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Epistemic Communities in the European Medicines Agency and the case of ellaOne

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Abstract

EU institutions increasingly rely upon opinions from scientific experts in decentralised agencies as the basis for EU-level legislation. At the same time, the role of private actors as drivers of integration is becoming more important as the availability of goods and services on the internal market depends upon proactive behaviour on their part. With regard to European governance, this expanding role of non-elected and non-governmental actors raises questions about democratic accountability and legitimacy. In early 2015, the European Commission modified the marketing authorisation for the emergency contraceptive brand ellaOne from prescription to non-prescription status. This decision was based upon a positive opinion from the European Medicines Agency (EMA) and effectively made emergency contraception available over the counter in five EU Member States (MS). This case illustrates the importance of the scientific experts employed in EU agencies and raises questions regarding the role and influence of expert communities in EU policy-making. Departing from the theoretical framework of Epistemic Communities as a specific type of expert group, this thesis aims to better understand the role of scientific experts in EU medicines regulation by analysing eight semi-structured interviews with members of the Committee for Medicinal Products for Human Use (CHMP) at the EMA.

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Abbreviations

BMI	Body-Mass-Index
CHMP	Committee for Medicinal Products for Human Use
ECJ	European Court of Justice
ECR	European Conservatives and Reformists Group
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMEA	European Agency for the Evaluation of Medicinal Products
EU	European Union
FDA	Food and Drug Administration
LNG	Levonorgestrel
MAH	Marketing Authorisation Holder
MEP	Member(s) of Parliament
MS	Member State(s)
OTC	Over the counter
PPE	European People's Party Group
UPA	Ulipristal Acetate
US	United States

Contents

1. Introduction

Balancing the competitiveness of the European pharmaceutical industry and the development of the internal market with public health and safety of consumer products is a challenging enterprise. Its outcome does not only have an impact on the private actors that are affected by the decisions of the European Medicines Agency (EMA), but also on the everyday life, health and fundamental rights of European Union (EU) citizens.

The difficulty of this balancing of different policy objectives became apparent in 2014, when the scientific experts in the Committee for Medicinal Products for Human Use (CHMP) of the EMA decided upon an application for a modification of marketing authorisation to prescription-free access for the emergency contraceptive pill ellaOne. While the final decision, which recommended a move to prescription-free marketing of ellaOne within the European Union, was supported by a majority of the CHMP members, two divergent opinions opposed the move upon different grounds. The first opinion concerned safety issues and uncertainties with regard to ellaOne and was signed by CHMP members from Germany, Croatia, Poland, Hungary, Lithuania and Italy, whereas the second divergent opinion, signed by Malta only, additionally contested the fundamental view of pregnancy as a medical condition that should be subject to termination as a medical treatment (EMA, 2014a). Seeing that the work in the CHMP is characterised by a usually high degree of consensus, these divergent opinions upon fundamentally different grounds point towards a conflict of opinions that is not restricted to the purely scientific evaluation of the medicine. This is further supported by the fact that most of the CHMP members opposing the move on safety grounds stem from countries in which no emergency contraceptive had been available over-the-counter (OTC), and where ellaOne thus was to be the first medicine of its kind to be accessible without prescription. The second divergent opinion was issued by the CHMP member from Malta – the EU country with the most restrictive policies regarding emergency contraception and abortion.

This case not only captures an interesting dynamic in European integration – market integration driven by a private actor that results in changes to social and reproductive rights – but it also indicates the difficulties of EU-level regulatory cooperation in the presence of national differences

of normative, political, and religious standards and conflictual views on several dimensions. Most importantly, it demonstrates that scientific knowledge cannot be detached from the political context and circumstances that it is utilised in. The role of scientific experts in EU-level policy-making is thus highly relevant and interesting from different disciplinary angles within the Social Sciences.

Experts can influence the policy-making process in various ways, dependent upon their organization as a group, relations to other actors (especially decision-makers), and intent. One of the most prominent concepts within the large body of research on scientific experts' involvement in policy-making processes is the theory of Epistemic Communities. According to Haas (1992a, p.3), an Epistemic Community is "a network of professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area". Previous research has shown that Epistemic Communities have been influential across a broad range of policy domains within European Union governance, especially concerning issues that require a high level of scientific expertise in order to take informed policy-decisions (Verdun 1999; Zito, 2001b; Cross, 2014). The analysis of the power and influence of such expert groups is thus crucial for understanding European-level policy-making in complex issue-areas.

Relating the ellaOne case to the theoretical framework on the role of scientific experts, questions arise regarding the legitimacy and accountability of scientific experts, but also concerning their role and influence, both individually and collectively. Preliminarily viewing the concerned expert group of the CHMP as an Epistemic Community enables a systematic analysis of its power and influence, and thus of the implications of technocratic regulatory governance in Europe. Furthermore, analysing the CHMP as an Epistemic Community utilising a conflictual and thus divergent case probes the limits of Epistemic Communities theory and contributes to the theoretical development of the concept.

Interpreting the role of the CHMP with regard to the ellaOne case, this thesis aims to analyse the role of scientific experts in European medicines regulation by asking the following overall research question:

How do the scientific experts of the CHMP constitute an Epistemic Community?

While the CHMP presents the subject of this case study, the ellaOne case will be used as an example to emphasise the relevance of the CHMP and to improve the operational aspects of the study.

Chapter 2 and 3 provide a background on the European system of medicines regulation, the institutional context of the EMA and the example of ellaOne. Chapter 4 reviews previous research on scientific expertise in policy-making, and explains the theoretical premises of Epistemic Communities. Chapter 5 accounts for the design and methodological choices of the study. The findings of the study are presented and analysed in Chapter 6. After a discussion of the findings and implications of the study in Chapter 7, the thesis ends with a conclusion in Chapter 8.

2. Background

2.1 Medicines Regulation in Europe

The regulation of medicinal products in the EU was initiated in order to address the shortcomings of the internal market (Abraham & Lewis, 2000). In line with many areas of European integration, the four movements, and, in this particular area, free movement of products, create a need for social protection and regulation. As regards the social dimension of medicines regulation, protecting public health while creating an internal market has, as stipulated in Directive 2001/83/EC, been the overarching aim of EU pharmaceutical policy.[1] Concerning the economic dimension of European medicines regulation, it aims to ensure the competitiveness of the European pharmaceutical industry on a globalised market. With a high number of multinational companies, high turnover and employment opportunities, the pharmaceutical industry is crucial to the European economy (Hancher, 2010). Furthermore, the pharmaceutical industry is among the most R&D-intensive economic sectors and very investment- and knowledge-intensive (Pashev et al., 2015; Hancher, 2010). The role of scientific knowledge and highly educated experts is thus very distinctive within this setting. In combination with a high level of secrecy and lobbying, this makes it an interesting case to study the role of scientific experts, especially since

[1] Public health in this regard concerns not only the immediate safety of products, but also long-term effects and consequences to regulative decisions. Since medicines regulation is an issue of risk evaluation and management, the precautionary principle applies in situations of scientific uncertainty, as advised by the European Commission (European Commission, 2000).

industry and regulation are closely intertwined and individual scientists often work "for both sides" during their career (Abraham & Lewis, 2000).

The first step to a Europeanised medicines regulation was taken with Directive 65/65/EEC in 1965, which aimed for harmonisation of the pharmaceutical policies of the MS of the EC (now EU). The directive was issued in reaction to the so-called Thalidomide tragedy. During the 1950s, the medicine Thalidomide was among others prescribed to pregnant women to alleviate nausea, and caused malformations to their babies (Guardian, 2012). This crisis showcases the reactionary nature of EU medicines regulation in response to the deficient capacity of the free market to ensure public health and safety. While the further integration of European drug regulation was rather weak during the following decades, it accelerated during the 1990s and 2000s, correspondent to the intensified market integration following the Single European Act (Hitiris, 2003).

2.2 The European Medicines Agency

In order to better organise and institutionalise the European cooperation on medicines regulation, the European Agency for the Evaluation of Medicinal Products (EMEA) was set up in 1995. In 2004, the procedures for European medicines authorisation were clarified with Regulation 726/2004, and the EMA was established to replace the EMEA.

The EMA evaluates, supervises and safety monitors medicines for human and veterinary use that pharmaceutical companies have developed and wish to market within the European Union (EMA, 2016a). Its committees, working groups, secretariat and an expert network of more than 4500 scientific experts comprise representatives from all EU countries as well as the EEA countries Norway, Iceland and Liechtenstein (EMA, 2016a). While the background of the scientific experts working in the EMA is not further defined in the agency's policy documents and on the website, a review of CVs and declarations of interest of the current CHMP members reveals that they are professionals within pharmacy and medicine with experience within research, regulation on a national level, and/or the pharmaceutical industry, and with at least a Master's degree in Pharmacy or a PhD in Medicine (EMA, 2016b).

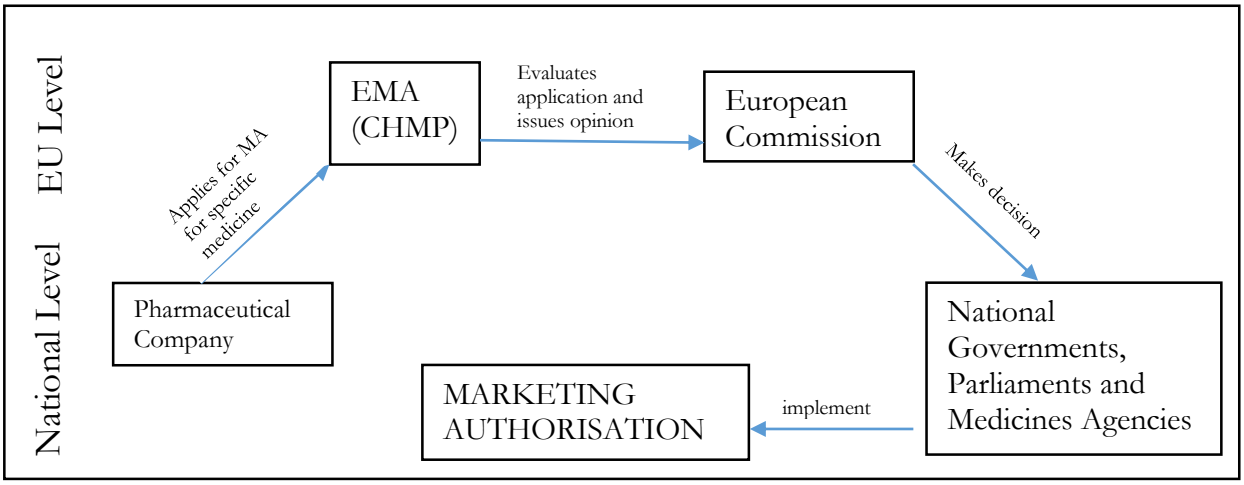
The seven committees of the EMA are in charge of different types of medicines and gather for monthly plenary meetings in order to vote and issue their opinions. Much of the day-to-day business of the Agency is conducted within working groups and meetings between committee

members (EMA, 2016a). The committee that is in charge of marketing authorisations for medicines for human use, and that issued the EMA opinion in the ellaOne case, is the Committee for Medicinal Products for Human Use (CHMP; formerly CPMP) (EMA, 2014a).

It consists of one member and one alternate from each EU MS plus Iceland and Norway, who are appointed by the MS in consultation with the Management Board of the EMA. The CHMP is headed by a chair and employs up to five additional co-opted members that possess special expertise on specific subject matters that the committee deals with (EMA, 2016b).

While the EMA works with a broad range of tasks, such as pharmacovigilance (safety monitoring of authorised medicines), referral procedures from national agencies, and stimulating innovation and research, its most important task is the evaluation of applications for EU marketing authorisations through the centralised procedure (Abraham & Lewis, 2000). Pharmaceutical companies apply to the EMA to obtain a marketing authorisation for individual medicines that is valid across the entire EU (and EEA), or to modify an existing one. The responsible committee votes[2] and issues an opinion, which the European Commission, who is in charge of issuing decisions that grant or amend marketing authorisations, then takes into account in their final decision (EMA, 2016b). The following graphic illustrates the process prior to the issuance of an EU-wide marketing authorisation for medicines for human use, and the division of competences and responsibilities between the national and the EU level.

Graphic 1: The EU marketing authorisation process for medicines for human use



Note: Own illustration

[2] For a detailed description of voting procedures, see EMA, 2016b.

2.3 Challenges and Criticism

Although the EMA is an independent agency without any competences to issue binding legislation, its opinions are d*e facto* binding (Groenleer, 2009; Abraham & Lewis, 2000; Gehring & Krapohl, 2007). As a scientific agency, it fills a technocratic position in the regulatory process and has no public mandate or claim to representation. However, due to the high level of expertise of the EMA staff, the European Commission has adopted a practice of "rubber-stamping“ its opinions (Abraham & Lewis, 2000). While this is problematic from a democratic point of view, it showcases the relevance of the agency and the necessity of critically analysing it.

