of investigation precisely because aligning positions for and against regulation of eHealth is premature at this stage of proceedings.

What are the expected outcomes of the research?

The expected outcomes are both generic and specific. The generic outputs include an expansion of the so far sparse literature on the use of QTA to study influences on policy processes, insights into the type of policy proposal where it can be most effective, and guidance for others in its use. The specific output is the generation of evidence on the nature and impact of industry or advocacy influence on public consultations on EU policies.

Chapter 5. Pharmaceutical Policy and Healthcare Systems

The issue

Pharmaceutical spending (including pharmaceutical consumption in hospital and purchase of drugs in the retail sector) in OECD countries reached US\$ 800 billion in 2013, accounting for an estimated 20% of total health spending (Belloni et al., 2016). Yet while the volume of medicines consumed and prices of innovative products continue to rise, pushing pharmaceutical spending up, cost-containment measures by funders and governments, coupled with the expiration of patents on a number of top-selling products have exerted downward pressure on pharmaceutical expenditures, slowing the pace of growth in spending over the past decade (Belloni et al., 2016). There are, however, many concerns about what is seen as market failure in the pharmaceutical sector.

These concerns are wide-ranging. The pharmaceutical industry is concerned about its profitability and what it sees as the regulatory burden placed on it when bringing products to market. Governments and payers are concerned about high prices of new medicines and how, as noted by the European Court of Justice (European Court of Justice, 2009), intellectual property rights have been used by manufacturers to delay generic competition (Hancher and Sauter, 2016). Health professionals and patients are concerned about a failure to invest in products that are truly innovative, rather than so-called “me too” medicines, adding little therapeutic benefit to what already exists.

There have been many responses to these concerns. Thus, a growing number of countries have implemented innovative mechanisms for assessing the costs and therapeutic benefits of new products, beginning with Australia and Canada in the early 1990s (Annemans et al., 2011). Similar mechanisms have been implemented in a number of EU Member States, where various organisations systematically appraise the cost-effectiveness, budget impact, medical/therapeutic needs of certain target groups, and any social and ethical considerations of such decisions (Annemans et al., 2011). Health-technology assessment (HTA) plays an important role in these decisions, which should not represent solely the perspective of the payers, but also incorporate the views of a wide range of stakeholders, as a means to promote better value through informed choice (Rotter et al., 2012). However, there is presently a patchwork

of national approaches to these issues, with various pricing arrangements in place. At the same time, third party payers (social health insurance institutions or national health services or bodies representing them) recognise that the pharmaceutical company is entitled to a sufficient return on investment to encourage them to seek new innovative medicines.

In addition, European governments have identified the pharmaceutical industry as a major contributor to economic growth and, recognising the power of the industry to relocate research, development, and manufacture to cheaper or more supportive environments, in the US, China, India, and Singapore, they have sought to provide manufacturers with a range of incentives to retain their activities in the EU. This raises complex issues that go beyond the scope of this thesis but recognition of this reality provides background to what follows in this chapter (Scullin et al., 2012).

The regulatory environment

The regulation of pharmaceuticals within the EU is complicated because certain aspects, such as manufacture and trade, fall within the remit of the single market and thus squarely within the competence of the European institutions. On the other hand, decisions about the use of medicines within health systems lie within the competence of Member States. With regard to the internal market aspects of pharmaceuticals, relevant decisions are made by representatives of governments of Member States meeting in the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO). Preparatory work for EPSCO meetings takes place in five working parties/ groups, one of which is the Pharmaceuticals and Medical Devices Council Working Group. The other four are: the Working Party on Social Questions, the Working Party on Public Health, the Senior Working Party on Public Health, and the Working Party on Foodstuffs (Council of Ministers, 2017). Other relevant structures related to pharmaceutical policy (Council of Ministers, 2015) are shown in Box 5-1.

Box 5-1 Institutional structures in the field of pharmaceutical policy in the EU

- The Commission expert group on “Safe and Timely Access of Medicines to Patients” (STAMP), comprised of experts from the European Medicines Agency and the Member States, discusses regulatory issues related to pre-market approval of medicines, including conditional marketing authorisations and accelerated assessment;
- The network of competent authorities on pricing and reimbursement (CAPR) is a voluntary network of competent authorities set up to deal with pricing and reimbursement policies, depending on the priorities of each 6-month rotating Presidency of the EU Council;
- The Process on Corporate Responsibility in the Field of Pharmaceuticals (2010-2013) convenes Member State representatives and stakeholders from industry, insurers, health professionals and patients to achieve a number of concrete consensus reports on facilitating supply in smaller markets, a mechanism for access to orphan drugs, capacity building for managed entry agreements for innovative medicines, good governance for non-prescription medicines and market access for biosimilars.

When it comes to healthcare however, as noted above, policies fall within the competence of Member States. Article 168 (7) of the Treaty on the Functioning of the EU clearly states that Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care:

“The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them.”

All EU member states, and health payers within them, are thus entitled to decide what medicines they will pay for, based on criteria such as budgetary impact and cost-effectiveness, although they are not required to do so. However, if they do, their decisions are subject to Directive 89/105/EEC, also known as the Transparency Directive (Council of Ministers, 1988). Specifically, the Directive lays down three major requirements with respect to individual pricing and reimbursement decisions:

- decisions must be made within a specific timeframe (90/180 days);

- decisions must be communicated to the applicant and contain a statement of reasons based on objective and verifiable criteria;
- decisions must be open to judicial appeal at national level.

The Transparency Directive covers decisions about whether or not to purchase a drug for inclusion on the positive list of reimbursed medicinal products, the price to pay the manufacturer for that drug, and the amount the patient is to be reimbursed.

Current developments

In 2012, a review of the Transparency Directive concluded that it no longer reflected the complexity of the pharmaceutical market in Europe and the Commission proposed a new Directive to replace it. This was intended to streamline and reduce the duration of national decisions on pricing and the reimbursement of medicines. The proposed new directive was portrayed as an important simplification of existing procedures. However, pharmaceutical policy is an issue that is fraught with endemic scepticism about the appropriateness of any EU-level action that would go beyond the existing *acquis* (accumulated body of EU law) and the present level of interstate cooperation. The scale of differences between the Member States' health systems is seen by many as precluding any silver bullet, or single solution that could suit all Member States when it comes to enhanced coordination on pharmaceutical pricing policies. These differences meant that it was impossible to reach any meaningful agreement, even after 16 meetings of the Pharmaceuticals and Medical Devices Council Working Group (see below). The objections raised by some Member States were seen as irreconcilable and the Commission concluded that there was no realistic possibility of producing proposals that would be acceptable to all Member States. This decision was announced on 7 March 2015. This also meant that a significant number of pending legislative initiatives were withdrawn.

Despite this setback, there was widespread recognition that some action was needed. Consequently, the 2016 Dutch Presidency of the European Council promulgated Council Conclusions on sustainability and affordability of pricing and reimbursement strategies related to purchasing medicines in the Member States (Council of Ministers, 2016). These Conclusions identified scope for greater co-operation among Member States to tackle high prices, supply shortages, and for some countries, deferred launches and problems associated

with small markets. One important proposal was to assess the scope for combining the purchasing power of several Member States to drive down prices.

Policy options

It is beyond the scope of this thesis to review in detail the many options that are being discussed to address the problems of the pharmaceutical market. Some relate to the approval of new products. These include ideas such as adaptive pathways, involving accelerated introduction of new products to the market, linked to enhanced post-marketing pharmacovigilance and monitoring, as well as moves towards a pan-European assessment of relative effectiveness of drugs, seen as a way to make sure that the most effective medicines make it to market while avoiding duplicating the same work 28 times. Other ideas involve challenging the existing system of patent protection, seen as a means of postponing the entry to the market by generics and biosimilar drugs, and in recognition of the fact that many patients with chronic, complex diseases require multiple medications, incentives to promote the development of fixed-dose combinations (FDCs). These may be advantageous in increasing patient adherence (Sawicki-Wrzask et al., 2015) but the existing intellectual property regime provides few incentives to develop them.

Others relate to payment and reimbursement, such as value-based pricing, seen as a means to link payment to manufacturers to the effectiveness of the product, but also other approaches to price setting, discussed in the next section.

Other approaches are less controversial, such as those that focus on providing more information to patients to help them make informed choices about their own treatment, as part of a wider patient engagement and empowerment/ health literacy agenda (Stacey et al., 2014). From this perspective, patient empowerment may *inter alia* be able to reduce over-prescription and overconsumption of medicinal products.

The decision being discussed

The focus of this chapter is on one particular aspect of pharmaceutical policy, the pricing of medicines. Drawing on an earlier study by Toumi et al (Toumi et al., 2014), the European Commission asked Gesundheit Oesterreich Forschungs- und Planungsgesellschaft GmbH, together with SOGETI (Luxembourg) and UMIT (Private University for Health Sciences,

Medical Informatics and Technology, Austria) to carry out a study on enhanced cross-country coordination in the area of pharmaceutical product pricing (Gesundheit_Österreich_Forschung-_und_Planungs_GmbH, 2016).

The study analysed the potential for use of two options, “*external price referencing*” (EPR) and “*differential pricing*” (DP) in terms of technical, economic and legal considerations, in order to investigate possible benefits from improved cross-country policy coordination in the area of pharmaceutical pricing. EPR is applied widely in Europe – according to the report, in 2015, apart from Germany, Sweden and the UK, all EU Member States and Iceland, Norway, Switzerland and Turkey set the prices of some medicines based on comparisons with other markets.

“Differential pricing” (DP), on the other hand, involves charging different customers different prices for the same product, i.e. setting the price of medicines according to ability to pay or the economic situation of the countries concerned. This is widely used at the global level, to enable access to drugs such as those for HIV/AIDS, malaria, and TB, as well as vaccines in low-income countries. There is however no experience of implementing such a policy in relatively high-income countries, while in the EU, with its single market, there are particular challenges related to parallel trade whereby a product placed on the market at a low price in one country can easily be exported to another.

The study entailed simulations of approaches to EPR using econometric modelling, illustrating the savings that could be generated for payers if EPR was applied in an appropriate manner. By publishing the details of the models and the assumptions underpinning them, interested parties could engage in detail with the process. The contractor was asked to engage with these interested parties, with the approach specified including interaction with a minimum of 20 stakeholders, one face to face stakeholder meeting, and collection of comments from stakeholders in writing (a written review). In line with the Tender Specifications of the study on ‘Enhanced cross-country coordination in the area of pharmaceutical product pricing’, the stakeholder review had to be “*open to participation of EU-level representatives from patients, public payers and medical industry*” (Gesundheit_Österreich_Forschung-_und_Planungs_GmbH, 2016).

The consultation

Based on experience with a previous, similar study (Vogler et al., 2014), the consultants proposed to extend the stakeholder groups invited to participate to include consumers, competent authorities for pricing and reimbursement, and healthcare professionals, especially doctors and pharmacists. On the manufacturing side, industry was represented by a variety of groups including the research-based pharmaceutical industry (also including the biotech industry), generics and biosimilar manufacturers, and producers of medicines for self-medication. Medical devices were beyond the scope of the consultation since the study targeted only pricing policies for medicines, not health technology.

The consultants were required to engage with up to 60 stakeholders for the written review (as set out in the Tender Specifications), so it would not be sufficient to engage with only the pan-European organisations. Consequently, some other stakeholders from Member States were also invited. However, the European associations were able to nominate these other stakeholders. The consultant's rationale for proposing this approach was that this had been done with the Working Groups for the Platform "Access to Medicines in Europe" under the Process on Corporate Social Responsibility in the Field of Pharmaceuticals.

The consultant applied a differentiated approach for the written review and the stakeholder review meeting: to allow for a constructive and comprehensive dialogue during the meeting, the number of participants in the meeting was limited to around 25 stakeholders, whereas the remaining stakeholders would have the possibility to comment in writing. For the written review, participants were invited to provide their feedback in a "feedback template", divided into "general comments" and "specific comments" relating to specific paragraphs of the draft report.

The principle of "one institution - one voice/representative" was applied. As a result, only one coordinated response per institution was accepted in the written stakeholder review, either a European association or national stakeholder organisation.

In line with these principles, the consultant proposed a list of stakeholders to be invited for the stakeholder review meeting. The consultant discussed this list of stakeholders with the European Commission at the kick-off meeting in Brussels in December 2014. In principle, the

list was accepted, and it was expanded with further suggestions from the European Commission.

In the stakeholder meeting, the presentation of the key findings and results was accompanied by a summary of the written comments submitted thus far, which were often contradictory. Following the presentation, some specific questions were discussed. How can EPR be improved in order to increase access to medicines and improve cost containment? Should a differential pricing scheme be developed in the European Union, and if yes, how to differentiate prices, what limitations should be imposed, and how would it be co-ordinated among Member States?

The meeting was held under Chatham House Rules. Possible ways forward, what was missing from the debate, and proposals for further research were also touched upon in the discussions.

Figure 5-1 Stakeholder consultation in the pharmaceutical pricing case study



Documents submitted to the consultation

The consultants emailed the draft interim report on 10 August 2015 to a total of 51 groups, encompassing 13 stakeholders (associations / interest groups), 32 Member State institutions (pricing authorities), and 6 differential pricing experts (that had been available for interviews).

Prior to the stakeholder meeting, written feedback was received from a total of 23 groups, of which 7 were stakeholders, 16 were institutions from 15 countries, and 2 were differential pricing experts. Written feedback was received between 14 August and 7 September 2015, with formats ranging from 50 page submissions to single paragraphs. Stakeholders providing shorter comments did not use the feedback template. I translated submissions in another language than English (i.e. German) into English and analysed them alongside the others.

Participation in the stakeholder consultation

According to Annex 15 of the published final report, a total of 34 participants attended the stakeholder review meeting held in Brussels on 17 September 2015. In addition to representatives of the European Commission and of the upcoming EU Presidencies (Netherlands, Malta and Slovakia), 11 stakeholder representatives and 11 country representatives (two of them also represented a stakeholder perspective) attended the meeting.

Table 5-1 provides detailed information on the participation in the stakeholder review meeting (Gesundheit_Österreich_Forschung-_und_Planungs_GmbH, 2016). However, I was not able to obtain all written comments (notably, those from the UK, CPME and differential pricing experts were not available). Only those that were accessible were included in the algorithm. These texts are described in Table 5-2. Appendix 3 contains a description of the type of organisations having participated in the stakeholder review process.

Table 5-1 Stakeholder review process – overview of participation and submissions

Stakeholder/Member State	Written comments (between 14 August and 7 September)	Participation in the workshop (17 September 2015)
Association Internationale de la Mutualité (AIM)	✓	✓
Bureau Européen des Unions de Consommateurs (BEUC) and national associations	✓	✓
Health Action International (HAI)	✓	✓
European Patient Forum (EPF) and national associations		✓
European Public Health Alliance (EPHA)	✓	✓
European Federation of Pharmaceutical Industries and Associations (EFPIA) and national associations	✓	✓
European generic and biosimilar medicines Association (EGA) and national associations	✓	✓
European Association for Bioindustries (EUROPABIO)		
Association Européenne des Spécialités Pharmaceutiques Grand Public (AESGP)		✓
AmGen	✓	
GAVI	✓	
WHO	✓	
European Social Insurance Platform (ESIP)		✓

Table 5-1 Stakeholder review process – overview of participation and submissions

(continued)

Stakeholder/Member State	Written comments (between 14 August and 7 September)	Participation in the workshop (17 September 2015)
European Association of Hospital Pharmacists (EAHP)		✓
Comité permanent des médecins européens (CPME) & n. assoc.	✓	✓
Euripid		✓
Austria		
Belgium		✓
Bulgaria		
Croatia	✓	
Cyprus		
Czech Republic		✓
Denmark		
Estonia		
Finland	✓	
France		✓
Germany	✓	✓
Greece		✓
Hungary	✓	✓
Iceland		
Ireland	✓	
Italy		
Latvia		✓
Lithuania	✓	
Luxemburg		
Malta	✓	✓
The Netherlands		✓
Norway	✓	
Poland		
Portugal		
Romania		
Slovakia	✓	✓
Slovenia	✓	
Spain	✓	✓
Sweden	✓	
Switzerland	✓	
Turkey	✓	
United Kingdom	✓	
DP experts	✓	

The Dutch representative also represented ESIP and the Hungarian representative also represented EURIPID (international database of pharmaceutical pricing hosted by the National Health Insurance Fund OEP Hungary).

The consultation

The consultation on the technical study ran from August to October 2015 and there were 24 non-identical submissions, with the exception of the differential pricing contributions from experts. Some submissions took the form of text in emails and some were submissions using the template. I combined them for each stakeholder when both forms were used, collated the contributions, and assigned the aggregated text to the same stakeholder group. For example, GAVI (Global Alliance for Vaccines and Immunization) submitted an email and a review template, which I combined into one text submission. To these 24 texts I added the stakeholder review report as published (Gesundheit_Österreich_Forschung_und_Planungs_GmbH, 2016) bringing the total to 25 texts. I also added the executive summary of the study before the consultation and after the consultation, bringing the total to 27 texts.

Submissions were clustered according to industry, government, or public health sources (Table 5-2). This yielded 5 from industry (including contributions from the social health insurance payers), 5 public health submissions and 14 government agency contributions, with the two executive summaries and the stakeholder review report being labelled as neutral and independent. The submissions from EFPIA (European Federation of Pharmaceutical Industries and Associations) and EGA (European Generic and Biosimilar Medicines Association) were used to represent the corporate/ industry end of the scale, whilst BEUC (Bureau Européen des Unions de Consommateurs, an umbrella consumers organisation) and HAI (Health Action International, a NGO campaigning for access to essential medicines) submissions were used as the public health end of the continuum. All four of these stakeholder groups submitted review templates, ensuring good coverage of concepts and a detailed text submission, meeting the basic pre-requisites for being selected as a reference text under the STATA algorithm Wordscores.

Table 5-2 *Format of submission by stakeholder group and cluster*

Stakeholder group	Stakeholder cluster	Format of submission
AIM	Industry	Email
AmGen	Industry	Review Template
EFPIA	Industry	Review Template
EGA	Industry	Review Template
DE AOK	Industry	Email (in German)
HAI	Public health/ Advocacy	Review Template
BEUC	Public health/ Advocacy	Review Template
EPHA	Public health/ Advocacy	Email
GAVI	Public health/ Advocacy	Email combined with review template
WHO	Public health/ Advocacy	Review Template
DE BMG (Ministry of Health)	Government Agency	Email (in German)
BE	Government Agency	Email
CH	Government Agency	Review Template
IE	Government Agency	Review Template
FI	Government Agency	Email
HR	Government Agency	Email
ES	Government Agency	Review Template
LT	Government Agency	Email
HU	Government Agency	Review template
SK	Government Agency	Review template
MT	Government Agency	Review template
SE	Government Agency	Review template
NO	Government Agency	Email
TK	Government Agency	Review template

I ran Jfreq and the Wordscores algorithm in STATA for the 27 text files in the written consultation. In parallel, I worked on a logbook, as presented in the Manual in Appendix 4. This Manual was pilot-tested and validated, and represents a stand-alone deliverable from this thesis.

As described previously, the scaling algorithm Wordscores has been used before in automatic content analysis research on health policy (Costa et al, Stuckler et al, Laver, Benoit and Gary, etc). Wordscores infers policy positions in new documents – so-called virgin texts – by calculating scores for these documents based on the scores of reference texts. Scores are derived from the frequency of words in a document relative to the total number of words.

First, I converted documents from portable document format to more manageable text files. Then I manually removed superfluous information i.e. names of interest groups, headers and

footers, contact details and citations. I then created a frequency matrix using the programme Jfreq in R, which estimated the frequency distribution of words across documents, reduced words to their roots and removed stop words, numbers and symbols.

The Martin-Vanberg Transformation

MV (the Martin-Vanberg) transformation compensates for the tendency of non-discriminating words to pull scores towards the middle of the scale, making the alignment less visible and clear. 95% confidence intervals based on standard deviations in score frequencies across documents are calculated. Then, I compare the score of the document before and after the consultation: for this I use the Executive Summary of the study as using the entire report would be too cumbersome and would not provide any meaningful results.

For the MV transformation, I selected the BEUC paper as the anchor to calculate the standard unit, as it had the lowest raw STATA-calculated score. Then I chose the EGA paper as the upper MV transformation anchor, as it had the highest STATA-calculated score.

The production of the Guide

The step-by-step guide in the Manual (Appendix 4) traces the different steps undertaken during the data sanitation and analysis stage. The following paragraphs describe the steps taken to carry out the data sanitation for this particular case study.

First, I converted the PDF/ Word text files into simpler text format (extension “.txt”), translated the texts from other languages into English⁶ and classified each text according to email or template submission. For the GAVI text (where there was email text as well as a template submission), I combined the two into one single .txt document.

Next, I removed all text pertaining to the template i.e. the template headings (“Chapter”, “Comment”, “Suggested Change”), the title of the study, interest group names, headers and footers, contact details, address formulae (“Dear”) and citations; I further removed the email subject phrase “*draft report for written review*”. Individual page numbers and chapters quoted in the templates are furthermore removed. Bibliographic references are kept in, as the bibliography that stakeholders choose to quote reveals their interests. Links in references

⁶ The translation process is important. In an ideal case, the translation would be conducted “blind” by someone who does not know the main distinctions driving the research.

(e.g. for BEUC) are kept. I corrected any typos. I treated the words “pharma”/ “pharmaceutical” as synonymous.

At first, I ran Jfreq with no pre-processing. After inspection and initial analysis, I established that it was more beneficial to tick all pre-processing options (no numbers or no currency, no stop-words in all files, no capitals). This proved more useful as there are fewer columns with unique word roots in the final results. Jfreq is extremely useful to detect errors in the sanitation of the data (spacing problems, words lumped together, etc). Then I ran the Wordscores algorithm in STATA.

To ascertain whether there was any change between the draft and final reports, I included the executive summaries of the documents pre- and post- consultation, re-running both Jfreq and STATA Wordscores. I considered including the entire report pre- and post-consultation but this was too complex for this case study.

Lastly, once the STATA Wordscores results were obtained, I proceeded to validate the findings by calculating the MV score using Excel to calculate the MV standard error and the 95% confidence interval. I undertook a sensitivity analysis, performed robustness checks, and plotted the results, including confidence intervals, in a graph. Finally, I proceeded to interpret the results.

Results

Main Issues and Limitations Identified with EPR and Differential Pricing

EPR is widely used in Europe – all EU Member States except for Germany, Sweden and the UK, and other countries such as Switzerland, Iceland, Norway and Turkey use comparisons with other markets to set the prices of the drugs prescribed, administered in hospital or available over-the-counter in their individual jurisdictions. The report notes that although German law allows EPR to play a role in the pricing of new medicines, *“it is claimed that EPR is not applied in the follow-up procedure”* (Gesundheit_Österreich_Forschung_und_Planungs_GmbH, 2016). Similarly, EPR is only used in Denmark in support of pricing in the hospital sector. A literature review undertaken as part of the study concluded that EPR could generate significant savings for public payers – however the extent of savings largely depended on the type of EPR applied. Surveys conducted as part of the study found that 20 of the 29 countries using EPR employ it as the sole or main pricing policy, with the number of

reference countries included in the basket varying from one (in Luxembourg) to 30 (in Poland and Hungary). Also, several Member States do not seem to perform regular (i.e. bi-annually, annually or at other defined time intervals) price re-evaluations, even if provided for in their legislation. Re-evaluations carried out more frequently could generate more savings for payers.

Some of the limitations of EPR include hidden discounts (whereby the manufacturers offer large discounts on the published prices to governments and other payers, so as to obscure the data on which EPR is based), delays in re-evaluations, and problems arising from parallel trade. There are two kinds of discounts: statutory manufacturer discounts and confidential discounts (e.g. rebates or other similar financial arrangements). Currently, the data that are exchanged are the undiscounted prices and the true prices paid are treated as commercially confidential. Delayed re-evaluations of comparative prices (even if provided for in legislation) create inertia with respect to real prices. Parallel trade, on the other hand, consists of the illegal import of indications of drugs from low-priced countries to high-priced countries.

Importantly, EPR has been fiercely criticised for incentivising the pharmaceutical industry to first launch in higher-priced countries and delay or even to forego entering the market in lower-priced countries.

These factors have led to endemic high prices and drug shortages (particularly in the Visegrad countries of Central and Eastern Europe) and in small markets (e.g. Luxembourg).

Some of the limitations of Differential Pricing include the appropriate starting price, as well as the identification of a maximum and minimum entry price threshold for each drug under consideration. Whilst Differential Pricing schemes have not been applied in high-income countries, such mechanisms would require economic indicators such as purchasing power parities and gross domestic product to be taken into account. The introduction of such a scheme would need significant political will.

Nature of Comments Received

As discussed in Annex 15 of the published study report (Gesundheit_Österreich_Forschung_und_Planungs_GmbH, 2016), responses to the draft report differed greatly among the various categories of stakeholders. Since Member States' representatives had already been involved in the survey of existing EPR systems, they saw the sharing of the interim study

report as a chance to validate the information about their country. Comments submitted by stakeholder associations not representing Member States, by contrast, were not country specific but more general in nature. The extreme manifestation of this phenomenon entailed comments so general and vague that they did not even refer to the draft report, but were general statements related to EPR, differential pricing and/or pharmaceutical policies, reflecting their organisation's positions on the matter.

The study had aimed, primarily, to initiate a reflection about improvements to EPR and exploring alternative pricing possibilities, including differential pricing in a "pedagogic exercise" to raise awareness and understanding of the latter concept. Stakeholders and Member States alike welcomed the critical discussion about the limitations of EPR that had resulted from the production of this report. Several comments thus concerned the limitations of EPR that were generally acknowledged by both stakeholders and Member States.

The different parts of the report were addressed in varying degrees. Most comments related to the validation of the country-specific information about EPR. For the remaining non-country specific information, considerably more comments referred to the EPR section than to the differential pricing section. One stakeholder critically addressed the methodology of the simulations, proposing to run a dynamic instead of a static model. The legal analysis part of the report (annex 13 of the published report) elicited no comments.

Several comments referred to the role of EPR within the spectrum of available policy options for cost-containment using price setting. Stakeholders', but also, to a lesser extent, Member States' comments stressed that EPR should not be employed in isolation, as a single tool, but only with other pricing policies. Furthermore, pricing is only one lever to ensure equitable access to medicines while containing costs. One stakeholder addressed the scope of this policy, stating that EPR should not be used for generics. It was suggested that the non-availability of medicines should be further highlighted. One stakeholder recommended considering it in the simulations, in connection with the disclosure of discounts.

Transparency

The most contested issue was transparency. One stakeholder stated that price information, in particular discounts, rebates, and managed-entry agreements, should remain confidential, as this was understood as part of the business. Other stakeholders and, especially, Member

States, expressed a preference for (full) disclosure of these price reductions. While there were polarised views between commenters about confidentiality, the proposal of the study authors to consider at least published mandatory discounts in EPR was addressed by only one stakeholder. This proposal was challenged since mandatory discounts were seen as a temporary measure only.

Possible Improvements

Proposals for improvements also attracted a host of comments. The first proposal was to establish an extended price database. This was the part of the report that attracted most comments. Member States confirmed the value of the existing pricing database, Euripid, as a resource for undertaking EPR (Council of Ministers, 2015). Stakeholders who did not have access to the Euripid database expressed reservations about its methodological limitations.

Some commentators objected to the database containing price data calculated on average margins (e.g. ex-factory prices based on average wholesale margins). Furthermore, Member States and several other commentators again broached the issue of confidential discounted prices, and advocated the inclusion of statutory discounts in a price database. Stakeholders without access to the Euripid database called for a price database that was open either to all stakeholders or at least to industry, allowing cross-checking if prices listed in Euripid.

Only a few comments discussed a coordinated EPR formula and no explicit written comments were made with regard to regular price monitoring. Generally speaking, the proposal of weighting prices by the income / wealth of the countries was welcomed by several commenters, both stakeholders and Member States representatives.

Parallel Trade and Differential Pricing

An industry representative felt that the issue of parallel trade was not sufficiently explicitly addressed by the study. Similarly, one industry stakeholder challenged the definition of “*differential pricing*” that was deployed in the study. In line with the Tender Specifications, the study elaborated on differential pricing as a coordination measure applied by governments, and did not consider “*Ramsey pricing*” or in other words, price differentiation applied by the seller with respect to line of business (upmarket versus downmarket), as a function of price elasticity of demand. The more inelastic the demand for a particular product, the more a seller may price the product upmarket as opposed to downmarket. Put more

simply, Ramsey pricing is where a seller who has a monopoly adds the greatest price mark up to products where demand is price inelastic as people will buy the product anyway. The stakeholder who insisted on “*Ramsey pricing*” would have preferred further assessment of the scale and nature of contemporary price differentiation deployed by industry in confidential discounts to different public payers. Another stakeholder expressed concern that differential pricing could run the risk of being employed as a commercial strategy, allowing the pharmaceutical industry to maximise the bottom line rather than to pursue the greater good.

Some commenters (both stakeholders and Member States) expressed concern about the feasibility of a differential pricing scheme in Europe and severe doubt as to sufficient *political will* favouring such a scheme.

