PUBLIC PRESSURE ON PHARMACEUTICAL ANIMAL TESTING

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Illustration on the cover

http://www.theage.com.au/ffximage/2007/07/10/ACITIVIST_wideweb__470x287,0.jpg

List of abbreviations

ACF	Advocacy Coalition Framework
B-M	Burson-Marsteller
CEFIC	European Chemical Industry Council
CSR	Corporate Social Responsibility
DG	Directorate General
EC	European Commission
ECEAE	European Coalition to End Animal Experiments
ECHA	European Chemicals Agency
ECSC	European Coal and Steel Community
ECVAM	European Centre for Validation of Alternative Methods
EEC	European Economic Community
EFPIA	European Federation of Pharmaceutical Industry Associations
EMA	European Medicines Agency
EP	European Parliament
EPAA	European Partnership to Alternative Approaches to Animal Testing
EU	European Union
ICAPP	International Council on Animal Protection in Pharmaceutical Programmes
ICAPO	International Council on Animal Protection
ICH	International Council on Harmonization
IFAH	International Federation for Animal Health
FECC	European Association for Chemical Distributors
GLP	Good Laboratory Practices
HSI	Humane Society International
NGO	non-governmental organisation
OECD	Organisation for Economic Co-operation and Development
OSOR	One Substance, One Registration
qmv	qualified majority voting
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals
SEA	Single European Act
SME	Small and Medium-sized Enterprises
TEU	Treaty of the European Union
UK	United Kingdom
USA	United States of America

Introduction

Among many people there has always been a natural distrust towards lobbying. Fuelled by movies such as *Casino Jack*[1], negative reports in newspapers on how lobbyists operate, and initiatives like the one announced by Lea Bouwmeester[2], the general feeling towards this profession is usually not one of affection. Politicians and policy makers will therefore in public never admit to being influenced by a lobbyist or of having accepted anything that could be mistaken for a bribe. Lobbyists themselves do not help their reputations by staying reserved about the way they operate.

Their reputation aside, lobbyists are a part of our decision making process. In the Netherlands and in the European Union (EU). And since the EU has gained more and more power the focus of lobbyists has shifted from national to European. Not completely, but ever increasingly. This thesis will look towards the EU.

Consequently, the part that lobbyists play within the workings of the EU is worthy of examination. Not just what their role is or whether this is a good or a bad thing. But simply, how do they do it? However, this is a rather unyielding and diverse subject. Far too big to discuss in this thesis.

In order to make the subject more manageable it could be wise to look at a single case. I have chosen to put the focus on animal testing. A number of reasons are behind this choice, but we will come to that in due time. First let us look at the work that already has been done on this particular research subject.

Lobby is an illusive activity. Impossible to contain and hard to measure. Therefore, it is important to define it correctly. Especially, since the act of 'lobbying' is an integral part of this thesis.

Aspinwall and Greenwood have chosen to define 'lobby' as "the investment of resources by individuals or organisations and the bringing together of these individuals or organisations in the collective pursuit of a common interest, which may result in selective or collective benefits"[3]. This is quite similar to the one Van Schendelen uses. The "build-up of unorthodox efforts to obtain information and support regarding a game of interest in order to eventually get a desired outcome from a power-holder"[4]. Both focus on how

[1] *Casino Jack* (2010), directed by George Hickenlooper. Based on the Abramoff-scandal, which brought the practices, such as bribery, of lobbyists in Washington DC to light.

[2] Every legislative proposal should include a paragraph which contains all contacts policy makers had with lobbyists on the subject and what has been discussed. http://nieuwsuur.nl/onderwerp/385341-lobby-moet-transparanter.html

[3] Greenwood and Aspinwall (1998), 11.

[4] Van Schendelen (2010), 48.

to take interest and turn it into a result. Van Schendelen differentiates from Aspinwall and Greenwood in broadening the definition by use of the term "unorthodox efforts" where Aspinwall and Greenwood only talk about "investment of resources". Van Schendelen also names a power-holder, which Aspinwall and Greenwood do not. Here Van Schendelens definition is closer to the ones that are in use at the European Commission (EC) and the European Parliament (EP). The EC defines lobbying as "activities carried out with the objective of influencing the policy formulation and decision-making processes of the European institution"[5]. However the EP is much more specific and defines lobbyists as "persons who wish to enter Parliament's premises frequently with a view to supplying information to Members in their own interests or those of third parties"[6]. A bit too specific for this thesis. The definitions of Van Schendelen and Aspinwall and Greenwood both have their merits too, but it is the EC that came up with the one that suits the needs of this thesis best. The inclusion of the European institutions as the power-holder makes it more useable and clear than the others. Especially, since the European institution involved in the cases will not always be the same ones. And in this definition the 'power-holder' from Van Schendelen has a name. In short, the definition given by the EC is more specific than the ones given by Van Schendelen and Aspinwall and Greenwood, but not too specific like the one used by the EP.

The conduct of lobbying is, obviously, carried out by 'lobbyists'. However, this is not the term that I will use in this thesis. Due to the before mentioned connotation that goes with it I will speak of 'interest representatives' instead. This has the added bonus of accurately describing what they are doing: representing an interest. Giving the discussion a less biased angle. I will however keep using the word 'lobby' to describe the activity. Resorting to an euphemism like Van Schendelen and Pauw[7] did when they coined the term 'public relations management' does not seem useful. I already detach the people doing the lobbying from the conduct by naming them interest representatives. Besides, public relations management is less accurate in describing the conduct then interest representatives is in describing the people doing it.

Doing research on lobby is hard. Mainly because is not possible to quantify lobby. And because sometimes the multiple (horizontal and vertical) levels of decision making diffuse the relation between action and outcome so much that no matter from what side you might look at the subsequent developments the actual way in which the decision has unfolded still remains a mystery. Recreating all the different moments where an interest representative has tried to exercise influence is almost impossible. Even more so because

[5] Carboni (2009), 11.

[6] European Parliament (2003), iv.

[7] Van Schendelen and Pauw (1998).

the people involved have no incentive in sharing the amount and depth of the contacts they have. Policy makers do not want to be known as someone who changes his or her opinions easily under pressure of interest representatives. Even though nowadays policy makers openly have an open door policy for everyone[8]. This is especially true for a neo-corporatistic entity like the EU. Meaning that in theory all groups in a society are represented by so called peak associations who are able to enforce agreements they have made with the government upon their members. It combines elements of both corporatism and pluralism. In corporatism the government can coerce agreements with the corporations which represent society. In neo-corporatism the corporations are much less subordinate to the state. This is where pluralism comes in. The division of political power among pressure groups so as to guarantee that not all power will be held by a single political elite. Political power then is distributed among society, but the government still stands above the pressure groups and corporations. As a consequence the neo-corporatist state is less decentralized than the pluralist state.

But why would you even lobby? It happens in all societies. No matter how pluralistic, corporatistic, or otherwise they are. Van Schendelen and Pauw divided the reasons for interest representation into four categories. Want (when their is a lot to gain, when others make efforts, or following previous successes), necessity (the only way to change a current undesirable situation; lacking alternatives), potential (probability of additional partners and resources, or expecting a reasonable effectiveness and efficiency), and invitation (others seek their information or support)[9].

In addition to this discussion I want to add the following question:

How does the pharmaceutical industry try to protect its interests at the European Commission in a public case such as animal testing?

There are a number of aspects to this question. These are determined by the boundaries that I devised for this thesis. The first boundary is the actors that are involved. In this question that comes down to the pharmaceutical industry and the European Commission. The second boundary is the use of a case study. A case that is under the attention of the public. And the third boundary is the conduct of lobby and the protection of interests. In the following section I will explain these boundaries.

The first boundary I would like to discuss are the actors that are associated with this subject. There are many actors involved in the field this research question covers. The closer you look, the more you see. At this point I will not look very close. That will come later on. Easiest to define as actors are the pharmaceutical industry and the

[8] Kok, Kramer and Van der Maas (2004).

[9] Schendelen and Pauw (1998), 13.

European Commission. Then when you look at the case there are the stakeholders involved in animal testing. Which are obviously the above mentioned, but also some other actors.

Here we come to an interesting point. A lot of stakeholders do not protect their own interests. They hire others to do this on their behalf: interest representatives. Often employed by a group of stakeholders.

The second boundary I have created is the use of a case study. Making use of a case study is a classical way to demarcate a research question. Exactly why I am using it. But it also has a big disadvantage. It is like walking around wearing winkers. You only see what is right in front of you. You are blind to the world outside your focus. In an attempt to attend to this problem I will sometimes bring in examples from an other case I worked on. A non public case. Direct-to-consumer-communications.

The many factors that are of influence on the development of this case need to be brought in perspective. Most of them will hardly be dealt with. For example, the technical progression that is of major importance to the replacement of animal tests by alternatives which do not rely on the use of animals. I will focus on the protection of interests and the issues that brings with it.

Having set these boundaries the next step is to establish how to answer my research question. The sub questions that I will deposit here will help me to get a satisfactory answer.

In the first part of the thesis I will try to answer the following questions:

'Who are involved in the protection of the pharmaceutical industries interests at the European Commission?',

'How does the European Unions policy making process work and what is the role of the European Commission in it?', and

'What makes a public case different from other cases?'.

In the second part of the thesis I will take a more chronological approach. Taking not only the events that are of importance to the animal testing case into account, but also a description of the development of the European Union, how the European pharmaceutical industry has fared, and lobbying in general. The question that will be central to this part reads:

'Have events moved in favour of the pharmaceutical industry?'.

In the third part the case study will be viewed at close range. Giving the historical context from which this case has developed. Bringing to the case study some depth and help lift it to a higher level. In doing so I try to get an answer to three questions:

'Where does the pharmaceutical industry stand on animal testing?',

'What are the positions of the other actors in this case?', and

'What is the role of ECHA in this case?'.

In the last part I shall look at the case study again, but now with the help of six themes. Themes derived from the Advocacy Coalition Framework (ACF). This framework has a couple of advantages in studying lobby. How it works and why I chose it will, of course, be explained in this part. The main question, however, will be:

'How can you describe the position of the pharmaceutical industry when you look at the resources used in the ACF?'.

Finally, I will combine the answers to these sub questions and attempt to answer the main research question.

Naturally, at this point I have some idea what that answer probably will be. But these assumptions have to be checked. Whether these are right on the money or totally misguided remains to be seen. For now, let us just see what these assumptions are.

My general hypothesis is that the pharmaceutical industry is able to use the connections they have cultivated over a long period to keep most issues under control. However, when a case, such as animal testing, goes public the pharmaceutical industry has to change tactics. Politicians and policy makers are usually sensitive to public outcry. I think that the rise of Corporate Social Responsibility (CSR) and the recently implemented Cosmetics Directive are good examples of how public opinion can have an effect on the policy making process.

At the same time, the pharmaceutical industry must have adopted to the growing number of interest representatives in Brussels and the institutional changes within the European Union. Most importantly the initiatives to do something about the lack of transparency that surrounded the European Union.

The best way to test these assumptions is logically to by getting the answers to the questions I asked. And this exactly what I set out to do.

Part One; The Parameters

This thesis will start off with a broad perspective that narrows down to the case study, just to widen the scope again towards the bigger picture. The broad perspective shall be build up by the description of the different actors, the policy making process and an introduction of the case that I will be using. The main goal of this part of the thesis is to create a context in which the case study takes place. It builds on the boundaries that have been set in the introduction. Being the actors, interest representation, and the case.

Because of these boundaries I have devised three sub questions that will be guiding for this part. The sub questions that will be answered in this part of the thesis are: 'Who are involved in the protection of the pharmaceutical industries interests at the European Commission?', 'How does the European Unions policy making process work and what is the role of the European Commission in it?', and 'What makes a public case different from other cases?'.

Who are involved?

Let us start with the first of these three sub questions. Who are involved in the protection of the pharmaceutical industries interests at the European Commission? In the introduction I already partially answered this question. The actors that were seen in there were the pharmaceutical industry, the EC and other stakeholders involved in the policy making process concerned with animal testing. To clearly answer this sub question we have to look deeper. All three actors are still very vague entities.

In order to give these actors a bit more body it is prudent to look a bit closer at them. A good place to start is the pharmaceutical industry. An important thing we should keep in mind is that the pharmaceutical industry is sometimes hard to distinguish from the chemical industry. Companies like Akzo Nobel, Bayer or DSM have divisions that are involved in the pharmaceutical industry, but they produce mainly other products[10]. DSM for example is the biggest supplier for the pharmaceutical industry. Half of the worlds top twenty most sold medicines contain products coming from DSM[11]. Bayer is listed as a chemical company. Even though their pharmaceutical division is bigger than a lot of companies that are listed as pharmaceutical companies[12]. A list of the biggest pharmaceutical companies therefore is not as representative as it might look. The problem lies in the fact that the pharmaceutical industry has originated from the chemical industry. Since then they are closely linked. So close that in a report from Eurostat they

[10] SOMO (2003), 7.

[11] Idem, 4.

[12] SOMO (2004), 14.

prove this link using statistics[13]. The chemical industry will settle where there is a pharmaceutical industry. Where the latter is small, the former will be small as well and visa versa.

The pharmaceutical industry is, however, a separate beast from the chemical industry. Unlike the chemical industry the pharmaceutical industry is one of the most influential actors on the field where it concerns lobbying the EC. So much so that Aspinwall and Greenwood in 1998 name it as "one of the most effective actors at the European level"[14]. More specifically the European Federation of Pharmaceutical Industry Associations (EFPIA). A trade association that represents national trade associations and pharmaceutical companies with a special interest in research and development of new medicines. Aspinwall and Greenwoods research suggests "that the most effective European groups in terms of attracting members tend to be those in business sectors characterised by a relatively high degree of concentration with only a limited number of potential members; where the firms are multinational and bring with them experience of operating in a variety of regulatory environments and collective structures; and where sectoral definition is marked, limiting the danger of competition from members in other sectors whose interests diverge"[15]. This is part of what makes the pharmaceutical industry so influential and why I choose them. The pharmaceutical industry is experienced, has the means to operate on the desired level, and is successful. In 2005 the British Parliament has taken a look at the pharmaceutical industry in the United Kingdom (UK). They concluded that the influence of the industry on the regulatory policy and process is strong and will increase, because the EU will take on more responsibilities. Suggesting that the hold that the pharmaceutical industry has over the EU is stronger than they have over the UK and that through the EU the pharmaceutical industry will force legislation upon the UK. More to the point, they noticed that it was the first time in over a hundred years that the British Parliament found it necessary to investigate the pharmaceutical industry[16]. A signal that the industry has, for a long time, been able to attend to its business without much interference from, or conflict with the UK government. In the Netherlands the pharmaceutical industry has moved without interruption as well. But recent events have put the spotlight on their involvement in the decision made by former health secretary Ab Klink to buy vaccinations in 2008[17]. Many

[13] Vekeman (2005), 4.

[14] Greenwood and Aspinwall (1998), 21.

[15] Ibid.

[16] House of Commons Health Committee (2005),77.

[17] A radio show, Argos, found that claims of professor Osterhaus, who had interests in vaccination producing companies, on the severity of the flu outbreak were highly overstated.

questioned the ties that his most prominent advisors, Roel Coutinho[18] and Ab Osterhaus, have to the pharmaceutical industry. These examples show that the stakes are high, but the freedom of the sector quite large. Which makes it all the more interesting to see if these national examples are an indication of what is going on at the European level.

