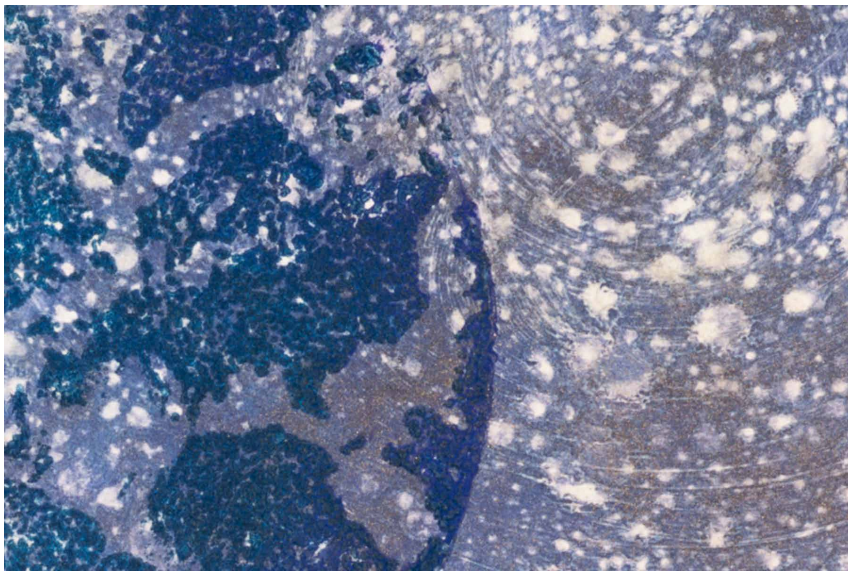

Between Centralization and Decentralization

Decision Behaviour in the EU's Multilevel Administrative System

Nina Merethe Vestlund

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Abstract

This report studies decision behaviour within an emerging multilevel European Union (EU) administration composed of the European Commission (the Commission), a growing number of EU agencies and national regulatory authorities. These actors are increasingly connected and integrated across levels of governance and national borders. The aim of the report is to contribute to a better understanding of what characterizes decision-making in the EU administrative system. There is disagreement among scholars as well as practitioners on the effects of these institutional developments, and whether they contribute to preserve executive power as decentralized and anchored within member states or if they contribute to centralize executive power at the EU level. The report introduces observations indicating that decision-making in the system is gradually becoming normalized, in the sense that it increasingly embodies many of the organizational and behavioural patterns that are highly typical of executives from national settings. Furthermore, the findings show that executive decision-making behaviour is gradually becoming more centralized, with the European Commission as a core executive. The findings of this report thus challenge existing images that portray the European administrative system as *sui generis* and executive power as being mainly decentralized. The report is composed of an introduction and four articles addressing decision behaviour in different parts of the EU's multilevel administration:

- Changing policy focus through organizational reform? The case of the pharmaceutical unit in the European Commission.
- Exploring EU Commission-agency relationship: partnership or parenthood?
- The quest for order: unravelling the relationship between the European Commission and European Union agencies (with M. Egeberg and J. Trondal)
- Pooling administrative resources through EU regulatory networks

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List of abbreviations

AESGP	Association of the European Self-Medication Industry
BEUC	The European Consumer Organization
Commission	European Commission
Council	Council of the European Union
CP	Centralized procedure
DG	Directorate-General of the Commission
DG Entr	DG Enterprise and Industry
DG Sanco	DG Health and Consumers
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EPF	European Patients' Forum
EPHA	European Public Health Alliance
EU	European Union
HMA	Heads of Medicines Agencies
MHCS	Ministry of Health and Care Services, Norway
MoH	Ministry of Health, Slovakia
NA	National agency
NOMA	Norwegian Medicines Agency
SIDC	State Institute for Drug Control

Introduction

This report studies decision behaviour within an emerging multilevel European Union (EU) administration (Egeberg 2006a; Trondal 2010).[1] Since the inception of the European Coal and Steel Community in 1951, an increasing amount of EU public policy has been developed, agreed on and put into action. In parallel, and especially the past twenty years, executive bodies have been established in order to carry out administrative tasks. An EU administration has evolved, understood as a system composed of the European Commission, a growing number of EU agencies as well as networks of national regulatory authorities that are increasingly connected and integrated across levels of governance and national borders. Covering multiple policy areas, and involving organizations at the EU and national levels, the EU constitutes a comprehensive and complex administrative system. After more than half a century of integration, however, 'the balance between levels of governance and institutions are still contested issues in the European Union, and there is still little agreement about how the institutional characteristics of the emerging European polity can best be described' (Olsen 2007: 12). Thus, the aim

[1] For valuable input and constructive comments on this introduction I would like to thank Frode Veggeland, Olav Schram Stokke, Morten Egeberg, Jarle Trondal, Mathias Johannessen, and Guri Rosén.

of this report is to contribute to a better understanding of what characterizes administrative decision-making in the EU system, and in particular, the significance of the system itself in shaping decision behaviour within and between its constitutive parts. The overarching question of the report is to what extent, how and why organizational factors shape decision-making within and between the constitutive parts of the EU administrative system?

The report is concerned with several aspects of the administrative dimension of Europe's executive order. It consists of four articles (part two) that in different ways contribute to answer the overarching question. The ambition of this introduction is to provide theoretical and empirical context for the four studies. The starting point is that the European political order cannot be understood without understanding the role of formally organized institutions (Olsen 2007). The recurring argument presented in the articles is that organizational factors, and changes in organizational factors, in the EU's administrative system contribute to shape decision behaviour within and between the constitutive parts of the system. Decision behaviour is understood as the continuing, everyday choices individual officials make as they carry out their day-to-day work, and it is examined by considering interaction and attention patterns within and between the Commission, EU level agencies and national agencies. The analytical framework applied in the report builds on institutional-organizational perspectives as well as existing literature dealing with Europe's executive order. The resulting analytical framework makes it possible to disentangle the organizational context public officials work within and to separate specific organizational factors that may influence decision behaviour. The first article studies administrative decision behaviour in the Commission and shows how a reorganization contributed to change decision-making behaviour and relationships to external interest groups in a sub-unit. The second and third articles explore decision-making within the frame of inter-institutional relationships between the Commission and EU agencies, and show that close Commission-agency connections have developed. The fourth article studies intra-EU regulatory network relationships, and shows how national agencies pool resources through mutual adaptation and specialization.

The architecture of the European polity, i.e. its basic institutions and their powers and relationships, has been contested since the original European Community (EC) design (Olsen 2007). The literature on Europe's executive order and its administrative dimension is characterized by ambiguity and lack of knowledge with regard to implications of establishing separate bodies to carry out executive tasks. Some argue that although the Commission, EU agencies and regulatory networks carry out certain tasks related to formulation and implementation of EU policy, executive power is principally decentralized, i.e., anchored among member states and their central administrations. This is compatible with a state-centric picture of EU's executive order, emphasizing intergovernmental behavioural patterns. A different part of the literature argues that a profound transformation of the European executive order is taking place – from a system based on relatively coherent delimited national administrations to an integrated, multilevel Union administration, partly bypassing national ministries and with the Commission as core executive (Egeberg 2006a; Curtin and Egeberg 2008; Trondal 2010). Such developments imply that although executive power initially was intended to remain decentralized and firmly in the hands of the member states, it can be questioned whether it has actually remained decentralized. However, a new order does not spring to life overnight, completely replacing an old one. It is more helpful to consider it as a continuous contest, with competing tendencies, with elements of the new and old order co-existing or mixed (Olsen 2007: 13). The new executive order can be portrayed as layered outside the 'old', intergovernmental order rather than replacing it (Curtin and Egeberg 2008). Thus, 'the scholarly challenge is to understand the scope of conditions and the interaction of the different forms, as well as the factors that drive the systems of governments towards one mix rather than another' (Olsen 2007: 46).

The empirical findings of this report display two overall decision-making patterns of EU's administration that supports the transformation literature. Firstly, the findings of articles 1-3 on the Commission and Commission-agency relationships support allegations that executive decision-making behaviour at the core of the system is gradually becoming normalized, in the sense that it increasingly embodies many of the organizational and behavioural patterns that are highly typical of executives as we know them from

national settings (Egeberg 2006a: 2: Wille 2013). Secondly, the findings of articles 1-4 support claims that executive decision-making behaviour is gradually becoming more centralized, in the sense that it contributes to executive centre formation at the European level by strengthening the capacity of the Commission as a core executive and its ability to act relatively independently from member states (Egeberg 2006a; Curtin and Egeberg 2008).

The remainder of this introduction will proceed as follows: first, in order to show the value added of this report, the literature and existing knowledge on the European administrative system and its constitutive parts is reviewed in the next section, followed by a section elaborating on the relevance of the overarching research question. Next, the analytical framework applied in the report (based on institutional-organizational perspectives) is presented, and an account for why it is useful in the study of the European administrative system is given. After that a short presentation of the pharmaceutical policy field is provided, since three of four articles concerns this policy field. Then the research design, methods and data of the report are presented, followed by a short introduction to the individual articles. The final section elaborates on empirical and theoretical implications and gives some suggestions for future research.

Background

The EU as a polity is characterized by tensions between the unity and the diversity of its constituent parts, integration and disintegration between levels of governance, and supranational and intergovernmental decision-making. A European executive order can be traced back to the peace of Westphalia. The Westphalian order was based on regularized bilateral diplomacy and intergovernmental cooperation between member states (Curtin and Egeberg 2008: 641). As noted in the introduction, there are indications that the intergovernmental order inherited from the past is under transformation (Egeberg 2006a; Curtin and Egeberg 2008; Trondal 2010). However, there is little agreement among scholars on the current relationship and balance between the 'old' and 'new' orders (Olsen 2007), nor on how establishing separate bodies to carry out executive tasks contributes to centralize or decentralize executive power. In general, centralization, or concentrating power, authority and control at a centre, vs. decentralization of executive power away

from the centre to constituent parts, has been a recurring topic of public administration (Aucoin and Bakvis 1988; Aucoin 1990). Establishing central executive powers outside the realm of the constituent states seems to have been a 'hard case' of institution building (Egeberg and Trondal 2011a: 869). It basically includes transferring capacity from the constituent states to a new centre (at the EU level) – capacity for action and execution of policies, and not just talk and formal decision-making – and this may be seen as threatening and challenging to state power and autonomy. Hence, governments may be less eager to transfer power upwards (Egeberg et al. 2012: 19). Rather than understanding centralization/de-centralization as a dichotomy, however, it can be conceived of as a continuum, on which administrative behaviour can move closer to one end or the other. The pendulum may swing back and forth depending on policy objectives and trends, how clearly policies and priorities are defined as well as issues and agendas (Aucoin 1990).

As already noted, a comprehensive and complex European administrative system is developing, contributing to EU policy formulation and implementation in a wide array of sectors. The Commission is a large and highly specialized organization with 33 Directorates-General, 11 services and six executive agencies. It occupies a pivotal role in the EU as the core-executive institution with key initiating powers that runs the everyday administration of the Union (Trondal 2010: 17). While the Council and European Parliament constitutes the legislators in the EU system, the Commission is in charge of developing policy proposals and monitoring their implementation by EU and EEA member states (Egeberg 2012b: 940). Furthermore, there are more than thirty EU agencies, and several in the pipeline. Especially since the 1990s these agencies have become an important part of the European administrative system. A wide range of (semi-) regulatory, monitoring, and coordination tasks have been delegated to EU agencies, some of which are novel and far-reaching (Busuioc et al. 2012). In addition, within each EU/EEA member state there are a number of horizontally and vertically specialized agencies that are connected to EU through different formal and informal arrangements, bodies and networks.