Voices from the consumers/ patient advocacy side confirmed findings of the literature reported in the study that other instruments, in particular generic competition, might be more effective to secure cost-containment and long-term access to medicines.

Consideration was given to the appropriate price to start with in a differential pricing scheme. One stakeholder challenged the proposal made in the interim report to design the differential pricing model in such a way that higher-income countries would not pay more with such a scheme than without it. One stakeholder expressed concern that the Member States might be under pressure to reimburse a differentially priced product. It was ultimately suggested to draw conclusions from literature related to risks and benefits of donations.

The above discussion and preliminary observations reflected the different power dynamics between stakeholders and Member States. One participant from an international organisation considered Member States in their current role as “*price takers*”, whilst industry referred to the authorities as “*price setters*”. Certain voices raised legitimate questions about how to establish a “*fair*” EPR and differential pricing scheme, i.e. what is a “*fair price*” for all and last but not least, about the cost of research and specifically who should shoulder the latter, i.e. manufacturers or public payers.

Summary of the positions of industry, governments and the public health community

All in all, the study only zoomed in on two of the three objectives as defined in European processes such as the Pharmaceutical Forum, i.e. access to equitable medicines and cost-containment/financial sustainability. The industry representatives were very much of the view that the objective of reward for innovation should also be taken into consideration. The government representatives had much more neutral views and corrected factual statements in particular, whereas the public health community took up the patient perspective and advocated for generic competition, a broader access and a more equitable price structure without launch delays for high-cost medicines and orphan drugs. Before discussing the main results, trends and key figures, it is worth pointing out that a more refined analysis could be done by operationalising market size, as this is a crucial factor to consider, driving the pharmaceutical industry's structure. This is however beyond the scope of this present analysis.

STATA and Jfreq analyses

In this section, we examine in-depth the word scores of the texts submitted by the different clusters of stakeholders: the industry versus the government versus the public health advocacy groups. Later on, we examine the movement of the neutral text (in this case, the executive summary of the report submitted for consultation) and its original starting point, as measured by the Wordscores algorithm.

Table 5-3 shows the word count and word scores (raw score, LBG score, MV score) of a selection of texts from the industry and advocacy camps. To recall, AIM is the International Association of Mutual Insurers, whilst AOK is one of the largest statutory health insurers in Germany. EGA is the European Generic and Biosimilar Medicines Association, EFPIA is the European Federation of Pharmaceutical Industries and Associations and Amgen is one of the world's leading biotechnology companies. BEUC is the European Office of Consumer Organisations, HAI is Health Action International and EPHA is the European Public Health Alliance.

Positions of stakeholders having similar interests (e.g. EGA, EFPIA, Amgen, AIM and AOK on the one hand and HAI, BEUC, EPHA and WHO on the other) translate into scores with very

similar values. As illustrated in the table, the industry cluster has adjacent raw scores based on the Wordscores algorithm in STATA with values converging around 0.66 values whereas the advocacy cluster has visibly lower raw score values converging around 0.35.

Table 5-3 Comparative Analysis of Scores of Stakeholder clusters

Stakeholder	Word count	Unique words scored	Raw score	LBG score	MV score
<i>Industry</i>					
EGA	1275	499	0.6987	1.7807	1
EFPIA	12,855	2482	0.6576	1.4885	0.8999
Amgen	5367	1223	0.63736	1.1678	0.7902
AIM	162	93	0.66934	0.7245	0.6385
AOK	588	225	0.66332	0.4256	0.5361
<i>Advocacy</i>					
BEUC	479	264	0.2878	-1.1416	0
HAI	2088	737	0.356	-0.6564	0.1659
EPHA	286	141	0.54547	0.0198	0.3974
WHO	238	125	0.62397	0.4775	0.5539

When Laver-Benoit-Garry (LBG) scores are considered (also calculated via the Wordscores algorithm in STATA), the order and positioning is conserved, except for the value of the WHO submission, which is slightly higher under this method than the AOK value. The same can be observed if MV scores are compared, with the WHO value jumping into the “industry” cluster and surpassing by a few hundredths decimal points the AOK MV transformed value. Overall, however, it is clear that the industry cluster has higher average scores under any of the three methods than the average score of the public health advocacy cluster.

The results obtained via Jfreq show the following key trends for truncated words:

- The longest submissions featured the highest use of the stop word/article “the” (Amgen, EFPIA, the summary report, HAI, etc);
- “Pharmaceutical” was used mostly by the longest submissions (EFPIA, Amgen, HAI, etc);
- “equitable” was used most frequently by the report of the stakeholder review, by HAI and once by EFPIA and by Amgen (indicating that the industry mimics and also adopts the language of the opponents);
- “discounts” the same as above, plus by IE and BE;
- “spend” used by EFPIA and Amgen and once by HAI;

- “negoti” used notably by Amgen, EFPIA and to a lesser extent by HAI and by the report;
- “agreement” used mostly by EFPIA and Amgen.

In the post-consultation summary, DE is reported as not applying EPR, with the added sentence: *“In Germany, though the law provides for prices in other countries to be considered as an additional piece of information in pricing of new medicines, it is claimed that EPR is not applied in the follow-up procedure”*.

Similarly, at the top of page 2, the following sentence was added in the post-consultation version: *“Germany, though not applying EPR, specified in its law that discounted prices are to be reported by the manufacturers”*.

One further sentence was added post-consultation: *“There are lost opportunities due to discounts, rebates and similar arrangements in the reference countries that are not considered in EPR”*.

Legal restraints to join a centralised database of Member State price data were also added e.g. *“no possibility to share the price data of the own country due to a lack of ownership”*;

- *“it is recommended adding an indication in the price database of whether, or not, discounts are applicable to that product”* changed into *“have been granted to that product”*;
- *“EPR could generate higher savings for public payers if the price comparisons were done at the level of real prices paid by payers (discounted prices) instead of list prices”* was turned into *“EPR could provide lower prices if...”*;
- Sentence added: *“to impact the differentiation of prices between countries along the lines of ability-to-pay”* (and thus improve access to medicines);
- *“medicines as such are no exception to the free mobility of goods in the internal market”* was added to the parallel trade paragraph; no ECJ ruling exists to date *“although the effects of parallel trade on health and safe access to medicines remain a matter of strong controversy”* added;
- Sentence added: *“The exact impacts of a possible differential pricing scheme within the European market are still unclear”*;

- Sentence added: *“It is recommended using fora, such as the stakeholder review meeting of this project, to openly discuss strategies among stakeholders on how to deal with new high-cost medicines.”*

In conclusion, the industry cluster tended to use words such as “agreement”, “negotiation” and “spend” more often than the public health advocacy and government clusters based on a certain framing of the discourse around reward for innovation. The rhetoric therefore focused on negotiation strategies and maintaining profit margins. By way of contrast, value-based concepts such as “equitable” tended to be used rather more by the public health advocacy groups.

Changes between the draft and final report

In this section, I examine whether there was a shift in the neutral text (the executive summary of the report submitted for consultation) from its starting point, as measured by the Wordscores algorithm.

As illustrated in Table 5-4, following the consultation, the score of the executive summary is marginally closer to the industry cluster than to the scores of the advocacy cluster (moving upwards from a value of 0.58277 to 0.58796) and its word count, as well as unique word count increases (the word count augments from 2260 to 2432 words and the unique word count from 599 to 627). This observation is valid under each of the three methods: the raw score, the LBG score and the MV score. Post-consultation, scores marginally increase in the direction of the industry scores. The report of the stakeholder review has word counts and scores similar or comparable to the executive summaries.

Table 5-4 Comparative Analysis of the Review Report and its Executive Summaries

Stakeholder or version of report	Word count	Unique words scored	Raw score	LBG score	MV score
<i>Industry</i>					
EGA	1275	499	0.6987	1.7807	1
EFPIA	12,855	2482	0.6576	1.4885	0.8999
<i>Neutral</i>					
Pre-consult (Exec Summary)	2260	599	0.58277	0.6371	0.60866
Post-consult publication (Exec Summary)	2432	627	0.58796	0.6669	0.61888
Report of the stakeholder review	2717	579	0.59511	0.4472	0.54368
<i>Advocacy</i>					
BEUC	479	264	0.2878	-1.1416	0
HAI	2088	737	0.356	-0.6564	0.1659

Based on Annex 15 of the published report, the main issues raised during the written stakeholder review by various actors were also mentioned during the meeting:

- Limitations of EPR were stressed.
- It was repeated that prices are not the only component of pharmaceutical policies.
- The issue of “layered transparency” emerged: the idea that different levels of transparency with regard to different target groups might be in place.
- The definition of “differential pricing” (the definition of a government-fledged differential pricing system) was challenged. The difficulties related to defining a starting price or a minimum/ maximum threshold were discussed.
- The scope of EPR policies was touched upon (one stakeholder repeated that EPR should not be used for generics, but rather for other types of pharmaceuticals).
- The crucial role of political will as a prerequisite for starting a new pricing policy such as differential pricing was highlighted.
- Stakeholders asked the consultant to elaborate on the industry perspective in general and the objective of reward for innovation.
- The importance of other tools and policies was stressed, especially compulsory licensing as well as policies regarding generics. The importance of horizon scanning and health technology assessment was also highlighted.

Continuing in this vein, the following suggestions were made by different stakeholders during the stakeholder review meeting:

- Citizens and consumers should be increasingly involved in the pharmaceutical pricing debate;
- Improving the capacity of procurers to negotiate and to become *price setters* (capacity building);
- Policy-makers should define what the health care system is willing, and can afford, to pay, and should then communicate this to industry (thus moving from an offer-based to a demand-based system);
- New ways of financing;
- Moving the focus away from medicine prices to a more comprehensive consideration of the treatments at hand;
- Investigating parallel trade related to medicines;
- Considering also the impact of pricing policies on the distribution part of the chain (wholesale and pharmacies);
- Collaboration between countries beyond pricing issues;
- It was suggested to launch research projects and practical pilots on the methodology for defining a “*fair*” price;
- An independent review on the cost of research was requested, to foster better understanding of the topic.

Reaching beyond the scope of the study, the following topics emerged during the stakeholder meeting:

- The importance of managed-entry agreements for certain pharmaceuticals (especially for orphan drugs), as an appropriate policy option to address current challenges, however limited capacity in many countries in this respect was identified;
- Increased pressure from the public about novel treatments could have an impact on technical assessments;

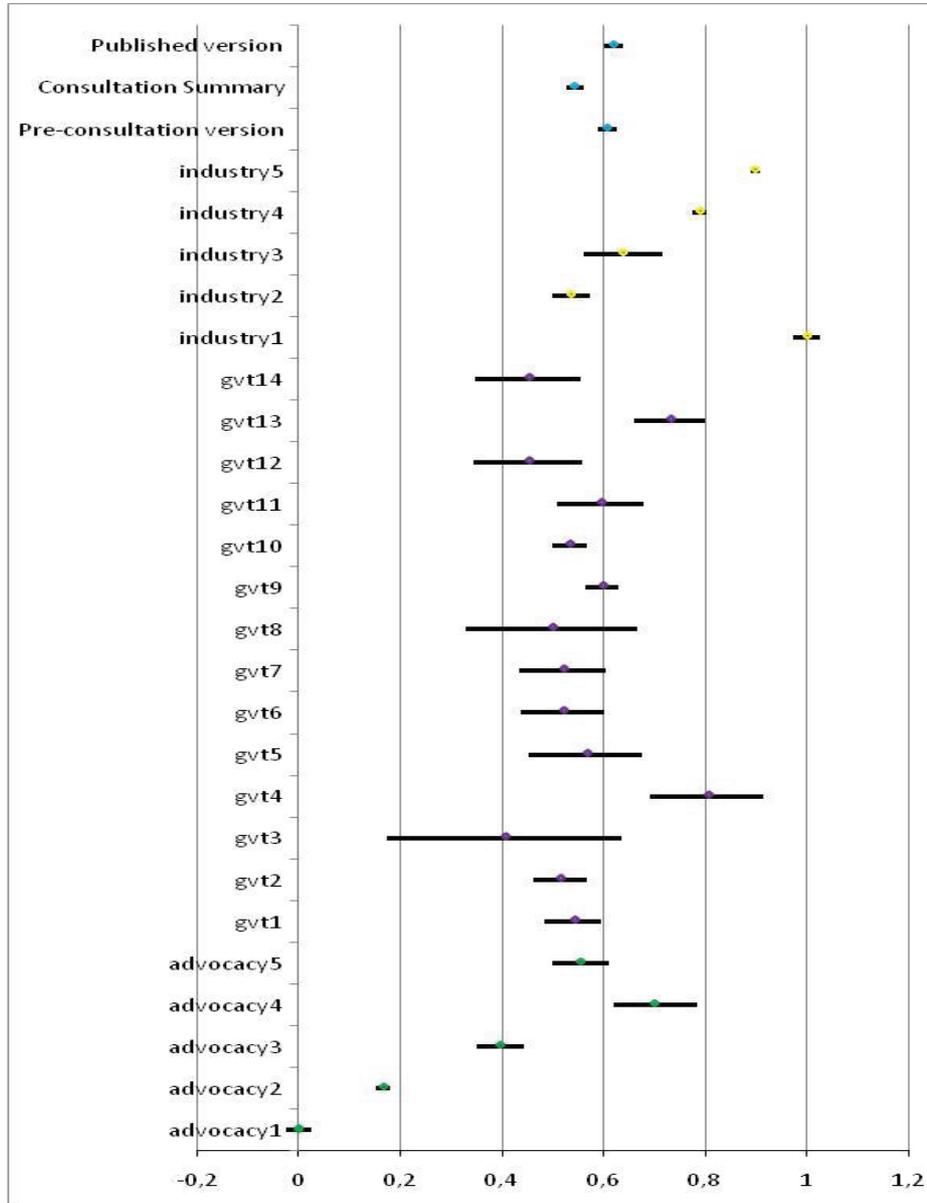
- Although limitations of EPR and differential pricing were revealed and discussed during the debate, these policies should not be stopped but adapted in a way that the ideas and elements could evolve in the future.

In conclusion, this section served to illustrate that following the written review and the stakeholder consultation meeting, there was indeed a shift in the neutral text (the executive summary of the report submitted for consultation) from its starting point, as measured by the Wordscores algorithm. The qualitative corpus analysis above also showed that the executive summary changed and very marginally reflected more of the concepts brought forward by stakeholders representing the industry. The next section in this chapter will plot the Martin-Vanberg scores and develop summary measures per cluster of stakeholders to crystallise results.

Plotting stakeholder positions based on MV scores to improve stakeholder analysis

Figure 5-2 shows a plot of Martin-Vanberg scores and their corresponding 95% confidence intervals for all the texts in the consultation and demonstrates that, when looked at in aggregate, the advocacy scores (namely, advocacy 1 to advocacy 5) are all aligned to the left of the industry scores (industry 1 to industry 5), with the governmental agencies' scores (gvt1 to gvt14) anchored in the middle of the spectrum. The published version of the study's executive summary (plotted as "published version" in Figure 5-2) is only marginally to the right of the pre-consultation version, with the consultation summary anchored in the middle ground, equally distant from the scores of the reference texts, namely 0 and respectively 1. While the change is extremely small, the executive summary does shift marginally to the right. This is further explored in the Discussion chapter at the end of this thesis.

Figure 5-2 Plotting stakeholder positions based on MV scores



As is visible in the colour-coded Figure 5-2 above, each stakeholder group translates into scores that are close to each other – the advocacy texts have scores plotted in green with corresponding confidence intervals, the governmental agencies have scores plotted in purple with corresponding whiskers for 95% confidence intervals and industry texts feature scores depicted in yellow. The neutral texts (the executive summary pre- and post-

consultation and the consultation summary) are plotted in blue. Figure 5-3 below renders the stakeholder clustering analysis easier to interpret by calculating summary measures across the 5 advocacy texts (“Advocacy Summary Measure”), across the 14 governmental agency texts (“Government Summary Measure”) and across the 5 industry texts (“Industry Summary Measure”).

Figure 5-3 *Plotting stakeholder positions based on MV scores (summary measures)*



In figure 5-3 above, the green triangle represents the summary measure of MV scores for that stakeholder category or neutral text, the red square represents the lower limit of the 95% confidence interval and the blue diamond the upper limit of the same confidence interval. Hence, the green triangle is always at the half-way point between the red square and the blue diamond. The figure illustrates that the advocacy summary measure just undercuts the 0.4

score, the government summary measure the 0.6 value and the industry the 0.8 score. Moreover, the consultation report giving an overview is anchored around the 0.5 mark, whereas the pre-consultation version of the executive summary is slightly above 0.6 with the post-consultation version marginally, yet visibly towards the 0.7 value. This effectively means that the post-consultation version moved in the direction of the industry scores, rather than being pulled into the direction of the much lower advocacy scores. The implications of the results above will be teased out in the Discussion chapter later in the thesis.

Last but not least, stakeholders from different categories expressed an interest to continue the multi-stakeholder dialogue as done in the stakeholder review meeting – the meeting on 17 September 2015 was seen as a step in the right direction for enhancing dialogue and coordination. Indeed, in line with these requests, a further multi-stakeholder dialogue meeting took place on 26 February 2016 to disseminate the results of the pharmaceutical pricing study to the consulted parties.

Chapter 6. Acrylamide

The issue

Acrylamide is a carcinogenic contaminant found in food items such as potato chips, crisps and soluble coffee. It is produced when ingredients containing starch and other complex polysaccharides are cooked at above 120°. It has attracted considerable attention in recent years as, although it was well known as an occupational hazard in the chemical industry, its significance as a potentially toxic food ingredient was not understood until some 15 years ago. It has assumed importance now because of the growth in industrial food processing.

Jorgen Schlundt, World Health Organization (WHO) coordinator of food safety research, suggests that it could have similar effects to heterocyclic amines which have been shown to cause cancer in animal studies. However, little is known about potential health risks in humans but, if found to be harmful at levels currently found in food, this is likely to have a significant impact on the food industry as a whole: if safety thresholds for food are defined then, under EU legislation, they would have to be noted on food labels and warnings may also be necessary. This could have a large impact on sales and require changes in food processing technologies.

The regulatory process

Over a decade ago, the European Commission issued a Recommendation that acrylamide levels in food should be monitored (European Commission, 2007). The European Food Safety Authority (EFSA) in Parma was given responsibility for compiling the results of the monitoring. A second Commission Recommendation (European Commission, 2010), adopted in January 2011, requested Member States to carry out checks at the premises of any food operator when monitoring reveals high acrylamide levels in their products. This latter recommendation established *indicative values* – in other words, if an indicative value is exceeded, an investigation should be carried out. However, indicative values are not legal limits and hence there is no requirement for enforcement measures if they are exceeded. Member States were encouraged to report the results to the Commission. On the basis of the information gathered, the Commission determined that there was a need for a new assessment as to whether further measures were required to reduce the presence of acrylamide in food. As a

result, the Commission asked the EFSA to undertake a comprehensive assessment of the risks associated with acrylamide in food products.

The draft Scientific Opinion issued by the EFSA on 15 May 2014 was subject to a public consultation prior to its final adoption by the EFSA Panel on Contaminants on the Food Chain (the CONTAM Panel). The consultation was web-based and lasted 10 weeks and ran between 1 July 2014 and 15 September 2014. It was very limited in its scope, considering only the identification and characterisation of any hazard, and specifically any toxicity or carcinogenicity, drawing on evidence from studies carried out on humans and animals. It did not propose any regulations, did not address whether there should be binding or non-binding maximum levels of acrylamide in food, and did not call for more stringent controls. Nor did it seek to quantify any health impact at population level or possible mitigation measures. In its technical report of the public consultation, EFSA states that questions related to the evaluation of remedial action fall squarely under the remit of the European Commission (European Food Safety Authority, 2015).

Even before the EFSA Scientific Opinion was published in its final form, however, the Commission had adopted a further Recommendation 2013/647/EU on investigations into levels of acrylamide in food (European Commission, 2013). That Recommendation endorsed the existing monitoring system, but in a more targeted manner, and with a review of the indicative levels used to select manufacturers for inspections. The industry had also acted, developing a toolbox designed to facilitate control and reduction of acrylamide in food, since updated several times (Food Drink Europe, 2014). In 2014, the Commission organised a workshop on acrylamide at which relevant industry sectors were asked to present in detail how the FDE-toolbox was being implemented in the production process. Consumer organisations were also asked to present their initiatives to make consumers aware of the importance of good cooking practices to keep acrylamide levels in home-prepared foods to a minimum (European Commission, 2014b). The Toolbox is an example of self-regulation intended to curtail the introduction of more stringent regulatory measures at EU-level.

The documents

Twenty-three parties submitted comments (European Food Safety Authority, 2015), from academia, industry and industry associations, national agencies/ authorities, and other

organisations and individuals in a private capacity. Only 17 could be identified; there were six submissions whose source could not be ascertained and which were impossible to assign to any single entity. This reflected the reporting format of the contributions in the Technical Report (i.e. by chapter of consultation and not in their totality).

The respondents are presented in Table 6-1, clustered in two groups. The first includes the food industry and associated bodies and the second includes public health bodies. Potential linkages between the actors are shown in appendix 3. The process yielded 120 comments.

Some submissions took the form of abstract feedback only, whilst others were more comprehensive as the authors had submitted comments under different sections of the consultation. I combined all those from the same stakeholder and excluded chapter-based anonymous submissions, as it was impossible to assign them a) an identity and b) a specific stakeholder position.

I added the draft scientific opinion, the final scientific opinion and the stakeholder review report containing a brief summary of the comments received and an explanation of how they were addressed by the Panel on Contaminants in the Food Chain (CONTAM Panel) to the 17 texts sent in by the 17 identified parties, increasing the total to 20 texts. Unlike in the previous case study which represented a pilot for the other case studies, the full texts of the scientific opinions were more representative than their executive summaries and were therefore used in their full length.

The analysed texts represented 9 industry texts including those from innovation-oriented companies, 7 public health contributions (PH), one was a ghost (anomalous) submission and three texts were neutral or their positions were to be tested. I use the term “anomalous” (or “ghost submission”) to refer to text that is irregular, or deviates significantly from its surrounding context (Guthrie, 2008).

Analysis

I ran **Jfreq** and the **Wordscores** algorithm in STATA for the 20 text files in the consultation (including the draft and the final EFSA scientific opinion and the technical report of the consultation). The scaling algorithm **Wordscores** was used (Costa et al., 2014, Laver et al., 2003). **Wordscores** infers policy positions in new documents – so-called virgin texts – by calculating scores for these documents based on the scores of reference texts. Scores are

derived from the frequency of words in a document relative to the total number of words. Given the polarisation of perspectives between industry and public health, for running Wordscores in STATA I devised a scale using texts from Food Drink Europe and European Coffee Federation as reference texts for industry and Kantonaales Labor Zuerich and the Austrian Public Health Institute as reference texts for public health organisations.

First, I converted documents from portable document format to more manageable text files. In this case, since the submissions were published in the Technical Report annex, I simply had to collate the contributions by author. The template headings were retained (e.g. “Abstract”, “Summary”, “Conclusions and recommendations”). Bibliographic references were retained as the bibliography that stakeholders quote reveals their interests; the links in references were also kept in.

I then created a frequency matrix using the programme Jfreq in R, which estimated the frequency distribution of words across documents, reduced words to their roots and removed capitals, stop words, numbers and symbols. Hence, all pre-processing options were ticked. This proved useful as there are fewer columns with unique word roots in the end. Jfreq is useful to detect errors in sanitation of the data (spacing problems, words lumped together, etc). Typos (although few) were corrected to the extent possible.

I built the MV scores in Excel and presented precision estimates (95% confidence interval) in a box on sensitivity analysis and robustness. However, one of the reference texts for public health, from the Austrian Agency for Health and Food Safety, is comparatively much shorter, which may limit its suitability as reference text. Thus, another algorithm was run in which the industry reference texts were kept constant and the Chilean Food Quality and Safety Agency replaced the Austrian Public Health Institute. This was to have a longer reference text (as measured by a higher word count) with a low STATA raw score. The Chilean Food Quality and Safety Agency fitted these criteria. However, the draft EFSA scientific opinion and the scientific opinion both yielded raw scores lower than each of the public health advocacy reference texts (which was not the case in the previous scenario). Hence this test was dismissed as having low face validity.

I then ran one further iteration, replacing the Chilean Food Quality and Safety Agency submission with that from the Instituto Superiore de Sanita (ISS) while keeping the others

constant. Again, the EFSA draft scientific opinion and the scientific opinion yielded raw scores lower than one of the reference texts (in this case, that of Kantonaes Labor Zuerich). On the same principle as before, this test was dismissed as having low face validity.

A final iteration employed the same algorithm, with the same public health reference texts as in the first attempt (Kantonaes Labor Zuerich and the Austrian Public Health Institute) and for industry – Food Drink Europe and the National Coffee Association US (NCFUS), the latter instead of the European Coffee Federation text. As in the first scenario, these results appeared to have acceptable face validity, with raw scores of the EFSA draft scientific opinion and final scientific opinion marginally higher than those of both public health reference texts. However, the first test was the one adopted as the final iteration did not present any additional advantages over the first and the first appeared to have more face validity based on initial results.

MV (the Martin-Vanberg) transformation compensates for the tendency of non-discriminating words to pull scores towards the middle of the scale, rendering the alignment less visible and clear. I calculated 95% confidence intervals based on standard deviations in score frequencies across documents. Then I compared the score of the EFSA scientific opinion document before and after the consultation. For this point, I used the entire report, not solely the Executive Summary of the scientific opinion as Wordscores allows for this and a variation was sought after the pharmaceutical pricing case study focused only on the Executive Summaries of the draft study report.

The Margin-of-Exposure Model

To interpret the findings, it is necessary to explain something of the Margin-of-Exposure (MoE) concept. This is an internationally established method for the estimation of the potential risk genotoxic and carcinogenic substances pose to human health. This concept underpins EFSA's Scientific Opinion on acrylamide and puts forward a harmonized approach for the risk assessment of substances in food with genotoxic and carcinogenic properties. However, not all stakeholders participating in the public consultation clearly espouse this concept in the wording of their submissions.

According to a recent paper that I translated from German (Andres et al., 2017), the MoE value is a dimensionless number, which describes the ratio of an active dose in which a slight

but measurable adverse effect is observed, and estimates the level of exposure to the substance in question, taking into account different consumption patterns. A critical observation is that in this case, such a ratio is calculated based on data retrieved via animal experiments only. This approach attempts to compare the extent of possible risks posed by different genotoxic carcinogens occurring in foodstuffs. It hinges on the assumption that the course of the risk curve is comparable to the relationship between carcinogenic activity and dose in the different substances.

In line with EFSA's proposition, two parameters can be calculated for the reference values of the active dose on the basis of the animal experiments carried out to date:

- One is the benchmark dose **"BMDL10"** ("benchmark dose-lower confidence limit 10%"), in which the incidence of cancer in a particular tissue is 10% higher. The calculation is based on a mathematical model of the dose-effect relationship and is only useful or possible if sufficient data across different dosages is available. To ensure that the concern about a possible cancer risk is low for humans, a BMDL10-related MoE value should be greater than 10,000 (Andres et al., 2017).
- Another reference value for the active dose, a so-called **"T25"** value can also be determined which indicates the dose which causes cancer in a particular tissue within the life span of 25% of the animals studied. In the calculation, a correction must be made with regard to the spontaneously occurring cancer rate in this tissue. To ensure that the concern about a possible cancer risk is low or negligible for humans, a T25-related MoE value should be greater than 25,000. The lower the MoE value of a given substance is below the above-mentioned value, the greater the health concerns for a cancer risk for humans (Andres et al., 2017).

As shown in table 6-1, the following submissions display unquestionable evidence of adoption of the MoE model: the Chilean Food Quality and Safety Agency; the Joint Submission by the Technical University of Denmark (DTU), the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), and the Swedish National Food Agency (NFA Sweden); Istituto Superiore di Sanita; Kantonalen Labor Zurich; and the Joint submission by the UK Committee on Toxicity (COT) and UK Committee on Carcinogenicity (COC).