The pharmaceutical interest representatives do not lobby the entire apparatus of the EU. Specific institutions get more attention than others. And the EU has given them a role in the decision making process. Lobbying has become an important part of how policy is formed[19]. So important that the European Transparency Initiative of 2006[20] has been deemed necessary. A, non-obligatory, register that interest representatives in Brussels who participate in certain processes are recorded in. The question is where do they lobby? The easiest answer is: everywhere they can. But the most influential lobby is done at the top of the pyramid.

The EU policy making process is layered. At the top are the treaties. Member States have sovereignty, which makes the EU in essence no more than a collection of treaties between these Member States. A part from that they meet each other in the European Council. This institution sets the political direction of the EU, but has no legislative powers. Below that are three institutions. The Council of the European Union also represents the Member States governments on more specific subjects and can pass laws. And it is responsible for the foreign policy of the EU. The EP represents the citizens of the EU, is directly elected, scrutinizes other EU institutions, especially the EC, and passes laws. And the third institution is the EC. This functions as the day-to-day government of the EU. This makes it for the purpose of this thesis the most interesting institute. The reason is that most agencies, directorates and commissions have to report in one way or the other to the EC. And above the EC level national governments with all their peculiarities will fragment the process so much that the focus will shift to how different Member States interact instead of how to lobby them.

[18] Professor Coutinho was critized by Hans van der Linden, a general practitioner, for overemphasizing the necessity and usefulness of vaccinating against cervical cancer. Coutinho was accused of doing so because he had ties to the pharmaceutical industry. On http://www.steunhuisartsinproces.nl/in-de-media Van der Linden posts all news items concerning this case.

[19] Kok, Kramer and Van der Maas (2004).

[20] EC European Transparency Initiative (2006).

How does the policy process work?

This brings me to the second sub question. All these actors are in some way active in the policy making process. But how does the European Unions policy making process work and what is the role of the European Commission in it?

So far the EU's policies can be divided into three different types, according to Sbragia and Stolfi[21]. Market-building policies, market-correcting policies and market-cushioning policies.[22] The market-building policies emphasize the liberalization and are generally regulatory. The creation of the Single Market is a good example of this. Market-correcting policies aim to protect citizens and producers from market forces and have a redistributive nature. The pharmaceutical market is highly regulated in this way to make sure developers get a chance to earn their investments back. Market-cushioning policies intend to mitigate the harm that economic activity can bring to individuals. Keeping prices at a level which consumers can afford, for example. The first is usually greeted with excitement by the industry, whereas the –correcting and –cushioning might not. In the case of animal testing the main focus has been on market-building. Regulating the reduction of animal testing and the promotion of alternatives.

One way of, for example, softening the blow of a market-cushioning policy could be to use the comitology to its fullest. As mentioned before the fine tuning happens here. Taking the sting out of a policy as well. It is a difficult and diffuse subject to get into and comitology as an issue has been talked about a lot recently. The main concern it carried with it had to do with transparency. As we shall see with the case on direct-to-consumer-communications. Outsiders were very critical on this point. They wanted to know what happened after a measure was decided upon. Annually 60 texts are adopted via co-decision, while up to 3000 decisions are taken by comitology groups[23]. So there was definitely something to talk about. The EC would invite (private) parties to send experts who could be put into committees that worked out the details of legislation they had decided upon. These experts then, could have great influence on how this would turn out. Without having the necessary checks and balances[24]. Because this system is efficient and cheap the EC was not very enthusiastic to change it. The EP was. With their strengthened powers they wanted more control and got it. Slowly the system opened up. Backroom politics are no longer one of the main concerns of the EP. Part of the solution to this problem seemed to be that the EU is based on the consensus principle. Rather than the winner-takes-all principle which is prevalent in the United States (USA). A consequence is

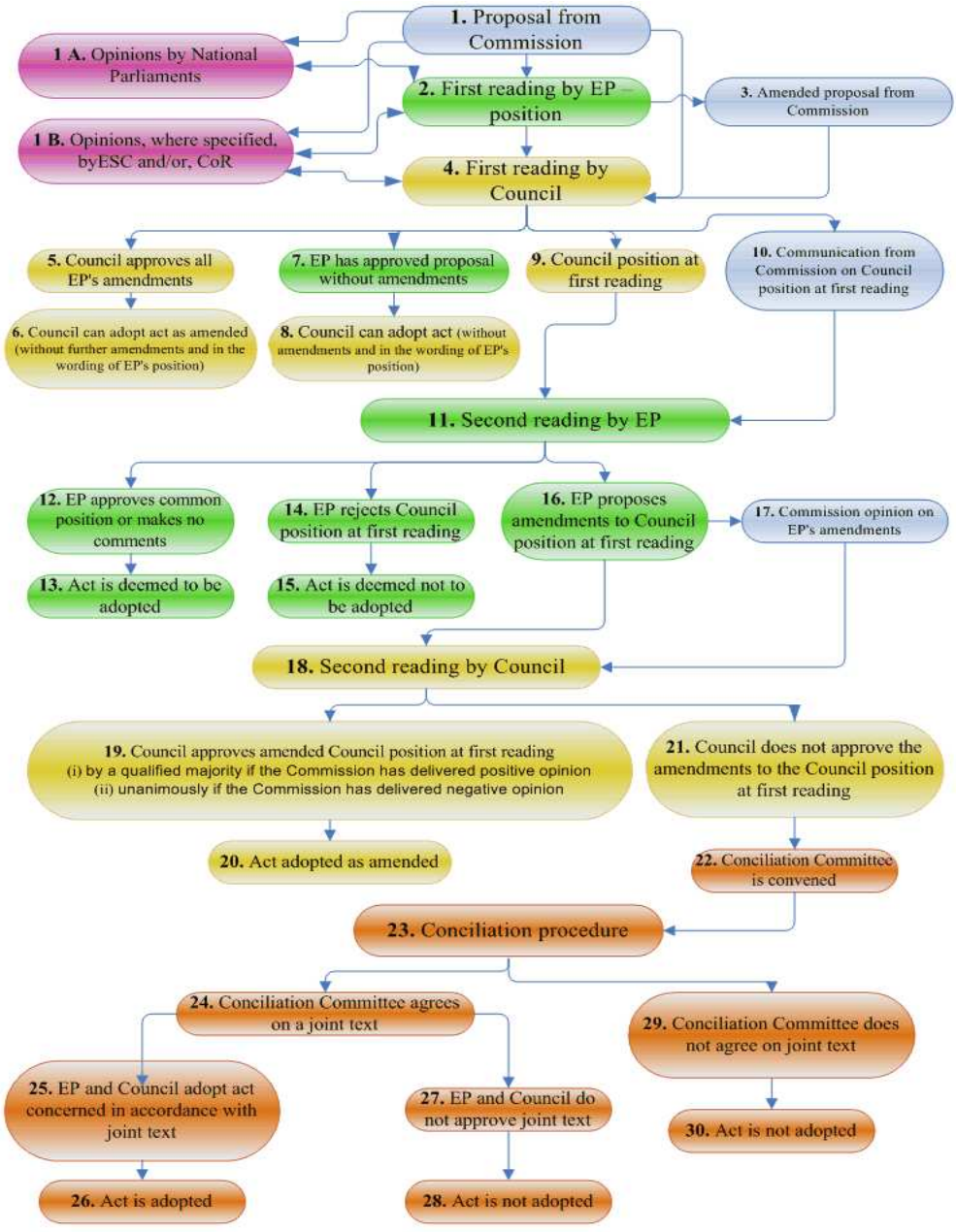
[21] Sbraga and Stolfi (2008).

[22] Mossialos (2010), 2.

[23] Guéguen (2007), 113.

[24] See the works of Mark Rhinard, Renaud Dehousse and others for more information on this subject.

that a potential debilitation problem, such as the discussion around comitology, is solved without going into extremes or actors overruling each other.



Co-decision flow chart[25].

To see how this works we have to take a good look at the policy making process in the EU. At what point do interest representatives try to intervene in the decision making process. The decision making process has numerous moments in which an interest representative can try to do his or her job. And although it has changed quite a bit since the Single European Act (SEA), above is a scheme on what the co-decision procedure looks like today. This is not the only procedure where the interest

[25] http://ec.europa.eu/codecision/stepbystep/diagram_en.htm

representatives can get involved. It is one of the most important ones. Primary law, for example, is left out. These are the treaties that national governments will sign with each other. Like the Treaty of Rome, the Treaty of the European Union (TEU or more commonly known as the Maastricht Treaty) or the SEA.

Secondary law is made using the co-decision procedure where necessary. It starts with a 'draft phase'. The EC has a reason and a proposal for a new piece of legislation. This measure will, of course, fall within the mandate of the EC as set out by the treaties. In this phase a lot can and cannot happen. Before the proposal is formally on the table and the 'consultation' has begun nothing has happened. New legislation can be stopped here from ever becoming legislation fairly easy. On the other hand, this is the point where an interest representative can 'help' the EC with useful suggestions or texts. When a proposal has been put forward by the EC the 'consultation' will begin. National parliaments of Member States, the EP and some committees have to be consulted on the proposal. If necessary a second reading by the EP will take place. The EP can then propose amendments. Lobbying in this stage has to be focussed on those amendments or on a total rejection of the proposal. When the Council does not agree with the amendments of the EP a Conciliation Committee has to be formed. This will start a conciliation procedure and is aimed at getting both parties on board on a joint text. For about fifteen percent of all legislation that is formed this is the route that is determined under the co-decision procedure.

The lions share of laws are delegated and discretionary. These consist of the detailed legislation that is needed to get the secondary laws implemented. This is the comitology I mentioned earlier. Since the co-decision procedure can take up to three years[26] it can be very interesting for an interest representative to get to the proposal, with all its amendments, accepted by all parties as soon as possible. Preferably before a second reading is necessary. Because once within the bosoms of the comitology a lot can happen and corrected. Amongst others, Mark Rhinard[27] and Daniel Guéguen[28] have done a lot of research on this particular part of the policy making process. The technical quality of Rhinards work on the more controversial aspects of the system, like the democratic and transparency deficits, are very useful for anyone that wants to look into this particular part of EU policy making procedures. Guéguen on the other hand makes an effort to open up the subject to a broader audience. Making his work easier to follow, but also less accurate (he acknowledges this himself). He explains, for example, that there are a few people who are able to work the system to their advantage. Mainly, because

[26] Carboni (2009), 17.

[27] Rhinard (2002).

[28] Guéguen (2011).

they are doing it for a long time and are able to spend a lot of time and resources at it. Industrial interest representatives, as one of the oldest and well endowed players on the field, are usually more experienced than their more recent counterparts, like non-governmental organisations (NGOs).

How these interest representatives actually do this is under the investigation of many people[29]. Not least by them selves as a publication by Burson-Marsteller (B-M) proves. In 2009 this public relations and communications firm wrote a guide on effective lobbying[30]. At the base of this guide was an enquiry that was designed to "identify perception among policy elites about lobbying and lobbyists"[31]. Proving that they practice what they preach, B-M found the vice-president of the EC, Siim Kallas, willing to write the foreword of this guide. Apparently a man of his stature, who will find himself often targeted by interest representatives, respects them enough to not only write a foreword for them, but also recognize them as a valuable asset to the decision making process[32]. The interest representatives are not the only ones who try to influence people and organisations. Kallas has an agenda too. He pushes for registration of interest representatives in the Register for Interest Representatives (a result from the European Transparency Initiative)[33]. Supported by the authors transparency runs through the guide as one of the main issues in lobbying. Being transparent equals, especially in the northern countries, a more trustworthy management. The surveys B-M did found that lobbying is seen as constructive input to decision making and sharing of expertise, but on the negative side they found that a lack of transparency and biased information were mentioned often. In 2005 a report from B-M showed that companies and NGOs were equally effective. However, now (2009) there are a number of fields where the industry is perceived to be much more effective. One of these fields is the pharmaceutical industry. Worryingly, one quarter of the respondents mention unethical inducements to be frequent. By which they mean corruption, an apparent lack of transparency or aggressiveness[34].

Public opinion

Now it is time to bring in the case study that plays such a big part in this thesis. I have chosen for animal testing as the subject of my case. One of the major reasons for this choice was the fact that animal testing is a very public case. Which immediately brings up a question. What makes a public case different from other cases?

[29] For more on this you could look at the works of Rinus van Schendelen or Erik van Venetië.

[30] Burson-Marsteller (2009).

[31] Idem, 7.

[32] Idem, 4.

[33] Ibid.

[34] Idem, 8.

Public opinion can be a very powerful weapon in the hands of a capable interest representative. Access can be forced by getting the public to demand that policy makers listen to your beliefs. Public opinion can help to get the policy makers and other coalitions to sway to your beliefs more easily as well. Some have become much better at influencing the public opinion than others. Playing on emotions that are already present in the public is one way to put the policy makers in a position that they are forced to act. At the same time the public opinion can be a powerful break on developments. Near the end of the eighties the public opinion favoured the EU. Treaties like the SEA and Maastricht helped boost confidence in the cooperation. Since the introduction of the euro, however, euro scepticism has been rising. More and more further integration was slowed down by governments who were held back by the public opinion at home. Now the economic crisis is hitting hard governments are acting again. Their constituencies expect them to do so and make sure that the promised economic recovery is assured.

That the public opinion can be manipulated into your favour by throwing more money at it than your opponents is false. John Wilson describes this claim quite thoroughly in an article on the influence of lobby groups on public opinion in environmental policy[35]. He starts of by recognizing that in the 2002 election cycle environmental groups spend much less on political contribution in the USA than private actors. Respectively 1.4 million dollars against 57.8 million[36]. This did not mean that the environmental groups were having a significantly smaller impact on environmental policy. They were spending their money elsewhere. Preferring to influence public opinion instead[37]. He found that a largely uninformed public will remain uninformed when parties polarize. Viewing their, informed, claims with scepticism.

The parameters that have been presented here shall shape the rest of this thesis. The way that the pharmaceutical industry is closely related to the chemical industry and the workings of the EU policy making process show how I shall approach the case. Just like the role of the public opinion. Using the public at your advantage can be very effective, but is no guarantee for success. The public does not always care as much as you do.

In the next part of this thesis I will put the focus even more on the pharmaceutical industry. Working up to animal testing in the process while providing a valuable context.

[35] Wilson (2005).

[36] Idem, 2.

[37] Idem, 33.

Part Two; The Context

In this second part of the thesis I will show how the European Union has developed, how the European pharmaceutical industry has fared, and how interest representation in Brussels has changed. The sub question that will be answered in this part of the thesis is: 'Have events moved in favour of the pharmaceutical industry?'. This will include situations and developments that the pharmaceutical industry has no power over.