The scientific experts working in the EMA have multiple affiliations and work within a complex network of actors. The EU institutions not only provide the reason for the existence of the agency, but it is also thanks to them that the EMA enjoys legitimacy and independence within the EU context. Thanks to the agency's track record of providing opinions that are simply adopted by the European Commission, the trust in the quality of its work is continuously high, and it is able to operate rather independently. A lack of trust from the side of the EU institutions would restrict the autonomy of the agency considerably and jeopardise the credibility of the European system of medicines regulation (Groenleer, 2009).

At the same time, the national agencies for medicines regulation that operate within the MS grant the EMA legitimacy by following the Commission decisions on individual medicines (which are based upon EMA opinions) and thereby acknowledge the legitimacy of the EMA's power. Furthermore, the pharmaceutical industry is an important actor that operates in reciprocation with the agency – in addition to the aforementioned close ties between regulation and industry, the agency is partly funded by the fees that pharmaceutical companies pay for applications for marketing authorisation (EMA, 2016c).

The scientific experts of the EMA are appointed by the MS on grounds of proportionality rather than representation. According to Abraham and Lewis (2000, p.113), this equates the agency in general, and the centralised procedure of marketing authorisation in particular, with supranational governance. This assumption departs from the notion of a universality of science, and a clear delimitation between science and politics. As the case of ellaOne shows, however, both spheres are interlinked in a complex way, and the evaluation of apparently clear scientific evidence is often subject to value judgments and political considerations.

Seeing the EMA in a broader context, it can be analysed in the framework of EU agencification.[3] While the establishment of agencies presents a solution for dealing with highly specific and scientifically and technically complex issues, it entails a fragmentation that can lead to a decoupling of conflicting policy aims (Majone, 2000). Furthermore, EU agencies have been criticised for a lack of accountability and legitimacy (Busuioc, 2013; Majone, 2000). These features are especially important for an EU-level agency due to its remoteness from the public and the resulting democratic deficit of EU-level governance (Krapohl, 2008; Abraham & Lewis, 2000).

The EMA has made considerable efforts to address these challenges, for the most part by increasing transparency and promoting the scientific nature of its endeavour. Transparency measures have included the publication of working reports, meeting agendas and protocols, and the accessibility of information on scientific experts' former or current employment in and other relations to pharmaceutical companies (EMA, 2016a). As for the scientific status of the EMA, the appointment of scientific experts on the basis of individual professional merits rather than as representatives of their MS was meant to increase the independence and scientific quality of their work. Furthermore, according to Abraham & Lewis (2000), "the thinking behind amplifying the 'scientific status' of the CPMP was to reduce the role of such national differences within the CPMP on the assumption that regulatory science is 'universalistic'" (p.120).

This corresponds to the intended legal role of the EMA within the EU regulatory framework – the Agency's work is supposed to be limited to scientific issues, and it is up to the Commission to consider all other factors, such as economic, ethical, social and political implications of the decision (Groenleer, 2009). However, regulating medicines involves social and political judgments, and "national differences in medical outlook may manifest themselves at the European level" (Abraham & Lewis, 2000, p.121). This captures the essence of the ellaOne case and further highlights the importance of studying conflictual cases. The CHMP evaluates marketing authorisation applications for a broad range of medicinal products. While most of their work concerns products whose conflictual dimension is limited to medical aspects of efficacy, ellaOne represents a category of medicines that are contested both within and in between countries for reasons related to morality, ethics, freedom and values.

[3] See Levi-Faur (2011) for an explanation of EU regulatory agencification.

3. The ellaOne case

3.1 Emergency Contraception in Europe

Emergency contraception is a method of contraception used to prevent pregnancy after unprotected sexual intercourse. Both biologically and legally, there is a crucial difference between emergency contraception and abortion. While medical abortion is induced with abortifacient pharmaceutical drugs and expels the fetus, emergency contraception delays or inhibits ovulation to prevent the fertilised egg from implantation (Raymond & Cleland 2015; Planned Parenthood, 2013). This distinction has resulted in fundamentally different legal frameworks governing the two procedures in most legal systems, and the instance of implantation presents a "regulatory cliff edge" (Sheldon, 2015, p.1). Methods of emergency contraception include the insertion of an intrauterine device (IUD) and the ingestion of pharmaceuticals with the substances levonorgestrel (LNG) or Ulipristal acetate (UPA). While emergency contraceptive pills on the base of LNG had previously been available without prescription in many EU countries, there had been a demand to enable OTC (over-the-counter) access of UPA-based products, which can be ingested up to 5 days after intercourse, as opposed to the 3 days' limit for LNG (Raymond & Cleland 2015). The European Commission's decision to make ellaOne available OTC as the first UPA-based emergency contraceptive can thus be seen as a landmark decision as regards emergency contraception.

The legal frameworks regulating emergency contraception differ vastly among the MS of the EU (Gissler et al., 2012). Issues regarding sexual and reproductive rights are affected by many different aspects of national traditions and culture. Even within countries, opinions on emergency contraception vary greatly and are influenced by the value-systems derived from political, religious and moral beliefs of individuals. This diversity of opinions translates to different national policies on the accessibility of emergency contraception, which change over time.

In most EU countries, LNG-based emergency contraceptives had, even prior to ellaOne, been available OTC at drugstores or pharmacies. Products with UPA as the active substance, though, had been subject to prescription all over the EU. OTC availability of ellaOne thus foreshadowed the greatest impact in those countries that did not provide prescription-free access for LNG-based emergency contraceptives, which were Croatia, Germany, Hungary, Italy and Poland.[4] In

[4] Malta is the only EU country where, in addition to extremely restricted abortion laws, emergency contraceptive pills are illegal.

some other countries, age restrictions applied for purchase of the product in order to prevent OTC access for minors without parental consent (EC-EC, 2016).

The seemingly technical and small proposed change from prescription- to non-prescription status of ellaOne actually implies a major change in the accessibility of emergency contraception. Multiple studies have shown that practical issues such as long distances to the nearest hospital/gynaecologist in rural areas, limited visiting hours and difficulties to get an appointment on short notice tend to disable women, and especially young women, from quick access to emergency contraception (Nappi et al., 2014; Marston et al., 2005; Black et al., 2008). The ellaOne decision should thus be seen as a substantial advancement for women's rights, triggered on the initiative of a private actor, and enabled by an EU decision.

3.2 Policy Review prior to ellaOne

The EMA's policy on emergency contraceptives containing LNG or UPA was re-evaluated in 2014, when the Swedish Medicines Agency referred an issue under Art.31 of Directive 2001/83/EC to the CHMP. The question was whether or not the legal status of these products should be maintained despite new studies questioning the efficacy of the products when used by persons with a high bodyweight and/or BMI (Body-Mass-Index). After a review of clinical studies, published literature and post-marketing experience on the efficacy of such products, the CHMP concluded that the leaflet information shall be changed to indicate a possible lower efficacy of the medicines for persons with a high bodyweight and/or BMI, but that the benefit-risk balance remains positive (EMA, 2014b). The ellaOne opinion should thus be seen in the light of this recent evaluation of emergency contraceptive pills in general.

3.3 ellaOne at the EMA

EllaOne is an emergency contraceptive with the active substance UPA which delays ovulation in order to prevent pregnancy. It comes in a single-dose tablet that has to be taken within 5 days of unprotected intercourse and is more effective the earlier it is ingested. The marketing authorisation holder (MAH), i.e. the company that has developed and owns the rights to the product, is the French pharmaceutical company HRA Pharma, which is specialised in women's health and endocrinology (HRAPharma, 2016a; HRAPharma, 2016b). The initial marketing authorisation for ellaOne was issued by the EMA in 2009, and the product had been available upon prescription across the EU countries where emergency contraception is legal. In February 2013, HRA Pharma submitted an application for a type II variation of the marketing

authorisation. This kind of variation pertains to a change of status from prescription to OTC as stipulated under Art.16 of Regulation 1234/2008.[5] In addition, HRA Pharma requested some changes in the product information in the leaflet of the product, among others a removal of the contraindication "pregnancy" (EMA, 2014a).

CHMP members Pieter de Graeff and Kristina Dunder were assigned the roles of rapporteur and co-rapporteur, respectively. A review of studies on the efficacy and safety of the product and the pharmacovigilance documentation was conducted. The CHMP discussed the four criteria that the European Commission has established for the classification of a product as subject to medical prescription (according to Art.71 of Directive 2001/83/EC) and evaluated them separately. The objections regarding a switch to non-prescription status concerned possible off-label use of ellaOne as an abortifacient and safety risks to the fetus when using it during an already existing pregnancy. Furthermore, the CHMP questioned whether the benefit-risk balance for adolescents and adults is equal and requested the MAH to provide clarification regarding these issues. After receiving the additional information provided by the MAH, the CHMP concluded that the benefit-risk balance of ellaOne would continue to be positive in a non-prescription setting. The arguments in favour of the switch were related to the possibility of quick access through pharmacies, which would enable the best possible efficacy of ellaOne, and ellaOne's higher efficacy as compared to LNG-based products (EMA, 2014a).

The final opinion (EMA, 2014d) recommended a variation of the marketing authorisation of ellaOne to non-prescription status. However, the opinion was adapted with 21 out of 29 votes and thus diverges from the norm of unanimity in CHMP votes. Two divergent opinions were issued by CHMP members from the MS of the EU that had not previously allowed OTC access to emergency contraception.

Divergent position 1 opposed the switch to non-prescription status based upon arguments related to the uncertainty regarding the use of ellaOne during an already existing pregnancy, and the resulting risk to the health of the fetus (EMA, 2014a). The opinion was signed by CHMP

[5] The prescription status for medicinal products is very particular to the EU context, since "in Europe, prescription medicines are, in general, therapeutically more powerful, potentially more toxic and scientifically more significant than their over-the-counter counterpart" (Abraham & Lewis, 2000, p.36).

members from Germany, Lithuania, Croatia, Italy, Poland and Hungary; all (except Lithuania) countries where no emergency contraceptives had been available OTC prior to ellaOne.

Divergent position 2 was signed by Malta only and, in addition to the concerns regarding off-label use and fetal health, included normative judgements regarding the use of emergency contraceptives per se. Firstly, the opinion stated that "Pregnancy normally cannot be considered a disease, and termination of pregnancy in a normal setting is not a therapeutic indication" (EMA, 2014a, p.74). This indicates fundamental differences in how pregnancy is seen in different MS. The demand to see pregnancy as a natural condition of human life rather than a medical condition subject to treatment points towards an opposition towards the process of pharmaceuticalisation.[6] Furthermore, divergent position 2 claims that "the medical termination of pregnancy involves the destruction and death of a human life" and considers it a risk to public health. This shows that the Maltesean definition of human life stretches to potentially fertilised eggs prior to implantation. Furthermore, it indicates that "public health" in this opinion not only includes the health of society and persons, but even the pre-embryonic stage. The opinion further makes a normative statement about the role of medicine, claiming that "this procedure is in direct conflict with the responsibility of medicine to protect and promote life" (EMA, 2014a, p.74).

It could be argued that the safety reasons mentioned in Divergent Position 1 were used as pretences for domestic political considerations, seeing that all of the authors stem from MS where the decision was controversial due to moral and/or ethical concerns on a civil society level. Divergent Position 2, on the other hand, did not attempt to disguise the normative nature of the definition of human life, which in Malta's position was in completely in accordance with that of the domestically powerful Catholic church (Benagiano & Mori, 2007).

3.4 Commission Decision

Despite the lack of consensus in the CHMP, the European Commission followed the majority opinion of the EMA and issued the Commission Implementing Decision of 7.1.2015 amending the marketing authorisation granted by Decision C(2009)4049 for "ellaOne – ulipristal acetate, a medicinal product for human use". While the implementation proceeded quickly in a number of MS, it met substantive opposition in others.

[6] For a definition of pharmaceuticalisation, see p.12

3.5 ellaOne in the European Parliament

Even in the European Parliament, ellaOne caused questions among a group of, mostly ECR- and PPE-associated MEPs. In February 2015, 15 MEPs posed a question for written answer to the Commission. Referring to the EU Charter of Fundamental Rights, they upheld that human dignity is inviolable and related this claim to the ECJ judgement Brüstle vs. Greenpeace(C-34/10), where the court had extended the definition of human dignity to the pre-embryonic stage of fertilised eggs. On this basis, the MEPs questioned whether the Commission was going to withdraw the decision granting OTC access for ellaOne (European Parliament, 2015c). The European Commissioner for Health and Food Safety, Andriukaitis, answered claiming that the decision on ellaOne and the ECJ judgement cannot be compared. Furthermore, he clarified that MS, under Art. 4(4) of Directive 2001/83/EC could maintain national legislation "prohibiting or restricting the sale, supply or use of medicinal products as contraceptives or abortifacients" (European Parliament, 2015a). This clarification provided MS with the opportunity to either abstain from implementing the Decision, or to initiate new legislation to solve the issue.