Table 6-1 Overview of all textual submissions by stakeholder & neutral texts

Text acronym in STATA	Stakeholder name (acronym)	Raw score in STATA	Wordcount score in STATA	Industry or public health?	Evidence of the Margin of Exposure model being adopted?	Evidence of the industry “toolbox” being referred to	Evidence of the enzyme-based solution “asparaginase” being referred to	Evidence of “yeast” being referred to
AT.txt	Austrian Agency for Health and Food Safety AGES	0.2337	135	PH – Ref. text	No	0	0	0
CHOPRABISCO.txt	The Royal Belgian Association of the Biscuit, Chocolate, Pralines and Confectionary (Choprabisco)	0.3564	197	Industry	No	0	0	0
CL.txt	Chilean Food Quality and Safety Agency (ACHIPIA)	0.3681	1669	PH	Yes	0	0	0
BDSI.txt	Association of the German Confectionary Industry (BDSI)	0.3412	235	Industry	No	1	0	0
DKSE.txt	Joint Submission by the Technical University of Denmark (DTU), the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), and the Swedish National Food Agency (NFA Sweden)	0.3745	554	PH	Yes	0	0	0
ECF.txt	European Coffee Federation	0.7504	1910	Industry – Ref. text	No	1	0	0
EFSADraft.txt	EFSA Draft Scientific Opinion	0.2838	79080	Test	Yes	17	0	0
EFSASciOp.txt	EFSA Final Scientific Opinion	0.2837	88777	Test	Yes	19	3	0
EPPA.txt	European Potato Processors’ Association (EUPPA)	0.3864	189	Industry	No	1	0	0
ES.txt	Spanish National Research Council (CSIC)	0.3406	259	PH	No	0	0	0

Text acronym in STATA	Stakeholder name (acronym)	Raw score in STATA	Wordcount score in STATA	Industry or public health?	Evidence of the Margin of Exposure model being adopted?	Evidence of the industry “toolbox” being referred to	Evidence of the enzyme-based solution “asparaginase” being referred to	Evidence of “yeast” being referred to
FoodDrinkEurope.txt	Food Drink Europe (FDE)	0.7361	3805	Industry – Ref. text	No	3	0	0
FPP.txt	Frozen Potato Products Institute (FPPI)	0.384	466	Industry	No	0	0	0
ISS.txt	Instituto Superiore di Sanita	0.3572	745	PH	Yes	0	0	0
Kantonaes.txt	Kantonaes Labor Zurich	0.2799	2736	PH – Ref. text	Yes	1	3	0
LTDH.txt	LTD H-Group	0.2718	80	Ghost/ snap/ anomalous	N/A	0	0	0
NCFUS.txt	National Coffee Federation/ Association USA (NCA)	0.6215	645	Industry	No	0	0	0
Novozymes.txt	Novozymes A/S	0.3236	337	Industry	No	3	12	0
Renaissance.txt	Renaissance BioScience Corp.	0.3069	370	Industry	No	3	0	18
TechnicalReport.txt*	Technical Report of the Public Consultation	0.3799	13268	Test	Yes	3	3	1
UK.txt	Joint submission by the UK Committee on Toxicity (COT) and UK Committee on Carcinogenicity (COC)	0.3708	1005	PH	Yes	0	0	0

N.B. the Technical Report contained the individual contributions in an annex that was removed from the text of the technical report analysed to avoid duplication.

Results from Jfreq and comparative reading via corpus analysis

- The longest submissions have the highest use of the article “the” (the EFSA Draft Opinion and Final Draft, the Technical report, etc);
- References to the “MOE model” mentioned by DKSE, UK, Kantonaes, CL, ISS as well as by the Technical Report and the draft and final scientific opinion;
- “Toolbox” used by Food Drink Europe, BDSI, ECF, Novozymes, Renaissance as well as by the Technical Report and the draft and final scientific opinion;
- “Asparaginase” was used only by Novozymes, by Kantonaes and by the EFSA Final Scientific Opinion;
- “Yeast” used only by Renaissance, a company that advocates a solution to reduce acrylamide based on yeast replacement and by the Technical Report who picks this notion up in summarising the consultation results;
- “Mitigation” (truncated “mitig”) used notably (4 times) by the Association of the German Confectionary Industry which focuses on the German signal values in order to explore the effectiveness of mitigation measures, but also by CL and EPPA, FoodDrinkEurope, FPPI, Kantonaes (5 times), Novozymes, Renaissance, CHOPRABISCO, Technical Report (22 times) and the draft (14 times) and final Scientific Opinion (19 times);
- “Home” used by Renaissance, Kantonaes, EPPA, CL and the EFSA draft and final scientific opinion as well as the Technical Report;
- “Elimination” (truncated “elimin”) used by the Technical Report, the draft and final scientific opinion as well as by Renaissance and Kantonaes;
- “Guidelines” (truncated “guidelin”) used mostly by the draft and final scientific opinion and by the Technical Report (with one occurrence also in the AT submission).

Therefore, JFREQ offers a good overview of the type of critical concepts that underpin subsets of submissions and the solutions put forward by them. For example, the “yeast”-based technology belonging to Renaissance Bioscience and Novozymes’s enzyme-based solution “asparaginase” for bakery products clearly identify the owner of the intellectual property rights and the proponent of the solution, as the two mostly overlap. For a more nuanced view,

an in-depth analysis of the textual changes between the draft and final versions of the abstracts of EFSA's scientific opinion is offered in box 6-1.

Box 6-1 Textual changes between draft and final versions of the abstracts of EFSA's Scientific Opinion on Acrylamide, 2015

The following textual changes between the draft and final versions of EFSA's Scientific Opinion Abstract on Acrylamide illustrate: (i) textual expansions linked to the addition of attributes invoking the weak quality of evidence e.g. insertion of the qualifier "*based on animal evidence*"; (ii) use of more specific descriptions of conditions and characteristics e.g. "*low moisture*" and "*solid (coffee)*" and (iii) usage of the phrase "*epidemiological associations*" instead of "*(MoEs) across dietary surveys and age groups*".

The draft version of the scientific opinion abstract included:

(1a) AA was found at the highest levels in "Coffee and coffee substitutes" followed by "Potato crisps and snacks" and "Potato fried products";

(2a) The CONTAM Panel evaluated 43 419 analytical results from food commodities collected and analysed since 2010;

(3a) The data from human studies were *not adequate* for dose-response assessment.

In the final version of the scientific opinion, these were amended to (changes in italics):

(1b) AA was found at the highest levels in solid coffee substitutes and coffee, and in potato fried products; (...) the main contributor to total dietary exposure was generally the category "Potato fried products (*except* potato crisps and snacks)";

(2b) The CONTAM Panel evaluated 43 419 analytical results from food commodities;

(3b) The data from human studies were *inadequate* for dose-response assessment.

Results from the STATA analysis

As in the previous case study, the findings that positions of stakeholders having similar interests (e.g. on the one hand, ECF and FoodDrinkEurope and AT and Kantonaes on the other) translate into scores with similar values are confirmed. ECF and FoodDrinkEurope converge around the 0.74 value and AT and Kantonaes around 0.25.

Table 6-2 Comparative Analysis of Scores of Stakeholder clusters

Stakeholder	Word count	Unique words scored	Raw score	LBG score	MV score
Industry					
ECF	1910	313	0.7504	1.8391	1
FoodDrinkEurope	3805	719	0.7361	1.7817	0.972324
NCFUS	645	97	0.6215	1.3236	0.750532
BDSI	235	111	0.3412	0.2022	0.208051
Novozymes	337	123	0.3236	0.1319	0.173989
Renaissance	370	109	0.3069	0.0649	0.141668
Advocacy					
AT	135	93	0.2337	-0.2279	0
Kantonaes	2736	886	0.2799	-0.0431	0.089414
DKSE	554	166	0.3745	0.3354	0.272499
CL	1669	326	0.3681	0.3098	0.260112
ISS	745	187	0.3572	0.2663	0.239017
UK	1005	259	0.3708	0.3206	0.265338

The analyses of submissions confirmed that it was possible not only to differentiate, quantitatively, responses from industry and the public health community, but also to differentiate innovators in industry proposing solutions from those whose manufacturing processes were being questioned. Therefore, Novozymes and Renaissance have raw scores, LBG scores and MV scores that are much closer to the advocacy cluster than to the industry cluster. They are proposing asparaginase technology and improved enzyme solutions to reduce acrylamide occurrence in foods. Unlike the rest of the industry, they are less reticent to accept regulatory change, in general. In these circumstances, the **first mover advantage** can be interpreted as a pre-emptive strike against the industrial competitors.

The analysis also made it possible to identify **anomalous submissions**, i.e. entries whose content is irrelevant to the questions asked rather than illegible or empty. These are characterised by having wide confidence intervals with low word-count and low raw scores (in this case, LTDH is the case in point). The fact that LTDH is an anomalous submission is confirmed by the Technical Report: *“The CONTAM Panel notes that the content of this comment is outside the scope of this risk assessment on AA in food”*, where AA is an abbreviation for “acrylamide” (European Food Safety Authority, 2015).

Table 6-3 summarises the results from the STATA analysis. The movement of the text consulted upon (the draft scientific opinion) is very marginally in the direction of the public advocacy (raw score of 0.2838 to 0.2837; LBG score of -0.0272 to -0.0277 and MV score of 0.09696 to 0.09676). ECF, FoodDrinkEurope and NCFUS have very similar scores given that not only their positions are similar, but also large parts of their submissions are copy-pasted, duplicated or shared. AT and Kantonaes have equally similar scores, on the other end of the scale, approaching the 0 MV value (assigned to AT). The technical review Report scores are: 0.3799 (raw), 0.3572 (LBG) and 0.2829 (MV), hence closer to the advocacy, than to the industry group.

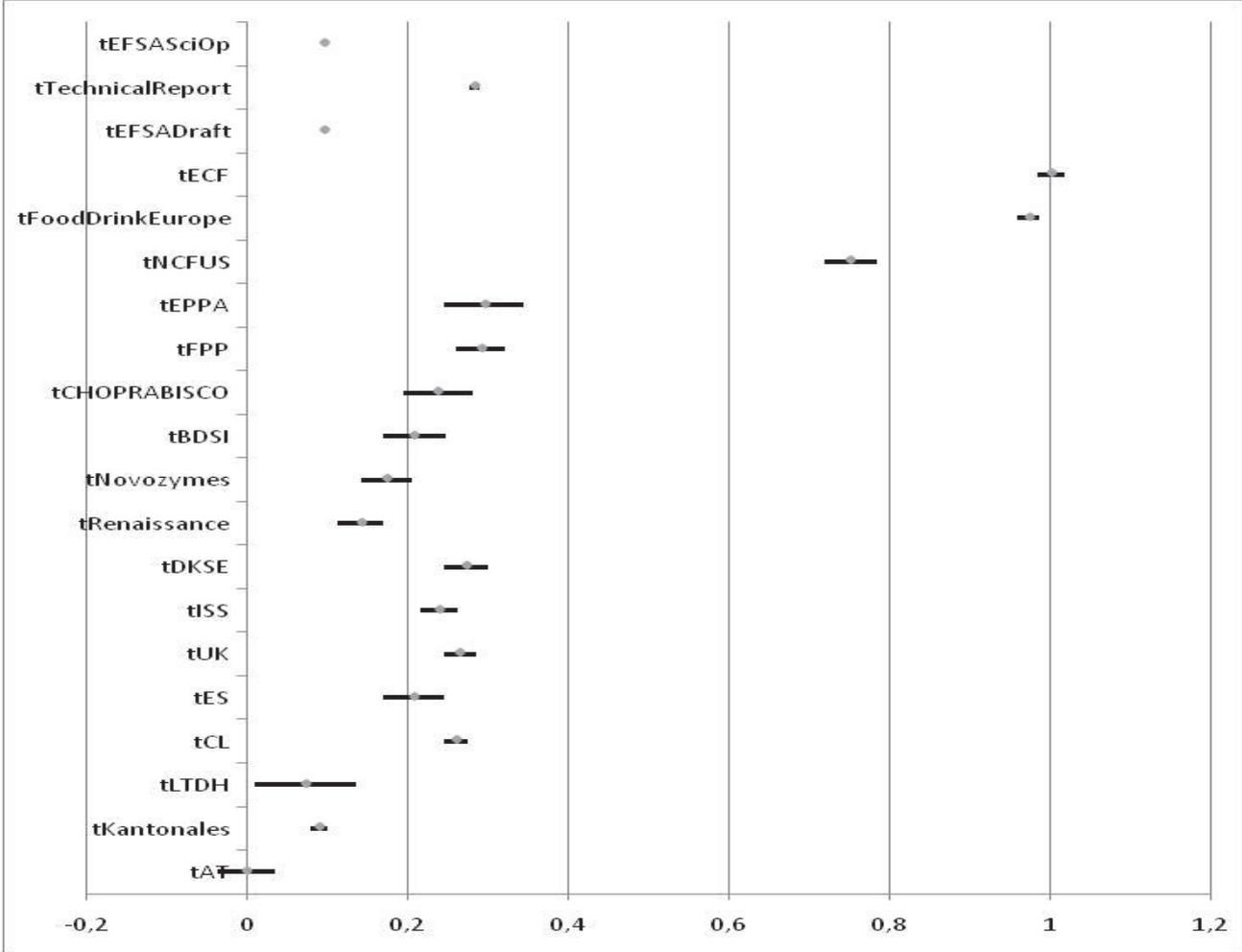
Table 6-3 Comparative Analysis of the Draft and Final Scientific Opinion compared to the industry and public health texts

Stakeholder or version of report	Word count	Unique words scored	Raw score	LBG score	MV score	Lower limit MV score CI	Upper limit MV score CI
<i>Industry</i>							
ECF	1910	313	0.7504	1.8391	1	0.9825	1.0174
FoodDrinkEurope	3805	719	0.7361	1.7817	0.972324	0.9593	0.9853
NCFUS	645	97	0.6215	1.3236	0.750532	0.7176	0.7834
BDSI	235	111	0.3412	0.2022	0.208051	0.1688	0.2472
Novozymes	337	123	0.3236	0.1319	0.173989	0.1429	0.2050
Renaissance	370	109	0.3069	0.0649	0.141668	0.1131	0.1702
<i>Neutral</i>							
Pre-consult (Draft Scientific Opinion)	79080	1043	0.2838	-0.0272	0.096961	0.0949	0.0989
Post-consult publication (Scientific Opinion)	88777	1059	0.2837	-0.0277	0.096768	0.0947	0.0987
Technical Report of the stakeholder review	13268	889	0.3799	0.3572	0.282949	0.2771	0.2887
<i>Advocacy</i>							
AT	135	93	0.2337	-0.2279	0	-0.0359	0.0359
Kantonaes	2736	886	0.2799	-0.0431	0.089414	0.07858	0.1002
DKSE	554	166	0.3745	0.3354	0.272499	0.24580	0.2992
CL	1669	326	0.3681	0.3098	0.260112	0.24492	0.2753
ISS	745	187	0.3572	0.2663	0.239017	0.21657	0.2614
UK	1005	259	0.3708	0.3206	0.265338	0.24524	0.2854

Plotting of the scores containing the Martin-Vanberg transformation results and their confidence intervals clearly shows that the industry (ECF, NCFUS, FoodDrink Europe, EPPA, FPP) is situated closer to 1 than the advocacy groups (AT, Kantonales, CL, ES, UK, ISS, DKSE), which are closer to 0. Innovators such as Novozymes and Renaissance have MV scores around the 0.2 value which situates them in the public advocacy cluster (since they are deliberately favouring a tighter regulation of acrylamide levels in food), compared to their competitors in the industry, labelled as “laggards”. Choprabisco and BDSI, also belonging to the industry cluster, have MV values that situate them between the two innovators Novozymes and Renaissance and the rest of the industry cluster, on a “middle ground”.

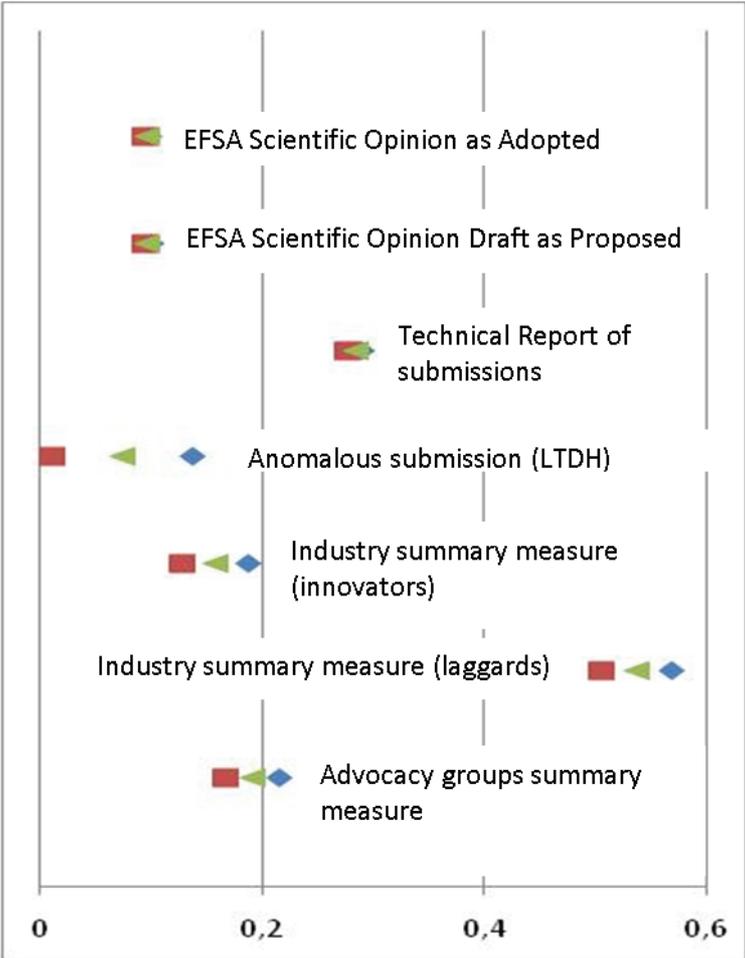
As for anomalous or ghost submissions, LTDH has the widest confidence interval in the diagram and is adjacent to the public advocacy reference texts, rendering it a perfect candidate for a spurious or anomalous submission. The fact that its word count is also rather low (80 total words scores, as per Appendix I, Table 2) confirms with certitude its anomalous nature.

Figure 6-1 Stakeholder position based on MV scores and their confidence intervals



In summary, analyses of submissions to the EFSA consultation on safety of acrylamide confirmed that it was possible not only to differentiate, quantitatively, responses from industry and the public health community, but also to differentiate innovators in industry proposing solutions from those whose manufacturing processes were being scrutinised (i.e. the laggards). The analyses offered important insights into how the issues were being framed by each group. I summarised these insights in Figure 6-2 using summary measures for industry (laggards vs. innovators), a summary measure for advocacy groups, and plotting the MV scores of the neutral texts (the Technical Report of submissions, the EFSA Scientific Opinion Draft as Proposed and the EFSA Scientific Opinion as Adopted), including the anomalous submission (LTDH).

Figure 6-2 Stakeholder position based on MV scores and their confidence intervals (summary measures)



In the figure 6-2 above, the green triangle represents the summary measure of MV scores for that stakeholder category, neutral text or anomalous submission, the red square represents the lower limit of the 95% confidence interval and the blue diamond the upper limit of the same confidence interval. Hence, the green triangle is always at the half-way point between the red square and the blue diamond. The figure illustrates how the advocacy summary measure just undercuts the 0.2 score, the industry laggard summary measure undercuts the 0.6 value and the industry innovator summary value is inferior to the 0.2 score, being plotted to the left of the advocacy group measure. This may reflect the fact that innovators are even more supportive of regulation than are advocacy groups.

Moreover, the technical consultation report giving an overview of submissions is anchored around the 0.3 mark, whereas the pre-consultation version of the scientific opinion is slightly above 0.1 with the post-consultation version marginally, yet visibly towards the 0 value. This effectively means that the post-consultation version moved in the direction of the advocacy scores, rather than being pulled into the direction of the much higher industry laggards' score. The implications of the results above will be teased out further in the discussion chapter.

Chapter 7. The Directive on Patients' Rights in Cross-border Healthcare

The issue

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare sets out the conditions under which a patient may travel to another EU Member State to receive medical care and have the cost reimbursed by their own health insurance scheme. It also encourages cooperation between national healthcare systems.

The European Treaties have given the EU a limited role in health policy. Article 168 of the Treaty on the Functioning of the European Union notes that Member States have responsibility for *"the definition of their health policy and for the organisation and delivery of health services and medical care."* The same article also states that: *"The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them."* Historically, therefore, there was considered to be virtually no EU dimension to policy around the management and provision of health services. In recent years that view has changed, for a number of reasons.

Firstly, EU legislation originating from other policy areas – for example, the Directive 2003/88/EC concerning certain aspects of the organisation of working time and Directive 2005/36/EC on the recognition of professional qualifications – has had significant impacts on health services.

Secondly, over a number of years, the European Court of Justice has developed the principle that healthcare was a service within the meaning of the Treaty on the Functioning of the European Union, and that the principles of the free movement of services therefore apply to health services, albeit with important safeguards.

The EU institutions and the Member States are therefore faced with a series of questions about how these principles apply to health services, and what this means in practice for health systems.

Directive 2011/24/EU was the first step towards answering some of these questions. This Directive codified and clarified the jurisprudence of the Court with regard to the rights of patients to be reimbursed for healthcare received in another Member State. The Directive did not just deal with the rights to reimbursement, but also introduced a number of significant

flanking measures to ensure that patients could use these rights in practice. As part of this there is now, for the first time, a minimum set of requirements which apply to all health providers and all healthcare provided within the EU. These requirements relate to transparency, information to patients, and safety and quality of care.

The intention in this case study is to examine whether and how the initial text proposed by the European Commission has been altered following the opinion of the European Parliament and the General Approach of the Council in the two readings of the co-decision procedure.

Regulatory environment and the decision being discussed

EU involvement in health goes back to the 1950s when standards for Health and Safety at Work were laid out in the Treaty of Rome and in the EURATOM and Coal and Steel Community origins (Bowis, 2016). Health was enshrined in the Treaty of Maastricht, signed in 1992. That Treaty widened the competence of the Community to cover new areas such as education, culture, public health, consumer protection, trans-European networks, industry, and the environment. Since then, a compendium of directives and regulations on matters relevant to public health has been adopted, addressing, among others, dangerous substances, pollution, waste disposal, water and air and soil quality, food safety and product liability.

Between 1991 and 2006 a succession of rulings by the European Court of Justice in Luxembourg expanded the role of health in the EU. In the landmark case of Kohll and Decker in 1998 (two Luxembourg citizens), the ECJ established that, under the Treaties, citizens had the right to travel to another Member State of the EU to receive medical treatment (to receive orthodontic treatment and to obtain spectacles respectively) (Kanavos et al., 1999). It further ruled that the patient should not bear the medical treatment cost alone, as long as the treatment was normally available in the home country and the reimbursable cost was no more than would have been assumed in the home country by the responsible health insurance.

The EU-regulated patient mobility provisions prior to the Kohll and Decker ruling were restricted to three procedures: first, the E111 form, which has now become the European Health Insurance Card – the traditional cross-border social security path, covering medical treatment in Europe for citizens on holiday, studying or working abroad. Second, a bilateral block-grant system of lump-sum transfers between countries to support the healthcare needs of retirees living in Malta, Spain, or Cyprus. The third route was the E112 form system, which

allowed citizens to travel to another EU country specifically for treatment. This system required a prior-authorisation form which de facto (except for some notable exceptions in small Luxembourg and liberal Sweden) was rarely granted by the home authorities to their applicants and hence rarely applied for. Awareness of the existence of such a system has been, up to the present, generally low (European Commission, 2015b).

With the ECJ ruling on spectacles and orthodontic treatment, the question of whether such services were limited to those provided as outpatient, non-hospital services was asked. Subsequent cases, such as those of Geraerts-Smits and Peerbooms (C-157/99), two Dutch citizens, revealed that hospital treatment could also be included within the scope of the previous judgment (these cases related to Parkinson's disease treatment in Germany and coma therapy in Austria). In 2003, in the ruling on the case of Muller Fauré and Van Riet (C-385/99), the ECJ stated that prior authorisation was not necessary for non-hospital treatment. Last but not least, in 2006, in the case of Yvonne Watts (C-372/04), the Court questioned whether a health authority could refuse a patient prior-authorisation by retrospectively reducing the waiting time for treatment and even challenged the pre-existing requirement for prior-authorisation for inpatient hospital treatment (in this case, a hip replacement in France to avoid long waiting times in England).

Following this body of ECJ rulings in a relatively short space of time, the European Parliament demanded legal certainty and procedural clarity. The Commission published a Communication on the ECJ judgments following a high-level reflection process on patient mobility (European Commission, 2004) and the European Parliament undertook a study on legislative proposals on patient mobility (European Parliament, 2008).

The process culminated in the European Commission's long-awaited legal proposal published in July 2008 on "The Application of Patients' Rights in Cross-border Healthcare" (European Commission, 2008). There were widespread calls for the case law on the application of the principle of free movement of goods and services in the field of health to be codified in a new Directive. The proposed Directive therefore included provisions on the regime of quality and safety to be applicable for cases of cross-border healthcare, the creation of information systems (National Contact Points) to offer information to citizens and further provisions that went beyond the ECJ rulings regarding e-Health, e-prescriptions, health technology assessment or centres of excellence for rare diseases.

Actors

The majority of delegations in the preparatory debate of the Council recommended that the Regulation on the coordination of social security systems (Council of Ministers, 2004) and its clearing house system of payments (bilateral lump-sum payments for retirees settled abroad and yearly bilateral settlements between countries triggered by the use of the European Health Insurance Card) should be incorporated within the Directive on cross-border healthcare and that a “third method” of reimbursement should be avoided. It is not the purpose of this case study to focus in detail on the different views expressed in the Council and therefore the Council will be treated as a unitary body (although de facto it is not, *a contrario*).

Five institutional actors submitted amendments, press releases or papers on the European Commission draft, including the EDPS (European Data Protection Supervisor Authority), the EESC (European Economic and Social Committee), the CoR (the Committee of the Regions), the EP (European Parliament), and the Council (both in its more formal ministerial function in EPSCO Employment, Social Policy, Health and Consumer Affairs Council and in the more basic Council of Ministers configuration).

The analyses of submissions confirmed that it was possible not only to differentiate, quantitatively, responses from the European Parliament and the Council, but also to differentiate early contributors proposing solutions from those who contributed later on in the decision-making chain – a reinterpretation of the “*first-mover advantage*” is therefore put forward. For a list of the actors, appendix 3 discussed a stakeholder analysis in detail.

Context

Against the legal regulatory background presented in the sections above, a political dispersion of interests and views formed during the co-decision procedure negotiations.

During the negotiations, the ministers asked that Member States should be able to make the use of cross-border healthcare subject to prior authorisation or to apply the “gatekeeping” principle (Council of Ministers, 2008), for example by the attending physician. This envisaged that the patient could only be reimbursed for care provided following a referral to a provider abroad.

Council delegations also wanted the Member State providing the healthcare to be responsible for giving patients information on the mechanisms by which they ensured the quality and safety of healthcare provided within their own jurisdiction.

Ultimately, a balance was struck between the rights of patients and of Member States. Mandatory reimbursement by a Member State should not exceed the level provided for by its own system. Particularly sensitive topics included the management of incoming patient flows, the definition of healthcare and the quality of care.

In parallel, the Council held a first exchange of views on the proposal for a Council Recommendation on a European action in the field of rare diseases (Council of Ministers, 2009). The Ministers agreed that the particular nature of rare diseases made this an area in which Europe could bring substantial added value.

The European Union initiated a policy in this area with the adoption in 1999 of the Regulation on orphan medicinal products. Then an overall strategy was published in the Commission Communication “Rare Diseases: Europe’s challenges”. These allowed the Council to adopt a common approach based on best-practice to combating rare diseases, working jointly with patient organisations.

A common definition of rare diseases throughout the European Union was also requested in the Communication. The latter also called for the Commission to cooperate with the World Health Organisation (WHO) in its work on codification of rare diseases. Lastly, Member States were invited via the Communication to promote the sharing of expertise via European reference centres, which have in the meantime been set up under the name “European Reference Networks”.

The consultation

The inter-institutional consultation on the draft Directive on cross-border healthcare lasted just under 3 years and ran between 2nd July 2008 and until 9 March 2011. The Directive entered into force on the 20th day following its publication in the Official Journal (hence, in April 2011) and the deadline for its transposition into national law was 25 October 2013.

Since institutional consultation does not specifically entail questions formulated by the organiser of the consultation process as would be the case in a standard public consultation,

the draft proposal for the Directive in all its parts was subject to the consultation. No parts were excluded and the basis for the consultation was the draft Directive text and the impact assessment accompanying it.

Methods

I ran **Jfreq** and the **Wordscores** algorithm in STATA for the 15 text files in the consultation (including the draft and the final Directive text and the Impact Assessment accompanying the draft proposal for a Directive). For the draft text of the Directive, the corrigendum version was considered, published on 16 July 2008 (European Commission, 2008), not the initial version adopted on 2 July 2008 (European Commission, 2008).

One publicly retrieved document that was initially considered but eventually dropped from the word scoring analysis was the Council Document adopted by the French Presidency after a Presidency-run public policy debate in the Council on the proposal for the Directive on the basis of a progress report and a Presidency questionnaire (Council of Ministers, 2008). I decided to deliberately exclude the latter from the analysis due to its short length (under 1 page) and to the fact that it was more of a political statement of support rather than a milestone in the adoption process. The score (extremely small) would have skewed the results, had it been included in the analysis.

The intention is to examine whether and how the initial text proposed by the European Commission has been altered following the opinion of the European Parliament and the General Approach of the Council in the two readings of the co-decision procedure.

Results

The analysis confirmed that it was possible not only to differentiate, quantitatively, responses from the Council from the European Parliament and other institutional partners, but also to differentiate early contributors proposing solutions from those who contributed later on in the decision-making chain. The analyses offered important insights into how the issues were being framed by each group.