As the start of this rather chronological account I have chosen the European Coal and Steel Community (ECSC). Beginning a story on the EU with the ECSC is almost classic. There are good reasons to start earlier with efforts of people like Guiseppe Mazzini and Victor Hugo or the Pan-Europa Movement of Coudenhove-Kalergi. The ideas of an united Europe and acknowledging this as a way to prevent future wars was already well established in intellectual circles when plans for the ECSC were made. One of the main goals behind the ECSC was to prevent a war between France and Germany (or any of the other member states[38]). To integrate these countries in such a way that war would be very unprofitable no matter what the outcome. The ECSC was established in 1951 with the Treaty of Paris, but its initiator, Robert Schuman, had much larger plans. On 9 May 1950 he made the Schuman Declaration public, and thereby creating the ECSC. But his declaration promoted a step by step creation of an unified Europe through democratic means. Until this day that process is still under way.

After this noble start the main drive behind the steps towards further integration was economic in its nature. The Treaty of Rome and the subsequent creation of the European Economic Community (EEC) show that it did not take long before economic motives had taken the lead. Most industries reacted quite distant and were hardly interested in the ECSC or any of the institutional endeavour that went along with it, except of course the ones directly affected by the ECSC. Networking activities during the first decades were not so much focussed on policy change as they were on the networking facet itself. Institutional arrangements and industrial programmes of the Community were of secondary importance.

The medical community adopted in this period the Helsinki Declaration[39] through the World Medical Association. They did this in order to produce a form of successful self regulation. Building upon a tradition of annual meetings since 1947, the member organisations declared that their physicians were bound to uphold the standards set out in the Declaration, even if local legislation does not demand this of them. Over the years the Declaration has been revised and clarified multiple times. However there are other problems. A lot of them have to do with research and the patents that result from that.

[38] One of the reasons why the EU got the Nobel Peace Price in 2012.

[39] WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects.

For example, Bhandari et al. conclude that trails financed by the industry are more likely to result in significant pro-industry findings than if they were financed in any other way[40].

I bring this example of international organisation from the medical profession into the story to show that even though initiatives like these run parallel to the development of the EU that does not have to imply any form of interaction. Talks remained very informal and stakeholders saw each other as partners in this new enterprise. "Although the EU initially shunned European big business during the Monnet years, it is clear that the European Commission has played an important role since the 1960s in encouraging the mobilisation of large firm associations" [41] . This constant exchange between governmental officials and industry representatives define a period that Daniel Guéguen[42] calls the time of construction. Full of enthusiasm this period lasted until the beginning of the 70s.

Though this optimism was not to last. The 70s and 80s became the low tide. The development of the EU is slowing down and the initial enthusiasm is gone. Interest representatives take on a lower profile and maintain their informal ways of doing business. It is Jacques Delors that changes this. His efforts to establish a single market puts the EU back on track and reinvigorates that initial enthusiasm. Important to note is that the single market was wholeheartedly endorsed by the European Round Table of Industrialists[43], then arguably the most influential interest group in Brussels. Typical for the change in the way interest representatives operate is the realisation that a lot of power has left the national governments and has taken residence in Brussels. Therefore, so will the lobbyists. They become much more aggressive in their tactics, better informed technically and rely on a bigger, global network. Increasing competition from other interest representatives leads them to try and get the best factual arguments. According to Guéguen technical credibility becomes crucial and the only way to be taken seriously. And therefore the only way to be listened to[44]. Maria Green Cowles describes the groups near the end of the nineties as tending to be "small, direct-firm organisations dedicated to shaping the agenda on specific Community issues through the use of organised, well-financed lobbying schemes" [45] . Amid all this a problem arises for the interest representatives. They were still arranged as they were in the 70s. The classical European association, formed around sectoral representation, had a monopoly of representation with the European institutions. But the raising stakes for the industry and the growing

[40] Bhandari et al. (2004) 477

[41] Cowles (1998), 124.

[42] Guéguen (2007).

[43] The ERT is an initiative of Volvo chief executive Pehr Gyllenhammer, who in 1983 collected a group of 17 businessmen from across the largest enterprises in Europe in order to lobby on behalf of Europe's industry.

[44] Guéguen (2007) 14.

[45] Cowles (1998), 109.

competition amongst themselves changes the balance while the increasing number of members the associations have to represent clog their wheels. Making it much harder and more time consuming to get consensus on issues. Usually ending up with compromises that did not fulfil the wishes of all members. In a reaction the members start to lobby on their own account. Undermining the authority of their trade association, but strengthening their own position. Nonetheless, they kept their membership of the trade association. Knowing what your competition does and perhaps being able to participate in a joint effort has its advantages.

In 1985 the Commission Delors came with a white paper on the internal market, which led to the SEA[46] and enveloped 279 legislative measures that had to be taken in order to be able to complete the internal market by 31 December 1992. The SEA was signed in The Hague on 17 February 1986 by nine member states (Belgium, France, Ireland, Luxemburg, the Netherlands, Portugal, Spain, the United Kingdom and Western-Germany), closely followed by Denmark, Italy and Greece on 28 February 1986 and became effective 1 July 1987.

For the pharmaceutical industry this meant not just the same as for every other industry. The breaking down of trade barriers within the EU had a major effect on all trade. Pharmaceutical products had an extra dimension. Because healthcare systems were still nationally organised and the market for many pharmaceutical products was attuned to these specific conditions, the transition was not smooth. Cases such as those of Kohll[47] and Decker[48] at the European Court of Justice in 1998 are excellent examples of this. Both gentlemen had made use of services that their health insurance would have paid for if they had done so in Luxemburg, where they came from. However, they did not and sued the insurance company. The European Court of Justice ruled that this was in violation of the free movement of goods and services under EU law, and that EU law would supersede national law. In the end they are a testament to how far the EU had progressed. It showed that EU law had much more power over national law than was previously thought. What made the situation more complicated was that the health sector was not included into the EU Services Directive. The directive that aims to break down trade barriers for services. In 2005 it was added to the Open Method of Coordination procedures conducted by the Social Protection Committee. Health related lobby groups had successfully kept health out of the Services Directive. Claiming the sector was to unique and that Member States would have difficulty managing their health systems with the additional EU oversight. The EC kept on pushing for harmonization on

[46] Information on the Single European Act comes from:
http://europa.eu/legislation_summaries/institutional_affairs/treaties/treaties_singleact_en.htm.

[47] Kohll v. Union des Caisses de Maladie (1998).

[48] Decker v. Caisse de Maladie des Employes Prives (1998).

the grounds of the SEA in connection with the cross border trade in medicines, but Member States have, so far, used the subsidiarity principle to thwart this. Under the SEA medicines are still treated as industrial goods[49]. The problem with this is that each Member State wants to control the prices of medicines sold to the consumer. As a result prices differ greatly within the EU. Traders will buy medicines in a country where they are cheap and sell them to pharmacies in a country where they are expensive. Health insurance companies will reimburse the prescription drug, at a rate determined by the government. But the pharmaceutical companies cannot sell the medicines they produce at the same price the traders will, because the government will not let them[50]. This practice is also known as parallel trade or grey-market imports and an important issue for the pharmaceutical industry that they try to address to the EC.

The SEA meant a lot of changes in the EEC-Treaty. The increase in power of the EC and the EP, the reformed decision making procedure of the Council and the extension of the responsibilities of the Communities were the most notable changes. The treaty also formalised the summits of the Heads of State and Government into the European Council. Still, this newly created institution did not have any official powers. But it is one of those glimpses into the long term vision of the treaty. The same goes for the mentioning of the creation of a European Union in the preamble of the treaty.

For the Council the reformed decision making procedure mainly came down to the introduction of qualified majority voting (qmv) instead of unanimity for all measures. This was supposed to make the procedure easier and especially more effective. Only measures concerning taxation, free movement of persons and the rights and interests of employees were still decided by unanimity.

In an attempt to tackle the 'democratic deficit'[51] the EP was from then on included in the concluding of association agreements. More importantly, the cooperation procedure was introduced, which gave the Parliament a far stronger position in the legislative process. However, this procedure is only applicable in cases where the Council acts by qmv and with the exception of environmental matters. On a judicial level the SEA created the foundations for a Court of First Instance. All cases, except (references for) preliminary rulings requested by Member States or institutions, may be presented here.

More importantly, the objective of the SEA was formulated in Article 8A as "an area without internal frontiers in which the free movement of goods, persons, services

[49] Carboni (2009), 8.

[50] Jack (2012).

[51] With regard to the discussions concerning the democratic deficit I have chosen two articles that could shed more light on the size and depth of the discussion in more recent years: Jensen, T., "The democratic deficit of the European Union" in: *Living review in democracy*, vol 1 (March 2009). and Follesdal, A. and Hix, S., "Why there is a democratic deficit in the EU: A response to Majone and Moravcsik" in: *Journal of common market studies*, vol 44, no 3 (September 2006) 533-562.

and capital is ensured in accordance with the provisions of this Treaty". All to be established before 31 December 1992. To get the less developed regions up to speed the Community has the European Agriculture Guidance and Guarantee Fund and the European Regional Development Fund to intervene. On the high end of the economy the Treaty provides for the implementation of framework multi annual programmes that can be unanimously adopted by the Council. Research and technical development should benefit from these programmes and become more competitive at an international level.

For the pharmaceutical, and other industries, this meant that decision making at the EU-level became much more dynamic and effective. Opening up an internal market within six years and the existence of those funds gave the interest representatives of various industries enormous future possibilities. As did the following treaties and reforms. The first time the SEA was amended was with the TEU of 1992. Again with the Treaty of Amsterdam of 1997, the Treaty of Nice of 2001 and the Treaty of Lisbon of 2007. The TEU [52] created the three pillars on which the EU would be build: the European Communities, a Common Foreign and Security Policy, and Cooperation in the Fields of Justice and Home Affairs. Another significant advancement was the laying down of a procedure and a timetable for the Economic Monetary Union with a single currency. Working towards becoming an efficient, but democratic community the principle of subsidiarity was introduced and the EP got more power in the legislative process through co-decision procedure. On top of that the Committee of the Regions was established in order to give the local and regional interests a voice.

The TEU had some big consequences for the pharmaceutical industry. Consequences that they did foresee with the SEA. One of these was that the entire EU had to implement and uphold the same patenting laws since 1992[53]. The climax of a development that was going on for over three decades.

As a controversial subject the patent regulations have had their profound effect on the pharmaceutical industry. Champions of these regulations will defend their argument with the claim that research is so expensive that without the reassurance of a patent developing new medicines would not be worth the trouble. Considering that it takes pharmaceutical companies about thirteen years to produce and patent a new kind of medicine. After which the patent lasts for twelve, in some cases up to twenty, years. In that time the company has to make its money back[54]. A lot of money. Especially when you take into account that a patent is usually given years before a drug enters the market. On average the cost of bringing a single drug to the market will be around 800 million dollars. Because of this no industry is more depended on patents than the

[52] Nugent (2003), 331.

[53] Boldrin and Levine (2005), 4.

[54] SOMO (2003), 4.

pharmaceutical industry[55]. Although other calculations, as seen below, will only go up to 400 million dollars, the argument still stands. It is incredibly expensive to develop a medicine and the success of one medicine has to pay for the failure of many others.

Overview of different stages of drug development[56]					
phase	**description**	**test group size**	**cumulative time (years)**	**success rate**	**cost ($ mln)**
pre-clinical	identify benefits and risks to participants in clinical trails	-	1-2	1%	<1
phase I	test safety, dosage range and side effects on volunteers	20-80	3-4	10%	0,5-1,5
phase II	test effectiveness and safety on patients	100-300	5-6	40%	2-100
phase III	confirm effects on patients, compare with other drug	1000-3000	8-9	80%	30-400
approval	-	-	10	95%	

At Bristol-Myers Squibb the turnover of three medicines dropped 90 percent in the first quarter after the patent ran out. Mostly due to competition of generic medicines[57]. That claim, however, is mainly true for large companies. A historical analysis of patents in this branch of industry tells a different story[58]. Prior to the First World War the introduction of patent protection in France was a reason for French chemical companies to move to Switzerland en masse. At that time the pharmaceutical industry was a part of the chemical industry. Since patents were forbidden in Switzerland this was the logical way to go. So many companies did this that on the eve of the war there was no chemical industry in France anymore. Apart from that the Swiss chemical industry was doing well for a few other reasons ass well. Contrary to England and France, from 1900 to 1915 the Swiss were catching up with the Germans. Thanks to collaborating with the German industry, specialization, quality, permissiveness and neutrality[59]. At that time the chemicals industry in the USA was underdeveloped and because patent protection the USA was forced to import chemicals from German companies, which held most patents. The German market was very competitive, innovative and highly productive, and successful on the European markets where patents were not protected[60]. So successful that with "reference to the organic chemistry industry in particular, more than half the

[55] Boldrin and Levine (2005), 1.

[56] SOMO (2004), 6.

[57] SOMO (2003), 10.

[58] Boldrin and Levine (2005), 5.

[59] Bueno and Nozal (2010), 464.

[60] Boldrin and Levine (2005), 5.

total of the chemical production exported by Germany in 1912 corresponded to dyestuffs, perfumes or drugs, and the sales abroad of these products exceeded the total figure of exports in the rest of the world."[61] The Anglo-Saxon markets were not at the same level. Boldrin and Levine think that this has to do with the fact that they do have a large degree of patent protection. The two World Wars made sure that German know-how was easily spread among the victors and their chemical companies could catch up with the Germans[62]. Already in 1924 Germany's share in the world trade had dropped to 40%[63].

Patents have the drawback that they slow down the spread of knowledge. For example, Peter Ringrose, the chief scientific officer at Bristol-Myers Squibb, told the New York times that there were "more than 50 proteins possibly involved in cancer that the company was not working on because the patent holders either would not allow it or were demanding unreasonable royalties." [64] Keep in mind here that Ringrose is complaining that others are not sharing their knowledge with him, but he is not saying that he wants to share his knowledge with them.

In 1978 Italy introduced patents on medicines under pressure of large multinationals. This lead to a big growth in the number of medicines that were invented in Italy, compared to the previous decades[65]. A consequence was that the market in Italy was first dominated by small and medium enterprises (464 in 1976) and now the big players took over (335 small and medium enterprises in 1985). The Italian companies lost the battle against the big foreign companies. Their method of copy and improve was not possible anymore[66].

In the USA it was for a long time already possible to patent the drug as well as the process of making it. In Europe the first was not possible until quite recently[67]. In France that started in 1959 for some pharmaceutical products and was completed in 1978 for all pharmaceutical products. The Germans were already there in 1967. Even Switzerland yielded in 1977. Italy was prior to the patent regulations the fifth producer in the world and the seventh exporter. In the beginning of the 80s they lost that position[68]. Spain had to introduce patenting because it joined the EEC in 1986. That this did not stop the European companies from investing in research and development is shown by the amount they spend on it. In 1990 the EU spend more on research and development in the pharmaceutical industry than anywhere else. And it kept on growing. In the USA

[61] Bueno and Nozal (2010), 463.

[62] Boldrin and Levine (2005), 6.

[63] Bueno and Nozal (2010), 463.

[64] Andrew Pollack (2001).

[65] Boldrin and Levine (2005), 8.

[66] Idem, 9.

[67] Idem, 2.

[68] Idem, 3.

the spending grew as well, and much faster. In 2005 the expenditures in the EU had tripled, but the USA had grown even faster and were now the ones who spend the most on research and development[69]. Despite the increase in spending up to the nineties, the number of patents granted and new drugs approved has actually diminished and development cycles are lengthening[70].