With regard to the Commission, different images exist in the literature (Ellinas and Suleiman 2012; Kassim et al. 2013; Hartlapp et al 2014). Some standard portrayals are the Commission as the technical regulator (Majone 2002), as dominated by national interests (Kassim and Menon 2003; 2010), as the political actor (Pollack 1997), as the hub of EU multilevel administration (Egeberg 2006; Trondal 2010), and as an international administration (Trondal et al. 2010). Generally, the Commission's existence has been referred to as a peculiar component of the EU institutional architecture, since a similar, separate executive unit organized outside the body where governments meet is not to be found in any other international organization (Egeberg 2006c: 31). It is formally independent from member-state preferences and the inherited intergovernmental order (Trondal et al. 2010: 7). It thus represents a supranational aspect of the EU: the Commission and its predecessor, the High Authority of the European Coal and Steel Community were deliberately designed as engines of integration, supposed to inject European interests into the policy-making processes of the Community. This contributed to legitimize its independence (Egeberg 2006c: 31), but it was clear from the start that running the Commission was a balancing act between autonomy and dependence on the member states (Egeberg 2006c: 35). Its peculiarity and treaty-given powers has caused a certain *sui generis* status. It has been portrayed as a unique institution (Ellinas and Suleiman 2012), due to its size, formal powers, and political leadership separate from the Council (Trondal 2010: 25). Moreover, it is referred to as 'one of the world's most powerful administrations' (Kassim et al. 2013: 1), and an 'ever-expanding executive in terms of policy competences' (Wille 2013: 43).

At the same time, executive power in the EU was intended to be closer to the decentralized end of the continuum than the centralized. With some important exceptions, the traditional mode was decentralized administration (Majone 1997). Public administration and its operation have traditionally been perceived as a core state power (Genschel and Jachtenfuchs 2013), and formulating and implementing public policy in Europe a prerogative of national administrations (Trondal and Peters 2013: 295). From the outset, a dual administrative order with a clear task division between the EU level and the national level was intended, with executive authority spread between the member states, individually and collectively, and the Commission (Kassim 2003: 140; Hofmann and Türk 2007).

Although the Commission proposes legislation and oversees its implementation, the initial division of tasks and responsibilities broadly reflected a strong linkage between public administration and nation state (Curtin and Egeberg 2008). The main principle of governance was that the European institutions decide on EU policies while administration was regarded as the domain of national control (Martens 2010: 6).

Some argue that except for a short, a-typical, period of time under the Delors Commission in the mid-1980s, when the Commission reasserted its influence with the single market programme and the re-launch of the European project, power is firmly placed in the hands of the member states (Kassim and Menon 2010). Even though its formal powers have not been curtailed, the Commission's power has been seriously challenged and in decline post-Maastricht (Kassim and Menon 2010; Kassim et al. 2013; Bickerton et al. 2014). Compatible with an intergovernmental view, it is argued that the Commission is no longer the engine of integration it once was, but has lost ground to the Council and the Parliament (Kassim et al. 2013: 150; Bickerton et al. 2014). In this view, the EU is constituted by sovereign states, conceived as unitary strategic actors cooperating voluntarily and pooling their resources in order to control their environments and improve their performance. Institutions are seen as organizational tools for achieving desired policy goals (Olsen 2007: 2). Moreover, the view of a Commission in decline is shared by several Commission officials (Kassim et al. 2013: 144). Although the Commission has been entrusted with a broad range of tasks, they have not been matched by increase in resources and capacity for independent action or ability to pursue its own preferences (Kassim 2003: 143-5; Kassim and Menon 2010). Since the beginning of the 1990s, national governments have been reluctant to delegate power to the Commission, and 'load' the tasks they assign with strict controls, which results in complicated and extensive procedures that must be followed, draining the Commission of capacity (Kassim et al. 2013: 72). The Commission's internal fragmentation has reduced its potential for action (Kassim and Menon 2010), and the Commission's ability to shape EU legislation resulting from its right of initiative has been further constrained by the European Parliament's rise in power. In addition, the forced resignation of the Santer Commission had a lasting impact on the institution, and the following reforms emphasized its managerial role rather than political (Kassim et al.

2013: 133). In sum, the Commission has been relegated to a secondary role while the heads of state and government assume an overall role of guidance and control (Kassim et al. 2013: 131-2).

In general, it is argued that member states have been unwilling to concede more powers to supranational institutions (Bickerton et al. 2014) or strengthen Community structures, even in areas where the treaty traditionally has facilitated Community action, such as the internal market. Member governments have altered the institutional balance of the Union both through a formal revision of the treaties and through asserting the role of the Council so as to strengthen and enshrine its authority. Member states have been more attentive to developments at the EU level and more likely to intervene, and they have sought to deny the Commission the opportunity to extend its influence (Kassim and Menon 2010: 12). Where new competencies have been delegated to the Union, the inclination of the members states has been to vest decision-making authority in the Council and only later to allow the Commission its traditional policy initiation function. Similarly, when new bodies or structures (e.g. EU agencies, networks) have been created they have been designed so as to ensure that the possibilities for bureaucratic creep or agent drift are limited, and that control by member governments is assured (Kassim and Menon 2010: 13).

It was expected that the global financial crisis would edge Europe towards further supranationalism, but it is argued that this has not yet happened (Bickerton et al. 2014). Instead of delegating more power to the Commission, other solutions have been chosen. Delegation, where it has occurred, has been to *de novo* bodies such as EU agencies and networks rather than traditional supranational institutions. These fulfil functions that could have been assigned to the Commission and tend to contain mechanisms for member state representation as part of their governance structure (Bickerton et al. 2014). It has been suggested that the choice of delegating to the Commission, EU agency or network of national regulatory authorities depends on the degree of distributional conflict in the area. Relying on networks, for instance, leaves each member state free to pursue their narrow economic self-interest. Networks are not necessarily effective in harmonizing behaviour and less likely to produce significant harmonization standards and/or market integration, but are chosen when member states are least interested in

delegating power 'upwards' (Kelemen and Tarrant 2011). National agencies are understood as government's agents, and leaving administrative tasks to networks basically implies that power remains firmly in the hands of the member states. Furthermore, aware that independent agencies may be intrusive and disturb the delicate balance within the EU's institutional setup (Majone 1997: 263), governments have insisted on keeping EU agencies under their control. This is most clearly expressed in the composition of their management boards on which national delegates usually constitute an overwhelming majority (Kelemen 2002; Dehousse 2008; Christensen and Nielsen 2010). In sum, the establishment of EU agencies and networks to perform Community tasks is understood as a weakening of the Commission in relation to national capitals.

A key feature of what Bickerton et al. (2014) calls the 'new intergovernmentalism' is that supranational institutions, far from resisting this turn towards decentralized modes of decision and policy-making, have often been complicit in it. The post-Maastricht period has been notable for its absence of a big push by the Commission for the centralization of decision-making in new areas of EU-activity. The role of supranational actors are not denied, but it is argued that their relative importance in determining the character and direction of the integration process has been in question since Maastricht (Bickerton et al. 2014). However, others argue that there are indications of the pendulum moving towards the centralized end of the continuum, and that a transformation of the European executive order is taking place. Some of the key properties of this move are the consolidation of the Commission as a core executive and strengthening of its capacity and ability to act independently from the member states, and that it is becoming less *sui generis*. Furthermore, a multilevel Union administrative system is increasingly integrated through closer connections between the Commission, EU agencies and national agencies, partly bypassing national ministries. It is argued that the Commission over time has increased its autonomy vis-à-vis national governments (Egeberg 2006a; Curtin and Egeberg 2008). Due to the division of work between the Council and Commission at the EU level and the fact that they are horizontally specialized according to different principles (territory and purpose/function), conflict and coordination patterns follows different lines in the two organizations. Changes such as increased permanent staff, new recruitment procedures and rules to

prevent national clusters of officials have lessened the importance of nationality in the Commission. Studies indicate that DG affiliation may be a more important factor than national backgrounds in understanding policy choices, not only for the Commissioners in the College but also for officials in the Commission administration ('the services') (Egeberg 2006a; Suvarierol 2008; Trondal et al. 2008; Trondal et al. 2010; Trondal 2012; Egeberg 2012b; Kassim et al. 2013; Hartlapp et al. 2014). There are also signs that the heterogeneity of the Commission may affect relations to external actors such as interest groups, as each DG has become associated with particular client groups (Mazey and Richardson 2006: Bouwen 2009).

Studies comparing the Commission to other international organizations and national administrations have raised questions regarding the *sui generis* status of the Commission (Trondal et al. 2010; Kassim et al. 2013; Balint et al. 2008). While starting out in the 1950s as a technocratic international body, it seems to increasingly be evolving into an executive body that is typical of the executives we are familiar with at the national level as regards organizational and behavioural patterns (Egeberg 2006a). Wille (2013) describes how the Commission gradually takes on 'normal' features of the executive branch of government and is slowly coming to be perceived as a 'normal executive'. Changes arising from treaty reforms and internal administrative reforms have contributed to this transformation (Wille 2013: 2). One indication is the evolving politics-administration dichotomy in the Commission, with Commissioners increasingly considered as executive politicians. Another is the increased importance of European Parliament in approving the Commission president and budget (Wille 2013).

EU agencies represent another key property of the European administrative system. They increasingly make up parts of an emergent, compound European executive order (Busuioc et al. 2012), and 'there is an immediate question with regard to how they relate to the core of the Commission powers and tasks and thus the institutional balance overall' (Curtin and Dehousse 2012: 197). Although the member states are represented in management boards and expert committees, a common feature among EU agencies seems to be that the Commission is a close interlocutor in their daily life, and it is asked whether EU agencies increasingly relate to particular 'parent' DGs (Egeberg and Trondal 2011a; Groenleer 2009; Martens

2008a). Apparently, this becomes even more likely within policy areas where the Commission itself disposes over considerable organizational resources (Egeberg and Trondal 2011a: 869). Thus, even though EU agencies are vertically specialized outside the Commission, they may be *de facto* integral components of the Commission when measured by their activity and by actors' perceptions. EU agencies are authorized to make individual decisions based on existing secondary legislation, and may potentially be 'instruments of centralization' of regulatory functions at the Union level (Majone 2005: 97).

Furthermore, according to Hofmann and Türk (2007: 258), EU agencies 'integrate national and supranational actors into a unitary administrative structure…'. National agencies, organized at arm's length from their parent ministerial departments, have become increasingly woven into the European administrative system through issue specific networks, and may be seen as additional building blocks in a EU multilevel administration (Hofmann and Türk 2006: Hofmann 2008; Martens 2010). The Commission lacks its own agencies at the national level for the implementation of EU policies, and in order to generate uniform implementation across the EU, the Commission in cooperation with EU agencies seems to establish partnerships with those national bodies that have responsibilities in relation to formulation and application EU policies, such as national agencies. In addition to vertical relationships with the Commission and/or EU level agencies, national agencies may establish horizontal relationships to sister agencies in other member states. National agencies may thus operate as 'double-hatted' (Egeberg 2006) or even 'multi-hatted' (Egeberg and Trondal 2009). This implies that they are influenced not only by national parent ministries in day-to-day decision behaviour but also may act on behalf of a second master or centre, or a transnational network in which the EU executive constitutes a node (Egeberg 2006b: 10; Curtin and Egeberg 2008). Studies include different policy fields, such as competition (Støle 2006; Barbieri 2006), food safety (Ugland and Veggeland 2006), telecom (Nørgård 2006), environment (Martens 2006) and statistics (Sverdrup 2006), and maritime safety (Gulbrandsen 2011). One implication may be tension in ministry-agency relationship. The Commission may play an important role both in networks and vis-à-vis national agencies (Martens 2008a; 2008b). Studies have shown that the Commission may initiate networks (Nørgård 2006; Gornitzka

2008), but also link to and/or 'take over' already existing networks (Eberlein and Grande 2005; Martens 2006). Networks may increase harmonization across member states, but not necessarily in accordance with the intentions of politically superior institutions (Curtin and Egeberg 2008: 651). Studies show that networks may influence national agencies' autonomy in national administrative systems and relationships to parent ministries. By connecting to networks national agencies may strengthen their autonomy vis-à-vis their national superiors and challenge ministries in specific policy issues, even in the policy formulation phase (Newman 2008; Yesilkagit 2011; Bach and Ruffing 2013; Danielsen and Yesilkagit 2013; Bach et al. 2014; Maggetti 2014; Maggetti and Gilardi 2011).