While the majority of the MEPs asking the question seemed to be satisfied with the Commission's clarification, two Polish MEPs, both affiliated with the ECR party group, posed another written question to the Commission in April 2015 (European Parliament, 2015d). The question challenged the Commission's statement that the ellaOne decision is not comparable to the Brüstle vs. Greenpeace judgement. It further emphasised the "destructive effect" of ellaOne and asked for a clarification of MS' possibilities to restrict sales of such products. In his final answer, Andriukaitis highlighted the design of EU legislation on medicinal products concerning emergency contraception and abortion (European Parliament, 2015b). He explained that MS had the right to ban such products "which infringe objectively defined concepts of public policy and public morality" under Recital 13 of Regulation (EC) 726/2004, and, again, referred to the special regime that applies for contraceptives and abortifacients under Art. 4(4) of Directive 2001/83/EC.

3.6 Implementation

Despite protests against the Decision in several countries[7], implementation on the national level proceeded quickly. As of November 2015, ellaOne was available without prescription in 23 EU

[7] The opposition to a prescription-free access of ellaOne was concentrated to the countries where no emergency contraceptives had previously been available OTC. The most substantive protests occured in Poland, where 200.000 citizens signed a petition urgeing the government to maintain the ban on prescription-free emergency contraceptives

countries, and the implementation was in process in Lithuania, Estonia and Latvia. The Hungarian government decided to maintain the ban on prescription-free access to emergency contraceptives due to safety considerations, and due to Malta's general prohibition of emergency contraceptive pills, ellaOne remains unavailable there (EC-EC, 2016).[8] In sum, the ellaOne case caused a significant improvement in the access to emergency contraception in several EU countries.

3.7 Relevance and Implications of the Decision

While at first glance, the type-II variation to the marketing authorisation of ellaOne might seem like a minor technical detail, the impact and relevance of the modification of prescription status showcase the power of the EMA and the great impact that the scientific assessment of medicinal products has on the life of EU citizens. The EMA opinion on ellaOne was adapted with 21 out of 29 votes, which is far from unanimous (EMA, 2014d). The role of each individual scientific expert is thus crucial, especially if the opposition to a decision is not unilateral, but stems from a number of different MS.

Shortly after the implementation of the ellaOne decision, even the LNG-based product PiDaNa was cleared for OTC-access in Germany (Pro Familia, 2016). This further highlights that ellaOne presents a landmark case that affects the further development of the legal status of emergency contraception in Europe. The controversy regarding the ellaOne case both in the institutional path of the EU decision (Divergent opinions in CHMP, written questions in European Parliament) and among a variety of actors on the national level (Professional associations of pharmacists and gynaecologists, pro-life organisations, groups affiliated with the Catholic church, political actors) is not surprising seeing that it touches upon issues that have been a national prerogative with fundamentally different policy approaches across the EU. What is astonishing is firstly, that the EU succeeded to legislate in this kind of controversial policy area, and secondly, that several MS changed their domestic policy regarding emergency contraception even though they could have made use of the exceptions provided by the EU acquis.

(Polskie Radio, 2015). Even in Germany, the switch had been controversial for a long time, both among the public and among gynaecologists' and pharmacists' associations (Bundestag, 2013).

[8] In April 2016, the Polish Minister of Health, Konstanty Radziwill, announced that Poland would reinstate its ban on OTC-access for emergency contraceptives, thus ending the OTC-availability of ellaOne (http://www.politico.eu/article/polands-church-state-alliance-to-ban-abortion/)

In the context of medicines regulation, the case is particular due to the composition of stakeholders with specific preferences regarding the outcome of the ellaOne decision. In medicines regulation in general, there are different groups of stakeholders, comprising consumer organisations who are interested in pricing and transparency issues, public health advocates who are concerned about the therapeutic value of medicines, and patient associations that promote the availability of medicines for the treatment of specific diseases (Abraham & Lewis, 2000). Due to the fact that emergency contraception is normally used in exceptional cases only, and due to the attached societal stigma, the organisation of patient- and consumer groups' interests is very weak. Women using emergency contraception are often very young (Nappi et al., 2014), and do so in exceptional situations only, which further disables the formation of interest groups working for the access of emergency contraception exclusively. The actors involved in the case were mostly involved for moral or normative reasons, which highlights the relevance of the case from a medicines regulation point of view.

Furthermore, the ellaOne case corresponds to a trend in the use of medicines that could prove very important on a European level. According to Abraham and Lewis (2000), society is undergoing a process of "pharmaceuticalisation". Put simple, it means that areas and phenomena of human life that were not previously regarded as diseases or illnesses are seen as such and treated accordingly. Taking into account the obvious parallel to the reasoning of the Maltesean CHMP member in Divergent position 2 of the ellaOne case, this theory highlights yet another dimension of the case. Pharmaceuticalisation is primarily happening "in the bedroom and in the kitchen" (Abraham, 2010; Fox & Ward, 2008), which means that it primarily impacts issues regarding sexuality (e.g. viagra, emergency contraception) and food (e.g. diet pills). Seeing that the norms and politics concerning these issues are subject to cultural and societal values and traditions, the number of conflicts regarding medicines regulation is likely to increase in line with pharmaceuticalisation, a growing number of EU MS and the resulting increased cultural and political diversity. It is thus crucial to understand and conceptualise the role of scientific experts in conflictual cases.

4. Previous Research & Theory

4.1 The Role of Scientific Experts in EU Policy-Making

The increasing role of experts in policy-making is mirrored in the institutional set-up of many democratic systems. Within the EU context, scientific experts are employed by the institutions themselves (e.g. the Commission), but also in the more than 40 agencies that have been established during the last few decades. (Groenleer, 2009). Due to their important role in EU policy-making, scientific experts have been a subject of interest in a growing body of research within Political Science and Sociology. Overall, the role of scientific experts in policy-making has mostly been studied within the fields of climate change and environmental governance (Sundqvist, 1991; Grundmann & Stehr, 2012; Ambrus et al., 2014). Previous research provides alternative typologies of expert groups such as the Advocacy Coalition Framework (Sabatier, 1998), which is a multidisciplinary group of experts (not necessarily scientific experts) with a common policy enterprise. However, due to the homogenous disciplinary background of the CHMP members within the area of medicines and pharmacy, the Epistemic Communities approach is the most relevant for this study.

4.2 Epistemic Communities

The concept of Epistemic Communities relates to the notion of *episteme*, i.e. "the accepted mode of acquiring and arranging knowledge in a given period" (Baldick, 2008). The episteme provides the basis for the emergence of an Epistemic Communities and "delimits… the proper construction of social reality" (Ruggie, 1975, p.570) among its members. Put simple, it is the sum of implicit and explicit assumptions about what presents solid knowledge and with what methods it should be obtained; and as a type of world view, it unites the group of individuals that form an Epistemic Community.

The concept was introduced to the field of International Relations thanks to an influential special issue of *International Organization*, in which Haas put forward the commonly cited definition of an Epistemic Community as "a network of professionals with recognised expertise and competence in a particular domain and an authorative claim to policy-relevant knowledge within that domain or issue-area" (Haas, 1992a, p.3). Haas further delineates four criteria that distinguish Epistemic Communities from other kinds of expert groups. They have

> 1) a shared set of normative and principled beliefs, which provide a value-based rationale for the social action of community members; 2) shared causal beliefs, which are derived from their analysis of practices leading or contributing to a central set of problems in their domain and which then serve as the basis for elucidating the multiple linkages between possible policy actions and desired outcomes; 3) shared notions of validity – that is, intersubjective, internally defined criteria for weighing and validating knowledge in the domain of their expertise; and 4) a common policy enterprise – that is, a set of common practices associated with a set of problems to which their professional competence is directed, presumably out of the conviction that human welfare will be enhanced as a consequence (Haas, 1992a, p.3)

Epistemic Communities gain access to the political sphere by virtue of their professional experience and expertise, and they can appear in the shape of independent individuals that cooperate to further a specific subject matter, as a pool of experts that is called upon by decision-makers in order to frame the political options prior to international agreements, or within the institutional framework of international organisations (Haas, 1992a; Cross, 2013a).

Further contributions to the 1992 special issue discussed matters such as the GATT-negotiations, nuclear arms control, food aid, and the Bretton-Woods Agreement and analysed the role of Epistemic Communities in those contexts. Furthermore, they refined the theoretical premises by defining what kind of activities these communities engage in. Epistemic Communities gather information, frame complex issues, define political options and help formulate policies. Furthermore, they disseminate knowledge and shape the political agenda (Drake & Nicolaidis, 1992; Haas, 1992a; Ikenberry, 1992). All of these activities influence policy-makers, either directly, or via other actors (civil society, or corporate actors that have an interest in the policy outcome). Furthermore, Epistemic Communities that are either a part of, or closely related to regulatory or advisory agencies exert influence by developing regulatory standards, and they possess more immediate opportunities to shape policies (Adler & Haas, 1992).

Epistemic Communities possess great amounts of experience and expertise, which is necessary in order to understand and explain highly complex issues of a scientific or technical nature. While the benefits of their involvement in policy-making are clear, the growing influence of both Epistemic Communities and other, more formal and transparent expert groups has been criticised

from a democratic point of view. The often very homogenous disciplinary backgrounds of Epistemic Communities can lead to a lack of interdisciplinarity in policy-making processes that these communities are involved in. This could in its turn result in one-sided outcomes that neglect the social ends that political decisions result in for the benefit of solutions that are optimal from a scientific point of view (Haas, 1992b).

Relating this criticism to the CHMP, the divergent opinions in the ellaOne case indicate that socio-political factors stemming from fundamentally different national ontological definitions played a role in the reasoning of Committee members. According to the legal framework that regulates the division of responsibilities in European medicines regulation, it is the role of the Commission to weigh in political and social factors, whereas the EMA and its committees shall present the scientific part of solving uncertainties. The ellaOne case thus highlights the difficulty of separating science from politics.

4.3 Epistemic Communities and the European Union

In line with the increasing European integration and the shift of governance of a broad range of policy areas from the national to the European level, the role of Epistemic Communities in EU policy-making has become steadily more relevant, and the topic gained popularity within European Studies during the last decades. Among others, scholars such as Zito (2001a, 2001b), Cross (2011, 2013a, 2013b, 2014, 2015), and Verdun (1999) have analysed the emergence and influence of Epistemic Communities that influence the outcome of the policies of the European Union. These communities appear both within and outside of the institutional setting of the European Union, for example within the EU institutions and agencies, in think-tanks and academia, or as independent experts that are consulted by virtue of their professional expertise on a specific subject.

Broadly speaking, two strands of research on Epistemic Communities can be identified within the EU context: The first strand deals with the emergence of Epistemic Communities and, beyond analysing specific cases and settings, seeks to define under what circumstances these communities can emerge and how to identify them. The second strand of research analyses the power and influence that Epistemic Communities have on policy outcomes by investigating what channels they have at their disposal for making their preferences heard, and by examining their relations to decision-makers on the national and EU level. However, the delineation between the

two strands is not always clear, since some studies investigate both emergence and influence of specific Epistemic Communities.

While the second strand provides the opportunity to trace and understand the influence of Epistemic Communities, and thus to better grasp the process of knowledge utilisation in the political system of the European Union, it assumes their existence. Since the case setting at hand, the European Medicines Agency, (to my knowledge) has not been analysed as concerns Epistemic Communities, the identification and conceptualisation of possible communities is a natural first step to better understanding EU medicines regulation in conflictual cases. This study thus aims to contribute to the first strand of research on Epistemic Communities within the context of the EU, and the remainder of this literature review will focus on previous research regarding the emergence and identification of Epistemic Communities in relation to EU governance.

4.4 Epistemic Community Emergence and Identification

In the context of the European Union, Epistemic Communities have been studied empirically across a number of different institutional settings and policy areas. Within EU monetary policy, Verdun (1999) analyses the role of the monetary experts in the Delors Committee in the creation of the European Monetary Union. By studying the institutional boundaries that the Committee operated within, and the actions of individual members as well as MS, she tracks the influence of the Committee during the process leading up to the Monetary Union and concludes that it did in fact constitute an Epistemic Community. Zito (2001a) detects and investigates an Epistemic Community that influenced the EU's acid rain policy by applying Haas' four criteria to a group of key players that he identifies by looking at the history and development of EU's acid rain policy. Mitchell et.al. (2007) have conducted one of few quantitative studies on Epistemic Communities by testing a large pool of scientists in the subject of nuclear policy for patterns that could point towards the existence of Epistemic Communities or other kinds of expert groups. Although the contribution of the study to the theoretical development of the Epistemic Communities concept is limited, it poses an extremely relevant question:

> Are policy preferences influenced by ideological and national differences within technically complex issue areas and even among members of a group internationalized by training, professional socialization and, to a large extent, by language? (p.753)

This question covers several aspects of the ellaOne case since it emphasises the role of nationally different views in sociotechnical controversies, thus capturing the essence of the problem.

The most extensive work on Epistemic Communities within one EU policy field has been conducted by Cross (2011, 2013b, 2014, 2015), who has focused on such communities within EU security cooperation. The EU Military Committee (2013b), The Coreper and the Political and Security Committee (2014), the European Defence Agency, and the EU Intelligence Analysis Centre (2015) have been at the focus of her work. Departing from four variables that determine the internal cohesion of an Epistemic Community (and reflect upon its external influence), Cross scrutinises the institutional structure, tasks, mandates and actual activities of the concerned groups and provides analyses of data collected during interviews with several group members.