The results precluded the identification of anomalous submissions in this case study, i.e. entries whose content is irrelevant to the questions asked. Also, it is important to mention that no questions were asked *per se* within the remit of the consultation run in this case study.

Therefore, in this case study I ask whether and how the draft text of the Directive on patients' rights in cross-border healthcare proposed by the European Commission shifted towards positions that could be seen to favour the Council, European Parliament and other institutions' perspectives against a more prescriptive regulation of patient rights and patient flows.

The scaling algorithm **Wordscores** was used as before (Costa et al, Stuckler et al, Laver, Benoit and Gary, etc). **Wordscores** infers policy positions in new documents – so-called virgin texts – by calculating scores for these documents based on the scores of reference texts. Scores are derived from the frequency of words in a document relative to the total number of words.

First, I converted documents from portable document format to more manageable text files. Then I manually removed superfluous information i.e. headers and certain footers, yet left contact details and citations in. Then I created a frequency matrix using the programme **Jfreq in R**, which estimated the frequency distribution of words across documents, reduced words to their roots and removed stop words, numbers and symbols. Given the polarisation of views (opinions) between institutional stakeholders, I devised a scale using texts from the European Parliament first reading and second reading as reference texts for the European Parliament views and the Council first reading press release and the Council first reading as reference texts for the Council's perspectives. However, the Council first reading press release is comparatively much shorter and so its suitability as reference text will be analysed in the Discussion section of this Chapter.

As explained in the previous case studies, MV (the Martin-Vanberg) transformation compensates for the tendency of non-discriminating words to pull scores towards the middle of the scale, rendering the alignment less visible and less clear. I calculate 95% confidence intervals based on standard deviations in score frequencies across documents. Then the score of the Directive text document before and after the consultation is compared.

I combined texts by iteration and identified stakeholder and collated all contributions according to stakeholder, e.g. in the case of the EPSCO text, the political agreement and the background text were combined into one manageable text file and for the Council first reading, the Draft statement of the Council's reasons and the Legislative Act were combined into one text.

The following table shows the 15 texts included in the analysis and the number of hits in Jfreq for a number of concepts explained above in the context section of this Chapter, also representing critical control points further discussed in the preliminary observations below.

Table 7-1 Overview of all submissions by stakeholder with critical control points identified

Text acronym in STATA	Stakeholder submission full name (acronym)	Raw score in STATA	Wordcount score in STATA	Type of text or stakeholder cluster affiliation?	Evidence of “gatekeeping” being referred to	Evidence of “rare” being referred to (“rare” or “rarer”)	Evidence of “authorisation” being referred to (pre-authoris*/ unauthoris*/ authoris)	Evidence of “quality” being referred to	Evidence of “safety” being referred to
COMoriginal.txt	Commission original proposal	0.435	21 359	Test text	0	0	48	40	24
IA.txt	Commission’s Impact Assessment accompanying the original proposal	0.395	27940	Commission	0	5	41	69	36
EDPSopinion.txt	Opinion of the European Data Protection Supervisor	0.3962	29334	Inst. Partners	0	0	12	13	2
EESCopinion.txt	Opinion of the European Economic and Social Committee	0.4069	3450	Inst. Partners	0	0	6	8	3
CoRopinion.txt	Opinion of the Committee of the Regions	0.3742	41270	Inst. Partners	0	1	20	73	25

Text acronym in STATA	Stakeholder submission full name (acronym)	Raw score in STATA	Wordcount score in STATA	Type of text or stakeholder cluster affiliation?	Evidence of "gatekeeping" being referred to	Evidence of "rare" being referred to ("rare" or "rarer")	Evidence of "authorisation" being referred to (pre-authoris*/ unauthoris*/ authoris)	Evidence of "quality" being referred to	Evidence of "safety" being referred to
EPfirstreading.txt	First Reading of the European Parliament	0.3991	77878	EP – Ref. text	1	15	209	135	94
EPSCO.txt	EPSCO Background and Political Agreement Text	0.4755	13455	CONS	0	0	38	18	22
EPSCOpress.txt	EPSCO First Reading Press Release	0.5418	1322	CONS	1	0	4	4	3
CONSfirstreading.txt	General Approach of the Council in the First Reading	0.4985	16602	CONS – Ref. text	1	0	55	22	28
CONSfirstreadingpress.txt	Press release on the General Approach	0.6444	948	CONS – Ref. text	1	0	3	5	3
COMonCONSfirstreading.txt	Commission Communication on the	0.4820	3437	Commission	0	1	24	15	16

Text acronym in STATA	Stakeholder submission full name (acronym)	Raw score in STATA	Wordcount score in STATA	Type of text or stakeholder cluster affiliation?	Evidence of "gatekeeping" being referred to	Evidence of "rare" being referred to ("rare" or "rarer")	Evidence of "authorisation" being referred to (pre-authoris*/ unauthoris*/ authoris)	Evidence of "quality" being referred to	Evidence of "safety" being referred to
	Council First Reading								
EPsecondreading.txt	Second Reading of the European Parliament	0.4579	15520	EP – Ref. text	0	11	48	25	22
COMonEPsecondreading.txt	Commission Opinion on EP Second Reading	0.4929	470	Commission	0	0	0	1	0
CONSonEPamendmentspress.txt	Press Release Council Approval of EP Amendments	0.5430	793	CONS	0	1	3	3	5
DirectiveAdoptedText.txt	Text of Directive as Adopted	0.4657	14386	Test text	0	9	45	20	19
<p>N.B. The Press Release for the 2916th Council Meeting of the Employment, Social Policy, Health and Consumer Affairs Council of 17 and 18 December 2008 was not included in the analysis since the directly relevant text was too short (under 1 page). The press release simply marked a public policy debate on the proposal for a Directive on the application of patients' rights in cross-border healthcare on the basis of a progress report and a questionnaire rolled out to the Member States by the French Presidency (the Directive had been proposed by the Commission under the French Presidency of the Council).</p>									

Results from Jfreq and comparative reading

The longest submissions have the highest use of the article **“the”** (the EPfirstreading, the CoRopinion, the EDPSopinion, the IA, the COM original, the CONSfirstreading, etc);

- References to the **“gatekeeping”** container concept (meaning a referral by a local General Practitioner as being necessary for accessing cross-border healthcare), mentioned by EPfirstreading (once), EPSCOpres (once), CONSfirstreading (once), CONSfirstreadingpres (once);
- **“Rare”** or **“rarer”** used by IA (five times), EPfirstreading (15 times), COMonCONSfirstreading (once), EPsecondreading (11 times), CONSonEPamendmentspres (once) and DirectiveTextAdopted (nine times);
- **“Authoris”** (from “pre-authorisation”, “unauthorised” or “authorise/ authorisation”) was used 48 times in the COMoriginal, 41 times in the IA, 12 times in the EDPSopinion, six times in EESCopinion, 20 times in CoRopinion, 209 times in EPfirstreading, 38 times in EPSCO, 4 times in EPSCOpres, 55 times in CONSfirstreading, three times in CONSfirstreadingpres, 24 times in COMonCONSfirstreading, 48 times in EPsecondreading, three times in CONSonEPamendmentspres and 45 times in DirectiveAdoptedText;
- **“Quality”** used 40 times by COMoriginal, 69 times by the IA, 13 times by EDPSopinion, eight times by EESCopinion, 73 times by CoRopinion, 135 by EPfirstreading, 18 times by EPSCO, four times by EPSCOpres, 22 times by CONSfirstreading, five times by CONSfirstreadingpres, 15 times by COMonCONSfirstreading, 25 times by EPsecondreading, once by COMonEPsecondreading, three times by CONSonEPamendmentspres, 20 times by DirectiveAdoptedText;
- **“Safety”** used 24 times by COMoriginal, 36 times by the IA, twice by EDPSopinion, three times by EESCopinion, 25 times by CoRopinion, 94 times by EPfirstreading, 22 times by EPSCO, three times by EPSCOpres, 28 times by CONSfirstreading, three times by CONSfirstreadingpres, 16 times by COMonCONSfirstreading, 22 times by EPsecondreading, 5 times by CONSonEPamendmentspres, 19 times by DirectiveAdoptedText;
- **“Right”** used by EPfirstreading (195 times), COMoriginal and EDPSopinion (67 times), IA (65 times), CoRopinion (60 times), CONSfirstreading (38 times), EPsecondreading

(35 times), DirectiveAdoptedText (33 times), EPSCO (31 times), EESCopinion (21 times), COMonCONScfirstreading (18 times), EPSCOpress (9 times), CONScfirstreadingpress (8 times), CONScapprovalEPamendments (5 times), COMopinionePsecondreading (4 times);

- **“Ehealth”** used by COMonCONScfirstreading (8 times), EPsecondreading (7 times), DirectiveAdoptedText (6 times), CONScfirstreading (3 times), EDPSopinione (twice) and once by IA, EPSCO and COMopinionePsecondreading; not used in the COMoriginal proposal.

In conclusion, the first reading in the European Parliament introduced a number of concepts that did not appear explicitly in the original Commission Directive text: **gatekeeping** and **rare** (diseases), and to a lesser extent, **quality** and **safety**.

The following table presents the raw, LBG and MV score in the following groupings: on the one hand, Commission and European Parliament (containing the IA text, the EPfirst reading text, the COMonCONScfirst reading text, the EPsecondreading text and the COMonEPsecond reading) versus on the other hand the Council and other institutional partners (containing the EDPSopinione, the EESCopinione, the CoRopinione, the EPSCO, the EPSCOpress, the CONScfirstreading, the CONScfirstreadingpress and the CONSonEPamendmentspress). The word count and the unique words scored are also included in Table 7-2.

Table 7-2 Comparative Analysis of Scores of Stakeholder clusters without Test Texts

Stakeholder	Word count	Unique words scored	Raw score	LBG score	MV score
<i>Commission and European Parliament</i>					
IA	27 940	1747	0.395	0.1101	0.130953
EPfirstreading	77 878	4935	0.3991	0.0775	0
COMonCONSfirstreading	3 437	710	0.482	0.5856	0.392479
EPsecondreading	15 520	1892	0.4579	0.3929	0.239706
COMonEPsecondreading	470	162	0.4929	0.6729	0.492608
<i>Council and Other Institutional Partners</i>					
EDPSopinion	29 334	1861	0.3962	0.1008	0.155756
EESCopinion	3 450	762	0.4069	0.0149	0.181939
CoRopinion	41 270	2 204	0.3742	0.2766	0.098668
EPSCO	13 455	1 556	0.4755	0.5332	0.333015
EPSCOpres	1 322	412	0.5418	1.0638	0.707816
CONScfirstreading	16 602	1 950	0.4985	0.7178	0.405218
CONScfirstreadingpres	948	342	0.6444	1.8845	1
CONSonEPamendmentspres	793	315	0.543	1.0737	0.662171

The box below discusses the textual changes between the draft and final versions of the Commission Directive proposal, in light of the consultation.

**Box 7-1 Textual changes between draft and final versions of the original
Commission Directive proposal**

**Box 7-1: Textual changes between draft and final versions of the original
Commission Directive proposal**

The following notable textual changes between the draft and final versions of the Commission Proposal for a Directive on the application of patients' rights in cross-border healthcare illustrate: (i) textual additions linked to the definitions article (originally Article 4, finally Article 3 of the Directive 2011/24/EU) e.g. insertion of the definition for "telemedicine", "medical records" and "health technology" and removal of the definition of "harm" (i.e. adverse outcomes or injuries stemming from the provision of healthcare); (ii) extension of the deadline for transposition into national law from one year to 2.5 years in favour of Member States and (iii) more recurrent reporting obligations bestowed on the European Commission on the operation of this Directive (reporting recurrent every 3 years) rather than once after 5 years of implementation.

The draft version of the original Commission proposal included:

(1a) Non-hospital care was not subject to the prior-authorisation scheme: *"The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security system"*;

(Article 7, Original Commission Proposal);

(2a) The COM was expected to update a list of *"specialised and hospital"* healthcare: *"This list shall be set up and may be regularly updated by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3)"*;

(3a) *"Member States shall, when setting out the time limits within which requests for the use of healthcare in another Member State must be dealt with, take into account: (a) the specific medical condition, (b) the patient's degree of pain, (c) the nature of the patient's disability, and (d) the patient's ability to carry out a professional activity"* (article 9 (4)(d) of Original Commission Proposal);

(4a) *“The Commission may, in accordance with the procedure referred to in Article 19(2), develop a standard Community format for the prior information referred to in paragraph 1”* (article 10(3) of the Original Commission Proposal);

(5a) *“The Commission shall, in accordance with the procedure referred to in Article 19(2), adopt: (c) guidelines on information to patients provided for in paragraph 2(a) of this Article.”* (article 12(3)(c) of Original Commission Proposal);

(6a) *“Member States shall facilitate the development of the European reference networks of healthcare providers. Those networks shall at all times be open for new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria”* (article 15(1) of Original Commission Proposal);

(7a) *“The Commission shall within five years after the date referred to in Article 22(1) draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council.”* (Article 20(1) of Original Commission Proposal);

(8a) *“Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by ... [one year after its entry into force].”* (Article 22 (1) of Original Commission Proposal) – N.B. . entry into force was to be established as being April 2011 following negotiations.

In the final version of the Directive, these were amended to (changes in italics):

(1b) The article was entirely removed;

(2b) The article was replaced with *“Member States shall notify the categories of healthcare referred to in point (a) to the Commission”*, whereby point (a) read *“Healthcare that may be subject to prior authorisation shall be limited to healthcare which:*

(a) is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial, technical and human resources and:

(i) involves overnight hospital accommodation of the patient in question for at least one night; or

(ii) requires use of highly specialised and cost-intensive medical infrastructure or medical equipment”;

(3b) *“the patient's ability to carry out a professional activity”* was replaced with *“the history and probable course of the patient's illness”* and *“the nature of the patient's disability at the time when the request for authorisation was made or renewed”;*

(4b) More specificity was added: e.g. *“In order to enable patients to make use of their rights in relation to cross-border healthcare, national contact points in the Member State of treatment shall provide them with information concerning healthcare providers, including, on request, information on a specific provider’s right to provide services or any restrictions on its practice, information referred to in Article 4(2)(a), as well as information on patients’ rights, complaints procedures and mechanisms for seeking remedies, according to the legislation of that Member State, as well as the legal and administrative options available to settle disputes, including in the event of harm arising from cross-border healthcare”* (Article 6(3) of the Adopted Directive) and *“National contact points in the Member State of affiliation shall provide patients and health professionals with the information referred to in Article 5(b)”* (Article 6(4) of the Adopted Directive);

(5b) Article dropped from the Adopted Directive in its entirety;

(6b) *“The Commission shall support Member States in the development of European reference networks between healthcare providers and centres of expertise in the Member States, in particular in the area of rare diseases. The networks shall be based on voluntary participation by its members, which shall participate and contribute to the networks’ activities in accordance with the legislation of the Member State where the members are established and shall at all times be open to new healthcare providers which might wish to join them, provided that such healthcare providers fulfil all the required conditions and criteria referred to in paragraph 4.”* (Article 12(1) of the Adopted Directive);

(7b) *“The Commission shall by 25 October 2015 and subsequently every 3 years thereafter, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council”* (Article 20(1) of the Adopted Directive);

(8b) *“Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 25 October 2013.”* (Article 21(1) of the Adopted Directive) – N.B. entry into force was to be established as being April 2011 following negotiations.

Results from STATA

As in the previous case studies, the findings that positions of stakeholders having similar interests (e.g. on the one hand, the Council and EPSCO and, on the other, the European Parliament and the Commission) translate into scores with similar values are confirmed.

The analyses of submissions confirmed that it was possible not only to differentiate, quantitatively, responses from the European Parliament and the Council, but also to differentiate **first movers proposing solutions** from those who intervened later in the consultation process.

Consequently, EDPSopinion, EESCopinion and CoRopinion have raw scores, LBG scores and MV scores that are much closer to the European Parliament cluster than to the Council cluster. Unlike the Council, the three institutional partners are less reticent to regulatory change.

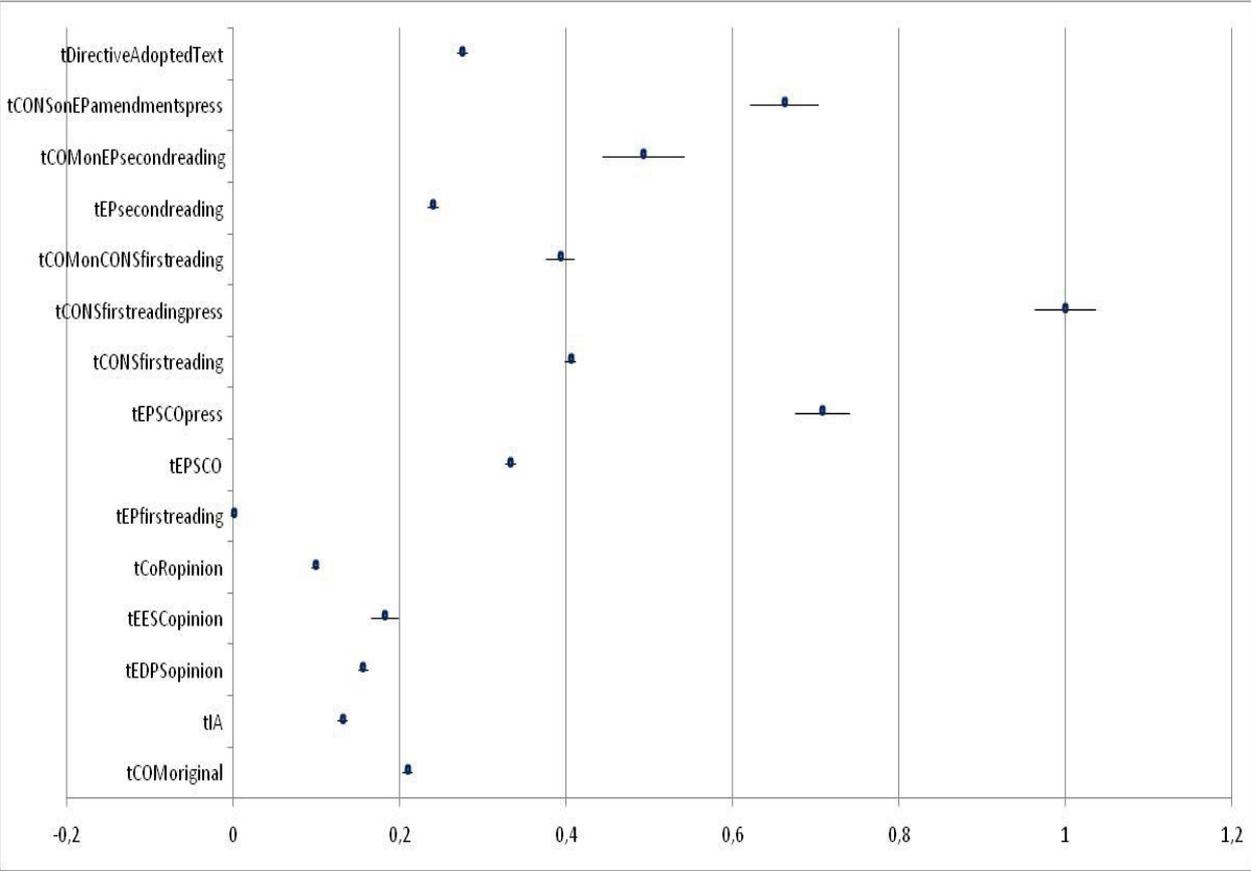
The analysis did not allow me to identify anomalous submissions, i.e. entries whose content is irrelevant to the questions asked rather than illegible or empty. As distinctive features, anomalous submissions tend to have large confidence intervals with low word-count and low raw scores (in the pharmaceutical products case study, LTDH was the case in point).

Table 7-3 Comparative Analysis of the Draft and Final Directive text

Stakeholder or version of Directive	Word count	Unique words scored	Raw score	LBG score	MV score	Lower limit MV score CI	Upper limit MV score CI
Commission, European Parliament and Other Institutional Partners							
IA	27 940	1747	0.395	0.1101	0.130953	0.1252	0.1367
EDPSopinion	29 334	1861	0.3962	0.1008	0.155756	0.1499	0.1616
EESCopinion	3 450	762	0.4069	0.0149	0.181939	0.1654	0.1984
CoRopinion	41 270	2 204	0.3742	0.2766	0.098668	0.0940	0.1033
EPfirstreading	77 878	4935	0.3991	0.0775	0	-0.0035	0.0035
COMonCONScfirstreading	3 437	710	0.482	0.5856	0.392479	0.3756	0.4093
EPsecondreading	15 520	1892	0.4579	0.3929	0.239706	0.2337	0.2456
COMonEPsecondreading	470	162	0.4929	0.6729	0.492608	0.4436	0.5416
Test Texts							
COMoriginal	21 359	1 744	0.435	0.2091	0.208767	0.2029	0.2147
DirectiveAdoptedText	14 386	1 661	0.4657	0.4547	0.275309	0.2693	0.2813
Council							
EPSCO	13 455	1 556	0.4755	0.5332	0.333015	0.3269	0.3391
EPSCOpress	1 322	412	0.5418	1.0638	0.707816	0.6752	0.7405
CONScfirstreading	16 602	1 950	0.4985	0.7178	0.405218	0.3990	0.4114
CONScfirstreadingpress	948	342	0.6444	1.8845	1	0.9634	1.0366
CONSonEPamendmentspress	793	315	0.543	1.0737	0.662171	0.6208	0.7035

The table above shows again the raw, LBG and MV score as well as precision estimates for the calculated MV scores. The test texts (COMoriginal and DirectiveAdoptedText) show a movement to the right in all scores (raw, LBG and MV) of the draft text submitted to consultation. Moreover, in this iteration, the scores of EDPS, EESC and CoR opinions fit much better the European Parliament cluster than the EPSCO and Council cluster, hence the regrouping as per Table 7-3 above. Figure 7-1 presents a visual representation of the MV results, illustrating also the direction of travel of the test text to the right.

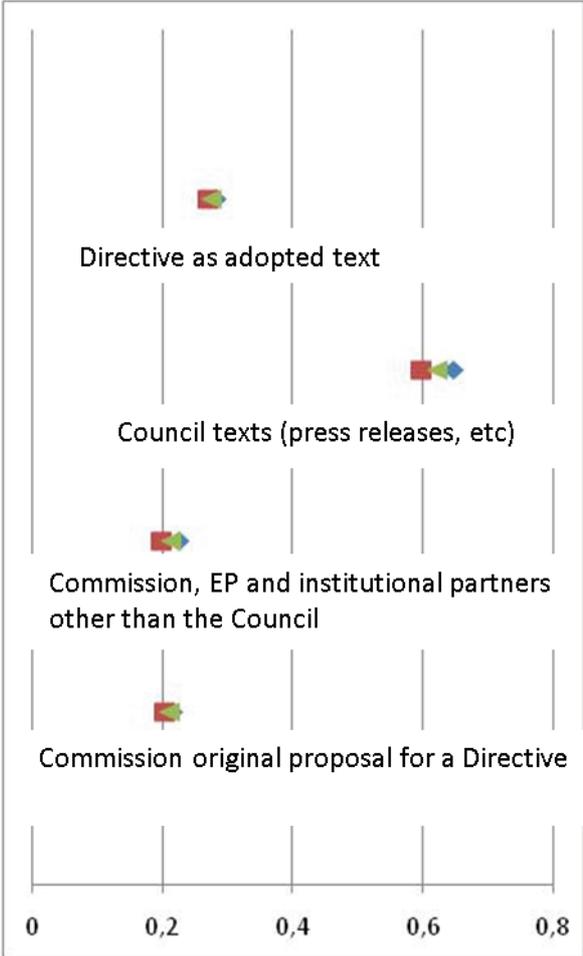
Figure 7-1 Stakeholder text position based on MV scores & their confidence intervals



Before moving on to the summary measure graph, it is worth highlighting that the **first mover advantage** is confirmed and translates into MV scores closer to the reference text score of the EP first reading (i.e. a score of 0) for the opinions of the first inter-institutional partners (i.e. EDPS, EESC, CoR all yielding scores under the value of 0.2) and for rather more right-oriented plotting of the texts towards the top of the graph, which were submitted chronologically later in the consultation process (for example, values around the score 0.65 for CONSonEPamendmentspress). This movement represents a *rapprochement* towards the CONScfirstreading and CONScfirstreadingpress values, 0.4 and respectively 1.

In terms of overall travel, the original Commission proposal migrated to the right from a value of 0.2 to just undercutting a score of 0.3 as adopted text. However, given the rather more extreme positions of the Council (mostly with values over 0.6 except for EPSCO and CONScfirstreading), this test text travel may be considered as surprisingly minimal.

Figure 7-2 Stakeholder text position based on MV scores and their confidence intervals (summary measures)



In Figure 7-2, the green triangle represents the summary measure of MV scores for that stakeholder category or neutral text, the red square represents the lower limit of the 95% confidence interval and the blue diamond the upper limit of the same confidence interval. Hence, the green triangle is always at the half-way point between the red square and the blue diamond. The figure reveals that the Commission’s original proposal is only slightly over the 0.2 score, the Commission, EP and institutional partners other than the Council summary measure undercuts the 0.25 value and the Council texts summary value is just over the 0.6 score, being plotted to the right of the Commission, EP and other institutional partners summary measure. This may reflect the fact that the Council has entirely different views from the EP and the other institutional partners. Last but not least, the adopted Directive text migrates to the right, approaching a score of 0.3. These results will be discussed in the next chapter.

Chapter 8. Discussion

Limitations of the case studies and of the thesis

There are a number of limitations to the present study, not least the assumptions that were made (e.g. importance of word choice in conveying a political position) but also the limited number of case studies and parameters chosen for the analysis. This means that the findings are subject to certain caveats. First, the case studies use recent examples and cannot be generalised to the whole population of public consultations. Nevertheless, future work should aim to extend the research into other policy areas and consultations. Also, a small number of translations were carried out by myself, introducing the possibility of bias. The translation process is important. In an ideal case, the translation would be conducted “blind” by someone who is not fully familiar with the main distinctions driving the research.

A number of questions to better understand the implications of the research findings to the theoretical basis of a public consultation process are outlined in Appendix B. The concern related to relationships of trust within a public consultation’s design and conduct has also been cited in previous research. Thus, it is necessary to recognise that the scale of undue influence of interest groups is likely underestimated here on account of the fact that the pre-consultation text may already have been under the influence of a certain group, or the text going out for consultation may have already incorporated a degree of compromise. This however cannot be examined via the methods employed in this thesis.

A further discussion point would revolve around the concept of what counts as a meaningful shift in the consultation document. This can equally well be conceptualised as distance covered (as measured by Wordscores or MV scores) in the direction of travel of the consultation document, i.e. towards industry texts or rather towards public health advocacy texts. One significant aspect pertains to the shift from the pre-consultation text to the consultation text and then, importantly, from the consultation version to the published version and how much of that shift may be perceived as random noise.

Finally, the opportunities and challenges of QTA have already been highlighted in the introductory chapters of this thesis (Table 3 - 1 provides more details). One particular opportunity arises from the theoretical framework chosen to underpin the present research. By combining dialogical theory with framing research and discourse analysis, the thesis explores the inner working of public consultation processes, through a number of constructs that are summarised and revisited below.

Observing and examining public consultations as knowledge encounters between stakeholders (and the wider public) through a dialogical lens allowed me to analyse whose voices are heard in different variants of consultations. “Knowledge” constructed in communication refers not just to technical knowledge but also to cultural, social, and political functions, which apply equally, leading to a plurality of knowledge, thus informing policy, through negotiation.

The findings discussed below support my contention that frames and discourse, alongside beliefs and narrative can be viewed as “ordering devices”, which explain how policy makers and stakeholders structure reality to gain a handle on practical questions. Acknowledging and handling ambivalence is therefore essential for prudent action (Hajer and Laws, 2006). This ambiguity was highlighted at length via the qualitative analysis of the texts before and after consultation in each of the three case studies (see notably boxes 6-1 and 7-1 for details).

The present research also corroborated findings from past alcohol pricing research (Hawkins and Holden, 2013) as acrylamide regulation, just as alcohol pricing policy, was not seen as a simple dichotomy between public health activists and a uniform, monolithic industry on the other. The industry was rather split between innovators and laggards.

Last but not least, this thesis contributes by making a recommendation for improvement. By endowing open consultation with greater visibility, public consultation managers (organisations, governments, or knowledge brokers) strengthen the level of policy literacy (civic educational attainment) and of policy performance in a jurisdiction. Such openness could, at least in theory, reduce the risk of regulatory capture by well financed groups of

interest or by groups with a deep legislative knowledge (Rodrigo and Amo, 2006). However, this will only be possible with full disclosure of responses to consultations, so they can be critiqued, and the reduction, and ideally elimination, of hidden mechanisms by which powerful interests exert influence. Some encouragement can be taken from the evidence presented in Chapters 2 and 3, from the original data analysis in Chapter 5 and especially the work of Stuckler et al on the process of guideline development on sugar by the WHO, where it seemed that industry influence was avoided at the stakeholder consultation stage. Publication of individual submissions to public consultations are essential, to make it possible to reduce the risk of spurious or anomalous texts under the guise of credible, legitimate submissions, which have in the past been criticised for unsettling or disrupting the public consultation process (e.g. the consultation on the Natura 2000 network recognising the importance of nature conservation in a living and changing landscape where crowd-surfing was used to intercede in the consultation process and burden it with duplicated contributions).