To sum up, there is disagreement in the literature and a call for studies on whether the administrative dimension of Europe's executive order implies a centralization or decentralization of executive power. The next section elaborates on how this report adds to the debate.

Relevance

What is the relevance of asking to what extent, how and why organizational factors shape decision-making within and between the constitutive parts of the EU administrative system? Public administration scholars still have imperfect and partial understanding of how the EU's multilevel administrations functions, how bureaucratic interactions occur horizontally and vertically among various political layers, how administrative structures across levels are developing, how supranational administrative actors cultivate and use resources, and how national bureaucratic structures and actors adapt to and exploit respective constellations (Bauer and Trondal 2015). In light of the differing images EU policy administration, more empirical knowledge on inter-and intra-institutional relationships involving the Commission, EU agencies and networks of national agencies is essential. Even though the Commission may be one of the most investigated executives in the world (Egeberg 2014: 241), few studies have investigated effects of Commission reforms on policy processes and outcomes. Focus has been mainly on describing and explaining management reforms (for instance Bauer 2008; 2009; Schön-Quinlivan 2011; but see Mörth 2000). Moreover, Commission studies have been relatively inward-looking, ignoring how Commission officials relate to the EP, the

Council, national administrations, EU agencies and interest groups. A better understanding of how the Commission is situated in the wider European political order is thus necessary. Being an executive at the EU level, the Commission has always represented a potential threat or, at least a challenge, to those traditionally holding executive power in Europe, i.e., national governments, most apparently in sensitive policy areas like foreign policy, border control, and currently, economic governance (Egeberg 2012b: 947).

Moreover, there is a question of whether and how EU agencies and EU networks can challenge the traditional, decentralized distribution of executive power. The process of agencification has also been accompanied by a quantum leap in the study of EU agencies (e.g. Busuioc et al. 2012; Rittberger and Wonka 2011). The majority of studies on EU agencies focus on institutional formation, institutionalization and intra-agency governance, while few studies have focussed on the effects of agency creation. Furthermore, few have examined and conceptualized the relationship between the Commission and the European agencies, or identified factors that condition such relationships. It is thus still an open question where EU agencies belong in the institutional landscape and how they contribute to the EU institutional architecture. Finally, with regard to networks of national agencies, previous studies have focussed on how the participation in EU networks impact ministry-agency relationships and agency autonomy, but there is little knowledge on how EU regulatory networks influence intra-network relationships between the Commission, EU agencies and national agencies. This report fills a gap in the literature by studying inter- and intra-institutional decision-behaviour of the Commission, EU agencies and national agencies in order to see whether it implies centralization or decentralization of EU executive power.

Even though some parts of the EU's administration are formally more centralized (or decentralized) than others through treaties or secondary legislation, this does not necessarily tell us anything about how it works in practice (Olsen 2007). The EU administrative system is a living, unsettled system, and this renders the European administrative system an interesting empirical laboratory for public administration studies (Egeberg 2012b; Bauer and Trondal 2015). Administrative structures are continuously created, reformed or developed in some way. These changes may be slow or rapid and

more or less planned, but still have important consequences for the content of public policy. Changes can contribute to modify or even reverse the developments like centre formation or normalization (Egeberg 2006b: 16). Currently, there is limited theoretical understanding of the processes through which European integration may persist, speed up, slow down, disintegrate or reverse itself (Olsen 2007: 11). Arguably, knowledge on the extent to which, how and why choices made by civil servants are influenced by their institutional and organizational contexts, or changes in it, is crucial to understand how EU public policy is shaped.

Finally and more generally, the EU can be understood as a public organization, producing large amounts of public policy. Civil servants act on behalf of public organizations, and how they use their influence and discretion in day-to-day decision processes has implications for policy processes, and may eventually shape policy outcomes. Although politicians are the formal decision-makers, choices are made throughout the policy cycle that influence the content of public policy – in the agenda-setting phase, the elaboration of policy alternatives, during implementation, and when interpretations of the effects are fed back into new policy processes. Power and influence are inherently linked to what takes place at other stages of the policy process; stages at which bureaucracy tends to play a crucial role (Bauer and Trondal 2015: 10). In the Commission, for instance, only 13,2 per cent of all Commission proposals between 2004 and 2008 were actually subject to decision-making at the political level (Hartlapp et al. 2014: 15).

In summary, this report contributes to a literature that is characterized by myths and images about how the European administrative system works, but lacks empirical studies. Arguably, the literature will also benefit from the use of an organizational approach. The next section elaborates more on this.

Analytical framework

The analytical framework applied in the report draws on institutional-organizational perspectives and the literature on the European executive order. The point of departure is that institutions tend to impose particular world views, ways of thinking, expectations and allegiances on their members, and more so under some organizational conditions than others (March and Olsen 1984).

A key assumption is that it is impossible to understand the content of public policy and public policy decision-making without analysing the way politico-administrative systems are organized and their modes of operation (Christensen et al. 2007: 1). This section elaborates on organizational theory, what constitutes its basic elements, and how and why it is relevant and useful.

There are several institutional and organizational approaches which all focus on public decision-making behaviour. When it comes to the driving forces behind decision-making in public organizations, i.e., the factors that can be used to explain features of decision-making processes and their effects, they can be divided into four categories (Christensen 2012: 150). One tradition focuses on the importance of formal normative organizational structures for decision behaviour; one tradition on formal theories, focussing on rational, utility-maximizing actors; a third perspective focussing on the cultural-institutional aspects of institutions and the importance of informal rules, values and norms; and a fourth type, focussing on the importance of an organization's technical and institutional environments for decision-behaviour, where the latter also is closely associated with the cultural-institutional perspective (Christensen 2012; 150-1; Thoenig 2012: 172). This report mainly draws on explanatory factors highlighted by the structural-instrumental approach – the organizational perspective (articles 1-4), but is complemented by explanatory factors drawn from the cultural-institutional approach, including institutional environments (articles 1 and 3). After a presentation of the perspectives, the reasons behind the choice of perspective are substantiated below.

The perspectives agree that organizations influence the thinking and actions of their members, but highlight different explanatory factors. As summarized by Stigen (2010: 13) and Christensen (2012), they are anchored in Weber's bureaucracy theory, Gulick's theories and research on different principles of specialization and policy consequences of various organizational designs, Simon's coupling of structures and behaviour through the logic of bounded rationality (Simon 1997), Selznick's theory on how public organizations gradually develop into institutions, infusing and adding value to the formal framework (Selznick 1957), Krasner's concept of path dependence (Krasner 1988), March and Olsen's logic of appropriate behaviour (March and Olsen 1989), as well as works on the

importance of socially created norms in organization's environments by Meyer and Rowan (1977), DiMaggio and Powell (1983), and Scott (1987) (Christensen 2012: 151; Stigen 2010).

The organizational approach

The organizational approach focuses on the relationship between bureaucratic structure and administrative decision behaviour, and how organizational structures might intervene in policy process and eventually shape its outputs (Egeberg 2012a). The organizational context provides individuals with action alternatives by nudging their attention towards particular alternatives and away from others. How organizational boundaries are drawn may thus have consequences for individual behaviour. It is not assumed that organizational and institutional structures provide exhaustive explanations of behaviour, or determine policy output in any detailed manner. Instead the structures tend to intervene in a systematic and understandable way in decision-making processes, making some choices and certain outcomes more likely than others (Egeberg 2012a; Christensen et al. 2007; March and Olsen 1989). Organizations are seen as capable of endowing individual actors with goals and interests, implying that how participants distribute their attention – how they think and act and what and who they attend to as they perform their daily tasks – is affected by their organizational position in a systematic and routine way. Reasons for expecting that people comply with organizational norms may be found in the different action logics that theoretically connect organizations and actor behaviour. The different perspectives highlight different key logics, bounded rationality and logic of appropriateness, although it more generally is assumed that different logics interact and should be understood as complementary (March and Olsen 2008: 19).

The organizational perspective highlights the concept of bounded rationality. Due to cognitive limitations and lack of information, individuals do not always have overview over all relevant alternatives when choosing how to act. The organizational context matches the individual's limited capacities by serving as a filtering mechanism, simplifying preference formation by systematically sorting some alternatives into the decision process and other alternatives out of it (Egeberg 2012a: 157). The perspective further identifies key organizational factors that may impact on individual decision behaviour: organizational structure, demography and locus

(Egeberg 2012a). Organizational structure expresses impersonal role expectations and norms for action. Who should do what, how and when in the everyday work is specified (more or less clearly), including which interests, values and goals that are to be pursued, or which problems and solutions are important. Formalization is thus an attempt to make more explicit and visible (and thus predictable and stable for participants and environment) the structure of relationships among a set of roles and the principles that govern behaviour in a system (Scott and Davis 2007: 37-8). The size of an organization, the sheer number of roles that are to be filled, may indicate an organization's capacity to initiate policies, develop alternatives and implement final decisions. The term specialization refers to how the division of labour is planned and how coordination is prioritized in an organization. Vertical specialization refers to the number of hierarchical levels in an organization. Horizontal specialization refers to the way tasks and activities are distributed among units at one level, and expresses how different issues and policy areas are supposed to be linked or de-coupled. As claimed by Gulick there are four fundamental ways in which tasks may be distributed horizontally: according to territory, purpose (sector), function (process) or clientele served (Gulick 1937). The drawing of organizational boundaries in accordance with specific specialization principles is assumed to affect information exchange and co-ordination processes in bureaucracies, more specifically within and between organizational units, but also with external actors, promoting specific contact, coordination, cooperation and conflict patterns and inducing different perspectives. For instance, specializing according to territory induces spatial perspectives and encourages decision makers to pay attention to territorial concerns, while organizing according to purpose induces sectorial perspectives among policy makers (Egeberg 2012a). Organizations internally specialized according to sector and function (such as the Commission) will encourage respectively sectorial and functional perspectives among the organization members.

Organizational demography refers to personnel composition in terms of different personal attributes such as gender, ethnicity, nationality, education and length of service within the social entity under study. In general, education seems to be the most important background factor (Egeberg 2012a: 159). Individuals may internalize certain values, norms and role expectations belonging to a particular

education or profession, which condition their decision behaviour. Finally, organizational locus refers to how features of location and physical space create physical boundaries that focus decision makers' attention and facilitate planned and random face-to-face contact, i.e., contact patterns, information flow and co-ordination behaviour (Egeberg 2012a: 160: Egeberg and Trondal 2011b).

The cultural-institutional perspective

The cultural-institutional perspective highlights the significance of the informal organizational dimension, in particular, the role of administrative-cultural traditions in explaining bureaucratic behaviour (Christensen 2012). The logic of appropriateness is a key mechanism connecting the organization and behaviour. Organizational culture entails a relatively consistent set of rules, norms and identities, and through a matching process, the individual links situations to culture in order to establish what actions are appropriate when facing complex decision making situations (March and Olsen 1989; 2008). An organization's degree of institutionalization is an essential factor in prescribing what is appropriate behaviour. Institutionalization refers to the process by which informal norms, practices and values evolve and become important for organizational activities. This implies the classical understanding by Selznick (1957) of how organizations grow into institutions as informal structures are gradually developed and infused with meaning over time (age is thus crucial). Typical characteristics of a political-administrative culture may entail balancing between loyalty to leadership and professional norms, and balancing between premises of professional norms and values on the one hand and basic facts and contexts they are specialists in on the other hand. Other common features may be procedural conditions, such as due process, predictability, equal treatment, transparency and information (Christensen et al. 2007: 49-50). Institutionalization of an organization's culture can also make an organization more robust and resistant to change, leaving for instance the relationship between structural reform and change in decision behaviour less evident (Olsen 1997: 206-6). In addition, institutional environments may be drive decision behaviour in a public organization (Christensen 2012: 151). Myths are norms and recipes for how organizations should be designed and operate that are perceived as legitimate and spread through imitation. Organizations may adopt

more or less clear norms and recipes to increase its legitimacy, support, and/or efficiency (Christensen et al. 2007: Thoenig 2012).