The most important contribution of Cross' work (beyond its empirical relevance) is the insight that the existence of Epistemic Communities is not a question of "to be or not to be"; rather, they can exist with varying degrees of internal strength and cohesion. Furthermore, the 2015 study of the European Defence Agency and the EU Intelligence Analysis Centre, which both proved to be non-cases, highlights the relevance of delineating the limits of the Epistemic Communities theory. Bringing this endeavour to the field of medicines regulation, a policy area that is similarly secretive as the security sphere, this study aims to further explore the limits of Epistemic Communities.

Previous research has provided a comprehensive conceptualisation and characterisation of Epistemic Communities, their emergence and their influence. The empirical work on Epistemic Communities within an EU context has been focusing on the policy areas of military and security, economics, and environmental issues. The field of medicines regulation presents a contribution to this body of research due to the multitude of stakeholders (Industry, national agencies, EU citizens, NGOs), and the increasingly normative dimension of the policy outcome in a culturally diverse EU.

4.5 The CHMP as an Epistemic Community

This section provides a preliminary assessment of the context and setting of the CHMP as a possible Epistemic Community. Two hypotheses are presented based upon this assessment. Investigating the CHMP as an Epistemic Community, this thesis poses the following specified research questions:

1) **How do the scientific experts of the CHMP constitute an Epistemic Community?**
2) **How is the internal cohesion within the CHMP as an Epistemic Community?**

Previous research presents a number of factors that determine whether an Epistemic Community is likely to emerge in a certain context. Illuminating the preconditions that enable Epistemic Community emergence and existence, this section provides a preliminary assessment of the CHMP as a breeding ground for Epistemic Community activity. It is, however, important to distinguish between preconditions that make the emergence of such communities more likely, and indicators that suggest their existence.

According to Haas (2014), "Epistemic Communities are likely to be found in issue areas where scientific disciplines have been applied to policy making and in countries with well-established institutional capacities for administration, science and technology" (p.35).

Seeing that the nature of the CHMP's involvement in the policy-making process is based upon their scientific expertise and merits, and that the EMA is an agency exclusively charged with the evaluation of medicinal and pharmaceutical aspects of medicinal products, this precondition clearly is in place in the issue area of European medicines regulation.

Cross (2015) considers Epistemic Community emergence likely in horizontal bodies with a sense of equality (for example equal numbers of representatives from each country), where the members interact on a level playing field, rather than in strict and hierarchical structures. Even though the EMA is an institution headed by an Executive Director and a Management Board, and governed by the regulations provided by the EU *acquis*, its institutional structure provides for a rather high degree of equality among the members of the CHMP. The equal number of representatives for each MS and the equal weight of the members' votes as well as the possibility to issue divergent opinions point towards a fair and deliberative working environment within the Committee.

Furthermore, Epistemic Community emergence is likely in situations that enable an expert group to extend its authority beyond possible formal mandates (Cross, 2013a). While the EMA has both specified goals (protecting public health and maintaining the competitiveness of the European pharmaceutical industry) and a formal mandate (providing opinions), it has, over the years, become a *de facto r*egulator (cf. Groenleer, 2009, Abraham & Lewis, 2000, Gehring & Krapohl 2007). Thanks to the quality of its decisions, is has been able to maintain the trust of its principals

(EU and MS) and to operate rather independently. While this is not an extension of the formal mandate of the EMA, it does, in practice, entail an increased power and authority.

Another precondition that promotes the emergence of Epistemic Communities are situations of crises, when decision-makers depend upon the help of experts to interpret scientific knowledge (Haas,1992a). Crises in this sense can be anything from high levels of environmental pollution (Zito 2001a) to needs for new economic solutions (Verdun, 1999) and security threats (Cross, 2013b). Cross (2013a) has advocated a broader view of uncertainty, rather than acute crises, as a precondition for Epistemic Community emergence. While it is clear that uncertainty is a key dynamic in medicines regulation, the identification of crises can prove valuable for a better understanding of the history and development of the CHMP, and the EMA in general. The CHMP has, in its current shape, only been in place since the EMA establishment in 2004. The absence of actual, dramatic crises in European medicines regulation during the last decade thus makes it unlikely that Epistemic Communities within the CHMP have developed in response to crisis during that time. Looking back further in the history of European integration, the beginning of the European cooperation on medicines regulation can be attributed to the Thalidomide tragedy, which clearly presents a major crisis. However, the institutional structure and the individuals involved, as well as the state of science in pharmaceutical and medical research were completely different at that time. If this analysis reveals a strong, and long-lasting institutional culture, it is likely that the culture entails a shared *episteme* among the scientists involved in European medicines regulation. However, it is difficult to trace back the origins of this shared worldview and common culture to the beginnings of cooperation in the 1960s and to relate it to the contemporary CHMP.

Cross (2015) sees professional areas that require and value secrecy as unfavourable to the emergence of Epistemic Communities. Activities such as information-sharing, deliberation and networked communications are crucial to the emergence and maintenance of Epistemic Communities and increase their internal coherence. The pharmaceutical area is commonly named among the most secretive, along with security and military matters (cf. Abraham & Lewis, 2000). However, this secrecy is stronger on the corporate side than in the regulatory sphere, which, as previously mentioned, has made great efforts to increase transparency. Even if a certain degree of secrecy remains even within the EU regulatory process (to mention an example from the ellaOne case, a part of the minutes of the CHMP meeting when the ellaOne opinion was adopted

is not disclosed due to its commercial confidentiality or sensitivity (EMA, 2014c)), it cannot be considered adequately substantive to solitarily disable Epistemic Community emergence.

Finally, Groenleer (2009) argues that it is difficult to foster shared values when working in supranational organisations such as the EMA due to the diversity of national backgrounds across the EU. This claim could be supported by the divergent opinions in the ellaOne case, which clearly showcase that value-based judgements are a part of scientific interpretations. However, Groenleer acknowledges that the experts at the EMA often have a background of working internationally, either in academia or the pharmaceutical industry, and thus tend to identify themselves as cosmopolitans rather than nationals of a MS (2009, p.152). Taking into account the literature on socialisation of EU staff (see e.g. Checkel, 2005; Busby, 2013; Suvarierol et.al., 2013), and the fact that, in contrast to EU institutions with in-house translational services, the EMA's working language is English (EMA, 2016a), the supranationality of the EMA cannot be seen as the sole reason for a possible absence of Epistemic Communities.

Based upon this preliminary assessment, the following hypotheses will be guiding the analysis:

1) The members of the CHMP constitute an Epistemic Community
2) The members of the CHMP constitute an Epistemic Community with a low degree of internal cohesion.

4.6 Case Selection

While there are seven different committees (and multiple working groups) at the EMA, the CHMP has a special role due to its competence area of human medicines. Its opinions regard medicines that, if a marketing authorisation is granted, will be publicly available, either with or without prescription, across the EU. Furthermore, the fact that the area of competence of the CHMP is limited to medicines for human use makes it a good case to study Epistemic Communities, in which human welfare and normative beliefs about humanity itself play an important role.

Beyond the selection of the CHMP as a case, the choice of ellaOne as an example presents a second, but equally important consideration. While ellaOne was not the first emergency contraceptive to be authorised for marketing by the CHMP, the special conditions surrounding the case make it exceptional – an opinion by the CHMP led to a decision by the Commission,

which in its turn caused actual, significant changes in the availability of emergency contraceptives in several EU MS.

The choice of emergency contraceptives as a relevant category of medicines depends upon their special status due to moral, religious and cultural reasons, and the diversity of their legal status across the EU. A marketing authorisation application for an emergency contraceptive is likely to create more discussion within the CHMP than a medicine with less social implications, such as for example a cough medicine that is similar to products that are already available OTC. Differences in principled beliefs are thus more likely to manifest themselves in discussions surrounding medicines in socially contested areas. In other words, the controversial issue of emergency contraception presents a way to find out if an Epistemic Community can exist on an EU-level despite cultural, social and political differences in the domestic setting that its members stem from.

5. Method

In order to analyse how the CHMP works as an Epistemic Community, semi-structured informant interviews have been conducted with several CHMP members. The theoretical framework on Epistemic Communities is operationalised departing from Haas' four criteria, and complemented with Cross' indicators of internal cohesion. The subject of study are the perceptions of the CHMP members, and their understanding of their work and situation. Reflecting the CHMP members' own perceptions of working in the EMA, the analysis takes an overarching interpretivist stance. According to Tracy (2012, p.41), "Interpretivists view knowledge as socially constructed through language and interaction, and reality as connected and known through society's cultural and ideological categories". This overall approach to the subject of enquiry of this study is thus well-suited both for the purpose of better understanding the context at hand, and for the conceptual development of Epistemic Communities theory.

A deductive approach is well-suited for this study due to its starting point in the existing theoretical framework on Epistemic Communities. This design provides the opportunity to support and extend the existing theory, while taking into account practical considerations. The deductively drafted categories presented in the coding scheme present as a starting point and they have been developed and complemented with sub-categories during the process of analysis. The

following sections will further explain the operationalisation of the theoretical framework and the methods utilised during the process of data collection and in the analysis of results.

5.1 Interviewing as a Method of Data Collection

Due to the lack of available data regarding the working culture, internal relations and personal beliefs of the members of the CHMP, the collection of data for the purpose of this study has been essential. Even though the documents available on the website of the EMA as well as previous research illuminate the institutional context of the CHMP and the procedure of the ellaOne case, they have primarily been used to grasp the context of the ellaOne case and to identify possible methods of answering the research questions.

The empirical data used to conduct this study has been collected through the method of interviewing. According to Tracy (2012, p.132), "through interviews, the respondents can provide their opinion, motivation, and experiences". This method is thus well-suited to study the possibility of an Epistemic Community within the CHMP using the members' own accounts of their work and community. Furthermore, interviews are "especially helpful for acquiring information that is left out of formal documents" (Tracy, 2012, p.133). Seeing that the official documentation of the assessment of ellaOne in the CHMP is limited to the (very brief) minutes from the CHMP meeting where the decision was adopted, an assessment report (with divergent opinions) and the EMA opinion, it was crucial to generate data that delivers insight beyond these formalised and technical official documents. Furthermore, available information on the working culture within the EMA is limited to very few studies (e.g. Groenleer, 2009), and does not cover the specific context of the CHMP to a sufficient degree.

Possible informants were identified through a strategy of purposeful sampling (cf. Tracy 2012, p.134). Only the members of the CHMP themselves possess the information that is of relevance for the study. Possible outside informants such as secretaries or other supporting staff and interns that could have insight into the functioning of the CHMP were thus excluded. In order to be able to inquire about the ellaOne case, the sample was further reduced to include only those CHMP members that were present at the meeting during which the positive opinion on ellaOne was adopted and which took place from the 17th to 20th of November, 2014. Some recently appointed current members of the committee were thus excluded and some previous members that were present at that meeting but whose appointment has ended since then were included. The list of persons that fulfil the criteria is publicly available on the CHMP website as an annex to the

minutes of the respective meeting.[9] The sampling process resulted in a sample of possible informants of 51 individuals. Using the contact details available on the CHMP website, all 51 persons were contacted during February 2016 by mail, with an individually customised letter presenting the project and asking for their participation in an interview.

While some possible informants answered by e-mail during the following weeks to either confirm their participation or request additional information, the majority did not answer. The interview request letters were thus followed up by phone calls to the respective individuals, and, if necessary, e-mails. Eight persons agreed to participate and phone interviews were scheduled and conducted on the 21., 22., 23., 24., 29. and 30th of March and the 5th of April.

5.2 Operationalisation

In order to find out whether the CHMP constitutes an Epistemic Community, the interviews were focused on analysing the indicators of Epistemic Community existence, as developed by Haas (1992a, 1992b) and Cross (2015). In addition to Haas' original four attributes (1) shared normative beliefs, 2) shared causal beliefs, 3) shared notions of validity, and 4) common policy enterprise), Cross puts forward three indicators that partly overlap with Haas' framework. Cross' first indicator is that a group of scientific experts acts as more than the sum of its parts (relating this to the preconditions for Epistemic Community emergence, it is enabled by the opportunity to extend one's formal mandate). Secondly, if the members of a group know each other and have interacted in various formal and informal settings, it indicates the existence of such a community. The third indicator concerns the professional norms and culture of a group of scientific experts. More specifically, factors such as effective meetings and frequent interactions between the group members point towards the existence of an Epistemic Community.

The cohesion of a possible Epistemic Community has been analysed based upon four elements that fall under the scope of Cross' third indicator for Epistemic Community existence (professional norms and culture):

1) the selection and training of group members
2) the frequency and quality of their meetings
3) shared professional norms;

[9] http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2014/12/WC500179548.pdf

4) common culture in a more normative sense (indicated by a common identity, symbolism and sense of purpose within the group)

Based upon these considerations, a thematic scheme (Appendix 1) gives an overview of the topics covered during the interviews. The scheme also serves to support the subsequent analysis of the interview transcripts.