There is a further reason why anomalous submissions erode the quality of public consultations. Since public consultation credentials (dictated by previously published submissions, not by stakeholder background) send a signal to the public about stakeholder abilities, equality of opportunity becomes deeper and more meaningful, increasing the information value of the credential. In a scenario where there is a level playing field, credentials tell citizens and the public more about a stakeholder's ability to represent their interests competently and fairly than in a context where opportunities for exercising one's consultation abilities are a privilege rather than a meritocratic exercise.

The inclusiveness of consultation (not least via use of plain, accessible language and an ability to dissect issues of technical complexity) alongside capacity to disseminate detailed and timely information on regulations can both provide a rationale for the emergence of open public consultations as a normative prescription and act as a plausible framing mechanism going forward.

Pharmaceutical pricing models

This case study showed that the QTA method can successfully be applied in an effective and insightful manner to consultations on a technical study: it reveals clear patterns of interest representation in the European policy process. The results show some migration of the executive summary score towards the industry end of the spectrum but elicited no association between consultation-ensued bias and policy direction, as the study was simply exploratory and did not invite any concrete policy action in the short term. Findings are robust and the suitability of advocacy reference texts (HAI and BEUC to be specific) in view of their comparative length (shorter than the industry reference texts) has not proven to be problematic *per se*.

The **initial raw score range** is 0.2878 for BEUC and 0.6987 for EGA. In this case study, no ghost or anomalous submissions were identified nor discussed (identifiable as having low word counts, low word scores, and broad confidence intervals).

The fact that the executive summary is closer to the industry cluster than to the advocacy cluster following the consultation is revealing. One may however argue that this is the only viable direction of travel given the already low score of the executive summary text to start off with. Although it can only be speculative, the observation that the movement is minimal could be attributable to one or several of the following three main observations:

1. The baseline executive summary started off as a much more public health-oriented text than an industry-oriented text given the nature and interests of the report author (in this case, Gesundheit Oesterreich);
2. The consultation organiser, i.e. Gesundheit Oesterreich, as the Public Health Institute of Austria is *de facto* a knowledge-intensive organisation more public health-oriented than most stakeholders in the field and in its role of honest broker, remained unconvinced of the arguments put forward by the industry;
3. The public health stakeholders mobilised enough to counterbalance the arguments of the industry and the minimal movement in the score of the report's executive summary denotes the level playing field that exists in this particular case study.

Certain authors have remarked that policy evaluations are often sponsored by the very organisations that designed and implemented the intervention in the first place (Vaganay, 2014) or strong allies of the latter. Such conflict of interest threatens the acquisition of valid and robust results. Research in the area of clinical trials has consistently shown that this type of arrangement creates a moral hazard and may lead to overestimates of the effect of treatment (Vaganay, 2014). Yet, the question remains whether social interventions or health economics policy interventions are also subject to such ‘confirmation bias’, notably, in our case, re-evaluations of the EPR system. I take the view that this confirmation bias does not apply to a similar extent in this present case study as EPR is not an EU-driven policy and the study consultation was merely exploratory in nature. Neither the consultation manager nor the body commissioning the research needed to defend EPR to the extent that they created a reputational risk since it is merely a practice and not a policy anchored in a legal text of the EU.

The “*reward for innovation*” argument or discourse/ frame was identified as one of the strongest in the industry camp. However, challenges to the reward for innovation argument are receiving more and more attention lately, not least via reservation and even scepticism against the Innovative Medicines Initiative, Europe’s largest public-private initiative aiming to speed up the development of better and safer medicines for patients. Shining a light on “*the pharmaceutical lobby’s firepower, and deconstructing its agenda, is a crucial step in serving genuine public health needs, and truly facilitating access to essential medicines the world over*” (CEO, 2015).

To conclude, the objective of this case study was twofold. Firstly, it assessed whether innovative methods of text analysis reveal patterns of interest representation in the European policy process. This has proven to be the case. Secondly, it examined whether various public consultation norms/ frames, constellations and mechanisms endemic in knowledge brokering help to decrease the relative disadvantage of public health advocacy groups in the policy arena. These issues will be explored further in the following sections.

Cross-border Healthcare Directive case study

The ordinary legislative procedure example shows that the adopted Directive text more closely resembles the Commission proposal and the EP amendments than the Council’s

General Approach. Secondary findings concerned the **First Mover Advantage** (those who engage earliest in the process are able to exert most influence), and confirmed that, also in this case study, opinions of institutions consulted in a first instance (e.g. EDPS, CoR, EESC) more closely resembled or reflected the stance of the Commission than Council counterparts did.

When analysing the pathways and the determining factors in the direction of the movement of the draft text for consultation, the pre-consultative version of text (in this case, the proposal draft Directive) is crucial in and of itself. As it kept the patient interest at heart, it leaned more heavily toward the European Parliament instead of the Council, to start off with.

The **initial raw score range** is 0.3742 for CoR opinion and 0.6444 for CONStreadingpress, indicating polarised views which are less pronounced than in the other case studies.

In this case study, no ghost or **anomalous submissions** were identified. These can be distinguished by the combination of a low word count, low word scores and broad confidence intervals.

Further questions for future research therefore are:

- Is the position of the pre-consultative text in relation to the European Parliament/ Council a prompt for the final result (more likely to drag it to one side or another) or if neutral – is it likely to stay as it is?
- Is there an incentive for pre-consultative documents to be middle-ground upfront i.e. to compress the compromise?
- What can be done to counter or mitigate this incentive going forward?

Incidentally, one of the chosen reference texts was indeed rather **short by comparison to other chosen reference texts** (948 words in the CONStreadingpress as opposed to 16 602 words in the CONStreading), yet this is not considered so low as to harm the face value validity of the case study.

This case study shows that the QTA method can successfully be applied in an effective and insightful manner to consultations run as part of an inter-institutional process: it reveals vivid patterns of interest representation in the European policy process. The results show some

movement as measured by the mild migration to the right of the post-consultation Directive text score towards the Council scores.

The fact that the adopted text of the Directive is found to be closer to the European Parliament cluster than to the Council cluster following the consultation is revealing. One may however argue that this is the only viable direction of travel given the already low score of the draft Directive text to start with (and its proximity to the European Parliament text scores). The observation that the movement is minimal (from 0.2 MV score to 0.3 MV score) might be attributable to one or several of the following three observations:

- 1) The draft Directive started off as a much more patient-, public health-oriented text than an industry-oriented one given the nature and interests of the Directive's main author (in this case, the European Commission);
- 2) The consultation organiser, the European Commission is *de facto* a knowledge-intensive organisation that is more public health-oriented than most stakeholders in the field. In its role of honest broker, it remained unconvinced of the arguments put forward by the industry via the Council; the organiser seemed rather more concerned with clarifying the jurisprudence of the Court and acting in the patient's best interest, no matter which Member State the patient happens to call home;
- 3) The European Parliament's movement from one reading to another (from MV 0 to MV 0.25) in the scores on the Directive's adoption denotes the level playing field that exists in this particular case study.

In conclusion, findings are robust and the suitability of advocacy reference texts in view of their comparative length (shorter for the CONStreadingpress Council reference text) has not proven to be problematic *per se*.

Acrylamide case study

The case study focusing on acrylamide is the one which enabled the detection of **anomalous submissions**, notably identified via a low word count, low word scores and broad confidence intervals. One should acknowledge that there may, of course, be instances of public consultations where anomalous submissions come with a high word count – these should be screened and carefully considered for future investigation.

The initial **raw score range** is 0.2337 for AT and 0.7504 for ECF, the largest range of the three case studies. This case study is also the one where the test text leans more towards public advocacy and innovators than towards the industry laggards, who resist more stringent regulation of acrylamide.

In this case study, I experimented somewhat with the choice of reference texts. At first, I chose the submissions of the Austrian Agency for Health and Food Safety and of Kantonaales Labor Zurich as the public health reference and the texts of Food Drink Europe and National Coffee Federation (US) as the industry reference. However, this choice resulted in the European Coffee Federation's raw Wordscores score being in between the scores of the two industry reference texts (Appendix 2, Table 3). I therefore decided to run the algorithm again, by re-estimating the scores with Food Drink Europe and European Coffee Federation as industry reference texts and keeping the same public health reference texts as in the previous iteration. This resulted in a sound alignment of virgin texts, without any interference between the two industry reference texts (Appendix 2, Table 4). This distinction is explained in the Manual (Appendix 4), particularly in the part entitled "The Top Ten Mistakes Analysts Make" (points 8 and 9).

Questions that remain for future research are:

- 1) Is the pre-consultative version of text important in and of itself? Is it significant whether it leans toward public health advocacy or industry to start off with?
- 2) Is the position of the pre-consultative text in relation to advocacy/ industry a prompt for the final result (more likely to drag it to one side or another) or if neutral – is it likely to stay as it is? Is there an incentive for pre-consultative documents to be middle-ground upfront i.e. to compress the compromise?
- 3) If the tools proposed by the thesis become standard (i.e. incorporated into official reviews of submissions), can the industry game it? Can the industry be successful by employing tactical games? It is beyond the scope of this thesis to assess such a risk, but it should be noted that the potential for gaming will only increase with the greater use of artificial intelligence.

In conclusion, findings are robust and the suitability of advocacy reference texts in view of their comparative length (shorter for the AT public health advocacy reference text) has not proven to be problematic *per se*.

Overview

The section above discussed in detail the results from each of the three case studies, the validation of the methods, and how the findings may be used to understand stakeholder positions. I examined whether various public consultation norms/ frames, constellations and mechanisms in knowledge brokering help to decrease the relative disadvantage of public health advocacy groups in the policy arena and whether a more mature policy dialogue can be developed via public consultation, taking into account the Overton window of realistic potential futures, also known as the window of discourse. The so-called “Overton Window of Political Possibilities” derives from a concept named after Joseph P. Overton and is based on the assumption that any collection of public policies within a policy area can be arranged in order from more free to less free. At any given time, some group of adjacent policies along the freedom spectrum fall into a “window of political possibility”. Policies inside the window are politically acceptable, meaning office-holders believe they can support the policies and survive the next election (Szalek, 2013).

When I started this research, only a few QTA projects had published results. However, meanwhile, I learned that a synergy of QTA and qualitative methods via a mixed methods approach can achieve maximum impact. Moreover, I am convinced QTA can improve stakeholder analysis, by attributing positions to stakeholders based on text production.

This thesis sought to answer two research questions:

- Can innovative methods of text analysis reveal patterns of interest representation in the European policy process?
- Can the various public consultation norms, constellations and mechanisms that characterise knowledge brokering help to decrease the relative disadvantage of public health advocacy groups in the policy arena?

The thesis successfully mapped policy positions onto written submissions. Secondly, it showed that constellations of positions can be distinguished (non-monolithic views of industry, first mover advantage, movement of text prior and after the consultation). The present work

furthermore identified anomalous or ghost submissions. The movement of text before and after the consultation was noted and discussed in all the three case studies, whilst the non-monolithic views of industry (laggards versus innovators) were highlighted in the acrylamide case study. The first mover advantage was discussed both in the Cross-border Healthcare Directive and in the acrylamide case study.

I argued that QTA, alongside qualitative methods, provides a lens through which value systems underlying contributions to public debate can be monitored, traced, and analysed over time and across policy fields and through which anomalous, irregular, or spurious submissions to public consultations can be identified and examined (for example, the LTDH submission under the acrylamide case study). I made a case that language is central to expressing political opinion and that public consultation norms and frames can help to decrease the disadvantage that certain policy groups have in the policy arena, by distinguishing the first mover advantage, detecting anomalous submissions and by carefully comparing scores of texts before and after consultation. The use of text mining, comprising quantitative and qualitative text analysis, as described in the thesis, has the potential to optimise the mechanisms of public consultation, to render them more inclusive by encouraging a greater diversity of submissions and to ultimately facilitate the resolution of protracted policy controversies, for example around issues pushed for by front groups protecting corporate views.

Chapter 9. Conclusions

The generic outputs of this thesis include an expansion of the so far sparse literature on the use of QTA to study influences on policy processes and guidance for others in its use. The specific output is the generation of evidence on the nature and impact of industry or advocacy influence on public consultations covering EU policies.

The objectives of this thesis were twofold. Firstly, it assessed whether innovative methods of text analysis reveal patterns of interest representation in the European policy process. This has proven to be the case. Secondly, it examined whether various public consultation norms/frames, constellations and mechanisms endemic in knowledge brokering help to decrease the relative policy arena disadvantage of certain consulted groups and help the playing field to evolve. The intention is to help policy entrepreneurs and policy shapers to cope better with their risk management and policy-making tasks, taking into account the Overton window of realistic potential futures, also known as the window of discourse.

What this study adds to the research to date – the “*differentia specifica*”

The relationship between QTA and qualitative text analysis is often touched upon, yet remains fundamentally unexplored. Past research has been largely qualitative (Ulucanlar et al., 2014), some of the quantitative research has included stakeholder analyses (Proksch and Slapin, 2010), and some has focussed on examining leaks of emails. Very little has been written about how open public consultation works in practice (Bunea, 2014), what it means to those involved and how they experience the process. The present work seeks to overcome the distrust that may exist in public consultation processes by revealing the inner workings of a relatively new tool to assess submissions: quantitative text analysis and its synergies with qualitative text analysis, as the parallel use of the two methods (qualitative and quantitative, as per the Manual in appendix 4) is greater than the analytical contribution of either method used in isolation.

Quantitative metrics help focus attention on quantifying influence expressed in a text that belongs to a series of texts in a public consultation, whilst qualitative methods, pioneered in sociological research, help identify the critical control points for best interpreting the metrics obtained previously. On the one hand, this thesis examines interest representation/ lobbying/

industry/ public health activists in order to contribute to the evolution of the playing field and on the other, it draws on theory in order to inform the future development of public consultation and especially the development of a generic reference tool such as QTA, which can upgrade the tools used to perform stakeholder mapping and analysis as well as qualitative text analysis.

My thesis successfully demonstrated that industry views are *non-monolithic* (innovators differentiating themselves from laggards) and confirmed “*the first mover advantage*”, as well as the possibility to detect *anomalous submissions*.

Doubtless, synthesising findings of complex evidence has the potential to provide knowledge and decision support to important questions being asked by healthcare policy-makers and managers. Advances in computing offer scope for mainstream usage of QTA in governmental institutions, drawing on text mining, computational linguistics and STATA-driven word-count analysis. This strand of work could be linked to perceptual signatures and mathematical modelling employed to distinguish and recognise gait, voice, movement and visual features.

Implications for policy and research: Production of a Manual and beyond

The implications for policy and research are three-fold: first, at the level of theoretical conceptualisation, the first mover advantage (non-monolithic views of industry) and anomalous submissions detection.

Secondly, in terms of strategic response, everyone can game the mainstreaming of such a QTA tool by changing meaning or standard interpretation of concepts and by inventing new policy constructs. However, to mitigate these effects, as concept use becomes more blurred, new dichotomies emerge which can be tracked (meaning change e.g. “Brexit”, “agreement”, etc).

Last but not least, the thesis also makes an original contribution to knowledge in the form of a manual (see appendix 4). The manual was pilot tested on a colleague and reviewed for clarity. The manual consists of a Step-by-step protocol for data sanitation and analysis, a sample STATA code for running the Wordscores algorithm, a set of FAQs on the strengths and weaknesses of QTA and a “Top 10 Mistakes analysts make when rolling out this QTA methodology” guidance document.

Avenues for further research

Future research should address two main needs: one revolving around methodological research and a second one geared towards policy research. In terms of policy research, further work should focus on propositions for developing a system of checks and balances to counter and mitigate tactics coined and documented in the literature (Moodie, 2017b), with a view to rendering decision-making systems and playing fields immune to non-direct influence or confrontation tactics from any vested interest or advocacy group. Further methodological research could focus on testing the main hypotheses presented here (the first mover advantage and the anomalous submission detector) and developing data visualisation techniques for better and clearer presentation of results. Further policy research could equally apply the technique to other policy fields and public consultations or look into ways to better identify industry front groups or how texts going out for public consultation may already have compressed the compromise before being subject to public consultation, a belief held by many in the field.

APPENDICES

A. Overview of research aims, objectives, questions and methods

Objectives	Research Questions	Data Collection methods
A. Landscape analysis of political/scientific texts submitted for public consultation	To assess the feasibility of applying different methods of textual analysis to written responses to EU consultations and determine whether they can differentiate material from different sources.	Policy analysis, text analysis and QTA
B. Detecting patterns (constellations of stakeholder mapping)	To determine whether the positions of individual texts and constellations of texts relate to the positions of the parties to a negotiation (interest representation in the policy process) and whether it is possible, quantitatively, to identify significant shifts in the content (and thus the underlying expression of interests) during the course of a consultation?	Mostly QTA via Wordscores
C. To develop further ways of visual analytics that are representative and meaningful for capturing QTA results (Dropped)	How can the results of text analytics be rendered visual to best effect? How could this field be improved in the future?	Gapminder software Wordgraphing software Stakeholder Consultation

B. Questions of generalisability based on incidental observations

This thesis will ask the following questions to better understand the implications of the research findings to the theoretical basis of a public consultation process:

- How could relationships of trust and knowledge encounter be improved within a public consultation's design and conduct? E.g. the Natura case where crowd-surfing was used to interfere with the consultation process and burden it with duplicated contributions
- What is specific about EU Public Health that might well not apply to public consultation more generally?
- What is specific about the three case studies chosen that might not apply to other contexts?
- Which analytical aspects may be applicable to other contexts?

Based on the answers provided to these questions, the present work will add to the evidence base and enhance the dialogue between marginalised stakeholder groups and the regulatory affairs system.

C. Brief account of public consultations in US, EU, Member States

In Europe, the process known as the European Semester ushered in health country-specific recommendations (Földes, 2016) and examinations based on textual analysis e.g. mentioning words related to "health" (Azzopardi-Muscat et al., 2015).

In the United States, public consultations have been running for decades (Evans-Cowley and Hollander, 2010). Since advocates in the 1960s first brought widespread public participation into the planning process, there have been many innovations and improvements. Today, technology allows for an entirely new generation of forms and practices of public participation that promise to elevate the public discourse in an unprecedented manner while providing an interactive, networked environment for decision-making. This is occurring with various communities interacting with one another on a variety of planning subjects, which allows for

what may be a more democratic more meaningful participation. In their paper, Evans-Cowley et al review the ways in which today's web-based virtual worlds, like Facebook, provide platforms for public participation in planning in a manner distinct from previous formats. The paper explores the different ways that citizens and communities are using web-based technologies for citizen participation, including the use of Facebook for community organising around planning issues and of Second Life for virtual workshops. The paper concludes by exploring the contribution that virtual participation can make to planning and examines the challenges that it poses.

Highly sensitive public policy fields such as public health genomics are therefore all the more good examples of where public consultations can help the effort of reaching a truly participatory form of regulatory decision-making (Modell and Citrin, 2012).

D. Access and participation in public consultations in the EU

A typical consultation strategy designed for use within the European Commission is an elementary document, which requires the endorsement of an Inter-Service Group or, alternatively, of the Secretariat-General / concerned Directorate-General. It must contain at least a Stakeholder Analysis.

The purpose of the consultation strategy is to encompass all the consultation methodologies and tools as well as all the initiatives aiming at stakeholder feedback that will be part and parcel of the strategy. It also serves as a checklist for a comprehensive consultation strategy, it will support the drafting of the consultation document and should contain relevant information on human and financial resource planning.

A potential table of contents for the consultation strategy would contain:

(1) *Setting consultation **objectives**.*

(2) *Developing a **stakeholder analysis** or at least **stakeholder mapping** that is conducive to determining who should be targeted. It should be further defined who would have access to each part of the consultation.*

(3) *A determined **consultation method, tools and how accessibility would be ensured** (physically and linguistically). Relevant documents or initiatives on which stakeholders need to be consulted or to provide feedback have to be defined.*

a. Method: open or targeted (at least one open question is compulsory under the current guidelines)

b. Tools: internet (EU Survey), email, telephone, workshops, etc.

c. Type of initiatives:

i. 4 weeks request for feedback on the roadmap (compulsory)

ii. 12 weeks public online consultation (compulsory)

iii. Other (workshop, surveys, stakeholder conference, etc)

Consultation documents are important documents that frame the debate and serve as background to support the consultation. They are presently not compulsory for all initiatives. They must be no more than 10 pages long and should be easy to understand.

(4) *A **planning team** should be established including the contractor developing a feasible timeline for the different consultation methods. It is paramount to coordinate carefully with the contractor to understand how to run the consultation and what is expected from each party.*

(5) *A **consultation webpage** should be created that has all the relevant information (including the consultation strategy containing the planned dates of the different consultation activities).*

(6) *The **stakeholder consultation** should be documented as Annex 2 of the Staff Working Document drafted for the evaluation, with Annex 1 containing procedural information concerning the evaluation process and Annex 3 focusing on Methods and analytical models used in preparing the evaluation. A brief summary of the consultation strategy/ process should be provided in Annex 2 – including details of how, who and on what consultation took place and an explanation of how it was ensured that all relevant stakeholders had a possibility to provide inputs. More specifically, it should be documented which groups of stakeholders have been consulted, at what stage in the process and how (via public or via targeted consultations).*

Dates for consultation will equally be included in the Commission's Consultation Planning Calendar, compiled by the Secretariat-General and published in «Your voice in Europe ».

The Better Regulation Toolbox

A toolbox to complement the Better Regulation Guidelines has also been published and presented in the form of a single document structured around eight chapters containing individual tools that are ultimately available as downloadable web tools on the dedicated website. The Toolbox presents a comprehensive array of additional guidance to assist practitioners in the application of better regulation principles.

The Toolbox contains 8 main chapters and introduces a standardized terminology as well as a specific rationale for EU policy-making, which is to reduce the administrative burden on political and economic systems as well as to increase the efficiency of law-making at EU level. Key to this undertaking is the improvement of the dialogue with stakeholders that are now more extensively consulted at different intervals in the process. We will look at this section in more detail further on.

Chapter 1 defines key principles and concepts underpinning Better Regulation at the European Commission while Chapter 2 relates to tools for carrying out an Impact Assessment (IA). Chapter 3 presents tools for assessing specific impacts, whether they are estimated prospectively in the context of an IA or retrospectively when carrying out evaluations or Fitness Checks (i.e. specific evaluation exercises spanning all the regulation applicable in a given sector).

Chapters 4, 5 and 6 provide a short summary of how to facilitate and verify the transposition and conformity of EU law, they describe how to establish monitoring systems which is a clear innovation in EU policy-making and provide guidance on how to carry out Evaluations and Fitness Checks.

Chapter 7 lays out how to consult stakeholders in the context of Better Regulation. A clear innovation is again here the need defined to dispose of a stakeholder consultation strategy that is collectively approved and based on a specific stakeholder analysis. The Commission intends with the emphasis on this tool to streamline the consultation process and to ensure that important parts of the stakeholder communities are not ignored or marginalised in the process.

In practical terms, all documents pertaining to a public consultation are published on a website that is linked to automatic alerts to subscribers allowing stakeholders to react in good time to the documents under consultation. The time allowed for the process has also been considerably extended, the minimum currently being 12 weeks.

Chapter 8 summarises methods to identify, assess and quantify costs and benefits of legislation. The tools are comprehensive and are expected to cover the relevant aspects of all initiatives and policy interventions.

Appendix 1. Supplementary material from Chapter 5

Section A. Full STATA results and sensitivity analysis

Appendix table 1 Full Results from STATA without Martin-Vanberg Scores

Virgin	Raw	Raw	Unique	Trans-	Trans-			Total	%	
Text	Score	SE	Scored	formed	formed	Transformed	[95% Conf. Interval]	Words	Tot	True Raw
			Words	Score	SE			Scored	Sc'd	score
tBEUC	0.2878	0.0098	264	-1.1041	0.0686	-1.2414	-0.9668	479	100	0.2878
tHAI	0.356	0.005	737	-0.6248	0.0349	-0.6946	-0.555	2,088	100	0.356
tepha	0.4511	0.0146	141	0.0433	0.1024	-0.1615	0.2481	286	82.7	0.545466
tgavi	0.5762	0.0228	84	0.9225	0.1603	0.6019	1.243	137	87.8	0.656264
tWHO	0.5154	0.0164	125	0.4954	0.1152	0.265	0.7259	238	82.6	0.623971
timg	0.5099	0.0163	123	0.4567	0.1142	0.2282	0.6851	269	82.8	0.615821
tBE	0.4988	0.0156	119	0.3784	0.1099	0.1585	0.5983	244	81.6	0.611275
tCH	0.4542	0.072	16	0.0651	0.5061	-0.9472	1.0774	16	66.7	0.68096
tIE	0.6181	0.0298	52	1.2172	0.2093	0.7986	1.6359	79	89.8	0.688307
tFI	0.5201	0.0324	46	0.5285	0.2275	0.0736	0.9835	75	83.3	0.62437
tHR	0.5009	0.0246	70	0.3935	0.1729	0.0477	0.7393	113	89	0.562809
tES	0.5009	0.0253	60	0.3935	0.1775	0.0385	0.7485	96	85	0.589294
tLT	0.4924	0.0502	28	0.3334	0.3527	-0.3721	1.0389	33	76.7	0.641982
tHU	0.5327	0.0094	271	0.6168	0.0658	0.4852	0.7483	726	86.2	0.617981
tSK	0.5066	0.01	253	0.4338	0.0703	0.2932	0.5744	794	86.8	0.583641
tMT	0.5323	0.0245	77	0.6141	0.1724	0.2694	0.9588	117	88	0.604886
tSE	0.4732	0.0323	57	0.199	0.2266	-0.2542	0.6522	74	74.7	0.633467
tNO	0.588	0.019	109	1.0051	0.1337	0.7376	1.2725	191	88	0.668182
tTR	0.4732	0.0318	38	0.1988	0.2236	-0.2484	0.6461	56	77.8	0.608226
tEGA	0.6987	0.0066	499	1.783	0.0467	1.6896	1.8763	1,275	100	0.6987
taok	0.5081	0.0112	225	0.4442	0.0787	0.2868	0.6015	588	76.6	0.663316
tAIM	0.5502	0.0217	93	0.7395	0.1526	0.4343	1.0448	162	82.2	0.669343
tAmgen	0.6125	0.0037	1,223	1.1774	0.0258	1.1257	1.2291	5,367	96.1	0.637357
tEFPIA	0.6576	0.0024	2,482	1.4943	0.0167	1.4609	1.5277	12,855	100	0.6576
tpreconsult	0.5379	0.0054	599	0.6531	0.0382	0.5768	0.7295	2,260	92.3	0.582774
tReport	0.5112	0.0051	579	0.4656	0.0361	0.3934	0.5378	2,717	85.9	0.595111
tpublic	0.5421	0.0052	627	0.6826	0.0363	0.61	0.7552	2,432	92.2	0.587961

Appendix table 2 Full STATA results with Martin Vanberg scores and estimates of precision (95% CIs)