Relevance of the perspective

As indicated, the main focus in this report is on the organizational perspective, and there are several reasons behind the choice of this approach. The main advantage is that it makes it possible to unpack organizational settings and separate individual organizational factors that are relevant in understanding decision making behaviour, are possible to manipulate and operationalize (Christensen et al. 2007: 176). The key factors outlined by the perspective are all factors that can be changed, to a certain degree, through deliberate manipulation. Empirical studies have shown that various formal structures, physical structures and compositions of personnel may have consequences for decision-making in organizations. Although some empirical work has been done that indicated a relationship between the factors outlined and decision behaviour, evidence-based knowledge about many of the connections between organizational forms and their effects are still uncertain and incomplete (Hammond 1990; Christensen et al. 2007: 176; Egeberg 2012a).

The organizational perspective is useful to look for explanatory factors at both the EU and national levels, and within the organizations that operate at the different levels.

National and international executive orders are often portrayed as separate politico-administrative systems with few interactions. One consequence of this is that scholars have dealt separately with domestic public administration and international bureaucracies (Trondal 2010: 1). Unlike for instance intergovernmental theories, organizational perspectives do not treat organizations (neither at the EU nor the national level) as coherent entities. The perspective assumes that the structuring, staffing and location can make a difference as regards administrative decision-behaviour. Thus, the perspective is well suited for understanding inter-institutional relationships across organizational as well as national borders and governance levels. In general, public administration studies have tended to be locked into national laboratories (Egeberg 2008; Trondal 2014; Bauer and Trondal 2015). Studying decision behaviour in European administrative system provides an excellent opportunity to sharpen public administration theoretical tools developed primarily

in the context of the sovereign territorial state and learn new theoretical lessons (Olsen 2007; Bauer and Trondal 2015).

The articles in this report study how organizational factors contribute to shape the perspectives and behaviours of public officials, including after a structural reorganization. From a public administration view it is not obvious that the organizational factors outlined by the organizational perspective matters to decision-behaviour. In fact, although theorists agree that organizations matter in explaining administrative behaviour, the relative significance of organizational structure is widely debated within the public administration literature. The lack of systematic empirical research on the relationship between bureaucratic structure and actual decision behaviour has been explained as a result of Herbert Simon's criticism of the so-called classical school of administrative theory where the importance of structures for decision behaviour was questioned and consequently de-emphasized in organizational studies (Hammond 1990). 'The new style was to downgrade the importance of the formal hierarchical structure of bureaucracy. What came to be known as the 'informal organization' was what was important' (Hammond 1990: 144). Moreover, studies have mainly concentrated on the causes of establishing new or changing old structures, i.e., explaining and describing reform processes, but the effects of structural reform on decision behaviour has been given less attention. Arguably, a study in which behaviour has been observed *subsequent to* reorganization has a value in itself and if behavioural changes can be traced under this circumstance, it is more likely that a cause-effect relationship really exists (Egeberg 2012a: 162). Recent years have witnessed a resurgence of interest in structural design in both national and international administrations (for a review, see Egeberg 2012a), but as argued above, more knowledge on the relationship is still necessary. Combining different institutional-organizational perspectives, such as the structural-instrumental and institutional-cultural perspectives, is quite common, and since they focus on different explanatory factors they are understood as complementary rather than competing (Christensen 2012: 151-2).

A more general point with regard to organization theory and public administration is that the systematic development of organization theory has traditionally been associated with private organizations,

while studies of public administration for a long time had no explicit basis in organization theory. Over the past few decades an organization theory more specifically geared to studies of public administration has developed (Christensen 2012: 149), and recent attempts to bridge public administration with organizational studies have been made (March 2009; Trondal et al. 2010; Bauer and Trondal 2015).

The pharmaceutical policy field

Three of the four articles in this report deal with the pharmaceutical policy field (one study is cross-sectorial). There are several aspects that distinguish the pharmaceutical policy area from other policy areas and make it interesting in light of the overarching research question.

First of all, a comprehensive legal framework has been developed since 1965 within this policy field. The Commission is delegated decision-making power in authorizing medicines for market sales, subject to comitology procedure to secure member state oversight (Hauray 2013: 86). Furthermore, an EU agency – the European Medicines Agency (EMA) – was established and has from 1995 carried out scientific-technical evaluations and delivered opinions to the Commission on medicines licensing. Even though the Commission is the formal decision-taker, studies have shown that EMA has grown into a large and strong agency with *de facto* decision power. EMA coordinates tasks related to EU policy formulation and implementation, and has a large permanent staff (785) that increasingly influences the EMA's work (Hauray 2013: 86). Although the EMA from the outset was meant only to support the member states in granting marketing authorisations, and its secretariat's formal role is rather anonymous,[2] it has grown into a comprehensive organization in its own right. Over time the agency has become renowned for dominating the decision-making procedure and is

[2] It is mentioned only two times in the founding regulation, at p. 3: 'The creation of the Agency will make it possible to reinforce the scientific role and independence of the committees, particularly through the setting-up of a permanent technical and administrative secretariat, and in article 56, for lack of transparency in decision processes, spelling out the composition of the agency '[The Agency shall comprise] a secretariat, which shall provide technical, scientific and administrative support for the committees and ensure appropriate coordination between them' (art. 56e EC726/2004).

often referred to as a quasi-regulatory agency, despite its formal advisory role (Permanand and Mossialos 2005: 698). The EMA's impact on the Commission has been interpreted as quite extensive, given its status as expert organization and the fact that the Commission never has any objections to its scientific opinions. As Gehring (2012) notes, 'in practice the EMA dominates the authorisation procedure, while political authority is almost negligible' (Gehring 2012: 113). The EMA has thus built up the reputation of strong *de facto* decision-making power (Hauray 2006; Gehring and Krapohl 2007; Krapohl 2008; Groenleer 2009). The relationship to the Commission has been described as balanced by mutual dependence, as it is in neither the Commission's nor the EMA's interest to risk the legitimacy of the system (Dehousse 2008; Groenleer 2009). Member states are represented both in the EMA committees and the Management Board. These are normally officials from national regulatory agencies. The national regulatory agencies have also initiated the Heads of medicines agencies (HMA). Whereas the EMA administers the centralized procedure for medicines licensing, the aim of HMA is to promote mutual recognition of licenses issued nationally or through decentralized procedures.

Secondly, there is the 'peculiarity' of pharmaceuticals (Permanand 2006: 3): they are industrial manufactured products with wide-ranging influence on public health. Consequently, the pharmaceutical policy area is situated between the industry sector and the health sector. The dual aspect of medicines makes pharmaceutical policy a highly complex policy field, characterized by a heterogeneous group of actors that are affected by pharmaceutical policy and have interests that are not easily combined. Consumer/patient interests organizations are primarily concerned with access to safe, affordable and efficacious medicines (Permanand and Mossialos 2005: 690). The pharmaceutical industry seeks a propitious regulatory environment to remain profitable and competitive. Member states face the parallel challenges of ensuring access to quality medicines, cost containment and (in some cases) providing support for local (high employment) industry (Permanand 2006: 6). This adds a potential of controversy to the policy field. The health aspect has always been present in the EU's pharmaceutical legislation[3] but the fact that pharmaceutical

[3] The first directive on pharmaceuticals (EEC/65/65) aimed at harmonising the member states' authorisation of pharmaceuticals (Permanand 2006: 2), and

policy was the responsibility of the Commission department in charge of industrial commodities, DG Enterprise and industry (DG Entr), became over the years an issue of conflict. DG Entr is responsible for promoting economic growth and favourable framework conditions for European industry as well as innovation and job creation throughout the EU (Shorthose and Smillie 2010: 16). It works to ensure the smooth functioning of the internal market for goods and strengthening businesses' competitiveness (Sabathil et al. 2008: 145-8). EU pharmaceutical policy was perceived as having an industrial leaning, generally favouring the pharmaceutical industry's interests by prioritizing an integrated market and a globally competitive industry above health concerns (see for instance Permanand and Mossialos 2005; Permanand 2006; Boessen 2008; Carboni 2009; Baeten 2010; Geyer 2011). In short, EU pharmaceutical policy was perceived as 'captured' by the industry.

However, under the Lisbon Treaty of 2009 the health article was slightly expanded, explicitly incorporating pharmaceuticals (Hauray 2013: 84). In 2010, the pharmaceutical portfolio was moved to the Commission department in charge of consumers and public health, DG Sanco, following the launch of the Barroso II Commission. DG Sanco aims to empower consumers, protect and improve public health and to 'make Europe a healthier, safer place, where consumers can be confident that their interests are protected'. DG Sanco's main task is 'to ensure that food and consumer goods sold in the EU are safe, that the EU's internal market works for the benefit of consumers and that Europe helps protect and improve its citizens' health'.[4] Scepticism has been raised, however, regarding whether such a reorganization can change policy focus (Permanand 2006; Boessen 2008).

Thirdly, until the reorganization there was an asymmetry in the organization of pharmaceuticals between the EU and national levels. Whereas DG Entr was in charge of pharmaceutical policy until 2010, at member state level this portfolio is normally organized within ministries in charge of health policy. The asymmetry between EU

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established the principle of medicine approval, to be compulsory and based on three criteria: efficacy, safety and quality (Hauray and Urfalino 2009: 435).

[4] See DG SANCO's website: <http://ec.europa.eu/dgs/health_consumer/about_us/who_we_are_en.htm>, last accessed January 2015.

single market interests and member state health interests is commonly referred to as a main reason for the lack of harmonization of application of pharmaceutical legislation (Permanand 2006; Permanand and Mossialos 2005). The health policy field is a field where member states traditionally have been reluctant to transfer authority 'upwards' (Greer 2009). It has historically been regarded as a sensitive policy field: related to the welfare state and pricing and reimbursement, medication is important in national economies and public finance (Greer 2013: 6; Hauray 2013: 81). Due to the weak treaty basis for Community action and the Commission's limited competence in health policy, DG Sanco has been regarded a weak DG, and this has also been the case in terms of administrative capacity (see for instance Greer 2009; 2013). Even though health policy has to some extent been 'nudged' into Europeanization, it is still regarded as a core national issue by member states (Lamping 2013: 19).

In sum, there are several features making it interesting to study administrative decision behaviour within the pharmaceutical policy field. Three articles in this report investigates how the field works in practice by studying effects on decision behaviour of the reshuffle of the pharmaceutical portfolio, the relationship between DG Sanco and EMA, and the network relationships between DG Sanco, EMA and national medicines agencies in Norway and Slovakia.

Research design, methods and data

The report consists of four studies that each contributes to answer the overarching question of to what extent, how and why organizational structures shape decision-making within and between the constitutive parts of the EU administrative system.

The aim is to describe empirically the development of EUs multilevel administration, and to use the organizational perspective to explain and understand different aspects of this process. The four studies are all stand-alone articles that differ slightly with regard to analytical framework, research design and methodological approach. Taken together, however, they can be seen as four cases shedding light on the larger phenomenon of decision behaviour in EU's multilevel administrative system.

The report focuses on the specific relationship between organizational structure and decision behaviour. Studying decision behaviour in this report involves mapping how the constitutive parts of the EU's multilevel administrative system are organized and the links that connect them, as well as the actual decision behaviour that takes place within what is perceived as the system's constitutive parts and within the frame of the relationships between the constitutive parts (see Figure 1.1 for an overview of the parts of the system that are under study and the inter-institutional links). As mentioned, the EU administrative system is a comprehensive and complex system, covering multiple policy areas and organizations at the EU and national levels. The Commission is a large, highly specialized organization encompassing 33 Directorates-General, 11 services and six executive agencies. There are more than thirty EU agencies, and several in the pipeline (Busuioc et al. 2012), and within each EU/EEA member state, there are different types of sector agencies that are linked to the European administrative system.