The interview guide in Appendix 2 is a standard version which, in some cases, was adapted to the specific informants. The first part of the interview guide serves to achieve insight into the general working environment and habits of the CHMP, whereas the second part aims at illuminating the ellaOne case. Relating back to the thematic scheme in Appendix 1, the first part of the interview guide concerns the more practical, working-related information needed to understand indicator 5-10, whereas the second part touches upon more normative and personal beliefs, as regards indicator 1-4. However, the division into two different parts primarily served to structure the interview, and the answers given in the different parts may overlap or coincide.

The interviews were conducted in a semi-structured manner, which means that probing questions were asked if necessary, informants were asked to clarify certain issues, and questions that had been answered already during the interview were skipped or modified.

The interview guide was continuously revised, and questions that during the first few interviews had been found to be unclear or in need of precision were improved thereafter. The section headlines served to further structure the interview and provide orientation during the process of interviewing, but they were not read out to the interviewees. To ensure the highest possible quality of results, the questions in the interview guide were formulated as clearly, openly, and non-leading as possible. Furthermore, some of the questions were adapted to the language of the informants by using terminology and abbreviations that they were familiar with.

A broad range of generative questions was incorporated into the interview guide in order to achieve comprehensive and informative answers and to create an open atmosphere that invited the informants to speak freely (cf. Tracy, 2012). Furthermore, the questions were sequenced in a way that enabled a smooth flow of the conversation. The interviews thus began by ensuring the informed consent of the participant and asking introductory questions about the personal background and experience of the informants. This kind of simple, introductory questions serves to "prompt the participant to tell stories – which later questions can refer to and follow up on"

(Tracy, 2012, p. 147). The interviews then moved on to factual questions about the work in the CHMP, and national issues such as appointment procedures. These questions provide information that is not otherwise available at the same time as prompting the informants to reflect.

Some of the interview questions make use of methodological techniques such as asking the informants to "pose the ideal", in this case for instance asking the informants to describe an ideal form of medicines regulation, or asking them to describe an ideal clinical study. According to Tracy, this gives participants the opportunity to "starkly contrast reality with their wishes, dreams and desires" (2012, p.148); it thus presents a good opportunity to gain insight into the personal goals, motives and beliefs of the informants. The interview guide ends with a reflective question on the work of the CHMP and what its 'usual cases' look like, thus enabling the informants to expand and touch upon topics that may not have been covered during the interview, but seem important to the informant.

During the initial contact with possible informants, several persons said that they were willing to participate in an interview, but did not want to talk about ellaOne specifically. An alternative interview guide was thus prepared, in which the informant was asked to either come up with an example of another medicine that was controversial in the CHMP, or the second part was entirely left out.

5.3 Method of Analysis

The material in the form of interview transcripts was interpreted through a directed content analysis. The method of directed content analysis can serve to "validate or extend conceptually a theoretical framework or theory" (Hsieh & Shannon, 2005, p.1281), and is thus well-suited for this study, which departs from the theoretical framework of Epistemic Communities.

The first step of analysis is to create coding categories by identifying important variables derived from the theoretical framework (Hsieh & Shannon, 2005, p.1281). The analytic scheme that comprises the ten indicators of Epistemic Community existence and cohesion provides a solid starting point for the analysis since it is based upon the theoretical work of Haas and Cross, and the categories are operational and well-suited for analysing the material at hand. However, the analysis was not strictly limited to these ten factors, but the coding scheme was refined by using sub-categories. This enabled the purpose of conceptually extending the theoretical framework

and increases the relevance of the study beyond the actual context at hand, i.e. the CHMP, and the case of ellaOne.

The following coding process served to structure and organise the generated material along the coding scheme in order to gain a manageable amount of text for analysis. The coding was conducted manually, by highlighting relevant passages in the text, assigning them the number of the indicator that they may contribute to illuminate, and adding remarks and observations during the initial reading. The entire material was examined several times in order to increase the reliability of the coding process. Each indicator was considered separately during the initial analysis, but the discussion includes a synthesis of the findings across and beyond the ten initial indicators.

5.4 Quality and Reliability

To ensure the highest possible quality of the collected material and the analysis itself, each step of the research process was planned thoroughly. During the development of the coding scheme and the interview guide, Mai'a Cross, who has done a great amount of research on the topic of Epistemic Communities, was consulted on topics such as the wording and sequencing of interview questions, the design of the coding scheme, and the analysis of results. According to Hsieh & Shannon (2005, p.1283), this type of auditor review increases accuracy and thereby ensures a high quality of the study. Furthermore, a preliminary draft of the study was presented and discussed at a conference arranged by the Swedish Network for European Studies (SNES) in Malmö during March 2016. The study thus benefits from the input of experienced researchers from different disciplines.

The elaborate coding scheme allows for a high degree of consistency during the process of analysis because it structures the material in a practical manner. This further limits the impact of subjectivity and increases the replicability of the study. Finally, a transparent approach to the practical aspects, possibilities and limitations of the study serves to ensure a high validity.

6. Results

6.1 Overview

Semi-structured interviews with eight CHMP members were conducted via telephone, audiotaped and transcribed. This process of data collection resulted in 5,6 hours of audio- recording which, after full transcription, corresponds to 95 pages of written text. The length of the interviews ranges from 28 to 61 Minutes, with an average of 42 Minutes. During the first contact, some informants had expressed hesitation towards discussing ellaOne specifically. However, all of them agreed to talking about it during the interview situation, which contributed to a large and detailed body of material.

A purposive sampling strategy was applied when reaching out to possible informants and resulted in a sample of eight CHMP members who agreed to participate in the study. The CHMP is a group of individuals that are highly specialised as regards education and expertise, and appointed on the basis of national affiliation. It is thus of great importance to treat any information that could reveal the identity of informants with the highest possible confidentiality. Passages in the text that could contribute to the identification of individual informants were anonymised in the interview transcripts, for example by removing the name, national affiliation, position in the committee, and information on previous working places and university education from the text and replacing it with square brackets.

Some background information on the compilation of the sample can, however, be disclosed without jeopardising the confidentiality of the informants' identities. The sample covers a broad range of MS in terms of geographical and cultural aspects, EU accession and welfare state systems (including health care and medicines regulation). The informants have between 3-21 years of experience within the CHMP (and some even in other EMA committees and working groups) and the sample includes both ordinary members, alternates and co-opted members. All informants have a PhD, and the sample covers a broad range of medical specialities. Most of the informants have previously worked in hospitals and national regulatory bodies, and some even in the pharmaceutical industry. Almost all of the informants have previous international experience beyond the CHMP, for example by working in other countries or attending international conferences or other working-related commitments. The sample includes seven men and one woman. This distribution does not mirror the gender balance of the population, i.e. the CHMP members who attended the meeting during which the ellaOne opinion was issued, which is 33

men and 18 women. However, the inclusion of a female informant is valuable for the quality of the study, seeing that the case at hand concerns a medicine with the clear-cut focus group of biological women. Even though the CHMP members do not legally act in a representative capacity, the gender identity of decision-makers can be of relevance for their assessment of the product. There is no information available on the age of the informants, but considering their accounts of previous work experience, it can be assumed that their age ranges from early/mid-thirties to pension age.

6.2 Analysis

1) Shared principled beliefs

The first indicator regarding the existence of an Epistemic Community are shared principled beliefs in the form of normative ideas or behavioural expectations that the members of such a community have in common (Haas, 1992).

A recurring principled opinion that was brought up during the interviews concerns the appointment and mandate of the CHMP members and how they should act. All informants agree that in principle, they should act as individual experts, nominated upon personal merits rather than in a representative capacity. This provides a "value-based rationale for the social action of community members", as envisaged by Haas (1992, p.4), by demanding the scientific experts to act out of personal conviction and to the best of their knowledge. Furthermore, several informants repeatedly pointed out that they are talking in a personal rather than a professional capacity, and act accordingly in the CHMP.

> It [the CHMP] is a scientific body, and I might need to repeat to you, that the delegates are not delegates. They are nominees. […] So I personally am nominated as [name]. I am not a [country] delegate. I have not a [country] sign in front of my seat. As opposed to what you would see in Brussels at the Commission. It's my name. And I'm there as a person, as an expert, and not as a [country] citizen […] (Interview 1, p.9)

This emphasis on the appointment of persons rather than delegates shows that the members of the CHMP perceive that they are nominated due to their humanity and personal capabilities and

act as one person in a group of persons rather than a remotely controlled, nationally delegated spokesperson.

Furthermore, several informants mentioned that their role at the CHMP should be limited to that of a scientific expert, and that they should not have to take political decisions or take a national perspective on certain issues (see interview 1,2,6,8). In practice, however, working in regulation entails the responsibility to make risk-benefit calculations when considering a drug for marketing applications. As informant 8 pointed out,

> […] there is always also sort of a value judgement, and it has to be acknowledged that it is about science, it's mainly about science, but of course we come from different countries, from different cultures and we may differ a little bit in terms of values and how that gives weight to the uncertainties. (p.95)

The scientific experts at the CHMP thus have to consider the societal implications of their decisions, which in some cases may differ across borders due to diverse national circumstances.

Talking more specifically about the case of ellaOne, informant 2 noted that "[…] it was clear that there was more involved than a simple drug." (p.24). Similarly, informant 3 mentioned that "When you asked about ellaOne, it was something that was of big interest for us, not only from the scientific point of view but also a, I would say, socio-political issue." (p.26)

These citations illustrate the case selection of this study by depicting ellaOne as a special, extraordinary case. They further add weight to the idea of ellaOne as an example that deviates from the 'science-only' principle of the CHMP, which the informants advocated when asked about their role. Furthermore, these examples show that the informants see the CHMP as exercising agency beyond the purely scientific part of their evaluation, be it through establishing the risk-benefit ratio of products with certain societal implications, or through positioning themselves in response to pressure from the public or from political actors (cf. Interview 3, p. 38).

To further enquire about the principled beliefs of the informants with the help of a practical example, they were asked to elaborate upon what kind of access to emergency contraceptive pills they considered appropriate. This question can, beyond illuminating the informants' approaches to the ellaOne case, show in how far they share normative views regarding emergency

contraception. While not all informants explicitly answered this question, those who did agreed that emergency contraceptives should be available without prescription at pharmacies. Informant 3, for instance, stated that

> I think that there should be access. The way how it is now, that you go to the pharmacy and you ask for it. That's what I think. I don't think there is any scientific reason why it shouldn't be that way. That's my opinion. (p.37)

Similar formulations can be found in Interviews 4,6, and 8. This finding, however, should not be overrated since none of the CHMP members that had voted negatively towards the OTC-switch of ellaOne was included in the sample of interview participants.

In sum, the informants appear to share certain principled beliefs; however, it is not clear whether this can be generalised to include the entire CHMP. While the principled beliefs regarding the role and behavioural expectations of being a member of the CHMP are likely to be shared by all members, the more specific beliefs on emergency contraception and ellaOne may be affected by sampling bias.

2) Shared causal beliefs

The shared causal beliefs of an Epistemic Community are based upon a common professional judgement and "derived from their analysis of practices leading or contributing to a central set of problems in their domain" (Haas, 1992, p.3). They shed light on the causal relation between policy action and outcomes.

The most prevalent causal belief expressed in the interviews concerns impediments to a common European drug market and regulatory system. Several informants explained that due to the vastly differing systems of healthcare in the different EU countries, it can be difficult to agree upon certain topics. The pricing of medicines, the design of social security systems and access to healthcare vary greatly across the EU, which in its turn leads to a necessity to take into account these national factors when evaluating medicines in the European assessment procedure. As informant 3 pointed out,

> […] and also what can play a big role in this is the fact that you can have different systems of health care. For example, I don't know, like in [country], you can access a doctor every day, all the time. Even if you are from a small village, you travel

> maximum 20km and you access a doctor. In Scandinavia, I understand it can take hours until you get to a doctor. So I think that's also a huge aspect. That the health care systems are different. So that means that some risks can be bigger, which some countries don't consider as risks. (p.41)

Similar concerns were addressed by informant 4, who claimed that "[…] the diversity across Europe has been a huge impediment […]" (p.49) when it comes to ensuring a comparable and safe control of medicines across the EU. Even the geographic diversity of Europe was mentioned as a factor that complicates the work of the CHMP:

> The prevalence of microbial resistance to antibiotics in Scandinavia is low, in Southern Europe it's high. So a toxic antibiotic which might be of interest in Southern Europe is not so in Northern Europe. Similarly, I can't remember the example, but Greece is a mountainous country, hot and mountainous, and the Netherlands is cool and flat. So a product for cardiac impairment might be more successful in the Netherlands than it would be in Greece. (Interview 4, p.49)

These statements demonstrate a reasoning based on a causal link between the policy action that is taken on the EU level and which will affect the different regions and MS of the EU in very different ways, and the specific policy outcome that may be inconsistent. This causal relation thus has to be taken into account by the CHMP when evaluating medicines in the centralised procedure. As will be discussed in the analysis of indicator 8, the members of the CHMP demonstrate a high level of mutual understanding and empathy, which is based upon the acceptance of the fact that different national preconditions create different outcomes of the same policy action.