A very informative figure in this discussion is that the cost of actually producing a drug, which are never disclosed, is estimated only five percent of the selling price[71]. The bigger companies have a hard time earning their money back. Bad research results over a longer period have lead to a change in tactics. More money is being spend on marketing and less on research. Cutting the cost of research can be done by taking a successful medicine of which the patent is about to run out and change it enough to get a new patent. This new medicine will than replace the old one and effective marketing will make sure that physicians will prescribe the new drug. This tactic is usually called a "me-too" drug[72]. According to Boldrin and Levine this is detrimental to the pharmaceutical industry. In their opinion money that is spend on a "me-too" drug is wasted[73]. It could be spend on new medicines. However, the top twenty pharmaceutical companies had almost 700 new medicines under development in 2004[74]. Harmonizing patent regulations has big consequences as we could see. Showing that it can be crucial for the pharmaceutical companies to be involved in the policy making process. After all, being able to steer this process in a favourable direction could mean that you retain a profitable local position which otherwise would be lost to powerful outsiders.

Whether or not patent protection is a good thing is still under debate. The arguments in favour of patent protection are compelling. Ensuring companies that they have a good chance to recoup their investments. But the competitiveness of markets where there is much less or no patent protection and the effects it has on the spread of knowledge make it a debate that could easily take another decade before it is resolved. For the time being patent protection seems safe. Pharmaceutical companies are still quite capable in explaining that they need the patents to pay for all their research failures and that without them development of new medicines would slow down to a crawl.

In the mean time the integration of the EU was still under way. Although the Treaty of Amsterdam[75] was far more modest in its accomplishments. Mostly, it came down to deepening and strengthening existing policy. Just as the TEU it entailed more

[69] EC (2006), 101.

[70] Vekeman (2005), 6.

[71] SOMO (2004), 7.

[72] SOMO (2003), 9.

[73] Boldrin and Levine (2005), 11.

[74] SOMO (2004), 13.

[75] Nugent (2003), 332.

qmv. And the co-decision procedure that was introduced then, was now extend in its applicability.

What also changed was that the EU finally got its mandate over public health. Not that this previously held the EU back much. In an attempt to improve public health the EC introduced eight points of interest in 1993. The Communication on the Framework for Action in the Field of Public Health can be seen as a flight forward by the EC. The eight points (health promotion, health monitoring, communicable disease, cancer, rare diseases, injury prevention, pollution related diseases and drug prevention) were chosen because of their urgency and possibilities in case of a EU mandate. Meanwhile, the EU was since 1999, the Treaty of Amsterdam, capable of complementing national policies, but is barred from harmonization. Limiting the EU to establishing public health programmes and incentives in the health policy field. It took until 2002 before it was agreed upon that health care systems share common principles of solidarity, equity, and universality. But no concrete action was undertaken[76]. In 2005 in the UK companies could still choose to have their drugs licensed either for the UK market, through the Medicines and Healthcare products Regulatory Agency, or for the entire European market, through the European Medicines Agency[77]. To avoid any hint of favouritism members of the European Medicines Agency are not permitted to have any ties to the pharmaceutical industry.[78] In 2003 the EC did present the first integrated approach in the form of the Public Health Programme 2003-2008. Directly followed by a second programme which runs until 2013. This programme has three objectives; improve citizens health security, promote health and generate and disseminate health information. The scale of the programme can be seen in the budget: 321.5 million euros.

The start of the first Public Health Programme was no accident in 2003. As these things never are. On 1 February 2003 the Treaty of Nice entered into force[79]. A direct consequence of the Treaty of Amsterdam and in preparation of further enlargement of the European Union this treaty aimed to do something about the size and the composition of the Commission, the weighting of votes in the Council, extension of qmv and adjust the enhanced cooperation system. They did this by giving the votes of the more populated Member States more weight in the Council, giving the President of the EC more powers, divide the tasks of the Court of Justice and the Court of First Instance again between them, extend the co-decision procedure and change the allocation of the

[76] Carboni (2009), 7.

[77] House of Commons (2005), 22.

[78] Mossialos (2010), 112.

[79] Information on the Treaty of Nice comes from:
http://europa.eu/legislation_summaries/institutional_affairs/treaties/nice_treaty/nice_treaty_introduction_en.htm.

seats in the EP. These changes made it possible to go towards the integrated approach laid down in the Public Health Programme.

Before that health related issues were already greatly discussed and policies adopted. One such issue is a great example of the dealings between the pharmaceutical industry and the EC. It shows how well these two actors can, if they desire, work together and how opponents can be put on the sidelines. Interesting is that it begins with a very assertive EC.

The Pharma Review was in 2001 an initiative of the Directorate General (DG) Enterprise, who was (and still is) responsible for drafting pharmaceutical legislation, as a programme to revise pharmaceutical legislation. It would give the pharmaceutical industry limited opportunities to approach the general public with information on certain medicines for a period of five years. The EP and Council blocked the proposal, because they feared it would lead to direct-to-consumer-advertising.

The EC, however, wanted new legislation on this subject. Current legislation was obsolete. The spread of the internet brought with it a paradox. Producers of medicines were not allowed to provide information on these medicines to consumers, but everyone else could. To be able to reach its goal of getting reliable, good quality, non-biased information to the consumer the EC asked the EP to draft a proposal.

At the same time another initiative took of. Partially to insure that the topic remained on the table and would not be forgotten. Enterprise Commissioner Erkki Liikanen and Health Commissioner David Byrne set up the 'High Level Group on Innovation and Provision of Medicines in the EU' or more commonly known as the G10 Medicines Group[80]. The goal was to explore ways of improving competitiveness in Europe while encouraging high levels of health protection. The group met on 26 March 2001 for the first time and consisted of thirteen health and industry ministers from five Member States, representatives from different sectors of industry, mutual funds and a specialist in patient issues. After two additional meetings and one year the group reported to EC President Romano Prodi. It had divided its work into three agenda areas: the provision of medicines to patients; the single market, competition and regulation; and innovation. One of the aspects that made this initiative work was, in the words of Mossialos, that the "rationale and remit of the Group came in part from DG Sanco's role as co-initiator"[81]. Both initiatives complemented each other very well, because the G10 Medicines Group could bypass the formal channels and institutions that the Pharma Review had to go through[82]. Together reforming legislation on a broad basis. The involvement of the stakeholders through the G10 Medicines Group made it a success.

[80] Mossialos (2010), 111.

[81] Ibid.

[82] Ibid.

In contrast to, for example, the Bangemann Rounds[83]. In 1996 and 1997 Commissioner Martin Bangemann consulted the industry in two round table talks. The problem he faced was in large part due to the expectations from the industry. They wanted to talk about parallel trade, but this was protected by the Treaty and therefore impossible to change. Disappointed, the industry representatives did not want to consider the proposals to regulate the pharmaceutical market in such a way that price-fixing might become unnecessary. An attitude which the EC could not understand[84].

The G10 Medicines Group led to the establishment of the Pharma Forum in 2005 (until 2008). An attempt to keep all stakeholders involved in the process and a follow-up to the G10 Medicines Group[85]. The Pharma Forum was the first time that all stakeholders, EC, Member States and representatives of the EP gathered to discuss healthcare policy. The goal was mainly to improve the competitiveness of the pharmaceutical industry and ensure that patients would have access to medicines within a sustainable healthcare budget. On top of that, the Pharma Forum involved a higher number of stakeholders than the G10 Medicines Group had. In December 2008 the DG Enterprise was confident enough (after public consultations and impact assessment) that it released a draft proposal. Which was to be included in the Pharma Package. The Pharma Package is a popular name for a series of measures that were put together by the EC and concerned the pharmaceutical industry. On closer examination, however, there is hardly any link in what was discussed in the Pharma Forum and the legislation put forward in the Pharma Package[86]. All difficult topics which the Pharma Forum was supposed to resolve were largely kept out of the Pharma Package. Mainly, because the focus of the Pharma Package were put on the other subjects, like improving the safety of medicines and fighting counterfeit medicines[87]. Nonetheless, there is a definite change to be seen in the measure of involvement of the pharmaceutical industry in the Bangemann Rounds and in the Pharma Forum. Even if the talks themselves do not always have the result the parties would like them to have.

Separate from this another issue was tackled. At the basis of this issue was the threat of generic medicines. These medicines will enter the market when a patent has ran out and are usually substantially cheaper. The difference with the "me-too" drugs is that these are so similar to the first drug that a new patent will not be issued. The main producers of these generic medicines can be found in lower cost countries, such as India, China or South Africa. Sometimes even in the same factories where the brand medicines

[83] Idem, 112.

[84] Transparency Committee (1999).

[85] Carboni (2009), 21.

[86] Idem, 26.

[87] Idem, 25.

are made. A not uncommon situation, since the production of medicines has moved to these countries in the last decades. Even the research and development departments are moving, slowly, here as well[88]. The pool of educated employees is growing in these countries and they are much cheaper. Furthermore, the pressure from animal rights groups and strict regulations can be added to the push factors[89].

One way to arm themselves against generic medicines is marketing is to spend huge sums of money on marketing. This way the companies that produce brand drugs can still keep an expensive, patented medicine (or its patented replacement) on the market and on to the prescription pads of physicians. If possible these expensive medicines will even be prescribed after the patent has run out, because physicians are used to prescribing them. Even though cheaper generic medicines are available. Effective marketing can achieve this[90]. Of course the chance of this happening is much bigger in high income countries. In the low income countries the drug that is the cheapest has the largest chance of being prescribed, because most people simply cannot afford the brand drug. As a result 90 percent of the money that is spend on research and development of new medicines is aimed at researching diseases that are prevalent in high income countries. Only ten percent is spend on diseases that are prevalent in low income countries. Whereas these diseases make up 90 percent of deaths[91].

In an attempt to make sure developments such as these would not hurt the competitiveness of the research and development sector in the EU the Lisbon Strategy was adopted in 2000. Its aim was to make the EU 'the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion'. In 2002 the Council added the aim to spend at least three percent of their GDP on research. Of which two thirds should be paid by businesses. That goal was a bit over ambitious. In 2006 only Finland and Sweden had reached this goal. On average the EU could not even reach two percent. After the Lisbon Strategy was re-launched in 2005 it was time to do more. In 2006 the Member States appointed knowledge and innovation one of the four priority areas of the EU.

But first the EU needed to reform. After the failure of the European Constitution[92] reforms where especially overdue and many Member States were since then pushing for another format for these reforms. One of the main reasons for this urgency was a result of the growth of the number of Member States. The apparatus of the EU was never built to service this many Member States and it was getting harder and harder to make sense

[88] SOMO (2004), 15.

[89] House of Commons (2005), 16.

[90] SOMO (2004), 14.

[91] Idem, 23.

[92] France and The Netherlands voted in a referendum against the proposed Constitution. For more on this issue: Lanting (2005).

out of the growing pile of treaties. The Treaty of Lisbon[93] would bring this reform. One of the things they changed was the voting system in the Council. They redefined qmv and effectively abolished weighted voting. At the same time the powers of the EP were increased further and the citizens initiative was created.

Meanwhile healthcare costs are rising throughout the decades and governments are concerned about this. Their policies to stimulate generic medicines are contrary to what they industry would like to see. Marketing efforts in vain, the market for generic medicines is growing and competition in the pharmaceutical industry is growing too[94]. As a result pharmaceutical companies have started to adopt the strategy of buying up competitors and are more and more concentrating on their core business. Selling off other activities[95]. The strategy seems to work. In 2009 the production of pharmaceutical and medicinal products rose by 11 percent despite the economic crisis. A great recovery since 2008 saw a little decline. The EU-27 was in 2009 the biggest trader of pharmaceutical products with 123.3 billion euros of which 65 percent was export. The second largest was the USA with 74.9 billion euros. Quite a big gap. In the period 2000 to 2009 the USA was the main trade partner of the EU-27 and amounted in 2009 to 35 percent of extra EU-27 trade. Over this period the export and import of the EU-27 more than doubled. Starting at 52.1 billion in 2000[96]. The status of the USA as the most important trading partner of the EU-27 is emphasized by the fact that the value of the exports towards the USA have increased by more than 150 percent in the period from 2000 to 2007, dropped a little in 2008 and recovered in 2009. After the USA Switzerland is the most important trading partner for the EU-27. Still that trade holds only one third of what the trade with the USA is[97].

Destination of extra-EU export (CPA Group 24.4) in %[98]			
country	**1990**	**country**	**2000**
USA	15,9	USA	30,5
Switzerland	11,4	Switzerland	11,3
Japan	11,3	Japan	7,2
Australia	3,6	Australia	3,0
Saudi Arabia	2,8	Canada	3,0
Rest	54,9	Rest	44,4

[93] Information on the Treaty of Lisbon comes from: http://europa.eu/legislation_summaries/institutional_affairs/treaties/lisbon_treaty/ai0033_en.htm.

[94] SOMO (2004), 8.

[95] Idem, 15.

[96] Gambini (2010), 1.

[97] Idem, 2.

[98] SOMO (2003), 21; Eurostat, Comext.

Origin of extra-EU import (CPA Group 24.4) in %[99]			
country	**1990**	**country**	**2000**
Switzerland	47,6	USA	43,9
USA	30,1	Switzerland	32,7
Japan	8,1	Japan	6,2
China	3,1	China	3,3
Norway	2,1	Israel	2,3
Rest	8,9	Rest	11,7

World pharmaceutical market by region, year prior to September 30, 2003.[100]		
Region	**Value (£ bn)**	**% of total**
USA	127	46
Europe	76	27
Japan	31	11
Asia Pacific (ex. Japan)	19	7
Latin America	12	4
Middle East, Africa	8	3
Canada	6	2
Total	279	100

As the tables above show the USA and Switzerland were already the most important trading partners of the EU in 1990. And still are in 2000. For the pharmaceutical industry this is important, because, as the other table shows, this is where their main market is as well. 86 percent of the pharmaceuticals market is to be found in what is called the 'First World'. Underlining what I previously stated on which diseases are targeted by their research. This is where the money is. 240 billion pounds of it.

Overall the external trade has had its own development. In the period 1995 to 2005 there has been a significant uninterrupted growth in imports and exports of the EU. However the trade balance shows another story. Until 1997 the surplus was growing rapidly to 48,6 billion euros. In 2000 it had shivered away to a deficit of 91,4 billion euros (both EU-15). It recovered in 2002, but was back in the red by 2005[101]. In 2000 and 2005 the main export countries for the EU were the USA and Switzerland. On imports in 2000 the largest trading partners were respectively the USA, Japan and China, but in 2005 this changed to respectively China, the USA and the Russian Federation[102].

[99] SOMO (2003), 22; Eurostat, Comext.

[100] SOMO (2004), 8.

[101] EC European Business (2006), 33.

[102] Idem, 34.

In 2000 the EU-25 added 50,579 million euros, Japan 42,133 million and the USA 69,426 million. To give these figures a bit more perspective: the EU-25 employed 542,900 persons, Japan 94,681 and the USA 302,483. Which makes for very interesting statistics[103]. Especially when you consider that the cost of employees was much higher in the EU-25 than it was in the USA. Meanwhile the EU-25 has a higher investment rate than the USA and one twice as high as in Japan[104]. In absolute terms the number of jobs the pharmaceutical industry offers, the sector is not very important to the EU as a whole. However, the pharmaceutical industry relatively offers a lot of jobs to personnel in the research and development sector. This again shows clearly that research and development is extremely important to the pharmaceutical industry[105]. Even though in 2002 the number of people that worked in the pharmaceutical industry was more than half a million this represents only half a percent of the people employed in the non-financial business economy. The level of added value is at the same time quite high which makes this a very interesting sector[106].