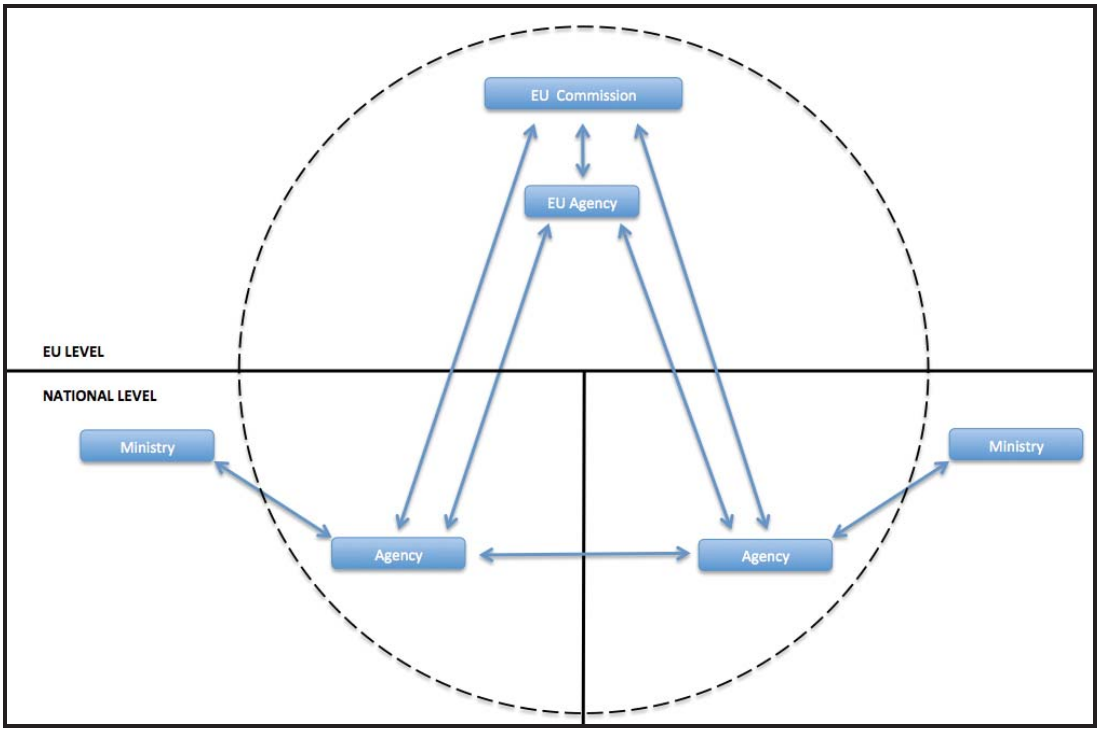

Figure 1.1: Overview of EU's multilevel administrative system (based on Egeberg 2006a: 9).[5]

[5] This figure is meant to illustrate the EU's multilevel administrative system and the parts of it that are studied in this thesis. It is not meant to describe the EU executive order as such, which for instance also would imply ministry-EU Commission and ministry-EU agency links (arrows).

Case study research

According to Yin (2014: 29), five components of a research design are equally important in case study research: the form of the research question (often framed as how and/or why questions); its propositions, which reflect theoretical issues and indicate the direction of the study as well as where you should look for relevant evidence; the unit of analysis, defining what 'case' is to be studied; the logic linking data to propositions (analytical technique); and criteria for interpreting a case study's findings, i.e. addressing rival explanations.

Article one presents a case study of a reorganization in the Commission, articles two and three present case studies of EU Commission-agency relationship, and article four presents a case study of intra-EU network coordination. The research questions in all the articles are framed in terms of how and/or why, and the analytical framework is used to develop propositions and identify potential explanatory factors. Selection of cases has been driven partly by empirical considerations, and partly by theoretical considerations. One aim behind choosing these cases resembles what Yin (2014: 52) refers to as the common case rationale, where the objective is to capture the circumstances and conditions of an everyday situation. Based on existing literature knowledge gaps were identified and different parts of the administrative system and potential study fields delimited. The aim was to conduct individual studies that could shed light on decision-making in different parts of EU's multilevel administration (the Commission, EU agencies and national regulatory authorities) and thereby contribute to the scientific discourse on decision behaviour in the larger European administrative system. The cases were hence chosen out of an interest in the case itself, but is at the same time understood as a typical instance of a class of phenomenon that there already exists some knowledge on. There was also an ambition to utilize existing theory to delimit, interpret, and explain empirical findings (Andersen 2014: 70-1). It was important that the cases under study were relevant in light of the organizational perspective and the different aspects of organizational factors (such as horizontal and vertical specialization, administrative capacity and professional background).

The analytic strategy applied in the studies relies on developing theoretical propositions (Yin 2014: 136), and employing the analytic

technique of pattern matching (Yin 2014: 143). This is close to what is termed a congruence approach (George and Bennett 2005; Blatter and Haverland 2012), and implies that sets of theoretical propositions and observable empirical implications are developed before data is collected. The relevance of each proposition is then considered by comparing them to a broad set of empirical observations (Yin 143-4). The conclusions thus rest on the (degree of) congruence between analytical propositions and empirical findings. Using pattern matching is assumed to strengthen the internal validity of the study because addressing different explanatory factors reduces the chance for incorrectly concluding about a causal relationship between x and y when it is actually z is causing y (Yin 2014: 47). Strong internal validity is generally assumed to be one of the advantages of case study research, as opposed to external validity (Gerring 2007: 43).

With regard to external validity – the extent to which the findings of a case study is relevant beyond the case – the status and usefulness of case study research is debated. The conventional objection to single case studies has been that one cannot draw general inferences due to lack of representativeness (see for instance Geddes 2003).

There are alternative ways of seeing this, however. Although case studies can never be statistically representative of a larger population, it can be analytically representative. In the words of Yin (2014: 40), 'rather than thinking about your case as a sample you should think of it as the opportunity to shed empirical light about some theoretical concepts or principles'. Gerring (2007) defines a case study as a spatially delimited phenomenon (a unit) observed at a single point in time or over some period of time. The purpose of the study is – at least in part – to shed light on a larger class of cases (a population). Each case – the unit of analysis – may provide a single observation or multiple (within-case) observations, and may be created out of any phenomenon so long as it has identifiable boundaries and comprises the primary object of an inference (Gerring 2007: 19-20). Case studies thus have a double function – they are at the same time studies of something particular and something general. The breadth of an inference is a matter of many degrees, however, and the particularizing/generalizing distinction should be understood as a continuum, not a dichotomy (Gerring 2007: 76). It is crucial to define how the case fits into a theoretical universe and to specify the breadth, domain or scope or population of each inference

and clarify how the intensively studied case fits into some broader population of cases. Case study research can result in a new proposition (or a significant modification of an existing proposition) (Gerring 2007: 80-4), either to be applied in reinterpreting the results of existing studies of other concrete situations (other cases), or to define new research focusing on yet additional concrete situations (new cases). Empirical and theoretical implications of the studies in this report will be addressed in the final section of this introduction.

Data sources

This section describes the data sources that the project builds on and what kind of information the respective sources have provided. The central aim has been to gather empirical information on decision behaviour in the European administrative system and the Commission, EU agencies and national regulatory authorities respectively, to map institutional and organizational characteristics as well as investigate how the system works in practice. The report builds on a data material consisting of official documents, interviews and secondary literature. These types of data sources evoke questions of accessibility, relevance, authenticity, and trustworthiness (Grønmo 2007: 122) that will be discussed below. Ensuring that data are not collected from only one source or one type of source contributes toward the research goal of triangulation, where collected data is cross-checked through multiple sources. This is assumed to increase the possibility of revealing the weaknesses of sources that might otherwise have been viewed as reliable, and generally strengthen the robustness and credibility of the findings (Tansey 2007: 766). See Table 1.1 for an overview of data sources.

Secondary literature and document analysis has been important in particular in the initial phase of writing each of the articles. Official documents have been gathered mainly from the websites of the different organizations under study, but some have also been made available by informants (such as English versions of the Slovak medicines agency's annual report). Most official documents are available online and easy to access, but some required request for access and were received by email (such as the Commission's comments on EU agencies' work programmes). With regard to relevance, the document search has been guided partly by the individual research questions of the articles and partly by the advice of informants.

Table 1.1: Overview of data sources

Documents	**Interviews**
EU legislation (regulations, directives) Inter-institutional agreements Legislative proposals, White papers Official hearings (EP, Commission) Annual activity reports Management plans Work programmes, Roadmaps Analytical fiches Comments, Opinions Communications Evaluation reports Staff regulations Financial regulations Press releases Allocation letters Minutes Rules of procedures (SOPs and WINs)	Council officials, General Secretariat (1) EP officials, Secretariat of the EP (2) Commission officials: DG Entr (3) DG Sanco (8) Secretariat-General (2) EU agency officials (4) Interest organizations (5) Ministry of Health, Slovakia (2) State Institute for Drug Control (SIDC), Slovakia (8) Ministry of health and care services, Norway (2) Norwegian Medicines Agency (NOMA) (14) National delegates, Norway (2)

One distinction that has been important when utilizing documents as a data source is the one between documents as normative and retrospective. On the one hand, documents can express opinions in the sense that they tell us something about ideas, aims, standpoints and normative considerations of those that have produced the document. On the other hand, documents can provide factual information about circumstances, actors or events (Grønmo 2007: 120). Since the aim was to learn both about the normative dimensions of the European administrative system and its constitutive parts, and about the way day-to-day organizational practice, both types of information have been utilized in this report.

Documents such as regulations and directives, work programmes, management plans and allocations letters are examples of documents that have been used to identify normative dimensions. These documents (more or less clearly) express how the organizations (i.e. their participants) are expected to work and the intended division of tasks and responsibility (both intra- and inter-institutionally). Furthermore, they may indicate positions and approaches as well as values and concerns that should be perceived as important in the day-to-day decision processes. Annual activity reports and minutes from meetings are typical documents that are valuable in learning

about actual practice, for instance how organizations actually work and relate to each other, what are the actual solutions and concerns that are chosen and the concerns that guide the priorities that are made. The fact that the documents have been produced and made available by public organizations and government authorities is assumed to increase the authenticity and trustworthiness of the sources. In order to get a rich picture of how decision behaviour functions in practice, however, it was necessary to complement the document analysis with interviews (Tansey 2007: 676).

Interview data constitutes an important part of the empirical material in this report and have been useful to map and reveal practices and aspects of decision behaviour that could not be read out of the official documents (Tansey 2007). The interviewees were utilized as informants rather than respondents (Grønmo 2007:120). While respondents provide information about their own background and status, informants provide information about other actor's background, status, actions, meanings, processes or general social conditions. The aim of the interviews was to obtain 'detail, depth and an insider's perspective' (Leech 2002: 665). The informants were asked about their perceptions of decision behaviour in their own organization and about inter-institutional relationships in the European administrative system. The interviews normally started with an introduction of my project, after which the interviewees were invited to introduce his/her professional background and institutional history. Next, they would be asked typical *grand tour* questions, that is, they were asked to give a verbal tour of something they know well (Leech 2002: 667). These were questions regarding their daily work and the tasks of their organizations, where the aim was to learn about their interaction and attention patterns: who are their contacts and how they cooperate and coordinate; what concerns and considerations are important; whose arguments do they listen to; and what are perceived as problems and potential solutions. The interview data is utilized in the report as 'thick descriptions', meaning that the data is presented through verbatim quotations from the recorded data (Myers and Newman 2007: 10).