With reference to the ellaOne case, informants were asked how they would explain the divergent opinions to the CHMP decision granting non-prescription status. Informant 2 pointed out that "the whole registration process of ellaOne was more or less in line with politics which had already been followed in the past" (p.24). Informants 3, 4, and 6 expressed similar views attributing the divergent opinions to path dependence, and to what the policies in these countries had previously been. This belief thus illuminates the causality between established policies in MS and the respective CHMP members' action within the European assessment process.

Explicitly asked about the policy impact of the OTC-switch of ellaOne, all informants provided a very similar line of reasoning. Since all informants' home countries had previously allowed OTC-access for emergency contraceptives based upon levonorgestrel, they did not expect the ellaOne decision to have a big impact domestically. On a European level, however, most informants agreed that the access would be improved (see interview 3, 4, 6). Informant 8 even expanded this opinion to possible effects on the number of abortions, and the healthcare system in general:

> […] I hope that the easy availability to emergency contraception, not only ellaOne but also other products, serves a good purpose of reducing the number of abortions, with all the distress caused to a woman who is going to undergo an abortion, but also with regard to the healthcare costs. (p.93)

In sum, the causal beliefs of the informants, both regarding the general functioning of the European regulative system, and the specific case of ellaOne, coincide to a large extent.

3) Shared notions of validity

According to Haas, the shared notions of validity of a group of experts are "intersubjective, internally defined criteria for weighing and validating knowledge in the domain of their expertise" (1992, p.3). This indicator thus concerns the group's common appreciation of certain scientific methods of generating and evaluating knowledge.

In the context of the CHMP, the matter of assessment plays a great role in decision-making. The informants agree that each case is individual and has to be looked at on its own merit. The expertise of the individual members of the CHMP is thus crucial. This expertise consists of different elements such as the scientific education and experience of the experts, in combination with knowledge and understanding of the regulatory system and the national preconditions in the respective MS. It is then used to determine the risk-benefit balance of each individual medicine by validating the documentation brought forward by the pharmaceutical company that applies for a marketing authorisation in the European assessment. Even though there is legislation to take into account, much of the requirements for the pharmaceutical companies' applications, as well as the standards for assessment for the experts, are in the form of guidelines. Therefore, the matter of assessment is crucial, and the difficulty of this task is acknowledged among the experts. As informant 3 put it,

> […] of course a guideline is not a law. It's not something that you can't cross, and then it's a matter of assessment to see, when somebody doesn't follow the guideline, if it's still acceptable or not. And that is the moment when actually the expertise comes in. (p.32)

The expertise of the members of the CHMP is thus a tool that is necessary to fulfil the responsibility of exercising good judgement, and making sound assessments. While this does not explicitly concern methodological standards applied in the medical sciences, it gives insight into what factors and knowledge the informants consider important when forming an opinion.

Expanding this argument to the day-to-day work of the CHMP, i.e. the assessment of applications for marketing authorization, there is a high degree of consistency when it comes to the informants' view of what determines the quality of studies submitted by pharmaceutical companies.[10] All informants referred to the guidelines and recommendations that are applied within the EMA as well as general standards in medical science, such as Good Clinical Practice (GCP) and ICH (International Conference on Harmonization). While those guidelines and recommendations provide some overall orientation, they do not prescribe exactly how clinical trials need to be conducted in order to prove that the medicine is sufficiently safe and corresponds to the producers' claims with regard to efficacy etc. The majority of informants (1,2,4,5,8) explained that the methodological requirements depend completely on the individual product at hand and the type of disease it aims at treating. For instance, the sample size, the number of studies, and how they should be weighed is up to the expert to rate. Again, this approach highlights the importance of expertise and the matter of assessment.

Asked more specifically about what constitutes a sound methodology in studies, several informants mentioned that they usually prefer randomised, placebo-controlled studies (Interview 1,2, and 6). This is, however, not based upon strict instructions or rules, but on the personal development and experience of the individual members. One informant explicitly stated that "[…] I'm a conservative person, I like a randomised trial with a good quality and size, and even better two of them." (Interview 6, p.65). This reference to the personal level and individual preferences further highlights the importance of personal expertise and the agency of the CHMP

[10] In the centralised marketing authorisation procedures, pharmaceutical companies submit documentation on the research that has been conducted regarding the respective product in order to support their claims. This documentation usually provides the basis of the assessment conducted in the CHMP.

members as experts rather than delegates. Discussing the scientific approaches of the CHMP members regarding methodology and knowledge validation from a comparative perspective, Informant 8 mentioned that

> Of course we have different members, and we all come with our perspective on things, so there could be differences. But of course we are all, to a large degree, trained the same way, and look at methodology the same way. So there's a huge overlap. But of course there are also nuances and differences between members, how they look at some issues. But I think overall, we come from the same sort of school of thought in terms of methodology and how things should look. (p. 89)

This points towards a common understanding of methodological aspects among the members of the CHMP, which is further confirmed by the informants' descriptions of methodological considerations with regard to ellaOne, and emergency contraceptives in general. Upon the question whether they treat these kinds of applications the same way as other drugs when it comes to methodological requirements to the supporting documentation, most informants answered positively. This shows that there is a (possibly implicit) common understanding that the knowledge utilised to test medicines with specific social implications should be weighed just as in other cases.

4) Common policy enterprise

The common policy enterprise of an expert group concerns "common practices associated with a set of problems to which their professional competence is directed, presumably out of the conviction that human welfare will be enhanced as a consequence" (Haas, 1992, p.3). It implies that the group acts as more than the sum of its parts and strives towards a common goal.

The informants are in agreement about their ultimate goal, both in general, and when talking about the ellaOne case specifically – the safety of the European patient. This corresponds to Haas' definition of a common policy enterprise as being directed towards the enhancement of human welfare. High safety standards for medicines can be seen as a goal aiming for greater welfare. In addition, the work of the CHMP is limited to medicines intended for human use – the human dimension of this goal is thus clear. However, the informants do not agree on how to achieve the highest possible safety. Informant 1 stated that "I think the principle is the safety of the European patient. And of course, if something is dangerous in Greece, it's probably

dangerous in Estonia likewise" (p.12). The safety of medicines is seen to be achieved the same way in different countries due to the biological preconditions of citizens being equal across the EU.

Informant 4 took a contrasting position, saying that the diversity of MS can give rise to variations in the use of medicines:

> The prevalence of microbial resistance to antibiotics in Scandinavia is low, in Southern Europe it's high. So a toxic antibiotic which might be of interest in Southern Europe is not so in Northern Europe. Similarly, I can't remember the example, but Greece is a mountainous country, hot and mountainous, and the Netherlands is cool and flat. So a product for cardiac impairment might be more successful in the Netherlands than it would be in Greece. (Interview 4, p.49)

This discrepancy in how diverse or equal the informants see the European medicines market reveals two entirely different rationales as to how high patient safety can be achieved. While the goal of enhancing human welfare through high patient safety is present in both statements, the practices to address this challenge do not seem to coincide.

Despite the afore-mentioned difficulties that some informants see in the EU-wide regulation of medicines, all of them are very positive to the system in general and see a great added value in their cooperation at the EMA. They consider that this type of European cooperation has substantive advantages when compared with a sheer coordination of national system. There are some minor suggestions for improvement, but broadly speaking, all informants seem to have confidence in the system. This finding is pronounced in the following quote by informant 8:

> Yes, of course there is lots of things where I could see some improvement, but on a general level, I think the European regulatory system is working well. I think the vast majority of our decisions are good and well-qualified. So I think there's a lot of strength in the European system. And I would hate to go back to the old days where we had solely national approvals. (p.91)

This quote indicates strong feelings beyond the professional appreciation of the practicalities of EU-level regulation. The European system is portrayed as a modern and progressive achievement that fits the post-national reality of a common European market for medicines. Similarly,

informant 1 expressed appraisal for the European system, saying that "at the end, you have thousands of experts contributing once in a while, not on a daily basis of course, contributing to the system. And that's unique for Europe." (p.11). The informant is aware of the uniqueness of the European context and the statement insinuates that the EMA is seen as more than the sum of its parts due to the collective expertise utilised in the European system.

One problem to the European system, as addressed by several informants, concerns communication with the public. Informant 1 expressed discontent with the knowledge about the EMA from the side of the general public as well as medical professionals:

> You know, my son is a doctor. He did not know what the EMA was. He knew FDA [US Food and Drug Administration]. But when I started, and nowadays of course, he knows. Or ask here in my hospital, people never heard about the EMA. They all know the FDA, nobody knows the EMA. So there is a huge problem to me, of communication, outside the industry, of course industry knows, but in the citizens. About the agency, what they do. (p.14)

Informant 1 contrasted the group that he is a part of, the doctors working for the EMA, with 'regular' doctors who work at hospitals and may not have heard of the EMA. This type of demarcation indicates that the CHMP is seen as an enclosed group of scientific experts with the special experience of working in regulation that distinguishes them from other individuals with the same professional qualifications.

A final indicator of the common policy enterprise of an Epistemic Community are attempts to extend its mandate. Several of the interview informants brought up the legal status of the EMA and the CHMP, informant 7 for instance mentioned that "Because EMA is one of the European institutions, it is one of the European agencies, therefore Europe communicates with Member States via diplomatic channels" (p.74). Disregarding the simplified description of the communication process, the most striking formulation in this citation is the reference to the EMA as a European institution, which presents a clear overstatement. Another informant touched upon the formal competences of the CHMP, saying that

> It's very stimulating but also something that is associated with a high degree of responsibility because we are the committee that basically puts new medicines on the market in Europe, at least the ones that are centrally approved. Of course it's not us

> who take the formal decision, that is taken by the European Commission. But we advise the European Commission. So in that respect, it feels as if we are the committee that sort of approves new medicines in Europe. Even though from a formalistic perspective, that's not entirely true. (Interview 8, p.85)

This statement showcases awareness of the formal limits of the competences of the CHMP, and the EU-level regulatory mechanisms. The described difference between what the informant calls a 'formalistic perspective' and reality corresponds to the de-facto regulatory status that has been attributed to the EMA (Groenleer, 2009). There are, however, no explicit desires to extend the formal mandate of the CHMP. This is not surprising seeing that the de-facto regulatory status provides the CHMP with a relative freedom of both decisions and accountability. An extension of formal competences would put the CHMP under a much higher degree of scrutiny, and possibly constraint its freedom.

Overall, the common policy enterprise of the CHMP is not as distinct as the previous three indicators. While the CHMP thrives for the same goal and acts as more than the sum of its parts, there are different understandings of how this goal can be achieved. Furthermore, the CHMP does not attempt to extend its formal mandate and rather advocates for a maintenance of the current legal status, which enables its members to act largely unconstrained from the demands for accountability that actors with greater formal competences need to address.

5) Previous contact between members

An Epistemic Community is likely to emerge if its prospective members have previously met in different circumstances (Cross, 2015). A few of the informants stated that they had gotten to know other experts who were already members of the CHMP before they were nominated themselves. Members who had had long scientific careers before starting to work in regulation, and especially those who act within highly specialised areas, had previously met at conferences, or associations dedicated to their specialities (Interview 4 & 6). Even previous work 'on the other side of regulation', i.e. in the pharmaceutical industry, could serve as a setting for interaction (Interview 8). However, the majority of informants had not met their colleagues in person before their nomination to the CHMP. Informant 4 explained that

> You read assessment reports and so on, so you know the names. And when I started attending as an appointed member it was interesting to put faces to the names, some of which I was familiar with. (p.44)

Similar formulations can be found in interview 2, 3, 5, 6, and 7. The previous contact in these cases was limited to knowing who the other person was, and possibly dealing with the results of their work. Overall, the majority of informants did not meet prior to their cooperation in the CHMP in any setting that would enable grand discussions or foster personal relations on a deeper level.

6) Selection and Training

Epistemic Communities with comparable selection and training experiences, a consistently high level of expertise and highly competitive selection processes are likely to have a high degree of internal cohesion (Cross, 2013a).

The analysis of this indicator is twofold – it comprises a comparison of the actual professional backgrounds of the informants, as available on the EMA website, as well as their perceptions, as narrated in the interviews. Although the trajectories and career paths of informants are very individual, some common denominators can be discerned. All informants have a high level of education with at least a PhD degree, and comprehensive specialist training. All of them have some kind of practical working experience as a doctor, most of them from public hospitals, and all have worked at their respective national agency for medicines regulation.

The experts' own perceptions of each other's (and their own) backgrounds differ – some informants (2, 6) said that the professional backgrounds of CHMP members are very different due to age, specialities etc., whereas others said that they are very similar (Interview 4, 8). While this points towards a varying characterisation of the CHMP from the inside, different backgrounds do not necessarily preclude a strong Epistemic Community. On the contrary, one could say that the different backgrounds of CHMP members, in sum, form an entity in which every member, due to her or his individual profile, constitutes a crucial part. Informant 2 said that

> Well, I mean, I think that's an enrichment, because you have various people with various expertise, and you have clinicians, and you have more, you know, pharmacists, you have quality people, so that is a heterogeneous group, I think. Everybody has

> expertise so I think in total we cover, I would not say the full spectrum, but it gives a very good background, very good expertise. (p.17)

This implies that the diversity of CHMP members is an advantage, since it enables the community to gather a comprehensive medical expertise that cannot be achieved by a professionally homogenous group of experts. Furthermore, informant 5 mentioned that recruitment for the co-opted positions in the CHMP differs from the regular appointment procedures. When expertise on a certain field is missing, experts can apply for a co-opted position and thereby become a member of the committee. This further points towards the CHMP as a professionally diverse community that thrives to cover as many medical fields as possible. This division of fields of expertise demands mutual trust and thereby strengthens the ties between community members.