This picture is in accordance with the before mentioned report of the 2005 committee of the House of Commons. The committee calls the British pharmaceutical industry "large, profitable and highly competitive" and "The industry has an outstanding record in developing new medicines, and is a major source of funding of medical research". They only see a problem in the fact that the industry has become more involved with making a profit. But that this is a global problem and the UK is no worse of than any other country[107]. They continue by claiming that the "industry's ability to compete internationally requires a legislative and organisational framework for research that protects the interests of all stakeholders – patients, researchers and pharmaceutical companies"[108].

Overall, a couple of developments stand out. These are the developments that have had the most influence on the pharmaceutical industry. And therefore give us the clearest picture towards answering the sub question this part of the thesis is build around. In the first place the growing power of the EU and the professionalisation of the lobby in Brussels that went along with that. This is of great importance to the pharmaceutical industry, because, as I showed, the EU is one of the most important markets for them. Issues such as parallel trade, generic medicines and patent protection are therefore high on the agenda for the industry. It is worth noticing that, at first sight, these issues are all moving in favour of the pharmaceutical companies. And they are

[103] Vekeman (2005), 2.

[104] Idem, 3.

[105] Wilén (2007), 5.

[106] Vekeman (2005), 1.

[107] House of Commons (2005), 97.

[108] Idem, 17.

moving slow. Outside of Europe this is not always the case. The recent events in India, concerning the revocation of a cancer drug patent held by Novartis[109], shows that the EU situation is not as apparent as it might seem. Closer to home was the failure of the Lisbon Strategy not a positive development for the pharmaceutical industry, but the fact that they were targeted as one of the main beneficiaries of this strategy was positive. The answer to the sub question that stands at the basis of this part of the thesis is therefore not a wholehearted 'yes'. But overall the claim can be made that events have moved in favour of the pharmaceutical industry.

With this in mind the mood is set for the case study. Getting to the core of the thesis.

[109] Reuters, 8 April 2013.

Part Three; The Case

At this point it comes down to the case itself. We can now look at animal testing. There are a few sub questions that need to be answered in this part. First of all, what are the interests that the pharmaceutical industry wants to protect? What are the positions of the other actors in this case? What is the role of ECHA in this case?

Historical background

Before going to the actual analysis of the case I will go into the history of animal testing. Animal testing in itself is very old. But only since the nineteenth century did people began to protest it. The first laws to protect animals stem from that time. In 1822 the British parliament passed the first law that was aimed specifically at protecting animals. The first anti animal testing law dates from 1876, again in the UK. It is also in the second half of this century that the first animal rights groups began to appear. Of course, the reason why the discussion around animal testing is so complicated and slow moving is because the advances in research that have been made thanks to animal testing. Especially in the medical field many useful discoveries can be accredited to animal testing. These advantages are the reason why, besides the before mentioned anti animal testing groups, there are groups that promote or at least actively defend animal testing. Mainly in countries where the discussion around the subject is very polarized, like in the UK.

Naturally laws in the beginning of the nineteenth century concerned with animal welfare were less strict than they are now. It is, however, not a straight line towards a more animal friendly environment. Were in the USA a drug could be taken off the market after it was proven to be dangerous in 1937 this changed. Drugs needed to be proven safe through animal testing before they could enter the market. A complete reverse in the approach towards drugs. Cause of this change was the mass poisoning and death of more than a hundred people after using the elixir sulfanilamide. In the fifties again things got catastrophic. From 1957 to 1961 a medicine against morning sickness and to aid sleep, thalidomide, was sold to pregnant women. More than 10,000 children whose mothers used the drug were born with deformities. Until that time it was unknown that medicines taken by the mother could affect their child. Very quickly laws were passed that obligated pharmaceutical companies to test their medicines on pregnant animals whenever pregnant women were to use their drug.

An important fact in the discussion around the development of legislation for animal testing is the introduction of the three Rs. Replacement, Reduction and Refinement. Rex Burch and William Russel published these principles in 1959 as a guide

on how to approach animal testing[110]. This became the golden formula for policy change and indirectly led to the first World Congress for Alternatives for Animal Testing in 1993. Those three Rs were already in 1986 known at the EC. While working on a guideline for animal testing the EC made use of these three Rs. Prove of that is the, in 2005 established, European Partnership to Alternative Approaches to Animal Testing (EPAA). A joint initiative of the EC, seven European trade associations and individual companies. Among them the EFPIA.

In an effort to phase out all animal testing the cosmetics sector is the first to be taken on. A ban on testing of finished cosmetics products is in place since 2004 and a ban on the testing of product ingredients applies since 2009. It is important to note that the first directive concerning the reduction of animal testing in cosmetic products dates from 24 July 1979. And in 2013 a full marketing ban will be effective on all cosmetics that have products in them that are tested on animals. This is a major step towards an EU wide ban on animal testing. The cut off date of 11 March 2013 was already proposed in a working paper in 2004 for the import of cosmetics containing ingredients that have been tested on animals. Even if this ban only affects one percent of all tests that are done on animals in the EU. So far Member States were regulating this on an individual basis. The EC is trying hard to establish a policy, but industry lobbying and Member State stubbornness have made progress slow. In 2007 REACH[111], the Registration, Evaluation, Authorisation, and Restriction of Chemicals, regulation and the European Chemicals Agency (ECHA) came into action. ECHA is the agency that is responsible for the execution of REACH. This agreement, which took seven years to pass, concerns the improvement of the protection of human health and the environment from the risks that can be posed by chemicals, wile enhancing the competitiveness of the EU chemicals industry. But more important for the subject of this thesis, it also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals. Meaning that the regulations in REACH directly affect anyone who is involved in animal testing. Future steps towards reduction of animal testing will probably be done through this agency. The EC faces a daunting task getting all stakeholders aboard regulations such as the cosmetics directive. An example of the challenges the EC faces is that in the US mice are not even regarded as test animals[112]. While eighty percent of test animals used are mice. And even though the US is outside of the EU it shows the kind of differences that apply to different countries. Within the EU Austria does not allow testing on monkeys and apes. Most other countries do allow testing on monkeys, but not on apes. What does not make the discussion much easier is that nobody seems to know how

[110] Russell and Burch (1959).

[111] EC Regulation No 1907/2006.

[112] www.informatiedierproeven.nl/dierproeven-in-het-buitenland.

many animals are actually tested each year. The numbers vary widely. The EC estimated in 2004 that in the next ten years about 2.6 million animals would be tested in the EU. In 2009 ECHA announced that the number of animals tested in this period would be more likely to be around 9 million. More than three times the original estimation.

The pharmaceutical industries interests

From the previous section the first sub question can be partially answered. Where does the pharmaceutical industry stand on animal testing? Considering the history of animal testing the industry seems to be scared of two things. Causing dangerous situations for the public health and high costs to prevent these situations. This might seem problematic, but it does show that the industry sometimes has to look for a balance between the two. A good way to find out how the stakeholders feel about a particular subject is to look at position papers. But first we have to establish who these stakeholders actually are. In this part of the thesis I would have liked to separate the stakeholders between the pharmaceutical industry and the others. Unfortunately, this division does not work for several reasons. Of the other stakeholders I will speak in a minute. First I have to bring into memory that the pharmaceutical industry is historically very close to the chemical industry. And because pharmaceutical companies work a lot with chemicals it is not uncommon for a chemical industry association to represent pharmaceutical companies. This is for example the case at the European Chemical Industry Council (CEFIC). Therefore it is possible to place the chemical industry and the pharmaceutical industry in the same corner in this case.

The main interests that the pharmaceutical industry need to protect concerning animal testing are very closely linked with what has been said above. The industry does not mind cutting back the number of animal tests. They seem very willing to do so. The only problem is that they cannot afford to bring a product on the market that has they are not sure about safety wise. Testing a product thoroughly will ensure that, but to do so they need animals. Directly testing on human test subjects is just too dangerous. Most organisations that defend animal rights will agree upon the principle of this argument. The debate then is not about whether or not there should be testing on animals. The debate is about how and how fast to minimize these tests. There are a number of sub issues involved here. The Good Laboratory Practices (GLP), International Council on Harmonization (ICH) guidelines et cetera.

The European Association for Chemical Distributors (FECC) is not a big fan of REACH or of its GLP, which concerns the use of animals in the testing of chemicals. There position is that GLP is to expensive, especially for small and medium enterprises, and

should only be applied to newly generated animal data[113]. However, FECC does not see this as a focus point for their efforts. Representing chemical distributors and not chemical producers they are hardly touched by legislation concerning animal testing. A passive stance and a conservative standpoint are therefore justifiable. Especially, if you take into account that many of their associate members are members of CEFIC. And CEFIC on the other hand is much more lenient towards banning animal testing. Executive Director for Research & Innovation Gernot Klotz formulates their position as follows: "The chemical industry has an obligation to foster a genuine open dialog on alternatives for animal testing,"[114] to which he adds: "The industry is well aware of the ethical challenge, but we are forced by stringent European legislation to do the testing."[115] As a result they are pushing for the use of realistic legislation that is based on the three Rs through EPAA. EFPIA, as a member, stands on the same principles as EPAA. With an EU lobbying budget of 570.000 euros not a financial giant, but certainly a stakeholder to take into account. And as one of the main representatives of the pharmaceutical industry it is legitimate to claim that the pharmaceutical industries position on animal testing coincides with EPAA. Meaning that the 3Rs should be the guiding principles in getting rid of animal experimentation over time.

Other stakeholders

Still, the position of the pharmaceutical industry can be described as ambiguous. They are willing to end animal testing, but they claim they are not able. Their opponents are much clearer about their aims. This helps a lot in answering the second sub question; What are the positions of the other actors in this case?

A very specific group in the list of other stakeholders that concern themselves with animal testing are the NGOs that aim to abolish the practice. On the ECHA stakeholder list there are three that take it a bit farther than the rest. ECEAE, Eurogroup for Animals, and HSI.

The European Coalition to End Animal Experiments (ECEAE) represents national animal welfare organisations and its sole existence is the ending of animal experimentation. It is the principle on which they are founded. One of the founding members, Geoffrey Deckers, has been jailed for very questionable actions involving threats to employees of the Biomedical Primate Research Centre in Rijswijk and the kidnapping of an administrator of an auction house for fur producers in Nederasselt[116]. They are not very well funded if you look at their budget for European lobby activities.

[113] FECC (2006) 2.

[114] CEFIC (2010).

[115] Ibid.

[116] Meeus (2003).

Which is under 50.000 euros. As a member of the International Council on Animal Protection in Pharmaceutical Programmes (ICAPP), and of the International Council on Animal Protection (ICAPO), which has expert observer status at the Organisation for Economic Co-operation and Development (OECD), and accredited at ECHA and the European Medicines Agency (EMA), they have access to the right people. Perhaps in order to keep being salonfähig they utter their opinions in a mild mannered way and promote, through ICAPP, the ICH, (ICH was established in 1990 to get the EU, Japan, and the USA on the same regulations; which lead to ICAPP) and VICH (the V stands for veterinary) guidelines through their Human Cosmetics Standard Leaping Bunny. Another sign that ECEAE is taken seriously is the meeting[117] they had with CEFIC on 7 September 2010 to discuss their positions on REACH. But to answer the question on what they actually want more is needed. ECEAE states that they are "opposed to all experiments on live animals as a matter of principle, and campaigns for an end to their use for this purpose"[118]. A little further in the same document they show what I consider to be their policy core beliefs when they say: "While animal experiments continue, the ECEAE campaigns for the maximum protection of animals in laboratories, to ensure that these animals receive the legal protection they are supposed to under EU and Member State legislation and supports initiatives to develop new methods to reduce their suffering, reduce their numbers and ultimately replace their use"[119]. Here an acceptance of the reality forces them to compromise.

The Eurogroup for Animals is a federation of NGOs and has a lot more manoeuvrability in its budget of 1.4 million euros. The main focus of their effort lies in promoting animal welfare. Not banning animal experimentation specifically, or even at all. Experimentation is detrimental to animal welfare and should therefore be banned, but is recognized as a necessary evil. In 2010 they pushed in a policy paper[120] for faster approval of alternative methods and a more consolidated approach. They state this in their mission statement as well. The Eurogroup for Animals strives for an Europe "that cares for animals"[121] and where cruelty to animals is not tolerated, animal welfare is protected by legislation and every animal can live in an environment where they can perform their natural behaviour. This gives us the same position as ECEAE in that their position comes down to no more testing on animals, but to accept a certain level of testing as long as alternatives are preferred and move towards overtaking all forms of animal testing.

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[117] CEFIC (2010).

[118] Transparency Register ECEAE entry.

[119] Ibid.

[120] Eurogroup for Animals (2010).

[121] http://eurogroupforanimals.org/about-us/our-mission.

The Humane Society International (HSI) has the same priority as the previous two organisations. Promoting alternatives for animal experimentation. Backed by an EU lobbying budget of one million euros and 11 million supporters worldwide they are not easy to ignore. HSI believes the same as the two before mentioned organisations. "Working to save more than 12 million animals from suffering and death in laboratories across the EU"[122]. Predictably they focus on reducing and replacing animal testing.

A bit more to the middle of the spectrum there are a lot of NGOs that are against animal testing in principle, but who do not seek it with the same fervour as the above mentioned organisations. In this category you will find organisations like ClientEarth, Greenpeace, WWF, Friends of the Earth, EEB, et cetera. One thing these organisations share is their focus on the environment. A much broader subject than animal welfare alone. Usually, these organisations also have a much larger budget (the four mentioned all have budgets that exceed two million euros) and a much larger range of topics they concern themselves with.

In March 2005 the EEB, EPHA, Friends of the Earth, Greenpeace, WWF and WECF published a paper[123] with five points to improve the REACH agreement on. One of the points includes the reinstatement of three non-animal tests. Showing their collective commitment towards these kinds of tests. In April 2011 a proposition paper[124] by CHEM Trust states there should be a pragmatic approach towards minimizing the amount of animal testing and that there is an urgent need to find robust non-animal methods. Among the supporters of ChemTrust are the EEB, Friends of the Earth and WECF. Apparently still working together on this subject. And neither in this paper does it say that animal testing should stop all together. Making their effort much less urgent and more flexible than that of the ECEAE, HSI and Eurogroup for Animals. A reason for this is that the mission statements of BEUC, ChemSec, ClientEarth, EEB, Friends of the Earth, Greenpeace, HEAL, WECF and WWF do mention the environment, but not animals in particular. Like I just claimed; Their focus lies in caring for the environment as a whole.

Even though, each stakeholder has their own specific issues and priorities sometimes patterns emerge. EEB, HEAL, Friends of the Earth, Greenpeace, WECF, WWF, Client Earth, BEUC, ChemSec and others have, as I have shown, published position papers concerning, among other things, animal testing. Not all of them have endorsed the same position papers, but combining the different papers and gives us this group of like-minded stakeholders. Their positions tell us they would like to see animal testing disappear, but understand that they might be necessary for the good of mankind.