Potential informants were approached either through emails (with formal letters attached) or phone calls. They were selected based on their centrality in the processes and organizations under study, and on the basis of what they might know, which could help to fill in

pieces of the puzzle or confirm the proper alignment of pieces already in place (Aberbach and Rockman 2002: 673). The aim was not to draw a representative sample of a larger population that can be used as a basis to make generalizations about the full population, but to draw a sample that includes the most important players who have participated in the events being studied (Tansey 2007: 765). Informants were identified with the help of documents (names emerging repeatedly in relevant documents such as public hearings, meeting minutes or reports), or by the help of the relevant organization's websites, such as the online staff directory of the European Commission. Others were approached based on the snowball sampling method, i.e., they were contacted on the advice of other informants once contact was established. Combining different approaches to potential interviewees may be helpful in avoiding the problem of selection bias, i.e., that you end up with only a certain group or type of people. Obtaining interview appointments have been challenging throughout the project, as public officials have busy schedules and limited time and capacity. Several interview requests were denied, and some of the organizations that were approached would only allow very few interviews. Interviewing former employees was helpful in mending this. The advantage of interviewing former officials is that they can speak more freely about the organization, but you also face the problems of retrospective rationalizations. All in all, interviewing both current and former employees is assumed to contribute to balance the data material.

Altogether, the report builds on 53 interviews conducted from November 2008 to April 2014.[6] Four informants were interviewed twice at different points in time. Eleven interviews were conducted by phone, the rest were face-to-face interviews. The interviews were semi-structured, meaning that I used interview guides with open-ended questions (Leech 2002). My project was approved in 2011 by the Norwegian Social Science Data Services (NSD).[7] Following the instructions of NSD, all my informants received a letter beforehand, outlining my project and the intention of the interview, stating that they at any point could withdraw the information provided in the

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[6] One interview was conducted by a co-author.

[7] NSD is the Data Protection Official for around 150 research and educational institutions, including all Norwegian universities, university colleges, health enterprises, hospitals and independent research institutions and centres of expertise. http://www.nsd.uib.no/personvern/en/index.html

interview. The interviews were taped and recorded, and followed up by e-mails where the informants were asked to approve interview transcripts and potential citations. All interviewees were promised full anonymity in scientific publications, and this turned out to be important to several of the interviewees due to more or less sensitive issues that were touched upon. One interviewee preferred not to have the interview recorded, and one interviewee did not want to be quoted. In accordance with the rules of NSD all the data obtained in relation to this project will be completely anonymized after the end of this project (February 2015). A complete list of interviewees can be found in the Appendix (pp. 52-53).

Findings and implications

This section briefly presents the four articles of this report, including research questions, analytical frameworks, data and methods, analysis and the main implications for the literature on the transformation of the European executive order.

Changing policy focus through organizational reform? The case of the pharmaceutical unit in the European Commission

The article investigates the effects of a reorganization of the pharmaceutical portfolio in the Commission, which was moved from the Directorate-General (DG) for Enterprise and Industry to DG Health and Consumer in March 2010. Theoretically, the article contributes to a debate in the public administration literature on the potential for deliberate design and redesign of public policy by demonstrating the significance rearranging organizational structure may have for administrative decision behaviour. The study is particularly interesting in light of that the shift in DG affiliation was *the only* thing that was changed: the unit itself was moved intact, and its structure, tasks, size, professional composition and physical location largely remained the same in both DGs. In addition to official documents and secondary literature, the study builds extensively on 18 semi-structured interviews with Commission officials as well as actors in the Commission's close environment.

The analysis shows that in the process of developing a regulatory framework for information to patients, the officials in the pharmaceutical unit were continuously exposed to and needed to balance between multiple competing actors, solutions, interests and concerns. DG affiliation was crucial when it came to how problems

were understood and solved, as well as which contacts, concerns and interests that were prioritized during the decision process. The change of DG affiliation implied that unit officials went from mainly prioritising industry actors, interests and concerns to emphasising public health actors, interests and concerns. Eventually, this influenced the content of a policy proposal on information to patients.

It is argued that the findings support the hypothesis that the Commission as an executive is becoming normalized. The move of pharmaceutical policy to the 'health department' and its strengthening of the public health perspective has increased the Commission's pharmaceutical policy administration resemblance with similar administrations at member state level. These are developments that may indicate that a transformation of the European executive system is taking place.

There have been some interesting developments after this study was conducted. First, in December 2011, the unit was physically moved out of DG Entr's building (although not to DG Sanco's building, which did not have room for the unit). The unit was also split in two in 2012 order to strengthen its capacity to follow up the work of EMA (duplication). In relation to the presentation of Jean-Claude Juncker's Commission fall 2014, it was suggested to move the pharmaceutical portfolio back to DG Entr (under the new name DG Markt). This suggestion led to strong reactions both in the European Parliament and among patient and consumer groups and health professionals. A lobbyist working for the pharmaceutical industry commented to the EUobserver[8] that the move 'will make our life much easier' because DG Markt is more pragmatic about holding meetings with the industry. 'Back when they were in DG Sanco, even setting up a meeting with officials, to explain our views, was impossible'. In the end, however, the reshuffle was not carried through and the pharmaceutical portfolio remained in DG Sanco. According to Juncker this was due to the concerns raised during EP hearings.[9]

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[8] 'Juncker defends lobby-friendly restructuring of commission services', EUobserver 30.09.2014.

[9] See 'MEPs worried by Commission restructuring', European Voice 18.09.2014; 'Juncker defends re-shaping of Commission', European Voice 25.09.2014; 'Health experts wary of commission reshuffle', EUobserver 21.10.2014; 'Juncker's team confirmed after further portfolio changes', European voice 22.10.2014.

Exploring the EU Commission–agency relationship: partnership or parenthood?

The study explores the relationship between the Commission and the European Medicines Agency (EMA), and asks what characterizes the inter-institutional relationship in terms of distance (how close they are in terms of interaction) and impact (the extent of mutual/unidirectional influence). The two organizations are structurally connected by both being central parts of the EU pharmaceutical policy administrative system, administering policy across organizational boundaries. Few, if any, studies have explicitly examined and conceptualized the relationship between the Commission and the European agencies or identified factors that condition such a relationship.

Theoretically, this topic taps into the question of implications of 'agencification' at European level for decision behavior, that is, the balance between politico-administrative and scientific/technical considerations in decision-making processes. The study draws on an organizational perspective to identify factors that condition distance and impact in the relationship. The study builds on three data sources; 16 interviews with Commission officials, EMA officials as well as representatives from national regulatory agencies and stakeholder organizations that observe the relationship from the outside; official EMA and Commission documents; and secondary literature.

The analysis shows that the establishment of an agency in the pharmaceutical field resembles vertical specialization in the sense that tasks that were initially administered by the Commission became increasingly specialized and decentralized, until the establishment of the agency with a permanent secretariat and a management board. The Commission and EMA are perhaps surprisingly close, and the relationship arguably characterized by an informal hierarchy, with the Commission influencing the agency's activities more than vice versa. 'Parenthood' thus seems like a more suitable label than 'partnership'. The inter-institutional distance and influence vary according to several factors, however: the policy stage, the implementation task and politicization, and the organizational structure of EMA and the Commission.

It is argued that a close, dependent relationship indicates centralization of the European executive system, in the sense that it

contributes to the Commission's capacity and independence vis-à-vis national governments. At the same time, it may indicate a 'normalization' of the Commission in the sense that although it started out in the 1950s as a technocratic international body, it is increasingly evolving into an executive body with organizational and behavioral patterns typical of national level. The relationship between the Commission and EMA resembles in many ways a traditional ministry-agency relationship, with dynamics similar to those one finds in national administrations.

The quest for order. Unravelling the relationship between the European commission and European Union agencies

The article asks where agencies belong in the EU politico-administrative landscape. The question is discussed and contested in the literature that deals with EU agencies, and there are different images of where agencies belong. The study provides new insights about what characterizes the institutional ties between EU agencies and the Commission, and demonstrates fairly strong relationships between the European Commission and EU agencies. Theoretically, it is suggested that the development of a close relationship has been facilitated by certain organizational factors: Firstly, that commission and agency personnel both have EU-level bodies as their primary affiliation. Secondly, Commission and agency personnel share the same executive functions in the EU polity. Thirdly, that the Commission has more and relevant organizational capacity to monitor agencies and incorporate them into its realm. Finally, institutionalized environments may push the Commission and EU agencies into more typical ministry-agency relationships, as we know them from the national level. The data material mainly consists of documents produced by the Commission and EU agencies, such as annual activity reports, analytical fiches, comments, communications and opinions.

The study reveals that the EU has developed an 'agencification policy' which seems to be anchored in common understandings and agreements across the EU's key institutions. The Commission stands out as the driving force behind this policy development, and has given itself a prominent place in the area. Moreover, the Commission has created its own administrative infrastructure within as well as across the affected DGs in order to follow up its agencification policy in practice. Also, the Commission has systematically allocated the

agencies among its DGs according to issue area. Finally, the study shows that agency attention is directed significantly more towards the Commission than towards the Council or the EP. In sum, the interpretation of a tight Commission-agency relationship is that it signifies a centralization of executive powers and a quest for executive order.

Pooling administrative resources through EU regulatory networks

The final study of this report examines how and why national agencies (NAs) interact in EU networks and finds that national agencies in a routinized way pool resources. Theoretically, the article draws on an organizational perspective and suggests that pooling of resources can be understood as a consequence of several factors: vertical specialization and loose ministry steering at the national level enables NAs to operate relatively independent in the network, without ministry interference. This allows NA officials to focus on scientific-technical concerns rather than national, political concerns, when they interact in the network. Additionally, horizontal specialization at the EU and national levels (shared sector affiliation) and the demographic composition of the network (shared educational backgrounds) facilitate end enforce focus on common, sector-specific issues, challenges and solutions, as well as professional standards and values among officials. Furthermore, lack of agency administrative capacity at the national level and the existence of administrative capacity at the EU level contribute to resource pooling among NAs.

The article reports from a case study of the medicines agencies in Slovakia and Norway, which participate in the European medicines regulatory network (EMRN). In addition to official documents and secondary literature, the study builds on 32 interviews with officials in the two agencies, the Slovak and Norwegian health ministries, the Commission and EMA.

The analysis demonstrates how NAs in a routinized way pool resources through the EU network by sharing workload and expertise through mutual adaptation. This enables NAs to focus on fewer tasks and specialize in certain fields of expertise, leaning on other agencies for the capacity and expertise they themselves do not possess. NAs may contribute to and profit from a pool of resources in

different ways, seemingly depending on administrative capacity at the national level. The findings are surprising from the state-centred perspective that so far has dominated the literature on national agencies, where EU policy formulation and implementation is held to be channelled via the ministry, and agencies are considered to be governments' agents. It is argued that pooling of resources through EU networks has implications for the role of agencies in national administrations; it may improve their performance, but also increase their dependence on the network. Arguably, agencies pooling resources through EU networks indicate administrative integration and centralization in an emerging multilevel union administration.

Implications and suggestions for further research

This section discusses the relevance of the knowledge derived from the studies in this report for the European administrative system more generally, both empirically and theoretically. The overarching question that was outlined at the beginning of this introduction was to what extent, how and why organizational structures, and changes in organizational structures, shape decision-making within and between the constitutive parts of the EU administrative system.

The report provides new empirical knowledge on what characterizes decision behaviour within and between the constitutive components of the system – the Commission, EU agencies and national agencies. Different images exist in the literature of executive power and decision-making in the EU, and the EU polity is often characterized as *sui generis*. However, this report contributes to demystifying the Union and de-emphasizing its uniqueness (see Olsen 2007: 2). The empirical findings display two overall decision-making patterns of EU's administrative system. Firstly, articles 1-3 on the Commission and EU Commission-agency relationships support the claims that executive decision-making behaviour at the core of the system is gradually becoming normalized, in the sense that it increasingly embodies many of the organizational and behavioural patterns that are highly typical of executives as we know them from national settings (Egeberg 2006a; Wille 2007; 2013). Secondly, the findings support claims that executive decision-making behaviour in the system is gradually becoming more centralized, in the sense that it contributes to executive centre formation at the European level by strengthening the capacity of the Commission and its ability to act relatively independently of member states (articles 1-4). The findings

of this report thus demonstrate that it is problematic to see EU executive power as merely decentralized and in the hands of the member states, which is the impression one gets from intergovernmental images. Centralization and normalization of EU's multilevel administration may be understood as two indications of the transformation of the European executive order (Egeberg 2006a; Curtin and Egeberg 2008).