Virgin	Raw	Raw	Unique Scored	Trans- formed	Trans- formed	Transformed	Total Words	% Tot	True Raw			Standard Unit	Reeves MV transfor	Variance	MV Variance	MV SE	MV low 95	MV high 95
Text	Score	SE	Words	Score	SE	[95% Conf. Interval]	Scored	Sc'd	score	Difference								
tBEUC	0.2878	0.0098	264	-1.1041	0.0686	-1.2414 -0.9668	479	100	0.2878	0	2.433682161	0	0.002593	0.004420124	0.012795	-0.02507791	0.0250779	
tHAI	0.356	0.005	737	-0.6248	0.0349	-0.6946 -0.555	2,088	100	0.356	0.0682	2.433682161	0.165977	0.000675	0.001423251	0.00726	0.151746795	0.1802075	
tEpha	0.4511	0.0146	141	0.0433	0.1024	-0.1615 0.2481	286	82.7	0.545466	0.1633	2.433682161	0.39742	0.005755	0.015376944	0.023865	0.350645792	0.4441948	
tgavi	0.5762	0.0228	84	0.9225	0.1603	0.6019 1.243	137	87.8	0.656264	0.2884	2.433682161	0.701874	0.014036	0.04789988	0.04212	0.619319311	0.7844286	
tWHO	0.5154	0.0164	125	0.4954	0.1152	0.265 0.7259	238	82.6	0.623971	0.2276	2.433682161	0.553906	0.007262	0.022167851	0.028654	0.497744911	0.6100672	
tbmg	0.5099	0.0163	123	0.4567	0.1142	0.2282 0.6851	269	82.8	0.615821	0.2221	2.433682161	0.540521	0.007174	0.021664651	0.028327	0.485000733	0.5960409	
tBE	0.4988	0.0156	119	0.3784	0.1099	0.1585 0.5983	244	81.6	0.611275	0.211	2.433682161	0.513507	0.006571	0.019411859	0.026813	0.460952697	0.5660612	
tCH	0.4542	0.072	16	0.0651	0.5061	-0.9472 1.0774	16	66.7	0.68096	0.1664	2.433682161	0.404965	0.139968	0.376534885	0.118092	0.173504689	0.6364247	
tE	0.6181	0.0298	52	1.2172	0.2093	0.7986 1.6359	79	89.8	0.688307	0.3303	2.433682161	0.803845	0.023977	0.087777408	0.057018	0.692090577	0.9155999	
tFI	0.5201	0.0324	46	0.5285	0.2275	0.0736 0.9835	75	83.3	0.62437	0.2323	2.433682161	0.565344	0.028344	0.087310878	0.056866	0.453887105	0.6768016	
tHR	0.5009	0.0246	70	0.3935	0.1729	0.0477 0.7393	113	89	0.562809	0.2131	2.433682161	0.518618	0.016339	0.048474432	0.042372	0.435569406	0.6016659	
tES	0.5009	0.0253	60	0.3935	0.1775	0.0385 0.7485	96	85	0.589294	0.2131	2.433682161	0.518618	0.017282	0.051272389	0.043577	0.433206244	0.6040291	
tLT	0.4924	0.0502	28	0.3334	0.3527	-0.3721 1.0389	33	76.7	0.641982	0.2046	2.433682161	0.497931	0.068041	0.198434399	0.085729	0.329902979	0.6659598	
tHU	0.5327	0.0094	271	0.6168	0.0658	0.4852 0.7483	726	86.2	0.617981	0.2449	2.433682161	0.596009	0.002386	0.007527138	0.016697	0.563283047	0.6287345	
tSK	0.5066	0.01	253	0.4338	0.0703	0.2932 0.5744	794	86.8	0.583641	0.2188	2.433682161	0.53249	0.0027	0.008101336	0.017322	0.498538661	0.5664407	
tMT	0.5323	0.0245	77	0.6141	0.1724	0.2694 0.9588	117	88	0.604886	0.2445	2.433682161	0.595035	0.016207	0.051095202	0.043502	0.509771574	0.680299	
tSE	0.4732	0.0323	57	0.199	0.2266	-0.2542 0.6522	74	74.7	0.633467	0.1854	2.433682161	0.451205	0.028169	0.078948024	0.054074	0.345219571	0.5571898	
tNO	0.588	0.019	109	1.0051	0.1337	0.7376 1.2725	191	88	0.668182	0.3002	2.433682161	0.730591	0.009747	0.033945015	0.035457	0.661095003	0.8000878	
tTR	0.4732	0.0318	38	0.1988	0.2236	-0.2484 0.6461	56	77.8	0.608226	0.1854	2.433682161	0.451205	0.027303	0.07652273	0.053237	0.346860207	0.5554591	
tEGA	0.6987	0.0066	499	1.783	0.0467	1.6896 1.8763	1,275	100	0.6987	0.4109	2.433682161	1	0.001176	0.004867098	0.013426	0.973684645	1.0263154	
taok	0.5081	0.0112	225	0.4442	0.0787	0.2868 0.6015	588	76.6	0.663316	0.2203	2.433682161	0.53614	0.003387	0.010192406	0.019429	0.498058811	0.5742215	
tAIM	0.5502	0.0217	93	0.7395	0.1526	0.4343 1.0448	162	82.2	0.669343	0.2624	2.433682161	0.638598	0.012714	0.041431584	0.039173	0.56181964	0.7153768	
tAmgen	0.6125	0.0037	1,223	1.1774	0.0258	1.1257 1.2291	5,367	96.1	0.637357	0.3247	2.433682161	0.790217	0.00037	0.001340914	0.007047	0.776404021	0.8040292	
tEPIA	0.6576	0.0024	2,482	1.4943	0.0167	1.4609 1.5277	12,855	100	0.6576	0.3698	2.433682161	0.899976	0.000156	0.000605725	0.004736	0.890692156	0.9092592	
tpreconsult	0.5379	0.0054	599	0.6531	0.0382	0.5768 0.7295	2,260	92.3	0.582774	0.2501	2.433682161	0.608664	0.000787	0.002508306	0.009638	0.589772495	0.6275553	
tReport	0.5112	0.0051	579	0.4656	0.0361	0.3934 0.5378	2,717	85.9	0.595111	0.2234	2.433682161	0.543685	0.000702	0.002126291	0.008874	0.526291153	0.561078	
tpublic	0.5421	0.0052	627	0.6826	0.0363	0.61 0.7552	2,432	92.2	0.587961	0.2543	2.433682161	0.618885	0.00073	0.002344108	0.009318	0.600622758	0.637148	

The standard unit, according to equation 2 of the classical Martin Vanberg paper (Martin and Vanberg, 2007) is 2.43668. To perform a sensitivity analysis for the Martin-Vanberg transformation scores and obtain estimates of precision for each document scanned via the algorithm, I recalculated the MV transformation using the formal transformation in equation 4 of the classical Martin-Vanberg paper (Martin and Vanberg, 2007). We then recalculate the variance for these scores and transform this variance using the equation on page 360 in a critical methodological review paper (Lowe, 2008). This then results in estimates which are tight around the point estimates just as the original standard errors.

Section B. Glossary of terminology

Generic drugs can be:

- Branded generics (generics with a specific trade name)
- Unbranded generics (using the international non-proprietary name and the name of the company)

Generic drugs, according to European legislation are pharmaceutical products which have the same qualitative and quantitative composition in active substances and the same pharmaceutical form as a reference medicinal product, and whose bioequivalence with the reference medicinal product is evidenced by appropriate bioavailability studies. However, it should be noted that there is a variety of different, sometimes overlapping, definitions of the term 'generics' due to differences in the requirements for registration of generics between countries, especially related to the degree and proof of therapeutic equivalence and the fact that they can be sold under brand (branded generics) or International Nonproprietary Name (unbranded generics). The World Health Organization (WHO) defines generics as multi-source pharmaceutical products that are therapeutically equivalent, not taking into consideration of whether or not the 'originator' molecule is, or was, under patent protection.

Biological medicines are medicines that are made by or derived from a biological source, such as a bacterium or yeast.

A *biosimilar* is a biological medicine that is similar to another biological medicine that has already been authorized for use.

Specialty medicines do not benefit from a unique definition. They usually include injectable and biologic agents used to treat complex conditions such as rheumatoid arthritis, multiple sclerosis and cancer and often require special handling or delivery mechanisms.

Orphan drugs refer to medicines developed for rare conditions.

The categories of pharmaceuticals above refer to *retail pharmaceuticals*, delivered to patients via pharmacies and other retail outlets. Pharmaceuticals can also be dispensed in other care settings – primarily *the hospital inpatient sector* – where the pharmaceuticals used are considered as an input to the overall service treatment and not separately accounted. Present health accounts do allow for additional reporting items to monitor a total pharmaceutical

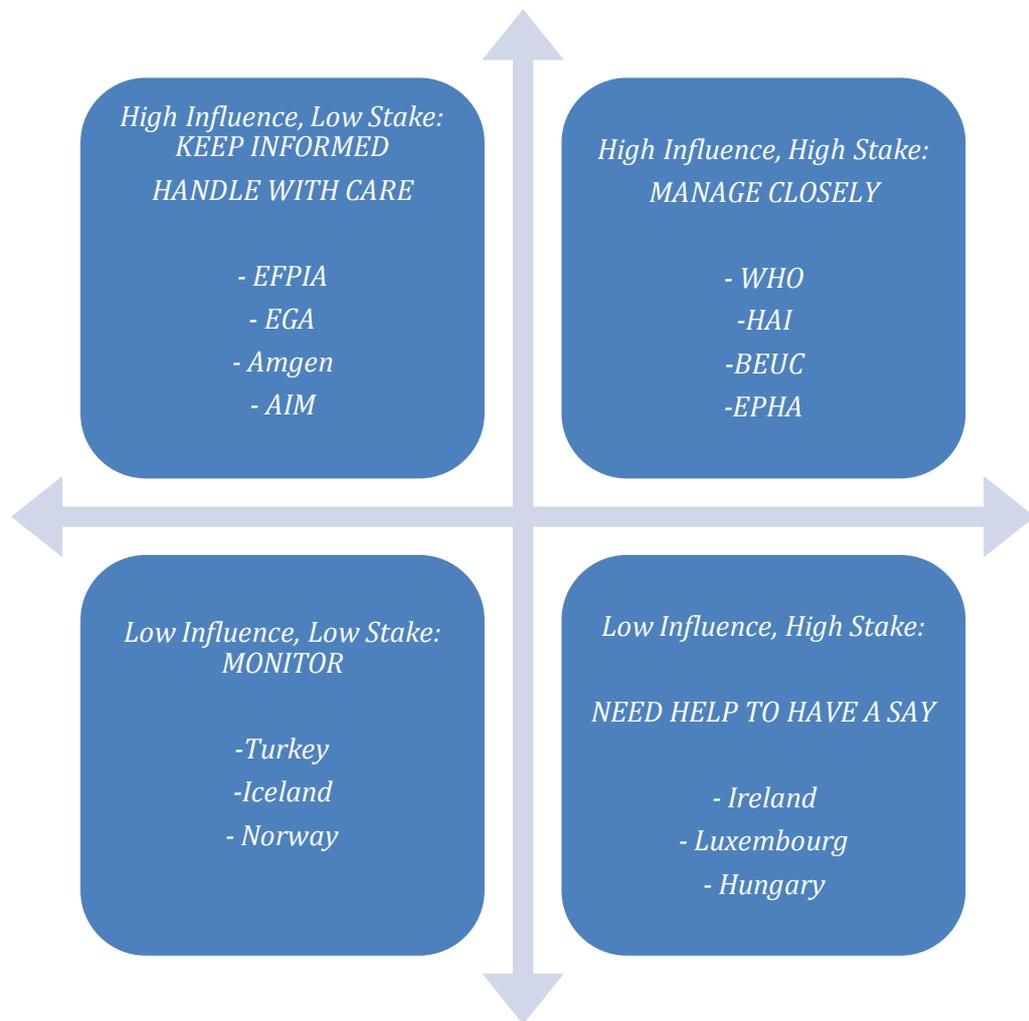
spending estimate covering all modes of provision (inpatient and retail). Currently though, only a handful of countries report such figures to OECD.

Section C. Stakeholder analysis

I performed a stakeholder analysis, based on Schmeer's methodology (Schmeer, 1999), which I linked to the findings of my corpus analysis of the submissions. The diagram below provides an illustration of the average raw scores that emerged for each submission. The diagram results from an additional layer of generalisation and abstraction, which runs counter to the conventional wisdom that stakeholders should be analysed at the level of individual topics or subjects, notwithstanding the need to take into account their heterogeneity.

We refer to:

- Position/ Interest, along the x-axis, whether the stakeholder supports, opposes or is neutral with regard to a more stringent regulation of pharmaceuticals;
- Power/ Influence, along the y-axis, the stakeholder's ability to influence the pharmaceutical-related policy.



Key messages that emerge from the analysis include:

- The key stakeholders are those in the top right quadrant, which have both a high level of interest in the more stringent regulation of pharmaceuticals, and some level of influence over its implementation. These are the innovators or the “first movers” who have a “natural” interest in acting as policy entrepreneurs and supporting the push for tighter regulation and more equitable access to pharmaceuticals.
- The groups in the bottom right quadrant are potentially interested, but their influence is limited due to small national markets, which translates into their engagement being strategically important yet less vocal.
- The stakeholders in the top left quadrant are of note, as their high level of influence coincides with relatively low levels of interest in tighter regulation – they are the exponents of the industrial core.

- Finally, the bottom left quadrant contains the stakeholders that combine low levels of interest with a low level of influence over EU policy and they are the governmental agencies regulating pharmaceuticals outside of the EU bloc.

Appendix 2. Supplementary material from Chapter 6

Appendix table 3 STATA, LBG and MV Transformation results with AT, Kantonales, FoodDrink Europe and NCFUS as reference texts

Virgin Text	Raw Score (ST/ SE)	Raw Score (ST/ SE)	Unique Scored Words	Trans-formed Score	Trans-formed SE	Transformed [95% Conf. Interval]	Words Scored	% Tot Sc'd	True Raw score	Difference	Standard Unit	Reeves MV transfor	Variance	MV Variar	MV SE	MV low 95	MV high 95
tAT	0.2071	0.0187	93	-0.2721	0.0678	-0.4076 -0.1366	135	100	0.2071	0	1.67729	0	0.006994	0.004075	0.014274	-0.0279767	0.027977
tCHOPRABISCO	0.3777	0.0196	77	0.3462	0.0709	0.2044 0.4881	197	69.1	0.546599	0.1706	1.67729	0.286146	0.007683	0.008164	0.020204	0.24654573	0.325745
tCL	0.3639	0.0066	329	0.2961	0.0239	0.2484 0.3439	1,674	76.3	0.476933	0.1568	1.67729	0.262999	0.000871	0.000892	0.006678	0.24991022	0.276088
tBDSI	0.3411	0.0178	111	0.2135	0.0645	0.0844 0.3426	235	73.7	0.462822	0.134	1.67729	0.224757	0.006337	0.006081	0.017437	0.1905805	0.258933
tDKSE	0.355	0.0115	168	0.2639	0.0418	0.1803 0.3475	556	74.2	0.478437	0.1479	1.67729	0.248071	0.002645	0.002642	0.011493	0.22554553	0.270597
tECF	0.7154	0.006	308	1.5703	0.0219	1.5265 1.614	1,904	99.7	0.717553	0.5083	1.67729	0.852566	0.00072	0.001449	0.008512	0.83588265	0.86925
tEFSADraft	0.2928	0.001	1054	0.0383	0.0037	0.0309 0.0457	80,348	58.2	0.503093	0.0857	1.67729	0.143744	0.00002	1.65E-05	0.000908	0.14196482	0.145523
tEFSASciOp	0.2925	0.001	1,070	0.0371	0.0035	0.0301 0.0441	90,178	58.1	0.503442	0.0854	1.67729	0.143241	0.00002	1.65E-05	0.000907	0.14146254	0.145019
tEPPA	0.371	0.0207	102	0.3218	0.0752	0.1714 0.4722	189	77.1	0.481193	0.1639	1.67729	0.274908	0.00857	0.008945	0.021148	0.23345805	0.316357
tES	0.337	0.0172	112	0.1986	0.0624	0.0738 0.3233	260	75.4	0.44695	0.1299	1.67729	0.21788	0.005917	0.00561	0.016748	0.1850547	0.250705
tFoodDrinkEurope	0.7128	0.0044	719	1.5607	0.016	1.5287 1.5927	3,805	100	0.7128	0.5057	1.67729	0.848205	0.000387	0.000776	0.006231	0.83599291	0.860418
tFPP	0.3696	0.0131	162	0.3169	0.0473	0.2223 0.4115	465	73.7	0.501493	0.1625	1.67729	0.27256	0.003432	0.003569	0.013358	0.24637763	0.298741
tISS	0.3454	0.01	192	0.229	0.0363	0.1565 0.3016	751	66.9	0.516293	0.1383	1.67729	0.231969	0.002	0.001943	0.009858	0.21264833	0.25129
tKantonales	0.2768	0.0054	886	-0.0198	0.0196	-0.059 0.0194	2,736	100	0.2768	0.0697	1.67729	0.116907	0.000583	0.000454	0.004765	0.10756721	0.126247
tLTDH	0.2746	0.032	39	-0.0277	0.1161	-0.2598 0.2045	80	61.1	0.449427	0.0675	1.67729	0.113217	0.02048	0.015821	0.028126	0.05809004	0.168344
tNCFUS	0.8033	0.0077	120	1.8888	0.0277	1.8333 1.9443	715	100	0.8033	0.5962	1.67729	1	0.001186	0.00268	0.011575	0.97731213	1.022688
tNovozymes	0.321	0.0145	124	0.1407	0.0524	0.0359 0.2455	338	66.1	0.485628	0.1139	1.67729	0.191043	0.004205	0.003797	0.013779	0.16403576	0.218051
tRenaissance	0.3099	0.0137	109	0.1002	0.0495	0.0011 0.1992	370	63.2	0.490348	0.1028	1.67729	0.172425	0.003754	0.003273	0.012792	0.14735299	0.197498
tTechnicalReport	0.3672	0.0025	898	0.3081	0.009	0.2901 0.326	13,314	71.8	0.511421	0.1601	1.67729	0.268534	0.000125	0.000129	0.002541	0.26355375	0.273514
tUK	0.3606	0.0088	265	0.2841	0.0318	0.2206 0.3476	1,011	74.8	0.482086	0.1535	1.67729	0.257464	0.001549	0.001571	0.008863	0.24009155	0.274836

The standard unit, according to equation 2 of the classical Martin Vanberg paper (Martin and Vanberg, 2007) is 1.67729. I decided against using these values.

To test the robustness of my results, I re-estimated word scores using a different classification method for the texts. I first used as reference texts only the four documents from the Austrian Agency for Health and Food Safety, Kantonales Labor Zurich on the one hand and FoodDrinkEurope and European Coffee Federation on the other to classify the policy positions of the other stakeholders in the confectionary, coffee and food industry and the public health bodies.

Appendix table 4 STATA, LBG and MV Transformation results with AT, Kantonalas, FoodDrinkEurope and ECF as reference texts

Virgin Text	Raw Score (ST/SE)	Raw Score	Unique Words	Trans- Score	Trans- SE	Transformed [95% Conf. Interval]	Words Scored	Total Words	% Sc'd	True Raw score	Difference	Standard Unit	Reeves MV transfor	Variance	MV Variar	MV SE	MV low 95	MV high 95
tAT	0.2337	0.0196	93	-0.2279	0.0784	-0.3847 -0.0711	135	100	100	0.2337	0	1.935359	0	0.007683	0.006725	0.018338	-0.0359421	0.035942
tCHOPRABISCO	0.3564	0.0191	77	0.2632	0.0765	0.1101 0.4162	197	69.1	69.1	0.515774	0.1227	1.935359	0.237469	0.007296	0.00974	0.022068	0.19421519	0.280722
tCL	0.3681	0.0066	326	0.3098	0.0266	0.2566 0.363	1,669	76.1	76.1	0.483706	0.1344	1.935359	0.260112	0.000871	0.001201	0.00775	0.24492272	0.275302
tBDSI	0.3412	0.0177	111	0.2022	0.0708	0.0605 0.3439	235	73.7	73.7	0.462958	0.1075	1.935359	0.208051	0.006266	0.008008	0.02001	0.1688322	0.24727
tDKSE	0.3745	0.0115	166	0.3354	0.0461	0.2431 0.4276	554	74	74	0.506081	0.1408	1.935359	0.272499	0.002645	0.00371	0.01362	0.24580285	0.299194
tECF	0.7504	0.0053	313	1.8391	0.0213	1.7964 1.8817	1,910	100	100	0.7504	0.5167	1.935359	1	0.00562	0.001579	0.008886	0.98258434	1.017416
tEFSADraft	0.2838	0.001	1043	-0.0272	0.004	-0.0353 -0.0191	79,080	57.3	57.3	0.495288	0.0501	1.935359	0.096961	0.00002	2.13E-05	0.001031	0.09494068	0.098982
tEFSASciOp	0.2837	0.001	1,059	-0.0277	0.0038	-0.0353 -0.0201	88,777	57.2	57.2	0.495979	0.05	1.935359	0.096768	0.00002	2.13E-05	0.001031	0.0947475	0.098788
tEPPA	0.3864	0.0209	102	0.3829	0.0836	0.2158 0.55	189	77.1	77.1	0.501167	0.1527	1.935359	0.295529	0.008736	0.012644	0.025144	0.24624799	0.344811
tES	0.3406	0.0171	111	0.1997	0.0684	0.0629 0.3366	259	75.1	75.1	0.453529	0.1069	1.935359	0.20689	0.005848	0.007461	0.019314	0.16903376	0.244746
tFoodDrinkEurope	0.7361	0.004	719	1.7817	0.0161	1.7494 1.8139	3,805	100	100	0.7361	0.5024	1.935359	0.972324	0.00032	0.000882	0.006642	0.95930631	0.985342
tFPP	0.384	0.0128	163	0.3734	0.0512	0.2711 0.4758	466	73.9	73.9	0.519621	0.1503	1.935359	0.290884	0.003277	0.004713	0.015351	0.26079647	0.320972
tISS	0.3572	0.0099	187	0.2663	0.0397	0.1869 0.3458	745	66.3	66.3	0.538763	0.1235	1.935359	0.239017	0.00196	0.002623	0.011451	0.21657241	0.261461
tKantonalas	0.2799	0.0054	886	-0.0431	0.0217	-0.0865 0.0003	2,736	100	100	0.2799	0.0462	1.935359	0.089414	0.000583	0.000611	0.005529	0.07857649	0.100251
tLTDH	0.2718	0.0318	39	-0.0755	0.1274	-0.3303 0.1792	80	61.1	61.1	0.444845	0.0381	1.935359	0.073737	0.020225	0.02059	0.032086	0.01084894	0.136625
tNCFUS	0.6215	0.011	97	1.3236	0.044	1.2355 1.4117	645	90.2	90.2	0.689024	0.3878	1.935359	0.750532	0.00242	0.005634	0.016783	0.71763715	0.783427
tNovozymes	0.3236	0.0144	123	0.1319	0.0577	0.0165 0.2473	337	65.9	65.9	0.491047	0.0899	1.935359	0.173989	0.004147	0.005027	0.015854	0.14291569	0.205062
tRenaissance	0.3069	0.0136	109	0.0649	0.0544	-0.044 0.1737	370	63.2	63.2	0.485601	0.0732	1.935359	0.141668	0.003699	0.004252	0.014581	0.11308876	0.170248
tTechnicalReport	0.3799	0.0025	889	0.3572	0.0098	0.3375 0.3768	13,268	71.5	71.5	0.531329	0.1462	1.935359	0.282949	0.000125	0.000178	0.002982	0.27710438	0.288795
tUK	0.3708	0.0087	259	0.3206	0.0348	0.251 0.3901	1,005	74.4	74.4	0.498387	0.1371	1.935359	0.265338	0.001514	0.002102	0.010253	0.24524185	0.285434

The standard unit, according to equation 2 of the classical Martin Vanberg paper (Martin and Vanberg, 2007) is 1.935359. I decided to retain these values.

Section D. Sensitivity Analysis for all texts under the Martin-Vanberg Transformation

To perform a sensitivity analysis for the Martin-Vanberg transformation scores and obtain estimates of precision for each document scanned via the algorithm, I recalculated the MV transformation using the formal transformation in equation 4 of the classical Martin-Vanberg paper (Martin and Vanberg, 2007). We then recalculate the variance for these scores and transform this variance using the equation on page 360 in a critical methodological review paper (Lowe, 2008). This then results in estimates which are tight around the point estimates just as the original standard errors.

Appendix table 5 Full STATA results including sensitivity analysis for individual MV scores

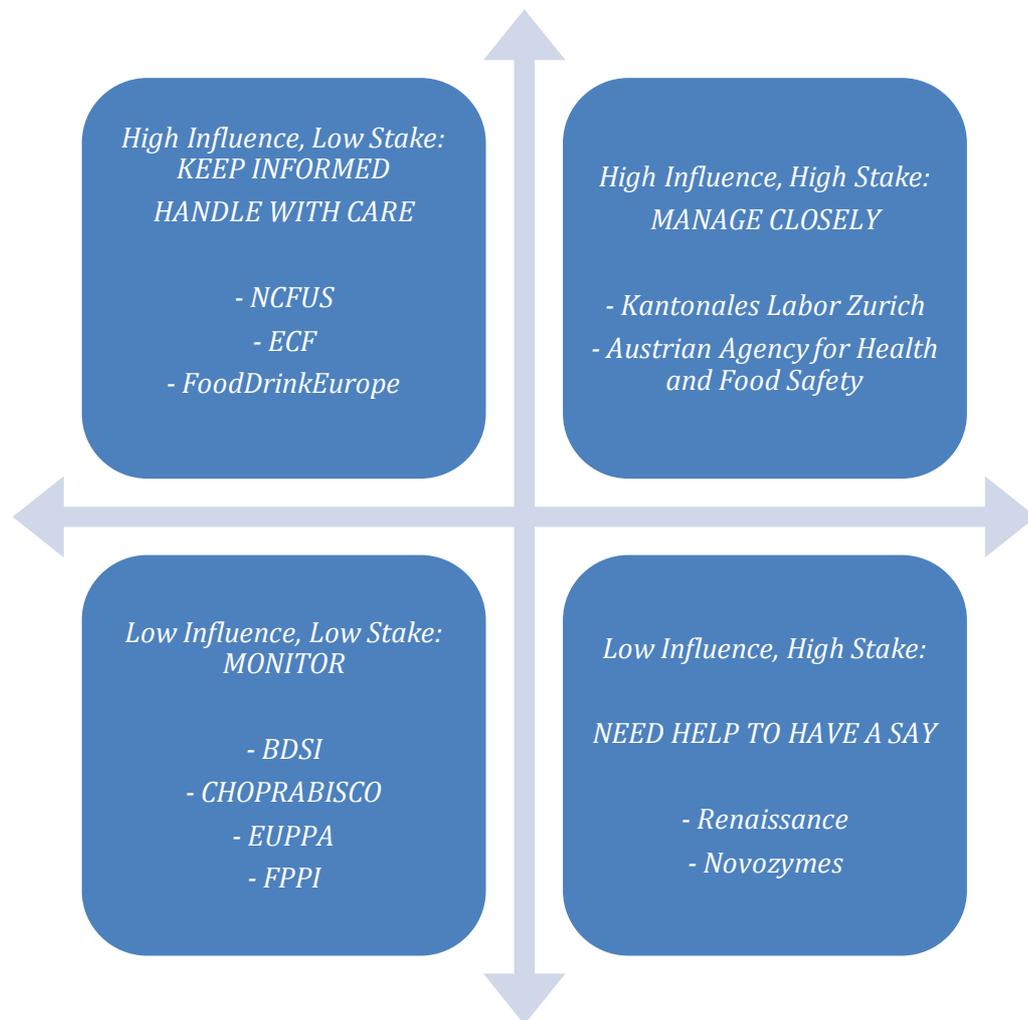
Stakeholder or version of report	Word count	Unique words scored	Raw score	LBG score	MV score	Lower limit MV score CI	Upper limit MV score CI
<i>Industry</i>							
ECF	1910	313	0.7504	1.8391	1	0.9825	1.0174
FoodDrinkEurope	3805	719	0.7361	1.7817	0.972324	0.9593	0.9853
NCFUS	645	97	0.6215	1.3236	0.750532	0.7176	0.7834
BDSI	235	111	0.3412	0.2022	0.208051	0.1688	0.2472
Novozymes	337	123	0.3236	0.1319	0.173989	0.1429	0.2050
Renaissance	370	109	0.3069	0.0649	0.141668	0.1131	0.1702
BE	197	77	0.3564	0.2632	0.237469	0.19421	0.28072
FPP	466	163	0.384	0.3734	0.290884	0.26079	0.32097
EPPA	189	102	0.3864	0.3829	0.295529	0.24624	0.34481
<i>Neutral</i>							
Pre-consult (Draft Scientific Opinion)	79080	1043	0.2838	-0.0272	0.096961	0.0949	0.0989
Post-consult publication (Scientific Opinion)	88777	1059	0.2837	-0.0277	0.096768	0.0947	0.0987
Technical Report of the stakeholder review	13268	889	0.3799	0.3572	0.282949	0.2771	0.2887
<i>Advocacy</i>							
AT	135	93	0.2337	-0.2279	0	-0.0359	0.0359
Kantonales	2736	886	0.2799	-0.0431	0.089414	0.07858	0.1002
DKSE	554	166	0.3745	0.3354	0.272499	0.24580	0.2992
CL	1669	326	0.3681	0.3098	0.260112	0.24492	0.2753
ISS	745	187	0.3572	0.2663	0.239017	0.21657	0.2614
UK	1005	259	0.3708	0.3206	0.265338	0.24524	0.2854
ES	259	111	0.3406	0.1997	0.20689	0.16903	0.2447

Section E. Stakeholder Analysis Acrylamide Case Study Submissions

I performed a stakeholder analysis, based on Schmeer’s methodology (Schmeer, 1999), which I linked to the findings of my corpus analysis of the submissions. The diagram below provides an illustration of the average raw scores that emerged for each submission. The diagram results from an additional layer of generalisation and abstraction, which runs counter to the conventional wisdom that stakeholders should be analysed at the level of individual topics or subjects, notwithstanding the need to take into account their heterogeneity.

We refer to:

- Position/ Interest, along the x-axis, whether the stakeholder supports, opposes or is neutral with regard to a more stringent regulation of acrylamide;
- Power/ Influence, along the y-axis, the stakeholder’s ability to influence the acrylamide-related policy.



Key messages that emerge from the analysis include:

- The key stakeholders are those in the top right quadrant, which have both a high level of interest in the more stringent regulation of acrylamide, and some level of influence over its implementation. These are the innovators or the “first movers” who have a “natural” interest in acting as policy entrepreneurs and supporting the push for tighter regulation.
- The groups in the bottom right quadrant are potentially interested, but their influence is limited, which translates into their engagement being strategically less important.