[122] http://www.hsi.org/world/europe/endanimaltesting.

[123] EEB ea. (2005).

[124] CHEM Trust (2011).

However, alternatives should be promoted and researched. Reduction is the key. For example through sharing of test results. The difference between this group and the first three NGOs I introduced can probably best be described with the words 'urgency and focus'. What these organisations have in common, and what separates them from the other NGOs, is that they represent the interests of animals and not the environment. And where the first group uses well balanced sentences like: "Given significant recent strides in biomedical science, there is enormous potential for developing alternative non-animal test methods. Examples of WWF's commitment to promoting alternatives to animal testing and to reducing the use of test animals include ..."[125], they are more likely to use statements like: "Imagine a syringe being forced down your throat and a massive chemical dose pumped into your stomach, or being squeezed into restraints and forced to breathe toxic vapours for hours. From drugs to pesticides and household cleaners, chemicals and products of all descriptions are still being tested in massive doses on dogs, mice, rabbits and other animals"[126].

Then there is the International Federation for Animal Health (IFAH). Representing the European animal health industry. Their position is a bit two sided. On the one hand they would like to be able to produce products that are safe and cheap, but on the other hand their core business is animal health. Experimenting on animals is therefore a bit counterintuitive. As a solution they came up with the 1-1-1 concept. All products should have one dossier, with one scientific assessment, and one European marketing authorisation valid in all member states. This sounds similar to what FECC supported in march 2006[127]. One Substance One Registration (OSOR), is based on the same principle that tries to get the bureaucracy to a minimum, reduce costs, and centralise the exchange of information. Reserving a large role for ECHA. FECC also wishes to protect small and medium-sized enterprises (SMEs). As they see it, the GLP is a good idea for new data, but is far too expensive for implementation by SMEs. For the same reason should SMEs be free from scrutiny concerning CSR if they are younger than ten years of age.

With that in mind it is no wonder that both organisations are members of EPAA. EPAA is a joint initiative of the EC and private parties with the goal of pursuing the 3Rs in regulatory testing. Started in November 2005 they can be considered a powerful group. The members of EPAA can be divided into three categories; the EC (through the DGs Enterprise and Industry, Research and Innovation, Health and Consumer Protection, Environment, and Joint Research Centre), European trade associations from seven

[125] WWF (2003).

[126] http://www.hsi.org/issues/chemical_product_testing/.

[127] FECC (2006).

industry sectors (IFAH-Europe on animal health, CEFIC on chemicals, Cosmetics Europe on cosmetics, ECPA on crop protection, IFRA on fragrances and flavours, AISE on soaps and detergents, and EFPIA on pharmaceuticals), and 35 individual companies. This collaboration tries to accelerate the implementation of their policy views and create a broad support at the same time. By pulling together their knowledge and produce common standpoints they aim to take the momentum into their direction.

In 2006 EPAA published their first progress report, describing among other things their goals. It claims EPAAs "objective is to accelerate the development, validation and acceptance of alternative approaches for the purpose of regulatory safety assessment."[128] Interestingly the ending of animal testing is not mentioned. Even though, replacement, refinement and reduction will benefit animal welfare it does specifically not mean that testing on animals will be abandoned altogether.

On another level EPAA is important as it deals with a perhaps illogical problem. By including all DGs that are involved in the policy making that surrounds animal testing the communication between them runs more smoothly. Therefore making it harder to play these DGs against each other. Situations like what happened around the Pharma Package can be avoided this way.

ECHA

So far there is one actor that deserves more attention than it has gotten. The European Chemicals Agency has a key position in this case. ECHA was established to manage and carry out the technical, scientific, and administrative aspects of REACH. But more importantly, they make sure there is a sound coherence within the legislation of the EU. These tasks are delegated to ECHA by the EC. Both REACH and ECHA came into action on 1 June 2007. They concern the treatment of chemicals. Animal testing therefore falls within the reach of this agreement. Reducing the number of tests on animals is one of its pillars. One of its goals is to avoid the use of animals as much as possible and where it cannot be avoid should the animals be treated as humanly as possible. REACH is promoting GLP. All in close cooperation with OECD. In-vitro tests that might replace an in-vivo tests will be judged by the European Centre for Validation of Alternative Methods (ECVAM). The 3Rs are central to what REACH, and therefore ECHA, is trying to do with animal testing.

Since its creation ECHA functions as the central institution around which this discussion presents itself. Recognising this themselves they have drawn up a list of their stakeholders[129]. More than sixty in total. The list, however, does not contain all the

[128] EPAA (2006).

[129] This list can be found on their website: http://echa.europa.eu/web/guest/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations.

stakeholders involved in what ECHA does. This has to do with the way the list has been put together. Organisations could apply to be recognized as stakeholder by ECHA. If they met with the criteria ECHA has set[130] the organisation would be recognized as such. Institutions and Member States that are a part of the institutional framework that are part of the policy process around this subject are not all included. ECHA is an agency of the EU and independent from the EC. But there is a heavy influence of the EC imbedded into ECHA. The EC is responsible for the implementation of REACH and Member States can hold the EC accountable. However, the EC has delegated this responsibility to ECHA. Stakeholdership of the EC and Member States is thereby guaranteed. This is why they do not appear on the list. Simply because they are already involved in the decision making process where they need to be.

In fact, one of the reasons why ECHA wants to get her stakeholders involved, apart from channelling information into the concerned fields, is to get input from different parties and make her policy acceptable to all who are touched by it. The reason why lobbying efforts focus on ECHA and not on the EC is because of the before mentioned delegated powers that ECHA holds. Which means ECHA decides whether a testing method is allowed or not. They even contribute to the development of alternative methods to animal testing and the promotion of these methods.

What it all comes down to is the REACH agreement. This is the piece of legislation that it is all about. I have been mentioning it on several occasions. All chemical substances are subject to this agreement. It focuses on the production and use of the chemicals and their possible impact on the environment and human health. Animal testing is therefore a part of REACH. Within REACH the aim is to avoid animal testing, but understand that they are necessary to understand the hazards of chemicals better. One of the measures it contains is that new tests are allowed to be carried out only once. After that companies that would like to use the results are able to buy these at the organisation that carried out the test. This organisation is obligated to sell to everyone who wants to buy and at a 'reasonable' price. Another regulation is that the lowest class of animals should be used in testing. Vertebrates are a last resort.

Two things are central to the entire discussion; public health and safety, and animal welfare. Since the sulfanilamide and thalidomide disasters in the previous century the value of animal testing has been irrevocably established. What is also clear is that everyone agrees that looking for alternatives to animal tests is the way forward. The 3Rs are irrefutable. Both the pharmaceutical and chemical industries and the animal welfare organisations are in agreement on this. The difference is in the urgency. Where the

[130] ECHA (2006).

industrial stakeholders are very hesitant in replacing animal tests for non-animal tests and sharing their results, the animal welfare organisations are much more progressive. ECHA as central organ has to find a route with which all parties can live. Their delegated powers allow them to operate quite independently within their mandate. In the next part I will go into the different resources that the stakeholders have at their disposal.

Part Four; A Different Approach

This last part of the thesis can be seen as an extra analysis of the previous part. Though, this time the analysis is themed. The Advocacy Coalition Framework, which I will explain in a little bit, defines coalitions and looks at the resources these coalitions have at their disposal. These resources will act as the themes here. The sub question is therefore constructed around these resources (financial resources, access to decision makers, public opinion, information, mobilizing troops, and skilful leadership). How can you describe the position of the pharmaceutical industry when you look at the resources used in the ACF?

The Advocacy Coalition Framework

The ACF was developed by Paul Sabatier[131]. Designed to show how the development of policy is shaped. Nadia Carboni uses it in 2009 to solve a number of research questions; "how does decision and policy making on health issue take place? Who are the key actors in the process? What is the role of interest groups in health care-related policies? How do national governments and EU institutions interact in the health policy making process and governance?"[132]. And just as this thesis does, she uses case studies. Her main assumption is that the balance between public health and health care on the one hand and industry policy on the other is one of the crucial elements in health policy making in the EU. If what she says about the two cases that she has chosen is right, it might be right for the entire subject.

Carboni uses the ACF because it enables her to take a look into how the policy process works, without being distracted by the detailed handlings of the different actor. Describing how different stakeholders behave in order to influence this process and explain the policy outcomes in conflicting political contexts. "The ACF views the policy process as a competition between coalitions of actors who advocate beliefs about policy problems and solutions. This competition takes place in the policy sub systems, defined as the set of actors who are actively concerned with an issue and regularly seek to influence public policy related to it"[133]. In other words, the ACF is based upon the theory that stakeholders can be categorised into coalitions and that these are held together by a certain set of beliefs. Actors might change coalitions whenever this suits them and it is possible that coalitions can disappear or new ones are formed.

The first step in building up this theory is to collect stakeholders. One of the ways to do that is to use a snowballing-sampling technique. Get a couple of stakeholders and

[131] Sabatier (1988).

[132] Carboni (2009), 3.

[133] Idem, 5.

see who they deal with on the subject. Then look to those actors and see if they are stakeholders. If they are see who they deal with and so on. After a while a network will be visible with all major stakeholders. Smaller or less important stakeholders might be missing from a list that has been created in this way, but these stakeholders can be defined as unimportant for the decision making process.

After having collected all stakeholders it is possible to categorise them into coalitions and define the different beliefs that hold those coalitions together. All coalitions have three kinds of beliefs. Deep core, policy core, and secondary aspects. Deep core beliefs are the most fundamental and will not change. Under no circumstances. They define how the members of a coalition will interpret the world. Policy core beliefs are a little less stringent. In broad lines these set out perceptions and policy positions which are necessary to achieve their deep core beliefs in the long run. Changing these is not an easy task, but it is not impossible. The ACF argues that coalitions form around policy core beliefs. That doesn't necessarily mean that their deep core beliefs are the same. Actors with similar policy core beliefs are inclined to cooperate with each other to influence the policy making process in their favour. Sometimes that means changing the policy core beliefs of another coalition. Two ways, described in the ACF, to do so are policy change and policy learning. Policy change is a transformation of the belief system in the policy subsystem. In other words; the world (in which the coalition operates) has changed significantly and has shocked the beliefs system. Policy learning is a much less intrusive means of change. Over time coalitions will adept to changing circumstances and will learn form past experiences. Usually this leaves the policy core in tact and only changes the secondary aspects. The secondary aspects can be described as the empirical beliefs on how to implement the policy core beliefs. Which means that the secondary aspects are the easiest to translate into actual legislation and compromise on.

No matter how deep beliefs run, achieving policy learning, influencing stakeholders, and pursuing policy objectives can only be done effectively if coalitions have enough resources at their disposal. The amount of resources different coalitions have at their disposal is very unequal. Industrial coalitions used to be much better financed and staffed than NGOs. Who, in turn, often can count on more public support.

The ACF divides the resources a coalition has at its disposal into six categories. Financial resources, access to decision makers, public opinion, information, mobilizing troops, and skilful leadership. Each of these resources can tilt the balance in favour of one coalition. The more of these resources a coalition can use, the better its chances of success. A properly balanced combination makes them even stronger.

Public opinion

In this thesis public opinion takes in a special place. It is therefore only logical to start with this resource. In the first part of this thesis I have already spoken about several aspects of this resource. What I will focus on here is where this resource has otherwise been used.

A case were public opinion has been quite influential in setting change in motion is CSR. Until thirty years ago only a select few people new what CSR was. Before then the general public was not involved in the discussions around the subject. Even though influential people like Andrew Carnegie and W.K. Kellogg were already engaged in formulating and spreading the ideas that make up CSR[134]. That, however, has changed dramatically since the 90s. And though CSR is not the bottom line for many organisations, it has moved up the priority list. Cases such as animal testing make clear that the pharmaceutical industry is very conscious about its CSR. What started as a marketing strategy (a secondary aspect known as 'green washing'[135]) to counter bad press has in some ways become a method of operating that businesses and institutions would want to follow if possible. Not withstanding the progress that has been made in this field, there are many examples were companies present themselves as compliant with CSR, but have in fact changed very little. Because of that some sceptics say that CSR has failed. Jill Murray[136] and James K. Rowe[137] claim that the debate has become stylized and that the main reason for corporations to engage in CSR is to keep governments from regulating certain subjects and to give them an opportunity to show off their CSR initiatives. It seems then that the public opinion can be countered as an instrument for lobby purposes.

One of the fiercest battles for the favour of the public has been fought in the UK. Opponents of animal testing were influencing the public opinion to a point where the proponents found it necessary to get involved too. Leading to the creation of an organisation called Pro-Test, which had as its main goal to campaign in favour of continued animal testing. After being active for five years the organisation was shut down in February 2011, because it had met its goals.

As an example of how public opinion has been used to influence the policy making process around animal testing the cosmetics directive[138] is a good example. Under pressure of the animal rights groups, who had been campaigning throughout the eighties and nineties, the EC first adopted the Cosmetics directive in 1993. Aiming to ban the

[134] Asongh (2007), 10–12.

[135] Karliner (2001).

[136] Murray (2004).

[137] Rowe (2005).

[138] EC (1976).

testing of finished cosmetic products and its ingredients on animals and the marketing and sales of such products in the EU on 1 January 1998. The entering into force of this directive has consequently been delayed several times (1998, 2000 and 2002), but has finally been completed on 11 March 2013. Every time a key date in this process approaches the media exposure on this subject peaks. As a result the policy makers feel pressured not to abolish the plan, even though the cosmetics industry would like to see this. Trying to convince people that safety is more important than animal welfare. A point which is much harder to explain to the public. Especially for cosmetics. This leaves them with delay as a best scenario.

A Good example of a case where publicity did not change the outcome is direct-to-consumer-communication. The Pharma Package, which involved legislation on direct-to-consumer-communication, was developed by the DG Enterprise. For its opponents this meant a disadvantage. They were embedded into the DG Sanco, whereas the proponents were embedded in the DG Enterprise. The call for moving the Package to the DG Sanco, in the letter to Barosso[139], was motivated from this background. It fuelled the debate about comitology again. AIM and ESIP complained about the lack of transparency during the process. If this criticism would just have come from BEUC and HAI, who were openly sympathetic to AIM and ESIP, it would not have had the same impact. These two organisations were no members of the Pharma Forum, but AIM and ESIP were. As insiders they should not have had any trouble with transparency. Or were these the crocodile tears of stakeholders who did not get their way?

Whatever the case, the public opinion did not change much. Newspapers, for example, did not change their tone about the subject. In 1999 Suzanne Baart[140] is basically reporting the same news, with the same urgency, as her college Joop Bouma in 2010[141]. We have to be aware that the rules are changing and that the industry tries to advertise prescription drugs. But they make no reference to any form of public outcry one way or the other.

Financial resources

Probably the most well known resource is finances. Partly, because it is by far the easiest to measure. It is not only the most familiar, but also the most overestimated. Money is necessary up to some point, but ever since bribery has become unattractive as a way of influencing policy makers other resources have gained importance. It still costs money and there is a minimum you need to be effective, but money is no longer a key factor. Many firms that conduct lobby on behalf of their clients are very small and therefore not

[139] AGE et al. (2008)

[140] Baart (1999).