Article one supports previous research indicating that DG affiliation is a crucial factor in understanding decision behaviour in the Commission, and shows that DG affiliation may impact on relationships to external actors as well (Cini 1997; Cram 1994; Egeberg 2006a; Egeberg 2012b; Suvarierol 2008; Trondal 2010; Trondal 2012; Trondal et al. 2008; Trondal et al. 2010), as has been the case also in national administrations (Egeberg 2012a). This highlights the difference between the Commission and the Council in terms of decision-making patterns, i.e., territorial vs. sectorial, and the importance of organizing principles in shaping behavioural patterns. Moreover, articles one and two show how the move of the pharmaceutical portfolio may have strengthened not only the health perspective in Community pharmaceutical policy, but also the health perspective and DG Sanco more generally in a wider Community perspective. The pharmaceutical portfolio is a large portfolio compared to other portfolios that DG Sanco was previously in charge of, and due to limited treaty competence, DG Sanco has often been perceived as a 'weak' DG. Arguably, the reorganization can be understood as concentrating and strengthening community health competence in DG Sanco – within the Commission (in particular vis-à-vis DG Entr), and vis-à-vis the EMA and member states. Further research should investigate the extent to which Community health policy is strengthened vis-à-vis member states more generally, for instance in other sub fields, and potential implications of this.

Also, the move of the pharmaceutical portfolio to the Commission's 'health department' arguably contributes to a normalization of the Commission. It has increased the similarities of the Commission's pharmaceutical policy administration with that at the national level, where pharmaceuticals normally are organized under health ministries. The main priorities of EU pharmaceutical policy have thus become more similar to those at the national level, and the same can be said about the relationships to external stakeholders, which went

from being mainly focussed on industry interest groups to public health organizations. A question for further research pertains to the actual degree of correspondence between EU and national health policies. As shown in article two, for instance, DG Sanco and national agencies disagree on the cost-benefit analysis in the evaluation of medicines, implying that DG Sanco executes a stricter analysis than member states by placing higher demands to the benefit of a product. To what extent does the strengthening of Community health policy competence result in tensions between the EU and national levels, and what are the implications for EU policy administration?

Articles two and three contribute to the debate on where in the EU institutional landscape EU agencies belong by demonstrating the development of tight EU Commission-agency relationships (Dehousse 2008; Egeberg and Trondal 2011a; Curtin and Dehousse 2012). The findings represent new insights and imply that images in the literature on EU agencies need to be adjusted. Instead of preserving executive power as decentralized, EU agencies contribute to centralize executive power. Arguably, the establishment of an EU agency in the pharmaceutical policy seems to have strengthened the capacity of the Commission rather than the member state's control of the EU pharmaceutical policy field (the findings of article four also substantiate this). By becoming integral parts of the Commission administration, EU agencies contribute to executive centre formation at the European level by strengthening the Commission's action capacity vis-à-vis member states. Moreover, close Commission EU-agency relationship is another feature that can be understood as a normalization of the EU executive, in the sense that they resemble relationships that are found between ministries and agencies at the national level. For instance, tensions that are common in vertical ministry-agency relationships seem to be unfolding also in EU Commission-agency relationships, i.e., between autonomous scientific-technical decision and politico-administrative steering.

Article four contributes to the debate of how networks impact intra-network relationships between the Commission, EU agencies and national agencies, and shows how national agencies interact and pool resources through mutual adaptation and specialization. The article presents new empirical insights on agency behaviour and introduces 'resource pooling' as a new concept describing extensive intra-network interaction. In particular the coordination of a strong EU

agency seems to be important in facilitating and reinforcing resource pooling. Arguably, this type of pooling between national agencies under the coordination of an EU agency signifies integration and contributes to centre formation at the EU level and the development of a multilevel administration across national borders and levels of governance. One question for further research is whether EU agencies and networks contribute to equivalent centralized administrative behaviour in other policy sectors as well. Another important question relates to the long-term influence of national agencies mutually adapting to and complementing each other, for instance whether it leads to 'centres of excellence' (Groenleer 2009: 168), and what the implications are for agencies' role in national administrative systems, for instance in developing national positions on EU policy.

These findings support the part of the literature arguing that a transformation of the European executive order is taking place – both normalization and centralization are key properties of a transformed, new order. Establishing separate bodies to administer executive tasks thus seem to have consequences for administrative decision behaviour. It should be noted lastly that since these developments are understood as influenced by institutional and organizational factors at the EU and member state levels, they are not seen as 'final' in any sense, but may potentially be reversed, modified or further strengthened depending on the development of the 'living' EU multilevel administration (Egeberg 2006a: Olsen 2007).

The report shows that it is meaningful to look at institutional and organizational features of the administrative system in explaining inter- and intra-institutional decision behaviour in relation to EU policy formulation and administration. This is not to say that it can explain everything, but that it does shed light on several significant aspects. The report demonstrates that studying organizational factors at the EU and national levels may be useful in increasing our understanding of how the administration of EU policy actually works, and how and why it seems to become normalized and centralized. The report builds on case study research with a main focus on the pharmaceutical policy field. However, relying on Yin's concept of analytical generalization (Yin 2014) the lessons from this report may also be transferable and useful in other contexts. The first article shows how a reorganization in the Commission contributed to

change decision-making patterns in the sub-unit responsible for pharmaceuticals, and demonstrates the significance of organizational structure in shaping decision behaviour. Arguably, the findings of the study may have relevance in the broader Commission context; it is likely that identical reorganizations, i.e., moving the responsibility of a policy area from one DG to another, may have similar consequences in other parts of the Commission. The findings may also be transferable to other organizational settings and be used to develop propositions in studies of national administrations or international organizations organized according to purpose or function. Article two and three shows how EU Commission-agency relationships have become close and how EU agencies have become integral in Commission policy-making and implementation activities, due to common functions and similar affiliations, the Commission's administrative capacity and institutionalized environments. This knowledge has relevance for developing propositions about and understanding EU Commission-agency relationships in future studies and similar relationships in national or other types of administrations. The final article shows how national agencies pool resources through a EU network. The findings may be transferable to other similar organizational contexts and used to develop propositions in further studies, for example of EU networks in other sectors. All in all, the findings of the report demonstrates the value of applying institutional-organizational perspectives in the study of EU's multilevel administration, and in identifying factors that are useful in explaining inter- and intra-unit decision behaviour. Arguably, the findings may have relevance for broader public administration studies. Each of the studies show that analytical frameworks applied in studies of the EU's multilevel administration can be built on more general public administration perspectives and lessons from studies of national administrations. As indicated above, lessons drawn from the present studies may also be useful for developing propositions in further studies of national, European or other international administrative settings.

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Appendix: List of interviewees

1. Official, MHCS, Norway: 11 November 2008
2. Official, NOMA: 14 November 2008
3. Official, NOMA: 17 November 2008
4. Official, NOMA: 19 November 2008
5. Official, NOMA: 21 November 2008
6. Official, NOMA: 24 November 2008
7. Official, NOMA: 26 November 2008
8. Official, NOMA: 26 November 2008
9. Official, NOMA: 27 November 2008
10. Official, NOMA: 28 November 2008
11. Official, NOMA: 5 December 2008
12. Official, NOMA: 10 December 2008
13. Official, NOMA: 12 December 2008
14. Official, DG Entr: 10 December 2008
15. National Health Delegate, Norway: February 2009
16. Official, DG Sanco (former): 25 October 2011
17. Official, MHCS, Norway: 23 November 2011
18. National Health Delegate, Norway: 6 December 2011
19. Official, DG Sanco: 8 December 2011
20. Official, DG Sanco: 8 December 2011
21. Official, DG Sanco: 8 December 2011
22. Official, DG Sanco: 19 April 2012
23. Official, DG Entr (former): 10 May 2012
24. Official, DG Entr (former): 28 May 2012
25. Policy officer, EFPIA: 13 March 2013 (phone interview)
26. Policy officer, EPHA: 21 March 2013 (phone interview)
27. Official, EMA: 8 April 2013
28. Official, EMA: 8 April 2013
29. Policy officer, EPF: 18 April 2013 (phone interview)
30. Official, NOMA: 29 April 2013
31. Policy officer, BEUC: 8 May 2013 (phone interview)
32. Policy officer, AESGP: 8 May 2013 (phone interview)
33. Official, DG Sanco: 22 May 2013
34. Official, DG Sanco: 22 May 2013
35. Official, DG Sanco: 22 May 2013
36. Official, EMA (former): 24 May 2013
37. Official, NOMA: 28 May 2013
38. Official, EMA (former): June 2013
39. Official, Secretariat of the European Parliament: August 2013 (phone interview)

40. Official, Secretariat of the European Parliament: August 2013 (phone interview)
41. Official, Secretariat-General, European Commission: June 2013
42. Official, Secretariat General, Council: January 2014 (phone interview)
43. Official, Secretariat-General, European Commission: February 2014 (phone interview)
44. Official, SIDC: 14 April 2014
45. Official, SIDC: 14 April 2014
46. Official, SIDC: 14 April 2014
47. Official, SIDC: 14 April 2014
48. Official, SIDC: 14 April 2014
49. Official, SIDC: 14 April 2014
50. Official, SIDC: 14 April 2014
51. Official, SIDC: 14 April 2014
52. Official, MoH, Slovakia: 15 April 2014
53. Official, MoH, Slovakia: 15 April 2014

Article 1

Changing policy focus through organizational reform? The case of the pharmaceutical unit in the European Commission

Abstract

This article contributes to the debate on the significance of organizational structure for administrative decision behaviour by exploring the effects of a reorganization in the European Commission. It is shown that the move of the pharmaceutical unit from DG Enterprise to DG SANCO impacted on the process of developing a regulatory framework on information to patients. After the reorganization, the focus of the policy process changed from industry to public health and other action alternatives became salient, which eventually led to changes in the policy outcome. The article demonstrates how horizontal specialization systematically tips the scales in the direction of certain actors, solutions, interests and concerns in decision processes, eventually resulting in a change of policy focus. The gap between organizational structure and administrative decision behaviour is thus not as large as is often assumed in the literature.

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Introduction

Structural reforms are frequently carried out within different policy areas and at different levels of public administration, with the aim of changing policy processes or outcomes.[1] At the same time, reports on flawed reforms and absent results are frequent. Reform effects are ambiguous and difficult to anticipate (Olsen 1997: 206). Theoretically, this taps into a heavily debated topic in public administration literature on the potential for deliberate design and redesign of public policy. The debate has been dominated by perspectives highlighting the importance of informal factors for decision-making behaviour, whereas perspectives emphasising the explanatory value of organizational structure has been downplayed (Hammond 1990). Although interest in the relationship between organizational structure and decision behaviour has recently resurged, the impact of reorganizations remains underresearched (Toonen 2012: 574). This article contributes to the debate by showing that the gap between organizational structure and administrative decision behaviour is not as large as is often assumed in the literature. Restructuring a policy field can change policy processes and eventually have consequences for policy focus by affecting which action alternatives that are perceived as salient.