Since hardly any information on the appointment processes of the CHMP is available on the EMA website, the interviews served to collect factual information about how the selection and nomination of scientific experts takes place in different countries. Comparing the informants' accounts of their appointment, the procedures seem to differ greatly between countries, depending upon the national traditions as well as the institutional set-up of the respective national system of medicines regulation. Furthermore, the informants do not have any insight into the procedures of other countries, which means that they do not know exactly how the appointment of their CHMP colleagues has occurred. Informant 6 raised the issue of political influence on the compilation of the CHMP, saying that "There are some countries where there is a political influence. In other words, if the government changes, then the CHMP delegate changes." (p. 45). Due to the lack of transparency on appointment procedures, this might be difficult to investigate more closely. However, it hints towards a politicisation of scientific expertise even in the case of the seemingly politically independent EMA.

In addition to the national appointment procedures, nominees for a position in the CHMP have to be approved by the EMA during a consultation period, in which even other MS can comment on the nomination (see Interview 8). This European part of the process is equal for all MS and presents a way to secure that new members possess a sufficiently high level of expertise.

Several informants pointed out that the nomination to the CHMP is not very competitive, and that it is hard to find candidates due to relatively low wages (as compared to the industry), a high workload, and the practical difficulties of travelling to London on a monthly basis (Interview 1,

4, 6). Informant 6 went as far as claiming that the work at the CHMP "eats your private life" (p.63). The incentives for being a member of the CHMP thus seem to be outweighed by the difficulties, which makes it less attractive to possible candidates and thereby might discourage otherwise well-suited candidates from taking the position.

A final question regarding the selection and training of CHMP members regarded the beginning phase of CHMP membership. According to informant 3,

> There is not any training per se. Of course you get some documents that tell you how everything works, how you are supposed to attend and all of this administrative work, but I think that the training is made by the other member from your country. […] But there is not anything like you would go for a summer camp and learn how to work for the CHMP. (p.29)

Similarly, another informant remembered great confusion in his first months of being a member:

> And I had no idea of what regulation was at the time when I started, and you can quote that, because I often mention that to new members when they join, during the six first months of my attendance in London, I was really asking myself what I was doing there. (Interview 1, p.2)

These statements depict a hardly existent and very inconsistent training experience. While informant 3 obtained guidance from the other CHMP member from the same country, informant 1 pointed at confusion and insecurity regarding the purpose of his attendance. Beyond illustrating the lack of common training routines, the statement by informant 1 showcases solidarity towards new members of the CHMP.

In sum, the selection and training experiences of the CHMP do not point towards a highly cohesive Epistemic Community. Even though the level of expertise is consistently high and there is a mutual solidarity, the very different professional trajectories, differing appointment processes, a lack of shared training routines, and a low degree of competitiveness indicate a weak cohesion.

7) Meeting frequency and quality

According to Cross (2013a), the frequency with which an Epistemic Community meets, as well as the quality and form of such meetings, influences its internal cohesion.

The members of the CHMP gather in a number of different contexts, most of which can be classified as either formal meetings, or informal meetings and social activities. The monthly plenary meetings in London usually take three working days and occur in a formal setting with a strict agenda and a large group of attendants. Furthermore, some CHMP members are also members of working groups at the EMA, other EMA committees, or temporary scientific advisory groups (SAGs). This provides the opportunity for CHMP members to meet in other professional circumstances, dependent upon the personal specialities and interests of the members. Each case or dossier that is processed by the CHMP is appointed to a rapporteur and a co-rapporteur from different countries. While co-rapporteurship in theory provides an opportunity for meetings and deepened cooperation, most coordination in practice happens via phone and e-mail (see Interview 7).

Several informants (1, 3, 6, 8) explained that a two-day informal meeting is held for the CHMP twice a year, usually by the country who chairs the Council of the EU. In these meetings, the discussions can revolve around bigger issues and provide the opportunity for an exchange of views beyond individual dossiers. These meetings are not organised by the EMA, but depend upon the initiative of individual MS. Informant 1 mentioned that "that's not within the regulation, that's not written anywhere, that's more an old tradition of, I would say, civility between the presidencies." (p.7). This type of informal tradition signifies a community and agency beyond formal expectations and the legal and organizational framework of the EMA.

Furthermore, various social events and activities are arranged in connection to the CHMP plenary meetings. Informant 4 reported that "There's been, in the last few years, a 'Ladies' Night Out' [chuckles], we have a party once or twice a year". Similarly, Informant 5 gave examples of what these social events can look like:

> And also we have social events, in the evening you go have dinner with your colleagues and for two or three years we have a picnic-party, as we say, and everybody brings some speciality from his country, wine, food and so on, and then it's a walking dinner cause that makes it easy to talk to each other, and this also of course has in order to come up with a good ambience. (p.57)

When it comes to the quality of meetings, all informants seem content and appreciative of the CHMP habits. The informants agree that the meetings are very productive and rewarding.

> And I was more surprised from the health perspective, how everybody can sit in one room for such a long time and not have any physical problems from it. But then I understood that it's so fascinating that everybody actually does sit there and doesn't mind to sit there for over twelve hours with just two coffee breaks, one in the morning, one in the afternoon, and one lunch. […] people just really sit there and work, and talk, and sometimes I'm really amazed how on wednesday evening – the third day of the meeting, we have very, very fruitful and very big discussions sometimes. People are still able to discuss very difficult situations and topics. (Interview 3, p.31)

This citation illustrates how seriously the CHMP meetings are taken by its members, and that the long and work-intensive days during the plenaries are very productive. In sum, the meeting frequency and quality of the CHMP appears to create highly favourable conditions for an internally cohesive Epistemic Community.

8) Shared professional norms

The shared professional norms of an Epistemic Community concern different procedural aspects of its operation, such as consensus-building, standards with regard to protocol and speaking time, etc. (Cross, 2013a).

Most of the informants stated that the CHMP reaches consensus most of the time, and that that is the official aim of the committee's decision-finding. Furthermore, the interviews reveal that the role of the chairman is very important in negotiating compromises while trying to find consensus, and that he is highly respected within the CHMP (Interview 1, 3, 4). Other strategies that are used when there is a lack of consensus are the convening of SAGs, preliminary votes, the postponing of votes, and especially discussions. Several informants (3, 5, 6) described that the concerns of individual members are taken very seriously and that the committee tries to address those concerns rather than convincing the members. When consensus cannot be reached, the divergent opinions are accepted by other CHMP members, and the discussion does not continue outside of the respective meeting:

> […] once the discussion has been done, it's over. Okay? We are not going later and saying 'What, we didn't get your votes there' and blah blah blah, no, that's not the case.

> We accept other positions, we accept other votes, and that is important (Interview 5, p. 57)

This acceptance for different views corresponds to the mutual understanding that the informants describe when talking about the ellaOne case as an example. All informants said that they could understand the reasoning behind the divergent opinions, and that the CHMP members have to take into account national preconditions when casting their vote. Even though no consensus was reached in this specific case, the members had a common understanding and could discuss on a level playing field:

> Of course I can understand the point of view of Malta, I can understand the point of view of Poland, for example, because they have very different views on this. And it's not a fight, it's a cooperation. And I think that everybody can understand. (Interview 3, p. 42)

This high level of tolerance for each other's opinions creates the impression of an open community that values the individuality and autonomy of its members. At the same time, however, the question rises whether shared principled and causal beliefs can exist in a community that tolerates and respects fundamentally divergent opinions.

9) Common culture

The common culture of an Epistemic Community regards the purpose and identity of the group. More specifically, if the group members share a common sense of purpose, and they identify with each other, they are likely to constitute an internally cohesive Epistemic Community (Cross, 2013a).

Several informants confirmed that the CHMP has a rather strong identity as a group. Informant 4 stated that

> It's a camaraderie, which has grown up over the years. […] you know, you're there, you're travelling, you're getting up, you're leaving home on Sunday evening or getting up early on Monday morning, and then you work three very long days together, and you know, […] that generates community, a feeling of community. (p.48)

While this statement signifies a common identity based upon the practicalities of their work, informant 6 related it to the outside perception of the CHMP, saying that "The CHMP wants to

be seen as a group and people feel belonging to it." (p.67). Regardless of the basis of the common identity of the CHMP, it is clear that this identity is limited to the immediate setting and the members of the CHMP:

> Well, CHMP, whatever it has been called, is older than the EMA actually. So CHMP has […] been well-established for some time. The EMA has struggled to find its identity and it's struggling being a secretariat and a scientific agency. So they are in trouble of finding their common identity, but the CHMP as a scientific committee is pretty well-established […]. (Interview 6, p.67)

The common identity of the CHMP thus seems to be independent of its formal embeddedness within the EMA. It presents a clear distinction between the scientific expert members of the committee, who work for their national agencies and travel to London once a month, and the EMA with its permanent staff and secretariat, who do not share the experience of double affiliation, travelling and plenary meetings.

In order to gain insight into the sense of purpose of the informants, they were asked several questions enquiring about their commitment to, and opinions on the European system of medicines regulation. The answers reveal an ambiguous relation to the EU and European integration.

On the one hand, all informants are supportive of the system in general and see the point of cooperating across borders. One informant stated that "I really think that it's an example of how Europe can work together. And I really think it's for mutual benefit." (Interview 3, p.21); similar formulations can be found in interview 3 and 4.

On the other hand, several informants expressed doubts whether a group of countries as diverse as the EU can be jointly regulated:

> What the Commission does is treat the European Union as a market. And you know, the issues such as geography and antibiotic resistance are irrelevant if you consider it as a market. But it's not a market." – "What is it, then?" – "[chuckles] It's a diverse collection of countries which has some political unifying factors. (Interview 4, p.50).

This passage captures the criticism that is directed towards the European institutions on the grounds that specialist knowledge is not sufficiently involved into the legislative process (see also Interview 5, p.59).

Three final factors that are prevalent in the interviews and that fall under the scope of "common culture" are community, solidarity and mutual trust.

Both the informants' answers during the interviews, and possible informants' communication prior to the interviews reveal that specific expertise is valued very highly. Many CHMP members referred me to the person who "knows best", or who has a specific expertise or insight into the matter of enquiry. Thanks to the members' knowledge of each other's professional strengths and specialities, they know who is the right person in the group to answer a specific question. This way, the community forms an entity, and every expert with his or her individual experience and expertise is a part. This collective approach presents a loyalty to the basis of the very existence of the group – the gathering of a broad spectrum of specific scientific expertise. It further shows that the experts seem to be striving for the greater good rather than their personal merit.

Informant 8 said that "I sense a big feeling of solidarity and helping out each other in the committee." (p.91). This solidarity was further confirmed in a practical example given by Informant 1. As described above, an informal meeting is arranged every half year by that CHMP delegation whose MS is chairing the Council. On one occasion, the respective CHMP delegation was not able to host the meeting due to budgetary constraints in their national agency. In that case, another delegation stepped in and arranged the meeting instead. While we cannot exclude that there was self-interest in the form of reputation and credit involved in this case, it presents a solidarity between MS not only in the formal framework of the EMA, but even in informal and social situations.

Talking about the European assessment procedure, informant 3 highlighted that "it actually works on trust, I would say. Because we trust that the rapporteur and co-rapporteur, the other countries who review the documentation, that they did it correctly." (p.27). This feeling of mutual trust can be related to the informants' great appreciation of expertise. They trust that the group member who is charged with a task executes that task to the best of their specialist knowledge, and that is why they consider that the person with the greatest expertise within a certain field is best suited to answer questions or be a rapporteur in that field. The strength of the CHMP thus lies in its

members' personal experiences and abilities, but also in their mutual trust, and knowledge of each other's backgrounds. Despite some criticism towards the institutional set-up of European medicines regulation, a strong common sense of purpose and identity, mutual trust, solidarity and community point towards a common culture within the CHMP.

10) Shared Culture and Professional Norms

The shared culture and professional norms of a group of experts, i.e. the sum of indicators 6-9, signify the existence of an Epistemic Community.

The selection and training of the CHMP consists of highly differing professional backgrounds and appointment procedures, a lack of shared training routines, and a low level of competitiveness. Despite the consistently high level of expertise that is shared by the informants, an Epistemic Community is not likely to emerge based on the basis of this indicator.

The conditions are more favourable regarding the meeting quality of the CHMP. Their meetings take place in various settings and forms – there are formal meetings in plenary and in smaller, more specialised working groups, as well as informal meetings and social activities that encourage discussion and foster personal relations. The quality of meetings is very high and the informants appreciate the fruitfulness of discussions.

When it comes to shared professional norms, the CHMP is characterised by a common, very high degree of respect for the chairman, an appreciation of deliberation as a strategy of consensus-building, and tolerance and understanding for each other's opinions. This creates favourable conditions for the emergence of an Epistemic Community.