[141] Bouma (2010).

very money consuming. Although there are companies that throw fists full on it. These small firms usually consist of no more than twelve persons and have an annual budget of less than a quarter of a million euros. Numbers such as these are no representation of the importance of an organisation. They do tell something about the priorities of an organisation. Microsoft, with a turnover of more than sixty billion dollars in 2010, spends more than four and a half million euros on lobbying in Brussels. In comparison, Philip Morris had a comparable turnover, but spend only one and a quarter million euros on lobbying in Brussels. The difference between the two budgets can partially be explained by Microsofts recent conflicts with the EC[142].

If you look at animal testing the financial resource paints an interesting picture. The amounts that will be mentioned here are the budgets the stakeholders have to spend on their EU affairs[143]. That of course means that not all that money will go to the cause of animal testing. Unless that is your raison d'etre, as it is for the ECEAE. It also means that the money can be shifted around if necessary. If need be the allocation can be changed without increasing the budget. More money therefore does make a difference even if it has to be spread over multiple issues. Unfortunately for the ECEAE, they and their ideological allies have the least of all stakeholders to spend. Together just under 2.5 million euros. To which the ECEAE contributes no more than 50.000. Compared to other stakeholders the gap is quite considerable. Take for example a group of much more moderate stakeholders that work together a lot on these issues; WWF, Greenpeace, ClientEarth and Friends of the Earth. Each of these organisations has an allocated budget between 2 and 4.7 million euros. Another group of stakeholders that is worth mentioning are the members of EPAA. CEFIC alone has 6 million available. Forty-three companies are a member of EPAA on their own account. These are companies the size of Bayer, Johnson & Johnson, Pfizer and Unilever. No small fish. Together, these four companies have four million euros to their name. Besides, there are five DGs[144] of the EC member, but they of course have no budget to lobby themselves or their colleagues.

Taking into account that the radical views have the least to spend it is a safe bet that they have to rely on other methods than financial means. But I must repeat that the millions the WWF spends on lobby will not all go towards animal testing related issues. The same goes for most other stakeholders. This picture is therefore very incomplete and cannot solely be relied upon.

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[142] An article relating to the arduous relationship Microsoft and the EC have. http://www.reuters.com/article/2012/10/24/eu-microsoft-idUSL5E8LO5LN20121024.

[143] All stakeholders registered in the Transparency Register have entered their budgets into the register. The mentioned financial resources are based on these figures.

[144] These are the DG Enterprise & Industry, DG Research & Innovation, Health & Consumer Protection, DG Environment and DG Joint Research Centre.

Access to decision makers

Far more important is access to decision makers. Without it you will have a hard time getting your beliefs turned into policy. Informal relationships are still a very important way of establishing and maintaining access. Even though the EC tries to include a large part of the stakeholders in the decision making process. According to Guéguen[145] NGOs get a preferential treatment where it concerns access to the EC. Grown over the years this is much less evident in their dealings with the EP or the Council. Although Carboni found two policy officers who certainly do not support what Guéguen claims. A policy officer from DG Enterprise says: "I think that NGOs are not able to make compromises, they are used to shout and make noise, that's it. I strongly believe that radical positions cannot change policy. We do not take into account aggressive attitudes"[146]. Her other policy officer, this time from DG Sanco, is less negative. He or she just says: "we are not interested in those groups who behave as 'ayatollah'. We need scientific arguments, not dogmatic ones... NGOs sometimes do 'religious battles'. They do not want to talk to industries as principle"[147]. Remarkable quotes, since these were expected in the late eighties and nineties, but not in 2009. NGOs are supposed to be more professional in their approach nowadays.

Perhaps unexpectedly, the EC has issues with access as well. The EC is not one coherent institution. Not even if you look at specific policy areas. Mainly, because a lot of policy subjects concern multiple DGs. This has resulted in an atmosphere of unavoidable, mostly friendly, rivalry among them and causes friction from time to time. Not least because each DG has its own domain and methods. As I mentioned before, communication between them turns out to be in practice not as logical as it seems on paper[148].

Because access is extremely hard to measure it is typically one of those resources that is impossible to contain in numbers. For animal testing the group of stakeholders that is recognized by ECHA as such all have at least a certain level of access to the policy makers and a certain level of involvement in the policy making process. A way to try and quantify access is to see how many people a stakeholder has working for them. FECC, for example, has 0,1 people working for them. It is easy to imagine that a person who spends ten percent of his or her time on a subject will not be able to utilize their resources to its fullest in relation to access. Even if you take in account that an interest representative with multiple dossiers clearly has advantages over one with just one. On the other end of the scale are organisations with many interest representatives working

[145] Guéguen (2007), 53.

[146] Carboni (2009), 14.

[147] Ibid.

[148] Idem, 27.

for them. CEFIC has 72. Among the ECHA accredited stakeholders they are by far the largest. Followed by ClientEarth with 48. With an average of just under nine interest representatives per ECHA stakeholder.

Again EPAA has an exceptional position. Within this group ties with policy makers are formalized. Not only are members of EPAA accredited stakeholders of ECHA, but the before mentioned DGs are incorporated. The lines of communication between stakeholders and policy makers are very short and secure for some through this arrangement. Giving them a definite competitive edge.

Information

Information, as said before, is becoming more and more important. Since the late 80s interest representatives need to be better informed and able to give the policy makers arguments that can be checked. The stronger the argument and the information behind the argument, the bigger the chance that policy will change in your favour. However, more is needed. The problem is that coalitions are never ironclad. Which can lead to half hearted attempts instead of a successful campaign. Having the previous resources in order is not a guarantee. Giving a member of parliament the research outcomes that will back up his or her arguments in favour of your suggestions can be very helpful in steering the policy process. Having better and more information makes convincing policy makers much easier. Pressure groups have some trouble with this. Their information is expected to be coloured. Having their own research institutions is therefore not always the best way to go. These institutions are very expensive as well and a solution has been found in sponsoring research of independent institutions, like universities. Some industries have a long history in this field and spend a lot of money on this. Governments themselves do a lot of research too and they have the tools to stimulate research in certain areas (for example by subsidisation).

In the whole discussion about whether or not animal testing is necessary scientific research plays a very important part. Where the radical NGOs call upon the emotional reaction of the public, the industry makes more use of research institutions to put more weight behind their arguments. CONCAWE and ECETOC are research institutions that can be considered on the side of the oil, chemical and cosmetic industry. Do not bite the hand that feeds you applies to all levels of society. The same could be said about ESTIV and EUROTOX. The main difference is that they have as their goals the spread of information on toxicology and alternatives to animal testing. This might be considered pro industry, but they actually promote research into alternatives to animal testing. EuCheMS is already more neutral in their judgement, because they use scientists from academies and governments together with scientists from the industry. EAERE on the

other hand is more prone to the NGOs as can be seen by their members. None of those represents the industry.

Besides these research institutions other stakeholders will do their own research or sponsor universities to do certain research for them. In the pharmaceutical industry the sponsoring of scientific research to manipulate the result is not unheard of. Stories of researchers that get paid to publish an article under their name while it was ghost written by a pharmaceutical company[149] or other questionable practices of that magnitude still find their way into the newspapers. Meaning that neutral research on pharmaceutical subjects should always be read with some form of reserve.

In an attempt to deal with this ECHA tries to get as much information from different parties as it can and aims to spread that information back into the field. This is one of the aims behind the list of stakeholders. To say that one of the coalitions has their research on a higher level than the others is too much.

Mobilizing the troops

A very important resource is the ability to mobilize the troops. Having the support of your followers. These can complement the coalitions efforts with the resources from their own channels. Large firms, for example, are usually not only a member of their branch interest representational organisation, but have their own organisation on the side. Combining the efforts of both can be very successful, but the danger is that the efforts of all these different organisations are hard to coordinate. At times they are willingly interfering with their own coalition[150]. Debilitating the capability of their branch organisations to mobilize its troops. Having loads of members does not have to mean anything. In the end a lot comes down to how capable a coalition is in mobilizing its troops. Can a coalition that wants to act get its members behind it. Members that have only subscribed to your newsletter are nice, but members that will use their resources to complement yours in the reaching of a common goal are better. This used to be less of a problem. Coalitions were quite small and able to efficiently come to a common position. Due to a growing number of members these coalitions clogged up. In a reaction today coalitions are much more fluid and based on ad-hoc agreements. NGOs have much less problems in this field. Being opportunistic and pro-active by nature helps them here to. As does their relation with the general public. Forming their opinions on a certain topic and getting them to be involved are not that different in approach. An approach that NGOs possess.

Other rules apply to the EC. For the most part it is organised very hierarchical. However, at the top of the hierarchical pyramid it has to deal with the Member States of

[149] Ross (2011).

[150] Guéguen (2007), 16.

the EU. Getting those behind a certain topic can be influenced a lot by current, national political affairs. Most of which the EC has little grasp upon. Being able to deal with this is the responsibility of the president of the EC. His leadership can make a big difference. As did the leadership of Delors when the SEA was introduced. On leadership I will speak in a minute.

NGOs, especially the more fanatical ones, have a history of being able to get their followers to take to the streets. This has to do with the way they are organised. Most funding comes from private sources and organisations that are visible are more likely to get funding than those that fly under the radar. Often, the more moderate and larger an NGO has become the further it is institutionalised. This is a good way, together with formalizing relationships, to secure collaboration. Committing to a common goal through initiatives like EPAA can therefore be seen as a powerful resource. Benefiting their capacity to mobilize their troops. Under the condition that they have their leadership in order.

Skilful leadership

Skilful leadership helps a lot in this type of situation. Having someone who is able to focus the organisations efforts, is creative enough to bypass pitfalls that his predecessors could not and convince others to join your cause often proves to be invaluable. Of course, having all these resources is ideal, but no one does. There is always someone better equipped with something. In an ideal situation the playing field in which the interest representatives operate is transparent, accessible to all actors, has a multitude of actors and offers equal opportunities to all actors.

The President of the EC has gotten a longer term to accomplish his goals with the Maastricht Treaty. Still, five years is not that long. Re-election is possible, but the Member States decide who gets the position. The leaders of industrial organisations, for example, stay much longer. NGOs do not elect their leaders and they have the advantage that those leaders can direct all their time towards interest representation. Plus, these leaders can boost their efforts with their powers as a manager. Industrial organisations will usually appoint a secretary-general to lead the interest representation. This secretary-general will have to keep all actors he represents happy and has limited powers[151]. On important issues the boards of directors of the different companies can get involved on their own accounts. The industry is therefore not as powerless as the position of the secretary-general might seem. Guéguen discovered another problem; the "Secretary General Syndrome"[152]. Organisations usually start off with a enigmatic and pro-active secretary-general. Over the years this will create tensions within the

[151] Idem, 56.

[152] Idem, 43.

organisation. When it is time to replace the first secretary-general, chances are that most members will opt for a less demanding or weaker secretary-general. After which the need for a stronger figure arises. And so on.

If this "Secretary General Syndrome" would be applied to the EC it paints an interesting picture. Jacques Delors was no doubt a pro-active President. Accomplishing the SEA and Maastricht Treaty and laying the foundations for the introduction of the euro his achievements are many. Jacques Santer did get to oversee the preparations towards the introduction of the euro, but is mostly known for the fraud scandal that forced him and his Commission to resign. Skipping Manuel Marin, who was interim-President for less than a year, Romano Prodi is next on the list. He was able to get more power with the Treaty of Nice to reign over his Commission. Powers which had already increased with the Treaty of Amsterdam. After him came José Manuel Barroso. Until now his Commission is the first to shrink in size, he had to deal with a lot of euroscepticism and in the Lisbon Treaty the controlling powers of the EP over the EC have increased. Making him the weaker President after the strong Prodi. Looking at the EC Presidency Guéguens theory seems to hold.

A collaboration such as EPAA is a very indirect way to lead efforts. The steering committee of EPAA has to listen to the feedback they get from their different organisations, who in the case of the industry branch representatives among them have to listen to the feedback they get from their members. NGOs like WWF, Greenpeace, Friends of the Earth and others have tackled this problem by operating in ad hoc coalitions. Publishing proposition papers together with other likeminded organisations. Which means that these coalitions have some usual suspects, but if one does not agree with the position they just do not sign.

A case were leadership proved a key resource was the Pharma Review and the following Pharma Package. The one constant in this case is that the initiative lies with the DG Enterprise for most of the time. The Pharma Review and the Pharma Package were both of their hand, the Pharma Forum and G10 Medicines Group were their initiative, and so were the Bangemann Rounds. Protesting parties such as BEUC, HAI, EPHA, AIM, and ESIP were effectively sidelined. It seems that this leadership, backed by industrial approval, proved decisive.

So what does that all mean for the position of the pharmaceutical industry? Most certainly the picture is a bit different from the one that was presented in the previous part. The public opinion has been used on multiple occasions. Examples like Pro-Test show that where opponents of animal testing get the public opinion too much on their side the pharmaceutical industry is capable of neutralising this resource. Financially there are definitely big differences. From half a grant up to six million. Unfortunately, these

figures are very inconclusive. The figures have all been entered by the organisations themselves into the Transparency Register voluntarily and unchecked. And they represent the budget that an organisation has for EU lobbying. Nowhere is specified how much of that budget is allocated towards animal testing. The financial resource therefore needs more investigating before it can be of any real use. Access gives us a clearer story. The members of EPAA are nearest to the DGs and share the 3Rs principle. Even though NGOs sometimes have preferential treatment, its seems that they would have to exploit this in order to compensate for the advantage EPAA members have. Information is an important resource in this case. Alternative methods to animal tests have to be invented, improved and assessed. This is one of the pillars of the 3Rs principle. Getting these alternatives. It is no surprise that quite a few organisations are involved into research and the spread of information on the subject. As a matter of fact, it is part of the core business of ECHA. The one place where the NGOs have an easier job is in mobilizing their troops. Being smaller and committed to a narrower field of interest does have its advantages. On leadership they have an advantage as well. For the same reasons. This means that glancing at the resources of the ACF gives no one side the absolute advantage. Although the combination of more money, the formalised access through EPAA and the spread of information give the impression that the pharmaceutical industry has a slightly better position.

Conclusion

Within the parameters, that have been set at the start of this thesis, the sub questions have provided a good picture of the case. Given that animal testing is a controversial topic and one in which certain stakeholders actively try to involve the public. I have ventured outside of the case. As I announced. The case study on animal testing is the primary focus of this thesis, but on several occasions I took a glimpse at other cases. Mainly to keep the thesis from becoming too narrow in its focus.

The first part of this thesis was committed to deepen these boundaries and had three sub questions at the heart of it. Each of these questions was derived from the parameters that had been set in the introduction. The first and second sub question; who are involved in the protection of the pharmaceutical industries interests at the EC? and; how does the EU policy making process work and what is the role of the EC in it?, address the stakeholders. Who are involved.

On the side of the pharmaceutical companies, and representatives thereof, we find the chemical industry. Both industries are closely linked since their creation. At the side of the EC there are numerous institutions and Member States involved. Though most are not very active. What is noteworthy, is that the policy making process of the EU is aimed at gathering information from stakeholders. Giving them an opportunity to defend their interests and contribute to new legislation. Not just the industry stakeholders, but NGO stakeholders as well. And by promoting and facilitating transparency the EU facilitates access to information for all stakeholders.