- The stakeholders in the top left quadrant are of note, as their high level of influence coincides with relatively low levels of interest in tighter regulation – they are the exponents of the industrial core.
- Finally, the bottom left quadrant contains the stakeholders that combine low levels of interest with a low level of influence and they are the smaller federations of industrial producers (often sectorial and national in nature).

Appendix 3: Supplementary material from Chapter 7

Appendix table 6 STATA, LBG and MV Transformation results with EPfirstreading, EPsecondreading, CONSpfirstreading and CONSpfirstreadingpress as reference texts

Virgin	Unique Raw	Trans Raw	Trans Scored	Trans formed	Trans formed	Total Transformed	% [95% Conf. Interval]	Words Scored	% Sc'd	True Raw score	Reeves MV transformed	Difference	Standard Unit	MV Variance	MV SE	MV low 95	MV high 95	
tCOMoriginal	0.435	0.0011	1,744	0.2091	0.0085	0.192	0.2262	21,359	96.6	0.45031056	0.04	4.076641	0.146351406	0.00001815	0.00013121	0.00296	0.140554506	0.152148
tIA	0.395	0.0011	1,747	0.1101	0.0089	-0.128	-0.0922	27,940	91.6	0.43122271	0.00	4.076641	-0.01671423	0.00001815	0.00011915	0.00282	-0.02223818	-0.01119
tEPfirstreading	0.3991	0.0007	4,935	0.0775	0.0057	-0.0889	-0.0661	77,878	100	0.3991	0.00	4.076641	0	0.00000735	4.875E-05	0.0018	-0.00353344	0.003533
tEPsecondreading	0.4579	0.0011	1,892	0.3929	0.0092	0.3746	0.4112	15,520	100	0.4579	0.06	4.076641	0.239706482	0.00001815	0.00013812	0.00303	0.233758953	0.245654
tEPSCO	0.4755	0.0011	1,556	0.5332	0.0089	0.5155	0.551	13,455	98.9	0.48078868	0.08	4.076641	0.311455361	0.00001815	0.00014343	0.00309	0.305394609	0.317516
tEPSCOpress	0.5418	0.0054	412	1.0638	0.0429	0.9781	1.1495	1,322	94.6	0.57272727	0.14	4.076641	0.581736649	0.0004374	0.00393843	0.0162	0.549977286	0.613496
tEESCopinion	0.4069	0.0031	762	0.0149	0.025	-0.0649	0.0351	3,450	91.7	0.44372955	0.01	4.076641	0.031797799	0.00014415	0.00097478	0.00806	0.515997545	0.647598
tEDSPopinion	0.3962	0.0011	1,861	0.1008	0.0085	-0.1178	-0.0838	29,334	90.6	0.43730684	0.00	4.076641	-0.01182226	0.00001815	0.00011951	0.00282	-0.01735459	-0.00629
tCoRopinion	0.3742	0.0009	2,204	0.2766	0.0076	-0.2918	-0.2614	41,270	88.4	0.42330317	-0.02	4.076641	-0.10150836	0.00001215	7.5559E-05	0.00224	-0.10590735	-0.09711
tCONSpfirstreading	0.4985	0.0011	1,950	0.7178	0.0087	0.7003	0.7352	16,602	100	0.4985	0.10	4.076641	0.4052181	0.00001815	0.00015036	0.00317	0.3990125	0.411424
tCONSpfirstreadingpress	0.6444	0.0057	342	1.8845	0.0454	1.7937	1.9754	948	100	0.6444	0.25	4.076641	1	0.00048735	0.00521917	0.01865	0.963439583	1.036556
tCOMonCONSpfirstreading	0.482	0.003	710	0.5856	0.0243	0.537	0.6343	3,437	97.3	0.49537513	0.08	4.076641	0.337953526	0.000135	0.0010814	0.00849	0.321311611	0.354595
tCONSpPamendmentspress	0.543	0.0069	315	1.0737	0.055	0.9637	1.1837	793	96.7	0.56153051	0.14	4.076641	0.586628618	0.00071415	0.00644457	0.02073	0.546002294	0.627255
tCOMonEPsecondreading	0.4929	0.0085	162	0.6729	0.0677	0.5374	0.8083	470	94.8	0.51993671	0.09	4.076641	0.382388912	0.00108375	0.00887754	0.02433	0.334706649	0.430071
tDirectiveAdoptedText	0.4657	0.0011	1,661	0.4547	0.0088	0.4371	0.4724	14,386	99.8	0.46663327	0.07	4.076641	0.27150428	0.00001815	0.00014047	0.00306	0.26550631	0.277502

Appendix table 7 STATA, LBG and MV Transformation results with EPfirstreading, EPsecondreading, CONSpfirstreading and CONSpfirstreadingpress as reference texts

Virgin	Unique Raw	Trans Raw	Trans Scored	Trans formed	Trans formed	Total Transformed	% [95% Conf. Interval]	Words Scored	% Sc'd	True Raw score	Difference	Standard Unit	Reeves MV transform	Variance	MV SE	MV low 95	MV high 95	
tCOMoriginal	0.435	0.0011	1,744	0.2091	0.0085	0.192	0.2262	21,359	96.6	0.450311	0.05	4.076641	0.208767	1.82E-05	0.000135829	0.003009	0.202869023	0.21466509
tIA	0.395	0.0011	1,747	0.1101	0.0089	-0.128	-0.0922	27,940	91.6	0.431223	0.03	4.076641	0.130953	1.82E-05	0.000130072	0.002945	0.125181064	0.13672442
tEPfirstreading	0.3991	0.0007	4,935	0.0775	0.0057	-0.0889	-0.0661	77,878	100	0.3991	0.00	4.076641	0	7.35E-06	4.87499E-05	0.001803	-0.00353344	0.00353344
tEPsecondreading	0.4579	0.0011	1,892	0.3929	0.0092	0.3746	0.4112	15,520	100	0.4579	0.06	4.076641	0.239706	1.82E-05	0.000138119	0.003034	0.233758953	0.24565401
tEPSCO	0.4755	0.0011	1,556	0.5332	0.0089	0.5155	0.551	13,455	98.9	0.480789	0.08	4.076641	0.333015	1.82E-05	0.000145023	0.003109	0.326921028	0.33910975
tEPSCOpress	0.5418	0.0054	412	1.0638	0.0429	0.9781	1.1495	1,322	94.6	0.572727	0.17	4.076641	0.707816	0.000437	0.004163241	0.01666	0.675162797	0.74046927
tEESCopinion	0.4069	0.0031	762	0.0149	0.025	-0.0649	0.0351	3,450	91.7	0.44373	0.04	4.076641	0.181939	0.000144	0.001063011	0.008418	0.165438831	0.19843849
tEDSPopinion	0.3962	0.0011	1,861	0.1008	0.0085	-0.1178	-0.0838	29,334	90.6	0.437307	0.04	4.076641	0.155756	1.82E-05	0.000131907	0.002965	0.149943327	0.16156783
tCoRopinion	0.3742	0.0009	2,204	0.2766	0.0076	-0.2918	-0.2614	41,270	88.4	0.423303	0.02	4.076641	0.098668	1.22E-05	8.54737E-05	0.002387	0.093988904	0.10334634
tCONSpfirstreading	0.4985	0.0011	1,950	0.7178	0.0087	0.7003	0.7352	16,602	100	0.4985	0.10	4.076641	0.405218	1.82E-05	0.000150365	0.003166	0.3990125	0.4114237
tCONSpfirstreadingpress	0.6444	0.0057	342	1.8845	0.0454	1.7937	1.9754	948	100	0.6444	0.25	4.076641	1	0.000487	0.00521917	0.018653	0.963439583	1.03656042
tCOMonCONSpfirstreading	0.482	0.003	710	0.5856	0.0243	0.537	0.6343	3,437	97.3	0.495375	0.08	4.076641	0.392479	0.000135	0.001114406	0.008608	0.375607886	0.40935036
tCONSpPamendmentspress	0.543	0.0069	315	1.0737	0.055	0.9637	1.1837	793	96.7	0.561531	0.16	4.076641	0.662171	0.000714	0.006664502	0.021078	0.62085712	0.70348456
tCOMonEPsecondreading	0.4929	0.0085	162	0.6729	0.0677	0.5374	0.8083	470	94.8	0.519937	0.12	4.076641	0.492608	0.001084	0.009364498	0.024986	0.443635317	0.54158041
tDirectiveAdoptedText	0.4657	0.0011	1,661	0.4547	0.0088	0.4371	0.4724	14,386	99.8	0.466633	0.07	4.076641	0.275309	1.82E-05	0.000140753	0.003063	0.269304895	0.28131285

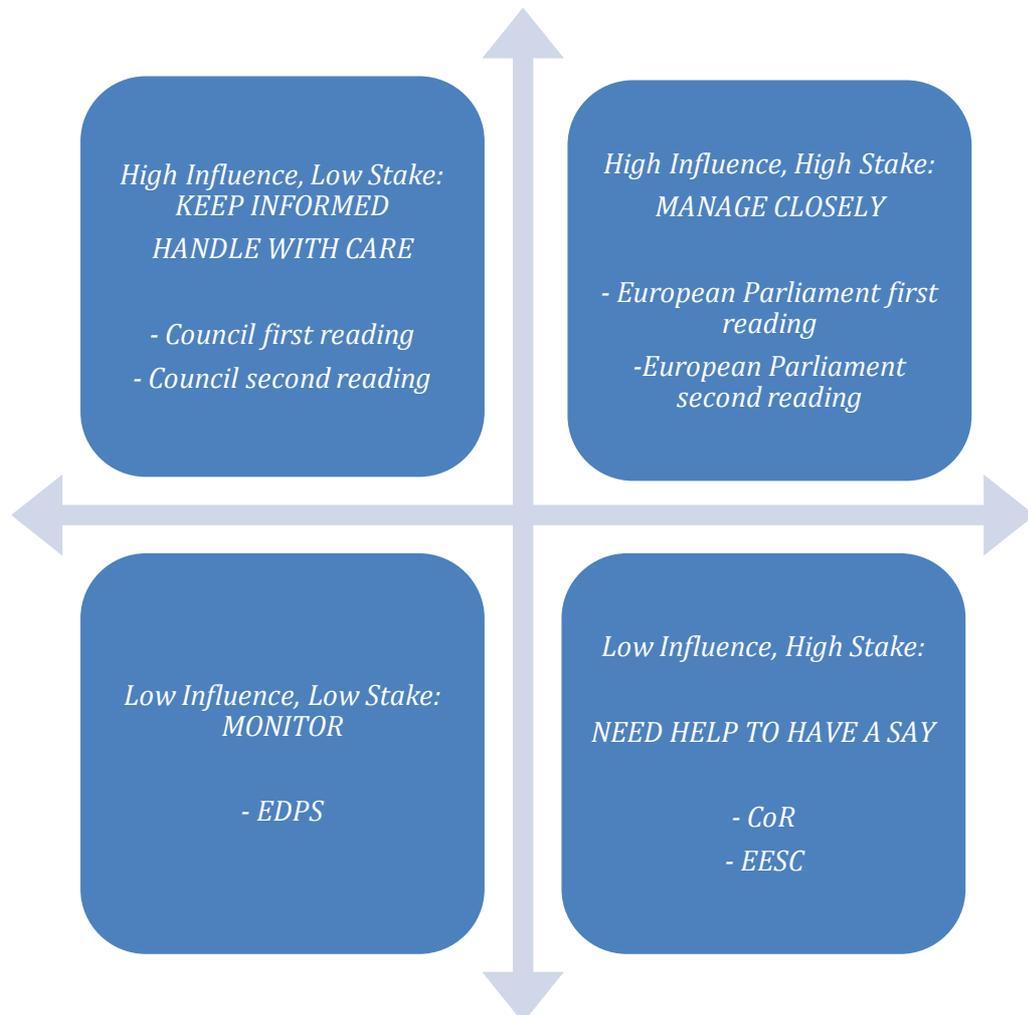
Section F. Stakeholder Analysis Directive Case Study

I performed a stakeholder analysis, based on Schmeer's methodology (Schmeer, 1999), which I linked to the findings of my corpus analysis of the submissions. The diagram below provides an illustration of the average raw scores that emerged for each submission. The diagram results from an additional layer of generalisation and abstraction, which runs counter to the conventional wisdom that stakeholders should be analysed at the level of individual topics or subjects, notwithstanding the need to take into account their heterogeneity.

We refer to:

Position/ Interest, along the x-axis, whether the stakeholder supports, opposes or is neutral with regard to a more stringent regulation of patient flows;

- Power/ Influence, along the y-axis, the stakeholder's ability to influence the cross-border healthcare policy.



Key messages that emerge from the analysis include:

- The key stakeholders are those in the top right quadrant, i.e. the European Parliament, which have both a high level of interest in the more stringent regulation of patient flows and patient rights, and some level of influence over its implementation. These are the innovators or the “first movers” who have a “natural” interest in acting as policy entrepreneurs and supporting the push for tighter regulation, without precluding more vigorous action in the field of rare diseases.

- The groups in the bottom right quadrant are potentially interested, but their influence is limited, which translates into their engagement being strategically less critical, yet imperative.
- The stakeholders in the top left quadrant are of note, as their high level of influence coincides with relatively low levels of interest in tighter regulation – they are the exponents of the industrial core, represented in the interests of Member States reunited in the Council.
- Finally, the bottom left quadrant contains the stakeholders that combine low levels of interest with a low level of influence (often sectorial, i.e. data protection oriented, in nature).

Appendix 4: A Manual for Quantitative Text Analysis in Policy Development

Step-by-step Protocol for Data Sanitation and Analysis

A systematic review is a review that strives to comprehensively identify, track down and appraise all the literature on a specific topic (Petticrew, 2003). Similarly, **quantitative text analysis (QTA)** is a tool used to review texts based on word frequencies in order to comprehensively identify, track down and appraise word usage by different actors, authors or stakeholders on a specific policy topic.

In 1979, human coders coded 2,500 party manifestos issued by 632 different parties in 52 countries. The undertaking “Comparative Manifestos Project” was well underway and it lasted 20 years. It yielded a mammoth data set generated by hand. The analytical team developed categories for a classification scheme, half classified as “pro regulation” and half as “anti-regulation”. All statements that could not be allocated to one of these categories were grouped into an “others” category. The units of analysis were natural sentences. First, the percentage of pro and anti-regulation categories in the total number of coded statements per text were calculated. Then, the pro percentage was subtracted from the anti-regulation percentage. Negative scores represented one camp positions and positive scores represented the other camp positions. Drawing on this pioneering manually run project, automated content analysis software has helped QTA methods to evolve considerably over the years.

In this manual, QTA is applied via running JFREQ and the Wordscores algorithm in STATA v14.0. Based on the underlying assumption that agents with different policy positions use different wording and different concepts that reflect their stance, Wordscores uses the frequency of words in each document, relative to the total number of words in a text to output scores for each examined document.

The five basic steps set out below are further detailed on the next page in a table presenting process workflow items and remarks or observations that can be of use to the operator.

Five steps to conducting QTA (Quantitative Text Analysis)

1. Collect written evidence per stakeholder, decide on a policy dimension fitting the case study
2. Sanitise data and prepare for analysis
3. Run JFREQ and in parallel, the Wordscores algorithm in STATA
4. Optional: Calculate estimates of precision for Martin-Vanberg transformations (in Excel)
5. Interpret the data, disambiguate and plot positions based on scores in a graph

The In-depth Step-by-Step Guide:

Process workflow item	Remarks/ observations	Date completed
1. Decide on a policy dimension fitting your case study	E.g. tobacco regulation (more or less regulation along an axis) – against tobacco control at one extremity and for tobacco control at the other	
2. Collect documents and convert files to text format (.txt) and classify files. Translate from any other languages into English further text contributions	Different text formats (email, template, translate if found in other languages). Important to also include the test text (pre and post consultation or official legislation at two or three points in time) into the analysis.	
3. Manually remove interest group names, headers and footers, contact details, address formulae (“Dear”) and citations; remove the template headings (Chapter, Comment, Suggested Change), the title of the study, the email subject phrase “draft report for written review”	Remove all text pertaining to the template of the consultation. Proceed to creating the text files. Combine these per stakeholder. Bibliographic references are kept as the bibliography stakeholders choose to quote reveals their interests. It is important to keep these in. Individual page numbers and chapters quoted in the templates are furthermore removed. Links in references are kept. Correct typos so that results are accurate.	
4. Run JFREQ (create a frequency matrix – this allows an examination of the word count data per word used in Excel format).	It is more beneficial to tick all pre-processing options (no numbers or no currency, no stop-words in all files, no capitals) – this proves more useful as there are fewer columns with unique word roots in the end. JFREQ is extremely useful to detect errors in the sanitation of the data (spacing problems, words lumped together, etc). For instance, it is interesting to verify if the industry uses with a higher frequency words like “agreement”, “competitiveness”, “innovation”.	
5. Run Stata Wordscores (see code example in this manual)	Examine scores. Reselect reference texts if scores do not appear aligned. Examine texts to decide on potential clusters (public health, industry) and skim through texts for critical control points.	

6. Re-run JFREQ and re-run Stata (if need be)	JFREQ is very useful in deciding on critical control points. Put together a table without test texts with incipient stakeholder clusters.	
7. Optional: Validation via the Martin-Vanberg transformation in Excel and building its respective 95% confidence interval	Simple re-scaling of texts to the original scale (as LBG transformation rescales the estimated raw scores to have the same variance as the original reference score), based on the most extreme values to render text scores directly comparable with reference texts. Calculate in Excel.	
8. Optional: create a box on sensitivity analysis, robustness check and plots/ confidence interval bar graph	Put together a diagram plotting the scores and a table including test texts and refine the stakeholder clusters.	
9. Interpretation of results	Look for anomalous submissions (low STATA raw score, low word count and a relatively broad confidence interval compared to other texts for the LBG transformation) and first mover advantage (innovators versus laggards, with the laggards closer to the industry reference score and the innovators visibly closer to the public health reference score).	

Points to consider prior and during Wordscores analysis:

1. If after an iteration, the two test texts (e.g. the text consulted upon prior to the consultation and the text following the consultation) yield raw scores lower than either of the Public Health advocacy reference texts, the test needs to be dismissed on grounds of low face validity and the public health reference texts need to be re-selected.
2. If two reference texts are chosen per stakeholder cluster (advocacy and industry), these should ideally be the ones with the two lowest and the two highest raw scores according to the Stata algorithm Wordscores.
3. If the text consulted upon (the text for which the public consultation is run) has a much higher word-count than any of the other submissions, then the direction of travel and the travel achieved *per se* on the axis through the consultation is expected to be minimal.

Sample STATA Code for running the Wordscores algorithm

~with special thanks to Dr. Helia Costa for the code

```
net install http://www.tcd.ie/Political\_Science/wordscores/wordscores, replace
```

```
*net install wordscores
```

```
*Change the directory to the folder where you have your texts (in txt format)
```

```
cd "E:\Meeting21-07\Texts"
```

```
*\\manor-road.ox.ac.uk\Store\Staff\Sociology\Data\myfolder
```

```
*Transform the documents into frequency counts:
```

```
wordfreq TRI2012.txt CONS.txt COM.txt PAR.txt 1.txt 2.txt 3.txt 4.txt 5.txt 7.txt 8.txt 9.txt 10.txt  
11.txt 12.txt 13.txt 14.txt 15.txt 16.txt 17.txt 18.txt 19.txt 20.txt 21.txt 22.txt A6.txt A7.txt A8.txt  
A9.txt A11.txt A14.txt A15.txt A16.txt A17.txt A18.txt
```

```
*Describe data:
```

```
describetext tTRI2012 tCONS tCOM tPAR t1 t2 t3 t4 t5 t7 t8 t9 t10 t11 t12 t13 t14 t15 t16 t17 t18 t19  
t20 t21 t22 tA6 tA7 tA8 tA9 tA11 tA14 tA15 tA16 tA17 tA18
```

```
*Classify position papers: texts 16 and 17 have known policy position situated at -1; 20 and 21 at 1
```

```
setref t16 0 t17 0 t20 1 t21 1
```

```
*Create scores for words based on these reference texts:
```

```
wordscore nameofestimation
```

```
*nameofestimation is the name you want to give to this scoring (eg. scoring1)
```

```
*Score other texts based on the word scores previously calculated:
```

```
textscore nameofestimation tTRI2012 tCONS tCOM tPAR t1 t2 t3 t4 t5 t7 t8 t9 t10 t11 t12 t13 t14 t15  
t18 t19 t22 tA6 tA7 tA8 tA9 tA11 tA14 tA15 tA16 tA17 tA18
```

```
*Include the reference texts as virgins (useful for rescaling step 7):
```

```
textscore nameofestimation tTRI2012 tCONS tCOM tPAR t1 t2 t3 t4 t5 t7 t8 t9 t10 t11 t12 t13 t14 t15  
t16 t17 t18 t19 t20 t21 t22 tA6 tA7 tA8 tA9 tA11 tA14 tA15 tA16 tA17 tA18
```

```
*nameofestimation will be stored, so each time you want to classify more texts based on the same  
reference texts you can; otherwise use:
```

```
*clear nameofestimation
```

```
*Note that here we included the reference texts as virgin texts again - this is useful
```

Strengths and Weaknesses of QTA

Frequently Asked Questions (FAQ)

Capitalising on existing Methods for Quantitative Text Analysis when
Examining Policy-related Texts

I. General Background

Wordscores in STATA v14.0 is an algorithm that infers policy positions, or scores, for new plain text documents, i.e. “virgin texts” on the basis of plain text documents with known scores, i.e. “reference texts”. It measures positions along an axis, for example right or left wing party manifestos or press releases for or against specific health regulations.

JFREQ⁷ (previously integrated in the statistical analysis programme R, now available as a stand-alone) is a quantitative text analysis programme taking plain text documents, counting words within them and producing a word frequency matrix across the sample. It is useful for identifying the most commonly used words across a sample of texts and hence, for identification of reference texts for the Wordscores code.

1) What’s the purpose of QTA?

QTA is applied via running JFREQ and the Wordscores algorithm in STATA v14.0. Based on the underlying assumption that agents with different policy positions use different wording and different concepts that reflect their stance, Wordscores uses the frequency of words in each document, relative to the total number of words in a text to output scores for each examined document.

2) What’s the purpose of the manual?

The manual consists of three guidance documents: the present FAQ on the strengths and weaknesses of QTA, the “Top Ten Mistakes Analysts Make” and the Protocol “QTA in Policy Development” step-by-step guide. The purpose of this manual is to guide users into mainstreaming QTA run via JFREQ and Wordscores in analysing texts for policy-related purposes. Coding syntax is included as an example.

3) How can QTA help to examine written texts?

Extracting policy positions from political texts using words as data has already been employed in the specialist literature, with varying rates of success. For an extensive list of relevant literature, the reference section of the present thesis provides a good introduction. QTA using Wordscores has been used previously in studies by Stuckler et al and Costa et al, as well as Kluever to quantify industry influence in environmental issues.

⁷ <http://conjugateprior.org/software/jfreq/>

4) Who is the target user of the manual?

The target user of the manual is any public health researcher, knowledge broker, policy entrepreneur or decision support analyst interested in tracking policy documents over time or capturing shifts in documents mapping the policy process. The initial review has identified Wordscores used jointly with JFREQ as having the greatest potential in selected fields of public health.

5) How will the manual be used?

The manual represents basic guidance that is made available together with the present thesis to help the research community in mainstreaming the use that is made of QTA for policy monitoring purposes.

6) What kind of added value is expected from the manual?

The added value in the manual refers mostly to the innovation brought by the present thesis and its *differentia specifica*. Advances in computing offer scope for mainstream usage of QTA in governmental institutions, drawing on text mining, computational linguistics and STATA-driven word-count analysis.

7) How was the manual put together?

The manual was drafted by the author as an aid to help uptake of the quantitative and mixed methods described in the thesis.

II. What to do specifically?

1) Am I expected to follow all the steps in the Manual/ Step-by-step Protocol ?

It is advisable to follow the steps described in the guide as they are evidence-based and have been empirically tested and pilot tested with volunteers. However, tailoring is possible.

2) Am I expected to systematically check that I avoid the “Top 10 Mistakes QTA analysts make”?

The errors outlined in the document referred to above should significantly increase the chances of the operationalisation being accurate and rigorous. They have been selected on the basis of their significance and severity, as assessed by the author.

3) How am I expected to help improve the manual based on my experience?

Outlining benefits and limitations of the present method is helpful – as is further guidance on how the method can be tested, refined and mainstreamed.

III. Other potential questions on strengths and weaknesses of QTA

1) Strengths: What is QTA particularly sensitive to?

There is a premium on conciseness. QTA is well equipped for anomalous submission detection (illegible, empty or irrelevant submissions) and it is sensitive to the first mover advantage, it can distinguish between laggards in industry versus innovators. It is also sensitive enough to detect certain stakeholders by their school of thought (corporate interests vs. public health interests).

2) Weaknesses: What is QTA blind to? What disparities can it not explain?

QTA is blind to legalese, pharmish, bankspeak and any other possibly distracting jargon. QTA is equally blind to tone, nuance and minor as opposed to severe wordiness.

3) Is there an alternative to Wordscores and how does it compare to Wordscores?

Wordfish is a possible alternative to Wordscores. Both are driven by the frequency distributions of words. Wordfish does not require reference values, Wordscores having this extra assumption, however in the health policy field this is relatively easy to establish (see above). Wordfish requires R or R studio. Wordscores runs in Stata v14.0. Moreover, Wordfish is more appropriate for analysis of party manifestos, where words are quite different, rather than for public consultation processes.

4) How does the Martin-Vanberg transformation compare to the LBG (Laver, Benoit and Gary) transformation included in the Wordscores algorithm?

The LBG transformation automatically applied by Wordscores to the raw score has good face validity based on this study. The main criticism of the LBG transformation is:

- a) the LBG-transformed score are non-robust to the selection of virgin texts (they depend on the combination of virgin texts scored and the dispersion of the raw scores, the standard deviation);
- b) the LBG transformation fails to place the virgin texts on the same metric as the reference texts.

Therefore, the Martin-Vanberg transformation is not a sine qua non for obtaining robust results. However, for a nuanced view, the MV transformation may be helpful.

5) What limitations are expected?

As with any statistical analysis tool, there will be limitations. The key assumption underlying the analysis is that stakeholders with different policy positions will use wording that reflects their ideology or stance. However, industry may seek to mimic the language of public health or vice versa. Also, it is statistically more difficult to prove that there was no influence rather than an adverse influence. Moreover, no large empirical data sets on the policy positions of interest groups are available yet (Kluever, 2009). The ultimate selection of sources remains the sole responsibility of the author.

6) What further research to help improve the manual and shed further light on its benefits and limitations is expected?

Further research is welcome and especially knowledge on benefits and limitations is in a position to help improve the manual. Future work should aim to extend the research to other policy areas and consultations elsewhere. This literature is based on recent studies and cannot be generalised to the whole population of public consultations.

The Top Ten Mistakes Analysts Make

This document sets out the top ten mistakes analysts make when rolling out the QTA methodology set out in the manual to a set of policy-related texts. The intention is to draw attention to these common errors so that operators and practitioners are aware of them and can thus avoid them in future practice.

Analysts of Jfreq and STATA make the following frequent mistakes in result interpretation, sensitivity analysis and confidence interval construction:

1. Not ticking all pre-processing options for Jfreq in order to obtain a robust frequency matrix

This may seem commonplace, but ticking all pre-processing options ensures that the text files are cleansed of numbers, currency, symbols, stop-words and capitals. This proves useful as there are fewer columns with unique word roots in the final frequency matrix output file.

2. Not starting by skimming through the summary consultation document

Reading the summary consultation document or the most balanced overview document primes the analyst to better assess the policy problem at hand, beliefs held by stakeholders, potential interests at play and likely concepts of note as well as initial clustering of stakeholders and their espoused policy positions.

3. Not skimming through the submitted texts searching for critical control points

It is good practice to skim through submitted texts so that:

- a) The stakeholder clustering (industry vs. public advocacy) becomes clearer.
- b) The reference texts for each cluster crystallise.
- c) The concepts promoted and the spin put on them (the specific framing of the problem) becomes clearer to the analyst.
- d) The analyst is in a position to identify any potential anomalous submissions.

4. Not performing a stakeholder analysis after initially skimming the texts

It is of considerable benefit to produce a rough stakeholder analysis as a first draft after an initial reading of the submitted texts, if the number of texts submitted are relatively limited and the task is feasible. If not, selecting a representative sample from each stakeholder cluster (industry vs. public advocacy or consumer groups) is of interest. The stakeholders in the selected sample should then be plotted on a basic stakeholder diagram.

5. Not refining the stakeholder analysis throughout the analysis

Needless to say, the stakeholder analysis can be iteratively and manually refined as the STATA algorithm Wordscores is run and perfected.