The common culture of the CHMP features a strong group identity independent of formal embedding, high appreciation for expertise, a feeling of solidarity, community, and mutual trust. It is thus a very strong common culture that seems to span the entire committee.

While the selection and training of the CHMP does not provide a sufficiently strong ground for the existence of an Epistemic Community, its meeting culture, professional norms and common culture showcase many characteristics of an Epistemic Community. In sum, these elements point towards shared culture and professional norms as an indicator for Epistemic Community existence.

7. Discussion

The research questions of this thesis concern how the CHMP constitutes an Epistemic Community, and how internally cohesive that Community is. Since both questions are interlinked, their answers cannot be treated separately. The initial hypotheses stipulated that the members of the CHMP do constitute an Epistemic Community, and that this Community has a low degree of internal cohesion.

The findings suggest that an Epistemic Community does exist, confirming the first hypothesis. In contrast to the second hypothesis, the cohesion of that Epistemic Community appears to be rather strong. The explanation for these findings can be found in the width of the present Epistemic Community. Rather than comprising the entire CHMP, it seems to be limited to a smaller group of people, including only certain members of the committee. The results indicate an Epistemic Community within the CHMP rather than an "Epistemic Community CHMP".

It can be assumed that the scientific experts who agreed to participate in an interview are generally more open and informative to the public than their colleagues who did not want to take part. All of the informants shared principled beliefs regarding the ellaOne case, and all of them voted positively on its marketing authorization modification. Due to the divergent opinions in the case, it is clear that there are committee members who do not share this principled view (or at least do not act in accordance with it). These members can be assumed to be rather conservative, either from a scientific point of view (i.e. that they exercise great precaution and demand high certainty in products), or from a personal or political point of view. This distinguishes them from the Epistemic Community which the subjects of this study belong to, and which can be regarded as a type of progressive alliance between the more liberal members of the CHMP.

Within this Epistemic Community, the internal cohesion appears high due to the shared culture and professional norms of the CHMP (Indicator 6-9). These cultural and normative aspects include for instance the high quality of meetings, the different types of informal and social gatherings, common procedures of consensus-seeking, mutual respect and understanding and a strong shared identity. However, the members of the Epistemic Community that is present within the CHMP share beliefs and opinions that go beyond the norms and culture of the work place CHMP. These beliefs affect their opinions in cases that are conflictual on a social or political level and thereby strengthen the bonds between the members of that Community, at the same time

creating a distinction between them and the rest of the committee. When controversial situations or cases are rooted in principled beliefs of different actors, it thus seems unlikely that an Epistemic Community can exist between those actors.

As for the delineation of the Epistemic Community within the CHMP, it is difficult to define who is a member of this Community, since the sample of this study does not comprise all members of the CHMP. Relating this to the theoretical framework of Epistemic Communities, it shows that Epistemic Communities that act within formal institutions can be difficult to trace and characterise. While the members of Epistemic Communities outside of formal settings have to actively seek out each other in order to cooperate, a formal context enables members of Epistemic Communities to interact under more discrete and effortless circumstances.

The formal setting in which an Epistemic Community is embedded has implications for its longevity. The members of the CHMP serve for a period of three years (with the possibility for renewal), and the compilation of the committee changes ever so often. In how far the Epistemic Community within the CHMP will continue to exist and exercise agency thus depends upon the individual members.

In addition to extending the theoretical understanding of Epistemic Communities, this study contributes to the empirical knowledge on the European Medicines Agency. The findings confirm the de-facto regulatory status that has been assigned to the agency in previous research, and they illuminate the working culture and self-perception of the scientific experts working there. They further contribute to the understanding of the special position of scientific experts' involvement in policy-making processes, and the blurred line between science and politics. The scientific and the political part of policy-making are not separable as long as the task of scientific experts is to determine the balance between the costs and the benefits of a product. How an individual expert weighs these costs and benefits does not only relate to the purely scientific expertise. It relates to the values that are assigned to those costs or benefits and the resulting assessment of uncertainties.

Adding to the broader field of research on EU agencification, the findings of this study show that the appointment procedures to the CHMP lack transparency and consistency. This study is limited to one of seven committees in one of the more than 30 decentralised EU agencies, but the decisions of the individual members of this committee have a great impact on the availability

of medicines. Even though ellaOne is a special and rare case, it greatly affected the access to emergency contraception in the concerned countries, triggered further changes in some countries[11], and affected women's abilities to exercise their reproductive rights. The staffing of scientific experts' positions in EU agencies is thus extremely important and goes hand in hand with a great responsibility. The current procedures for appointing scientific experts as members to the CHMP differ a lot between countries and lack transparency, thus casting doubt on their legitimacy. There is very little information available to the public as to how the selection and nomination processes take place. A clearer and more consistent system of appointment would be an important step to addressing the democratic concerns that arise due to an increase of technocratic forms of governance.

For EU policy-making in general, the results show that not only the political decision-makers matter, but that science can be political. In many cases, there is no purely political or purely scientific side to policy-making. Both sides are intertwined, and politically influenced value judgements have an impact on scientific evaluations. It is thus problematic that the decision-makers during the scientific, and seemingly non-political part of the policy process cannot be held accountable to the same degree as the politically elected actors. This sheds light on an underestimated angle of the democratic deficit of the European Union. Questions of democracy are not restricted to the EU institutions, but they also concern other EU-level actors, perhaps even more so if those actors have limited formal competences and are therefore able to operate independently and sealed off from public scrutiny.

To further explore Epistemic Community activity within the CHMP, written material such as meeting protocols, or participant observation and further interviews would be suitable. The use of already existing material would circumvent the limitation of material towards the participants of the study, which presents a shortcoming of this study. Furthermore, longitudinal quantitative studies could investigate the voting patterns of different countries and individual experts.

The broader setting of the EMA holds comparative potential, either by looking at other policy areas, for instance the food safety and the European Food Safety Authority (EFSA), or at other

[11] Shortly after the OTC-switch of ellaOne, even emergency contraceptives based on LNG were given non-prescription status in Germany (see Pro Familia, 2016).

geographic settings, such as the US system of medicines regulation with the Food and Drug Administration (FDA).

8. Conclusion

By illuminating the Epistemic Community that is active within the CHMP, this study has highlighted the importance of studying such communities that exist within formal institutions but not necessarily coincide with their organisational structures. In this case, the Epistemic Community was found to consist of certain members of one committee of a decentralised EU agency. Even though the working culture and norms that are shared by a group of scientific experts might seem beneficial for the emergence of an Epistemic Community, insufficiently strong shared beliefs and agency of that group may hinder the existence of such a community.

Furthermore, this study has shown that divergent cases can be a helpful practical tool for probing the limits. By illustrating the most extreme situations of controversy that a group of scientific experts is exposed to, it enables the analysis of that group as an Epistemic Community. As regards the study of scientific experts and their role in policy-making, it is important to not only focus on underlying political motives that individual experts might have. Even their cultural and epistemological background influence value judgements and thereby their risk-benefit calculations and risk assessment.

The European Medicines Agency proved to be a very fruitful and highly relevant setting for the analysis of the role of scientific experts. Their work, and the EU-level regulation of medicines in general are likely to increase in relevance with higher life expectations, the advance of scientific development and the pharmaceuticalisation of society. It is thus important to illuminate scientific and technological development from a social and political perspective, and to critically examine the phenomenon of EU agencification.

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Appendix 1: Thematic Scheme

	Attribute	Indicator/How to detect and interpret the attribute	Helps identify/assess...	
1	Shared principled beliefs (Haas,1)	Enquire about normative beliefs and behavioural expectations	Existence of EC	
2	Shared causal beliefs (Haas,2)	Shared professional judgement. Ask about causality between policy actions and desired outcomes	Existence of EC	
3	Shared notions of validity (Haas,3)	Scientific methods of validating knowledge & claims	Existence of EC	
4	Common policy enterprise (Haas, 4; Cross, 1)	Act as more than the sum of its parts. Value added of common ground at EMA as opposed to sheer coordination between MS? How do the scientific experts see the CHMP and the EMA? What is their ultimate goal? Is it a common goal? Does the group produce outcome beyond the expectations of its formal functions?	Existence of EC	
5	Previous contact between members (Cross, 2)	Have the members met prior to their contact in the EMA, in different circumstances? Have they previously interacted outside of work? Do they share networks? In what kind of situations have they previously interacted?	Existence of EC	
6	Selection & Training	Highly competitive selection and promotion, consistent procedures across national borders, high level of expertise, shared training experiences	Cohesion of EC	10) Shared culture and professional norms → 7)-10) in sum indicate the existence of an EC
7	Meeting Frequency & Quality	More face-to-face time = stronger ties. Especially informal meetings in smaller groups. Do the members meet outside of work, and informally?	Cohesion of EC	
8	Shared professional norms	Protocol, procedure and standards of consensus-building. Conflictual cases → Do they have a common understanding even in situations of disagreement? Is it possible to find compromises?	Cohesion of EC	
9	Common culture	A common sense of purpose, identity, symbolism, heritage. What does it mean to them to work in the CHMP? Do they identify with each other? How would they describe their purpose?	Cohesion of EC	

Appendix 2: Interview Guide Phone Interviews

Clarifications:

This interview will contribute to the research project resulting in my Master's thesis in European Studies at the University of Gothenburg. Your participation is voluntary, and you can choose to not answer any of the questions. Your identity will remain confidential, and the only information disclosed about you in the thesis will be that you are a member of the CHMP.

Is it ok if I record this interview?

(This is to ensure that I have an accurate and detailed account of what you tell me and that I am able to quote correctly).

Start with some questions about your background

Could you say a few words about your professional background?

How long have you been working at the EMA?

What does it mean for you personally to work at the EMA?

Did you know any other of the current CHMP Members before you started at the EMA? Under what circumstances have you met them?

How do you perceive that the professional backgrounds of CHMP Members from the different countries differ?

What is the selection/appointment process for the CHMP in your country?

Do you perceive that there are major differences compared to other countries?

Questions about the work of the CHMP

How often (beyond plenary meetings) do you meet the other CHMP members?

What do these meetings usually look like (Where, how many people present, why these people)?

Do you meet some colleagues more frequently than others? Why?

Do you perceive that there are differences in how CHMP members from different countries behave in meetings or discussions? (Here I'm thinking about practices such as speaking time, sticking to the protocol etc)

If members disagree on a topic, what are the processes to find consensus?

In situations of disagreement, do you perceive that CHMP members tend to break into similar coalitions? Do you think that there is more agreement between members from certain MS?

The review of studies on specific medicinal products is part of your task when evaluating medicines. What factors do you personally consider important for the quality of such studies?

With regard to the material that you base your assessment on, do you perceive that all CHMP members have the same demands or standards on methodological aspects?

Question about your relationship to national agency

Do you get specific instructions or advice from your national agency, or do you work independently, based upon your scientific knowledge?

Do you perceive that this is the same for all CHMP members or are there different national traditions?

Questions about the EMA and its role in European integration

Do you perceive that there is a sense of common identity among the members of the CHMP, and the EMA? How do you think that this differs from your home agency?

In your group (CHMP), do you perceive that people are generally pro-EU (favor more integration) or rather negative?

How do you perceive that your work (CHMPs work) impacts the policy outcome on the EU and national level?

Taking into account the role of the CHMP in the current institutional arrangement of the EU and the EMA, do you consider that role appropriate, or should it be different?

Taking a step back, do you think that the EU's system of medicines regulation is appropriate/ well-working? (For example compare to US system with the FDA)

In an ideal world, what role do you consider that you as scientific experts should play in the regulation of medicines?

As you know, I am particularly interested in the process before the marketing authorization variation of the emergency contraceptive pill ellaOne.

(If you can't, or don't want to talk about ellaOne, is there any other example of a medicine that the CHMP members had very different opinions about? Can you talk about that example instead?)

What kind of access to emergency contraceptives do you consider appropriate? How do you think that it should be regulated?

What factors do you think need to be taken into account when evaluating an emergency contraceptive for marketing approval? Do you perceive that all CHMP members agree on this, or are there people who think that certain aspects are more important than others?

What practical implications do you think that the OTC-switch of ellaOne has had so far, or will have?

Questions about process within CHMP prior to opinion. I know that there were very different national legislations prior to the discussions in the CHMP, and the divergent positions in the opinion show that even afterwards, some MS did not agree with the majority.

Was there any point at the process during which you perceived that there was a possibility for all of you to agree?

Do you think that there was any CHMP member who changed their mind during the process or was on the fence? Why/ why not?

(Do you perceive that anyone tried to persuade anyone else?)

In the ellaOne case, some CHMP members regarded the uncertainties that remained despite previous studies as more important than others. Why do you think that is?

Do you perceive that the members who had divergent opinions did so because they sincerely think that the risks/uncertainties of ellaOne outweigh the benefits? Do you consider this a purely scientific opinion or was there another kind of political or philosophical agenda at stake?

Even if you did not all agree on this specific case, do you feel like you had a common understanding and could have reasonable discussions?

Could you situate the ellaOne case in the broader body of all CHMP cases? Is it a typical case? A representative case?