In the second part of the thesis formed a purely historical narrative of the European Union and the pharmaceutical industry in Europe. With at the root the question whether or not events have moved in favour of the pharmaceutical industry. Since its creation the EU has moved constantly towards more responsibilities and the consolidation of powers. While the EU was on the road from evolving from the ECSC towards its current form, the pharmaceutical industry's interests grew closer. At first through informal relations, like the ERT. Policy makers and politicians could, and did, use these contacts to determine the course the European integration would take. As this development took shape and became more powerful the pharmaceutical industry began to formalize and professionalize its relationship with the policy makers.

The twentieth century marks a period of consolidation and growth in Europe for the pharmaceutical industry. The number of companies diminished, but the remaining companies grew in size. Changing patent regulations were one condition that made this possible. A harmonization in which the EU became more and more active.

That the relationship between the EU and the pharmaceutical industry is a good one can be derived from many examples, but a very significant one was the Lisbon Strategy. Although not targeted specifically at the pharmaceutical industry, the agreement did secure a place on the priority list of the EU policy makers. Competitive, durable, and knowledge based, the pharmaceutical industry met all criteria. And in being the second largest pharmaceutical market, the EU is of major importance to the pharmaceutical industry.

But have events moved in favour of the pharmaceutical industry? With such a good relationship with the EU policy makers in such an important market I would think they did.

With the third part of the thesis the case study became the focus once again. The differences between the Member States on animal testing legislation are slowly decreasing, but still apparent. The way to work towards more harmonization for the EU was to establish ECHA and give them the necessary tools and powers. This institution, however, would be nowhere without REACH. The agreement in which Member States have determined the way they want to regulate chemical substances. Animal testing is a part of that. What makes this construction interesting is that through delegating powers away from the EC the process is taken further away from the public. The policy process has thereby become less democratic. A complaint that has been heard about comitology for years.

The pharmaceutical industries position is very close to what the EC tries to accomplish. With the 3Rs as guiding principles moving towards a situation which no longer requires the testing of chemicals on live animals. The question is then what do their opponents want.

A very large group of stakeholders is represented in EPAA, like the pharmaceutical industry. But especially NGOs do not agree enough with EPAA to join. Within that group there seem to be two sub groups. The biggest of these two does not disagree with the stakeholders that have joined EPAA, but would like to see more and faster progress. The second group, with stakeholders like ECEAE, Eurogroup for Animals and HSI, is much more impatient. They see animal testing as a necessity that needs to be replaced as soon as possible. Preferably yesterday.

ECHA plays a key role in this case. You could even state that ECHA replaces the EC here. In effectuating REACH they try to find a middle ground between their accredited stakeholders.

The fourth part of this thesis has two functions. It not only brings more insight to the case study, but it can also serve as an impetus to further research. Let us start with

the contribution it makes to the case study. The ACF entails much more than this part shows, but the resources it uses can be applied without utilizing the entire theory.

In looking at these resources the pharmaceutical industry has a good position. Financially well endowed, good informed and with excellent access to decision makers. Only in leadership and mobilization of troops they lag behind some of their opponents.

When we look at the public opinion the pharmaceutical industry seems to be in a quite different situations from the Pharma Package case. In that case there is some evidence of what can be reached without using the public. Or when, some would say, the public does not care. But what happens when the public does care? What makes a public case different from other cases? That public opinion has an influence has been proven. In cases like CSR it has changed the policies of many companies. Animal testing probably has profited from this, but there is one issue. The public might change its mind. 'Green washing' has been a very effective way for companies the take the sting out of the methods which environmentalists use to engage the public. In the UK Pro-Test has turned the public opinion from enraged towards organisations that perform tests on animals to uneasy, but understanding. Given that there is not one organisation that actively promotes animal testing, while many are doing the tests, is a sign of the influence of the public. Most stakeholders in this case state that they would like to see alternatives for animal testing, but do not want to rush the changeover. Stressing that animal testing should, in due time, be completely replaced by these alternatives. Admittedly, this might look at what Murray[153] and Rowe[154] are warning about in the CSR debate. Stylizing the debate and trying to keep the initiative away from the government in order to stop or delay legislation.

Stylizing the debate can only be attributed to the opponents of animal testing, like HSI. Proponents are actually stressing that things are more complicated than they seem. Keeping the initiative away from policy makers to delay legislation sounds like what has happened to the cosmetics directive. The delay is there, but the policy makers are as well. What is also striking is that the cosmetics industry did not have the initiative. Thereby making it a very different situation from the CSR debate. The cosmetics industry was reactionary to what the opponents of animal testing were pushing.

With all sub questions answered it is now possible to return to the main question of this thesis. How does the pharmaceutical industry try to protect its interests at the European Commission in a public case such as animal testing?

If I take my assumptions as a starting point there are some unexpected differences. I expected the relationship of the pharmaceutical industry and the EC to be

[153] Murray (2004).

[154] Rowe (2005).

close and cultivated over time. What I did not see was that the pharmaceutical industry in a case such as animal testing operates in conjunction with the chemical industry. Or that the pharmaceutical industry and five DGs are represented in one organisation, EPAA, that formulates one agenda. What I also found, as a member of the public, intriguing was that the public opinion is just another resource. It can be manipulated by both parties, but that does not always mean that the sentiment of the public is useable or favourable. In this case the pharmaceutical industry, and their allies, make an effort to inform the public. Initiatives like Pro-Test aim at educating the public to make them understand why this morally dubious practice should continue. And while animal welfare organisations try very hard to sway the public towards their arguments, the public seems to be somewhat neutralized as a resource. Far more important is the access to and co-operation with the policy makers the pharmaceutical industry has through EPAA. Very low profile, but at the same time quite transparent. This powerful coalition is where I would put my money for the future of animal testing.

Still, here are many questions that surround this thesis and deserve to be answered. However, these would be best served with an integrated approach on several cases. Luckily there is no shortage of interesting cases, such as parallel trade, direct-to-consumer-communications, generic medicines, or patent protection.

Literature

Articles

Asongh, J.J., "The history of Corporate Social Responsibility" in: *Journal of business and public policy*, vol. 1, no. 2 (spring 2007).

Baart, S., "Koop die pil!" in: *Volkskrant*, 3 July 1999.

Bhandari, M. et al., "Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trails" in: *CMAJ*, vol. 170, no. 4 (February 2004) 477-480.

Bouma, J., "Wat mag patiënt weten over zijn pillen?" in: *Trouw*, 6 February 2010.

Bueno, A.G. and Nozal, R.R., "Innovation vs. tradition: the election of an european way toward pharmaceutical industrialisation, 19th-20th centuries" in: *Anales de la Real Academia Nacional de Farmacia*, vol. 76, no. 4 (2010) 459-478.

Carboni, N., "Advocacy groups in the multilevel system of the European Union: a case in health policy-making" in: *OSE paper series*, no. 1 (November 2009).

Gambini, G., "EU-27 trade in medicinal and pharmaceutical products rose 11% in 2009 in spite of global economic crisis", in: *Eurostat, Statistics in focus: External trade*, vol. 63 (2010).

Jack, A., "Pharmaceutical industry: Murky medicines" in: *Financial Times*, 7 June 2012.

Karliner, J., "A brief history of Greenwashing" in: *Corpwatch*, 22 March 2001. Accessible through *http://www.corpwatch.org/article.php?id=243*. Last checked 15 April 2013.

Lanting, B., "Brussel wil 'gewoon doorgaan'", in: *Volkskrant*, 3 June 2005.

Meeus, T.J., "Het is oorlog", in: *NRC Handelsblad*, 29 November 2003.

Pollack, A., "Bristol-Myers and Athersys make deal on gene patents" in: *New York Times*, 8 January 2001.

Sabatier, P., "An advocacy coalition framework of policy change and the role of policy orientated learning therein" in: *Policy sciences*, no. 21 (1988) 129-168.

Reuters, "EU regulators to charge Microsoft over browser choice-source", 24 October 2012. Accessible through *http://www.reuters.com/article/2012/10/24/eu-microsoft-idUSL5E8LO5LN20121024*. Last checked 15 April 2013.

Reuters, "India reserves right to act on drug patents after Novartis case", 8 April 2013. Accessible through *http://www.reuters.com/article/2013/04/08/trade-india-idUSL5N0CV3PZ20130408*. Last checked 15 April 2013.

Rhinard, M., "The democratic legitimacy of the European Union committee system" in: *Governance: An International Journal of Policy, Administration and Institutions*, no. 15, vol. 2 (2002) 185-210.

Ross, E., "How drug companies' PR tactics skew the presentation of medical research", in: *The Guardian*, 20 May 2011.

Vekeman, G., "The pharmaceutical industry in Europe", in: *Eurostat, Statistics in focus: Industry, trade and* services, vol. 44 (2005).

Wilén, H., "R&D in enterprises: Pharmaceuticals: Most R&D-intensive sector in Europe", in: *Eurostat, Statistics in focus: Science and technology*, vol. 39 (2007).

Books

Boldrin, M. and Levine, D.K., *Against intellectual monopoly* (Cambridge, 2005).

Burson-Marsteller, *A guide to effective lobbying in Europe* (Brussels, 2009).

Cowles, M.G., "The changing architecture of big business" in: Greenwood, J. and Aspinwall, M., *Collective action in the European Union* (London, 1998).

Greenwood, J. and Aspinwall, M., *Collective action in the European Union* (London, 1998).

Guéguen, D., *Comitology: Hijacking European power?* (Brussels, 2011).

Guéguen, D., *European lobbying* (Brussels, 2007).

Kok, F., Kramer, P. and Maas, T. van der, *Het Brussels labyrinth; hoe Nederlanders lobbyen in Europa* (Amsterdam, 2004).

Mossialos, E., *Health systems governance in Europe; The role of European Union law and policy* (Cambridge, 2010).

Nugent, N., *The government and politics of the European Union* (London, 2003).

Rowe, J.K., "Corporate social responsibility as a business strategy" in: Lipschutz, R.D. and Rowe, J.K., *Globalization, governmentality, and global politics: regulation for the rest of us?* (Routledge, 2005).

Russell and Burch, *The removal of inhumanity: The three R's* (London, 1959).

Sbraga, A. and Stolfi, F., "Key policies", in: Bomber, E., Peterson, J. and Stubb, A., *The European Union: how does it work?* (Oxford, 2008).

Schendelen, R. van and Pauw, B.M.J. (ed.), *Lobbyen in Nederland* (Den Haag, 1998).

Schendelen, R. van, *Machiavelli in Brussels* (Amsterdam, 2010).

Papers/reports

AGE Platform Europe et al., *Pharmaceutical Package* (19 November 2008).

CHEM Trust, *Environment and health NGOs', consumer organisations & trade union's position paper* (April 2011).

Court of Justice of the European Union, Case C-120/95, *Decker v. Caisse de Maladie des Employes Prives* (1998) ECR 1831.

Court of Justice of the European Union, Case C-258/96, Kohll v. Union des Caisses de Maladie (1998) ECR I-1931.

Eurogroup for Animals, "Pharmaceuticals", in: *Areas of concern* (2010) 100-101.

European Association of Chemical Distributors, *European Association of Chemical Distributors (FECC) position on the Council political agreement on the REACH proposal*, (Brussels, March 2006)

European Chemical Industry Council (CEFIC), *Chemical industry, animal rights NGOs meet on animal testing*, (2010).

European Chemicals Agency (ECHA), *MB/69/2011; ECHA's approach to engagement with its accredited stakeholder organisations*, (16 December 2006).

European Commission, *Council Directive 76/768/EEC* (27 July 1976).

European Commission, *European business: Facts and figures* (Luxembourg, 2006).

European Commission, *European transparency initiative*, COM (2006) 194 final.

European Commission, *Regulation (EC) No 1907/2006 of the European Parliament and of the Council*, (18 December 2006).

European Environmental Bureau, EPHA Environment Network, Friends of the Earth Europe, Greenpeace International, WWF, and Women in Europe for a Common Future, *NGOs' five key demands to improve REACH* (March 2005).

European Parliament, *Lobbying in the European Union; Current roles and practices* (2003).

European Partnership for Alternative Approaches to Animal Testing (EPAA), *First annual progress report* (December 2006).

House of Commons Health Committee, *The influence of the pharmaceutical industry* (2005).

Murray, J., *Corporate social responsibility: an overview of principles and practices*, no. 34 (World Commission on the Social Dimension of Globalization, International Labour Office, 2004)

Schipper, I., "De farmaceutische industrie: Een overzicht van de belangrijkste ontwikkelingen in de sector" in: *SOMO* (October 2003).

Transparency Committee, *Directive89/105/EEC: Summary report* (30 March 1999).

Weyzig, F., "Sectoral profile of the pharmaceutical industry" in: *SOMO* (October 2004).

Wilson, J.K., *The influence of lobby groups on public opinion: the case of environmental policy* (Centre for Regulation and Market Analysis, University of South Australia, 2005).

World Medical Association, "WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects". Accessible through *http://www.wma.net/en/30publications/10policies/b3/index.html*. Last checked 15 April 2013.

WWF International, *Animal testing policy* (July 2003).

Website

Eurogroup for Animals, *http://eurogroupforanimals.org/about-us/our-mission*. Last checked 15 April 2013.

European Chemicals Agency (ECHA), *http://echa.europa.eu/web/guest/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations*. Last checked 15 April 2013.

European Commission, *http://ec.europa.eu/codecision/stepbystep/diagram_en.htm*. Last updated 21 August 2012. Last checked 15 April 2013.

European Commission, *http://europa.eu/legislation_summaries/institutional_affairs/treaties/lisbon_treaty/ai0033_en.htm*. Last updated 14 July 2010. Last checked 15 April 2013.

European Commission, *http://europa.eu/legislation_summaries/institutional_affairs/treaties/nice_treaty/nice_treaty_introduction_en.htm*. Last updated 11 January 2008. Last checked 15 April 2013.

European Commission, *http://europa.eu/legislation_summaries/institutional_affairs/treaties/treaties_singleact_en.htm*. Last updated 26 October 2010. Last checked 15 April 2013.

Eurostat, Comext,
http://comext.eurostat.ec.europa.eu/comm/eurostat/comext/index_en.htm. Last checked 15 April 2013.

Humane Society International (HSI),
http://www.hsi.org/issues/chemical_product_testing/. Last checked 15 April 2013.

Humane Society Internatinal (HSI), *http://www.hsi.org/world/europe/endanimaltesting.* Last checked 15 April 2013.

Linden, H. van der, *http://www.steunhuisartsinproces.nl/in-de-media*. Last checked 15 April 2013.

Stichting Informatie Proefdieren, *http://www.informatiedierproeven.nl/dierproeven-in-het-buitenland*. Last checked 15 April 2013.

Transparency Register, *http://europa.eu/transparency-register/index_nl.htm*. Last checked 15 April 2013.

Miscellaneous
Hickenlooper, G., *Casino Jack* (2010).

NOS and NTR, "Nieuwsuur" (2012). Accessible through *http://nieuwsuur.nl/onderwerp/385341-lobby-moet-transparanter.html*. Last checked 15 April 2013.

VARA, Human and VPRO, "Argos" (2009). Accessible through *http://weblogs.vpro.nl/argos/2009/09/25/26-september-2009-ab-osterhaus-en-het-paniekvirus/*. Last checked 15 April 2013.