6. Not carrying out the anomalous submission test

The anomalous submission test consists in seeking out texts that obtain a low STATA raw score, a low Wordcount and a relatively broad confidence interval compared to other texts for the LBG transformation. This step is important as otherwise, anomalous submissions may be mistaken for reference texts for one stakeholder group or another – whereas they are merely anomalous or snap submission texts.

7. Not using Jfreq to decide on critical control points

When constructing the comparison data tables, Jfreq estimates the frequency distribution of words across documents and hence critical words can be picked out and included in the extracted data tables (as per the case studies in this thesis).

8. Not critically examining raw STATA scores and LBG and MV scores

The Wordscores algorithm should be run several times, varying the reference texts chosen. The STATA raw scores, LBG scores and MV scores should be examined via dedicated tables and an executive decision taken whether the virgin or the test texts yield raw scores lower than either of the two reference texts for the advocacy group cluster (or *mutatis mutandis*, higher than either of the industry reference texts). If this is the case, then this iteration should be dismissed on grounds of low face validity. A different pair of advocacy group reference texts (or *mutatis mutandis*, industry reference texts) should be chosen and a new iteration of the Wordscores algorithm run.

9. Not repositioning texts via coding and experimenting with the assignment of reference texts if the scores do not appear aligned at first glance

If after an iteration, the virgin or test texts yield raw scores inferior to either of the advocacy group reference texts (or higher than either of the industry reference texts), then the test needs to be discontinued based on questionable face validity and re-run with a different set of reference texts for the advocacy group (or for the industry group).

10. Not interpreting the results and not performing the sensitivity analysis for MV scores

This last important step is necessary as underlying assumptions in the choice of critical control points may reflect analyst or reviewer bias in the parameters chosen for analysis. It is likely that the scale of undue influence of interest groups is underestimated via QTA performed as per the manual, since the text submitted for consultation may already have compressed the compromise.

References

- ANDRES, S., SCHULTRICH, K., MONIEN, B., BUHRKE, T., BAKHIYA, N., FRENZEL, F., ABRAHAM, K., SCHÄFER, B. & LAMPEN, A. 2017. Erhitzungsbedingte Kontaminanten in Lebensmitteln. *Bundesgesundheitsblatt-Gesundheitsforschung-Gesundheitsschutz*, 1-8.
- ANNEMANS, L., CLEEMPUT, I., HULSTAERT, F. & SIMOENS, S. 2011. Valorising and creating access to innovative medicines in the European Union. *Frontiers in pharmacology*, 2.
- AZZOPARDI-MUSCAT, N., CLEMENS, T., STONER, D. & BRAND, H. 2015. EU Country Specific Recommendations for health systems in the European Semester process: Trends, discourse and predictors. *Health Policy*, 119, 375-383.
- BAIL, C. A. 2012. The fringe effect civil society organizations and the evolution of media discourse about Islam since the September 11th attacks. *American Sociological Review*, 77, 855-879.
- BAKHTIN, M. M. 2010. *The dialogic imagination: Four essays*, University of texas Press.
- BASHSHUR, R. L., REARDON, T. G. & SHANNON, G. W. 2000. Telemedicine: a new health care delivery system. *Annual review of public health*, 21, 613-637.
- BELLONI, A., MORGAN, D. & PARIS, V. 2016. Pharmaceutical expenditure and policies.
- BICQUELET, A. & WEALE, A. 2011. Coping with the Cornucopia: Can Text Mining Help Handle the Data Deluge in Public Policy Analysis? *Policy & Internet*, 3, 1-21.
- BOSTOCK, D. 2002. Coreper revisited. *JCMS: Journal of Common Market Studies*, 40, 215-234.
- BOWIS, J. Opening Speech. Accessible: http://ec.europa.eu/health/sites/health/files/cross_border_care/docs/ev_2016_1024_co11_en.pdf, 2016.
- BUNEA, A. 2014. Sharing ties and preferences: Stakeholders' position alignments in the European Commission's open consultations. *European Union Politics*, 1465116514558338.
- BURKE, K. 1969. *A grammar of motives*, Univ of California Press.
- CAMILLERI, I. 2017. *New film claims John Dalli unsuccessfully tried to obtain info about alleged conspiracy against him* [Online]. Times of Malta. Available: <https://www.timesofmalta.com/articles/view/20170727/local/new-film-claims-john-dalli-unsuccessfully-tried-to-obtain-info-about.654229> [Accessed 6th August 2017].
- CEO. 2011. *Corporate Europe Observatory* [Online]. Accessible: <http://corporateeurope.org/power-lobbies/2011/09/putting-brussels-lobbyists-map>.
- CEO. 2014. *John Dalli investigation* [Online]. Accessible: <http://corporateeurope.org/power-lobbies/2014/07/supervisory-committee-releases-29-page-critical-assessment-olafs-dalligate>.
- CEO. 2015. *Corporate Europe Observatory* [Online]. Accessible: <https://www.corporateeurope.org/power-lobbies/2015/09/policy-prescriptions-firepower-eu-pharmaceutical-lobby-and-implications-public>.
- CLEMENS, T., MICHELSEN, K. & BRAND, H. 2014. Supporting health systems in Europe: added value of EU actions? *Health Economics, Policy and Law*, 9, 49-69.
- COLLIN, J. 2012. Tobacco control, global health policy and development: towards policy coherence in global governance. *Tobacco control*, 21, 274-280.

- COLLIN, J. & HILL, S. 2013. Corporate involvement in public health policy is being obscured. *BMJ*, 346, f3429.
- COSTA, H., GILMORE, A. B., PEETERS, S., MCKEE, M. & STUCKLER, D. 2014. Quantifying the influence of the tobacco industry on EU governance: automated content analysis of the EU Tobacco Products Directive. *Tobacco control*, 23, 473-478.
- COUNCIL OF MINISTERS 1988. Council Directive of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems. 89/105/EEC. Accessible: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31989L0105>.
- COUNCIL OF MINISTERS 2004. Regulation (EC) No 883/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the coordination of social security systems. In: UNION, E. P. A. C. O. T. E. (ed.). Accessible: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:166:0001:0123:en:PDF>.
- COUNCIL OF MINISTERS 2008. 16825/08 (Presse 358), PRESS RELEASE, 2916th Council meeting, Employment, Social Policy, Health and Consumer Affairs Accessible: http://europa.eu/rapid/press-release_PRES-08-358_en.htm?locale=en.
- COUNCIL OF MINISTERS 2009. Council Recommendation on an action in the field of rare diseases. Accessible: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0007:0010:EN:PDF>.
- COUNCIL OF MINISTERS 2015. Innovation for the benefit of patients: Follow-up to the Council's conclusions. Accessible: <http://data.consilium.europa.eu/doc/document/ST-9869-2015-INIT/en/pdf>: Presidency.
- COUNCIL OF MINISTERS 2016. Council Conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States. Accessible: http://www.consilium.europa.eu/press-releases-pdf/2016/6/47244642812_en.pdf.
- COUNCIL OF MINISTERS 2017. List of Council Preparatory Bodies. In: COUNCIL, G. S. O. T. (ed.). Accessible: <http://data.consilium.europa.eu/doc/document/ST-10075-2017-INIT/en/pdf>.
- COUNCIL OF THE EUROPEAN UNION 2017. List of Council Preparatory Bodies. In: COUNCIL, G. S. O. T. (ed.). Accessible: <http://data.consilium.europa.eu/doc/document/ST-10075-2017-INIT/en/pdf>.
- DIETHELM, P. & MCKEE, M. 2014. Tobacco industry-funded research on standardised packaging: there are none so blind as those who will not see! *Tobacco control*, tobaccocontrol-2014-051734.
- DIETHELM, P. A., RIELLE, J. C. & MCKEE, M. 2005. The whole truth and nothing but the truth? The research that Philip Morris did not want you to see. *Lancet*, 366, 86-92.
- DRUCKMAN, J. N. 2011. What's it all about? Framing in political science. *Perspectives on framing*, 279-302.
- EUR-LEX. 2017. *Ordinary Legislative Procedure* [Online]. Accessible: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:ai0016>.
- EUROPEAN COMMISSION 2004. Communication from the Commission - Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union. Accessible: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52004DC0301>.

- EUROPEAN COMMISSION. 2007. *Commission Recommendation 2007/33/EC on the monitoring of acrylamide levels in food* [Online].
- EUROPEAN COMMISSION 2008. Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare {SEC(2008) 2163} {SEC(2008) 2164} {SEC(2008) 2183}. Accessible: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52008PC0414>.
- EUROPEAN COMMISSION. 2010. *Commission Recommendation 2010/307/EU on the monitoring of acrylamide levels in food* [Online].
- EUROPEAN COMMISSION. 2011. *E-health Action Plan* [Online]. Accessible: <https://ec.europa.eu/digital-single-market/en/news/report-public-consultation-ehealth-action-plan-2012-2020>.
- EUROPEAN COMMISSION. 2013. *Commission Recommendation 2013/647/EU on investigations into the levels of acrylamide in food* [Online].
- EUROPEAN COMMISSION. 2014a. *Guidelines Public Consultation* [Online]. Available: http://ec.europa.eu/smart-regulation/guidelines/ug_chap7_en.htm
- EUROPEAN COMMISSION. 2014b. *Summary Report of the Standing Committee on the Food Chain and Animal Health held in Brussels on 20 February 2014* [Online].
- EUROPEAN COMMISSION. 2015a. *Better Regulation Guidelines* [Online]. Accessible: http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf.
- EUROPEAN COMMISSION 2015b. Special Eurobarometer 425: Patients' Rights in Cross-border Healthcare in the European Union. Accessible: http://ec.europa.eu/commfrontoffice/publicopinion/archives/ebs/ebs_425_sum_en.pdf.
- EUROPEAN COMMISSION. 2017a. *CSRs* [Online]. Accessible: http://ec.europa.eu/europe2020/making-it-happen/country-specific-recommendations/index_en.htm.
- EUROPEAN COMMISSION. 2017b. *Public consultations* [Online]. Available: http://ec.europa.eu/yourvoice/consultations/index_en.htm.
- EUROPEAN COURT OF JUSTICE 2009. Joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKline Services Unlimited v Commission of the European Communities (C-501/06 P) and Commission of the European Communities v GlaxoSmithKlineServices Unlimited (C-513/06 P) and European Association of Euro Pharmaceutical Companies (EAEPC) v Commission of the European Communities (C-515/06 P) and Asociacion de exportadores espanoles de productos farmacéuticos (Aseprofar) v Commission of the European Communities (C-519/06 P)*[2009] ECR I-9291.
- EUROPEAN FOOD SAFETY AUTHORITY, A. 2015. Outcome of the public consultation on the draft Scientific Opinion of the EFSA Panel on Contaminants in the Food Chain (CONTAM) on acrylamide in food. *EFSA Supporting Publications*, 12, 817E-n/a.
- EUROPEAN PARLIAMENT 2008. Patient Mobility in the European Union: Study on Legislative Proposals on Patients' Rights in Cross-border Health Care. Accessible: <http://www.europarl.europa.eu/document/activities/cont/201107/20110718ATT24286/20110718ATT24286EN.pdf>.
- EVANS-COWLEY, J. & HOLLANDER, J. 2010. The new generation of public participation: Internet-based participation tools. *Planning, Practice & Research*, 25, 397-408.
- FISCHER, F. 2000. *Citizens, experts, and the environment: The politics of local knowledge*, Duke University Press.

- FÖLDES, M. E. 2016. Health policy and health systems: a growing relevance for the EU in the context of the economic crisis. *Journal of European Integration*, 38, 295-309.
- FOOD DRINK EUROPE. 2014. *Acrylamide toolbox* [Online].
- FOOKS, G., GILMORE, A., COLLIN, J., HOLDEN, C. & LEE, K. 2013. The limits of corporate social responsibility: techniques of neutralization, stakeholder management and political CSR. *Journal of Business Ethics*, 112, 283-299.
- FREUDENBERG, N. 2014. *Lethal but legal: corporations, consumption, and protecting public health*, Oxford University Press.
- GESUNDHEIT_ÖSTERREICH_FORSCHUNG-_UND_PLANUNGS_GMBH 2016. Study on enhanced cross-country coordination in the area of pharmaceutical product pricing. Accessible: http://ec.europa.eu/health/sites/health/files/systems_performance_assessment/docs/pharmaproductpricing_frep_en.pdf.
- GILENS, M. & PAGE, B. 2014. Testing theories of American politics: Elites, interest groups and average citizens. *Perspectives on Politics*, 12, 564-81.
- GLASER, B. G. & STRAUSS, A. L. 2009. *The discovery of grounded theory: Strategies for qualitative research*, Transaction publishers.
- GLYNOS, J., HOWARTH, D., NORVAL, A. & SPEED, E. 2009. Discourse analysis: Varieties and methods.
- GOFFMAN, E. 1974. *Frame analysis: An essay on the organization of experience*, Harvard University Press.
- GRIMMER, J. & STEWART, B. M. 2013. Text as data: The promise and pitfalls of automatic content analysis methods for political texts. *Political Analysis*, mps028.
- GRUNING, T., GILMORE, A. B. & MCKEE, M. 2006. Tobacco industry influence on science and scientists in Germany. *Am J Public Health*, 96, 20-32.
- GRÜNING, T., GILMORE, A. B. & MCKEE, M. 2006. Tobacco industry influence on science and scientists in Germany. *American Journal of Public Health*, 96, 20-32.
- GUÉGUEN, D. 2007. *European Lobbying*, Brussels.
- GUTHRIE, D. 2008. *Unsupervised Detection of Anomalous Text*. University of Sheffield.
- HAJER, M. & LAWS, D. 2006. Ordering through discourse. *The Oxford handbook of public policy*, 249-266.
- HANCHER, L. & SAUTER, W. 2016. A dose of competition: EU antitrust law in the pharmaceuticals sector. *Journal of Antitrust Enforcement*, 4, 381-410.
- HANSEN, W. L., MITCHELL, N. J. & DROPE, J. M. 2004. Collective action, pluralism, and the legitimacy tariff: Corporate activity or inactivity in politics. *Political Research Quarterly*, 57, 421-429.
- HAWKINS, B. & HOLDEN, C. 2013. Framing the alcohol policy debate: industry actors and the regulation of the UK beverage alcohol market. *Critical Policy Studies*, 7, 53-71.
- HAWKINS, B. & MCCAMBRIDGE, J. 2014. Industry actors, think tanks, and alcohol policy in the United Kingdom. *American journal of public health*, 104, 1363-1369.
- HOWARTH, D. 2010. Power, discourse, and policy: articulating a hegemony approach to critical policy studies. *Critical policy studies*, 3, 309-335.
- JENSEN, K. S. 2015. How to lobby the European Union effectively.
- JOHNSON-CARTEE, K. S. 2005. *News narratives and news framing : constructing political reality*, Lanham, MD, Rowman & Littlefield.
- JOVCHELOVITCH, S. 2007. *Knowledge in context: Representations, community and culture*, Routledge.

- KANAVOS, P., MCKEE, M. & RICHARDS, T. 1999. Cross border health care in Europe: European court rulings have made governments worried. *BMJ: British Medical Journal*, 318, 1157.
- KICKBUSCH, I., ALLEN, L. & FRANZ, C. 2016. The commercial determinants of health. *The Lancet Global Health*, 4, e895-e896.
- KLEMMENSEN, R., HOBOLT, S. B. & HANSEN, M. E. 2007. Estimating policy positions using political texts: An evaluation of the Wordscores approach. *Electoral Studies*, 26, 746-755.
- KLÜVER, H. 2011. The contextual nature of lobbying: Explaining lobbying success in the European Union. *European Union Politics*, 1465116511413163.
- KMIETOWICZ, Z. 2015a. Coca-Cola funded group set up to promote "energy balance" is disbanded. *Bmj*, 351, h6590.
- KMIETOWICZ, Z. 2015b. Coca-Cola funded group set up to promote "energy balance" is disbanded. British Medical Journal Publishing Group.
- KNAI, C., PETTICREW, M., DURAND, M. A., EASTMURE, E. & MAYS, N. 2015. Are the Public Health Responsibility Deal alcohol pledges likely to improve public health? An evidence synthesis. *Addiction*, 110, 1232-46.
- KOON, A. D., HAWKINS, B. & MAYHEW, S. H. 2016. Framing and the health policy process: a scoping review. *Health policy and planning*, 31, 801-816.
- KUCKARTZ, U. 2014. *Qualitative text analysis: A guide to methods, practice and using software*, Sage.
- LAVER, M., BENOIT, K. & GARRY, J. 2003. Extracting policy positions from political texts using words as data. *American Political Science Review*, 97, 311-331.
- LAVERTY, A. A., WATT, H. C., ARNOTT, D. & HOPKINSON, N. S. 2014. Standardised packaging and tobacco-industry-funded research. *The Lancet*, 383, 1384.
- LETSAS, G. & O'CONNOR, C. 2011. *Current Legal Problems 2010*, Current Legal Problems.
- LEXCHIN, J., BERO, L. A., DJULBEGOVIC, B. & CLARK, O. 2003. Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *Bmj*, 326, 1167-1170.
- LO, J., PROKSCH, S.-O. & SLAPIN, J. B. 2014. Ideological clarity in multiparty competition: A new measure and test using election manifestos. *British Journal of Political Science*, 1-20.
- LOWE, W. 2008. Understanding wordscores. *Political Analysis*, 16, 356-371.
- LUCHETTA, G. & AKSE, E. 2014. Influencing the Preparation of EU Legislation: A Practical Guide to Working with Impact Assessments. HeinOnline.
- MAANI HESSARI, N. & PETTICREW, M. 2017. What does the alcohol industry mean by 'Responsible drinking'? A comparative analysis. *Journal of Public Health*, 1-8.
- MARMOT, M., FRIEL, S., BELL, R., HOUWELING, T. A., TAYLOR, S. & HEALTH, C. O. S. D. O. 2008. Closing the gap in a generation: health equity through action on the social determinants of health. *The lancet*, 372, 1661-1669.
- MARTIN, L. W. & VANBERG, G. 2007. A robust transformation procedure for interpreting political text. *Political Analysis*, 16, 93-100.
- MARTIN, L. W. & VANBERG, G. 2008. Reply to Benoit and Laver. *Political Analysis*, 16, 112-114.
- MARTINO, F. P., MILLER, P. G., COOMBER, K., HANCOCK, L. & KYPRI, K. 2017. Analysis of Alcohol Industry Submissions against Marketing Regulation. *PLoS One*, 12, e0170366.

- MCCAMBRIDGE, J. & HARTWELL, G. 2015a. Has industry funding biased studies of the protective effects of alcohol on cardiovascular disease? A preliminary investigation of prospective cohort studies. *Drug and alcohol review*, 34, 58-66.
- MCCAMBRIDGE, J. & HARTWELL, G. 2015b. Has industry funding biased studies of the protective effects of alcohol on cardiovascular disease? A preliminary investigation of prospective cohort studies. *Drug Alcohol Rev*, 34, 58-66.
- MCKEE, M., BELCHER, P. & KOSINSKA, M. 2012. The EU Tobacco Products Directive must not be derailed. *Lancet*, 380, 1447-8.
- MCKEE, M. & DIETHELM, P. 2010. How the growth of denialism undermines public health. *BMJ*, 341, c6950.
- MCKEE, M., HERVEY, T. & GILMORE, A. 2010. Public health policies. In: MOSSIALOS, E., PERMANAND, G., BAETEN, R. & HERVEY, T. (eds.) *Health systems governance in Europe: the role of EU law and policy*. Cambridge: Cambridge University Press.
- MCKEE, M. D., PASCAL 2010. How the growth of denialism undermines public health. *BMJ*, 341, c6950.
- MCLEAN, S., SHEIKH, A., CRESSWELL, K., NURMATOV, U., MUKHERJEE, M., HEMMI, A. & PAGLIARI, C. 2013. The impact of telehealthcare on the quality and safety of care: a systematic overview. *PLoS One*, 8, e71238.
- MILLAR, J. S. 2013. The corporate determinants of health: how big business affects our health, and the need for government action. *Canadian Journal of Public Health*, 104, e327-e329.
- MODELL, S. & CITRIN, T. RESEARCH FINDINGS IN A PUBLIC CONSULTATION TO MAP THE FUTURE OF PUBLIC HEALTH GENOMICS. JOURNAL OF INVESTIGATIVE MEDICINE, 2012. LIPPINCOTT WILLIAMS & WILKINS 530 WALNUT ST, PHILADELPHIA, PA 19106-3621 USA, 728-728.
- MOODIE, A. R. 2017a. The Relentless Enemies of Science. *American journal of public health*, 107, 1016.
- MOODIE, A. R. 2017b. What Public Health Practitioners Need to Know About Unhealthy Industry Tactics. American Public Health Association.
- MOUSSIS, N. 2007. Access to EU-law, economics, policies. EDC, Rixensart (Belgique).
- ONARHEIM, K. H., IVERSEN, J. H. & BLOOM, D. E. 2016. Economic benefits of investing in women's health: a systematic review. *PloS one*, 11, e0150120.
- ORESKE, N. & CONWAY, E. M. 2010. Merchants of doubt. New York: Bloomsbury Press.
- PARLIAMENT, E. 2017. *Ordinary Legislative Procedure* [Online]. Accessible: <http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers>.
- PEETERS, S. & GILMORE, A. B. 2015. Understanding the emergence of the tobacco industry's use of the term tobacco harm reduction in order to inform public health policy. *Tobacco control*, 24, 182-189.
- PETTICREW, M., DOUGLAS, N., D'SOUZA, P., SHI, Y., DURAND, M., KNAI, C., EASTMURE, E. & MAYS, N. 2017a. Community Alcohol Partnerships with the alcohol industry: what is their purpose and are they effective in reducing alcohol harms? *Journal of Public Health*, 1-16.
- PETTICREW, M., FITZGERALD, N., DURAND, M. A., KNAI, C., DAVOREN, M. & PERRY, I. 2016. Diageo's 'Stop Out of Control Drinking' campaign in Ireland: an analysis. *PLoS one*, 11, e0160379.
- PETTICREW, M., SHEMILT, I., LORENC, T., MARTEAU, T., MELENDEZ-TORRES, G., O'MARA-EVES, A., STAUTZ, K. & THOMAS, J. 2017b. Alcohol advertising and

- public health: systems perspectives versus narrow perspectives. *J Epidemiol Community Health*, 71, 308-312.
- PROKSCH, S.-O. & SLAPIN, J. B. 2009. How to avoid pitfalls in statistical analysis of political texts: The case of Germany. *German Politics*, 18, 323-344.
- PROKSCH, S.-O. & SLAPIN, J. B. 2010. Position taking in European Parliament speeches. *British Journal of Political Science*, 40, 587-611.
- RADAELLI, C. M. & MEUWESE, A. C. 2008. The political economy of impact assessment. *Better Regulation in the European Union*.
- RECHEL, B., MCKEE, M., HAAS, M., MARCHILDON, G. P., BOUSQUET, F., BLÜMEL, M., GEISSLER, A., VAN GINNEKEN, E., ASHTON, T. & SAUNES, I. S. 2016. Public reporting on quality, waiting times and patient experience in 11 high-income countries. *Health Policy*.
- ROBERTS, C. W. 2000. A conceptual framework for quantitative text analysis. *Quality and Quantity*, 34, 259-274.
- RODRIGO, D. & AMO, P. A. 2006. Background document on public consultation. Available from the web site of Organization for Economic Cooperation and Development: <http://www.oecd.org/dataoecd/4/43/36785341.pdf> [accessed 30 March 2010].
- ROTTER, J. S., FOERSTER, D. & BRIDGES, J. F. 2012. The changing role of economic evaluation in valuing medical technologies. *Expert review of pharmacoeconomics & outcomes research*, 12, 711-723.
- SAVELL, E., FOOKS, G. & GILMORE, A. B. 2016. How does the alcohol industry attempt to influence marketing regulations? A systematic review. *Addiction*, 111, 18-32.
- SAWICKI-WRZASK, D., THOMSEN, M. & BJERRUM, O. J. 2015. An analysis of the fixed-dose combinations authorized by the European Union, 2009-2014: a focus on benefit-risk and clinical development conditions. *Therapeutic Innovation & Regulatory Science*, 49, 553-559.
- SCHMEER, K. 1999. Stakeholder analysis guidelines. *Policy toolkit for strengthening health sector reform*, 1-33.
- SCULLIN, C., HOGG, A., LUO, R., SCOTT, M. G. & MCELNAY, J. C. 2012. Integrated medicines management—can routine implementation improve quality? *Journal of evaluation in clinical practice*, 18, 807-815.
- SEDIG, K. & OLA, O. 2014. The challenge of big data in public health: an opportunity for visual analytics. *Online journal of public health informatics*, 5.
- SLAPIN, J. B. & PROKSCH, S. O. 2008. A scaling model for estimating time - series party positions from texts. *American Journal of Political Science*, 52, 705-722.
- SMITH, K. E., FOOKS, G., COLLIN, J., WEISHAAR, H. & GILMORE, A. B. 2010a. Is the increasing policy use of Impact Assessment in Europe likely to undermine efforts to achieve healthy public policy? *J Epidemiol Community Health*, 64, 478-87.
- SMITH, K. E., FOOKS, G., COLLIN, J., WEISHAAR, H., MANDAL, S. & GILMORE, A. B. 2010b. "Working the system"--British American tobacco's influence on the European union treaty and its implications for policy: an analysis of internal tobacco industry documents. *PLoS Med*, 7, e1000202.
- SMITH, K. E., FOOKS, G., GILMORE, A. B., COLLIN, J. & WEISHAAR, H. 2015. Corporate coalitions and policy making in the European Union: how and why British American Tobacco promoted "Better Regulation". *Journal of health politics, policy and law*, 40, 325-372.
- SOOD, S., MBARIKA, V., JUGOO, S., DOOKHY, R., DOARN, C. R., PRAKASH, N. & MERRELL, R. C. 2007. What is telemedicine? A collection of 104 peer-reviewed perspectives and theoretical underpinnings. *Telemedicine and e-Health*, 13, 573-590.

- STACEY, D., LÉGARÉ, F., COL, N. F., BENNETT, C. L., BARRY, M. J., EDEN, K. B., HOLMES - ROVNER, M., LLEWELLYN - THOMAS, H., LYDDIATT, A. & THOMSON, R. 2014. Decision aids for people facing health treatment or screening decisions. *The Cochrane Library*.
- STUCKLER, D., MCKEE, M., EBRAHIM, S. & BASU, S. 2012. Manufacturing epidemics: the role of global producers in increased consumption of unhealthy commodities including processed foods, alcohol, and tobacco. *PLoS medicine*, 9, e1001235.
- STUCKLER, D., REEVES, A., LOOPSTRA, R. & MCKEE, M. 2016. Textual analysis of sugar industry influence on the World Health Organization's 2015 sugars intake guideline. *Bulletin of the World Health Organization*, 94, 566.
- SZALEK, B. Z. 2013. Some Praxiological Reflections on the So-Called «Overton Window of Political Possibilities», «Framing» and Related Problems. *Reality of Politics. Estimates*, 237.
- TESLER, L. E. & MALONE, R. E. 2008. Corporate philanthropy, lobbying, and public health policy. *American journal of public health*, 98, 2123-2133.
- TOUMI, M., RÉMUZAT, C., VATAIRE, A.-L. & URBINATI, D. 2014. External reference pricing of medicinal products: simulation-based considerations for cross-country coordination. *Final report. European Commission, European Union*.
- ULUCANLAR, S., FOOKS, G. J., HATCHARD, J. L. & GILMORE, A. B. 2014. Representation and misrepresentation of scientific evidence in contemporary tobacco regulation: a review of tobacco industry submissions to the UK Government consultation on standardised packaging. *PLoS Med*, 11, e1001629.
- VAGANAY, A. 2014. *Evidence-based policy or policy-based evidence? The effect of policy commitment on government-sponsored evaluation in Britain (1997-2010)*. The London School of Economics and Political Science (LSE).
- VARVASOVSKY, Z. & BRUGHA, R. 2000. A stakeholder analysis. *Health policy and planning*, 15, 338-345.
- VOGLER, S., ZIMMERMANN, N. & HABIMANA, K. 2014. Study of the policy mix for the reimbursement of medicinal products. *Proposal for a best practice-based approach based on stakeholder assessment. Vienna: Commissioned by the European Commission*.
- WERMKE, C. 2017. *Europe's K Street - In one aspect at least, the European Union is fast catching up to the worst aspects of democracy in the United States: the power of lobbyists* [Online]. <https://global.handelsblatt.com/politics/europes-k-street-808094>.
- WHO. 1999. *Guidelines Conducting Stakeholder Analysis* [Online]. Accessible: <http://www.who.int/management/partnerships/overall/GuidelinesConductingStakeholderAnalysis.pdf>.
- WIIST, W. H. 2010. *The bottom line or public health*. Oxford: Oxford University Press.
- WIIST, W. H. 2011. The corporate play book, health, and democracy: the snack food and beverage industry's tactics in context. *Sick societies: responding to the global challenge of chronic disease*, 204-216.
- WIKIPEDIA. 2017. *John Dalli* [Online]. Accessible: https://en.wikipedia.org/wiki/John_Dalli