Empirically, the article investigates reform effects in a case where the pharmaceutical portfolio (i.e., the pharmaceutical unit) in the European Commission (the Commission) was moved from the Directorate General (DG) for Enterprise and Industry (DG Enterprise) to DG Health and Consumer (DG SANCO) in March 2010. EU pharmaceutical policy had long been seen as leaning towards pharmaceutical industry interests by both practitioners, experts and academics (Permanand 2006), and a desired shift in pharmaceutical policy was signalled by the inclusion of medicines in the health article in the Lisbon treaty (Art. 4c, 168 TFEU) in 2009. However, given the high incidence of failed reforms, what effects can one

[1] For helpful comments and suggestions I would like to thank two anonymous reviewers, participants at the panel 'Parliamentary and Executive Politics' at the ECPR Graduate Conference, Jacobs University, Bremen, 2012, and participants at the workshop 'The Transformation of the Executive Branch of Government in Europe', ARENA Centre for European Studies, University of Oslo, 2012. The author would also like to thank Morten Egeberg, Jarle Trondal, Tom Christensen, Johanne Døhlie Saltnes, Mathias Johannessen, John Moodie, Anne Elizabeth Stie and Guri Rosén for valuable comments.

expect of moving an organizational unit from one department to another? And how fast can one expect effects to materialize? These questions becomes even more pertinent in light of that the shift in DG affiliation was *the only* thing that was changed: the unit itself was moved intact, and it's structure, tasks, size, professional composition and physical location largely remained the same in both DGs. The article applies a structural-instrumental perspective and a cultural-institutional perspective that unpacks the organizational context and singles out these factors as independent variables that in different ways may shape decision behaviour. Given the limited change in the officials' organizational context, the case can be seen as a least likely case in the sense that the independent variables are at values that only weakly predict an outcome (George and Bennet 2005: 121). The research question is: To what extent and how did the change in DG affiliation affect decision behaviour within the pharmaceutical unit?

The independent variable, decision behaviour in the Commission, is understood as the many choices and decisions that officials make as they perform their tasks during the different phases of the policy cycle. The decision process concerns *more* than the formal decision that is made (e.g., a concrete policy proposal); it also includes agenda-setting, policy formulation, decision-making, policy implementation and evaluation (Howlett et al. 2009). The study concentrates on the process of developing a regulative framework on information to patients about prescription medicines, which took place from March 2004 to October 2011. This allows for a comparison of decision behaviour before and after the reorganization. The aim is to identify the extent to which behavioural patterns reflect organizational structure, in this case the sectorial DG specialization of the Commission, and to detect potential changes after the reorganization. Impact on decision behaviour is 'measured' by examining the officials' behavioural patterns in the policy process: who and what they paid close attention to, perceived as important and in the end prioritized during the policy process. Indicators for this are the officials' perceptions of problems and solutions as well as actors, interests and concerns.

The analysis shows that in the process of developing a regulatory framework for information to patients, the officials in the pharmaceutical unit were continuously exposed to and needed to balance between multiple competing actors, solutions, interests and

concerns. DG affiliation was crucial when it came to how problems were understood and solved, as well as which contacts were prioritized and what concerns and interests were stressed when decisions were made. The change of focus implied that the officials went from mainly prioritising industry actors, interests and concerns to emphasising public health actors, interests and concerns. Eventually, the content of the policy proposal became more focussed on patient and consumer rights than it was before the reorganization.

However, it is important to note that DG affiliation is not the only factor that can account for variation in decision behaviour. Alternative explanatory factors, such as the impact of the other community institutions and the wider EU institutional context, are also taken into account. In addition, findings revealed that certain behavioural patterns remained unaffected by the reorganization. It is argued that this can be explained by the continuity in the unit structure, its location, professional composition and organizational culture.

Why study the impact of organizational structures? Those who participate in public decision-making processes act on behalf of formal organizations, and how they use their influence and discretion is influenced by the constraints and possibilities offered by the organizations they represent (Christensen et al. 2007: 9). A greater insight into how organizing and reorganizing public administration impacts on decision processes and the content of public policy should be of interest to academics studying organizations as well as practitioners in a position to carry out organizational reforms. In the next section, relevant literature is reviewed and the theoretical framework outlined. Then follows a description of data and method. The empirical findings of the case study are then presented, and finally, the findings are discussed in a concluding section.

Studying the impact of organizational structure: An organzation theory approach

Although theorists agree that organizations matter in explaining administrative behaviour, the relative significance of organizational structure is widely debated within the public administration literature. The lack of systematic empirical research on the relationship between bureaucratic structure and actual decision

behaviour has been explained as a result of Herbert Simon's criticism of the so-called classical school of administrative theory where the importance of structures for decision behaviour was questioned and consequently de-emphasized in organizational studies (Hammond 1990) 'The new style was to downgrade the importance of the formal hierarchical structure of bureaucracy. What came to be known as the 'informal organization' was what was important' (Hammond 1990: 144). The following example is illustrative:

> Once systems are developed and patterns of organization behaviour are established, in most instances they cannot be altered significantly by interdepartmental reorganizations. This is particularly true when bureaus […] are moved intact from one department to another. Reorganizations may result in scarcely more than a new name on the letterhead. Where changes are produced, they are seldom those anticipated or intended by the proponents of the reorganization. *Vin ordinaire* cannot be transformed into champagne merely by shifting the location of the bottle in the wine cellar
>
> (Seidman 1980: 169-70)

Recent years have witnessed a resurgence of interest in structural design in both national and international administrations (for a review, see Egeberg 2012a). Comparable to national ministries, the Commission is divided into DGs that reflect sectors or function. A number of Commission studies indicate that this specialization has consequences for the decision-making processes taking place within it. The Commission has been depicted as a heterogeneous organization with competing DGs (e.g., Cram 1994; Cini 1997). Rather than for instance the nationality of officials, DG affiliation has been pointed out as one crucial factor for understanding policy choices, not only for the Commissioners in the College but also for officials at unit level (Egeberg 2006a; Suvarierol 2008; Trondal et al. 2008; Trondal et al. 2010; Trondal 2012; Egeberg 2012b). In addition, the heterogeneity of the Commission also seems to affect relations to interest groups, as each DG has become associated with particular client groups (Mazey and Richardson 2006: Bouwen 2009). Generally, it is argued that the Commission as an executive is becoming more *normalized*. While starting out in the fifties as a technocratic international body, it is increasingly evolving into an executive body as is typical of the executives we are familiar with at the national

level as regards organizational and behavioural patterns. This is one development that indicates that a transformation of the European executive system is taking place (Egeberg 2006a; Trondal 2010; Wille 2013).

When it comes to organizational reform, studies have mainly concentrated on the causes of establishing new or changing old structures, i.e., explaining and describing reform processes, but the effects of structural reform on decision behaviour has been given less attention. Arguably, a study in which behaviour has been observed *subsequent to* reorganization has a value in itself and if behavioural changes can be traced under this circumstance, it is more likely that a cause-effect relationship really exists (Egeberg 2012a: 162). A distinction can be made between two types of effect studies; the first group are those focussing on effects of reforming internal Commission administrative management (see for instance Bauer 2008; 2009; Schön-Quinlivan 2011), the second group are those that focus on effects of reforms aimed at changing policy content, such as the present study. Here, one exception to the lack of studies is Hult (1987), who found that organizational merger may foster shifts in policy direction and impact on relations to interest groups, by making networks more differentiated and diluting established 'iron triangles'. In addition, Mörth (2000) found that reframing the defence equipment and industry issue in the Commission activated other perspectives, actors and knowledge, and also strengthened the Commission's relationship with particular external actors.

This article draws on theoretical propositions from two strands of organization theory: a structural-instrumental perspective and a cultural-institutional perspective. These perspectives agree that organizations influence the thinking and actions of their members, but highlight different explanatory factors (structural and cultural respectively). Reasons to expect people to comply with organizational norms are found in the different action logics that theoretically connect organizations and actor behaviour; bounded rationality, logic of appropriateness, deliberative rationalism and incentive systems (Trondal et al. 2008: 257).[2] Although these perspectives represent

[2] Being well established in the literature the mechanisms are taken for given in this study. Although different perspectives emphasize different logics, they are here understood as interacting and complementary (March and Olsen 2008: 19).

different sides of the debate, the explanations are understood as complementary (Roness 2009: 50).

The structural-instrumental perspective (as developed by Egeberg 2012a) is useful because it unpacks the decision-makers organizational context by highlighting an organization's structure, demography and locus (Egeberg 2012a: 158). Organizations are seen as capable of endowing individual actors with goals and interests, implying that how participants distribute their attention – how they think and act and what and who they attend to as they perform their daily tasks – is affected by their organizational position in a systematic and routine way. Organizational structure is important as it expresses impersonal role expectations and norms for action. Who should do what, how and when in the everyday work, including which interests, values and goals that are to be pursued, or which problems and solutions are important, is built into the structure (Egeberg 2006b: 33). A key assumption is that individuals are bounded rationally and not capable of overseeing all alternatives and possibilities when they make decisions (Simon 1997). This means that when choosing between different action alternatives, an individuals' organizational context can work to simplify complex problems by narrowing down and sorting both feasible and unfeasible policy options (Egeberg 2012a).

The relevant dimension of organizational structure in this article is horizontal specialization, which refers to the way tasks and activities are distributed among units at one level, and expresses how different issues and policy areas are supposed to be linked or de-coupled. The specialization principle applied is central, as organizing according to the principle of purpose fosters sectorial perspectives among decision makers and makes it more likely that decision behaviour follows sectoral lines (Gulick 1937).[3] Structural designs, therefore, 'route' information exchange, coordination processes and conflict resolution (Egeberg 2012a: 161). In the present case, one would expect that DG structure impacts on decision behaviour in the pharmaceutical unit by inducing sectoral behavioural patterns. The change in DG affiliation would be expected to change behavioural patterns in terms

[3] Other ways to specialise tasks are according to territory, function or clientele served (Gulick 1937).

of how officials view the different problems, solutions, actors, concerns and interests they are exposed to.

Another factor that may impact on decision behaviour is *demography,* which refers to personnel composition in terms of different personal attributes within the social entity under study (Egeberg 2012a: 159). Individuals may internalise certain values, norms and role expectations belonging to a particular profession, which condition their decision behaviour. In addition, organizational *locus* may lay premises for the unit's decision behaviour. This refers to how features of location and physical space create physical boundaries that focus decision makers' attention and facilitate planned and random face-to-face contact, i.e., contact patterns, information flow and co-ordination behaviour (Egeberg 2012a: 160). Given this, one would expect that the professional composition of the pharmaceutical unit and their location impacts on how the officials view the different problems, solutions, actors, concerns and interests they are exposed to during the policy process. Since the pharmaceutical unit's composition and location where not reorganized, one would expect these factors to contribute to preserve existing behavioural patterns in the pharmaceutical unit.

The cultural-institutional perspective highlights the significance of the informal organizational dimension, in particular, the role of administrative-cultural traditions in explaining bureaucratic behaviour (Christensen 2012). The logic of appropriateness is a key mechanism connecting the organization and behaviour. Organizational culture entails a relatively consistent set of rules, norms and identities, and through a matching process, the individual intuitively links situations to culture in order to establish what actions are appropriate when facing complex decision making situations (March and Olsen 2008). An organization's degree of institutionalization is an essential factor in prescribing what is appropriate behaviour. Institutionalization refers to the process by which informal norms, practices and values evolve and become important for organizational activities. This implies the classical understanding by Selznick (1957) of how organizations grow into institutions as informal structures are gradually developed and infused with meaning over time (age is thus crucial). Typical characteristics of a political-administrative culture may entail balancing between loyalty to leadership and professional norms and

balancing between premises of professional norms and values and basic facts and contexts they themselves are specialists in. Other common features may be procedural conditions, such as due process, predictability, equal treatment, transparency and information (Christensen et al. 2007: 49-50). Institutionalization of an organization's culture makes the organization resistant to change, and the relationship between structural reform and change in decision behaviour less evident from a cultural institutional perspective (Olsen 1997: 206-6). 'Administrative culture is much more than just one item in a list of variables. It is what underpins all activity within institutions, creating a foundation of shared meaning, interpretation and values upon which all institutional activity rests' (Cini 1997: 73). In the present case, one would anticipate that decision behaviour reflects a particular unit culture, in terms of informal rules, norms and values that have developed over time. Formal structures would be less reflected in behaviour, and the reorganization would have little, if any, impact on how the officials view the different problems, solutions, actors, concerns and interests they are exposed to during the policy process.

Data and method

The decision behaviour of the officials in the pharmaceutical unit was studied within the process of developing a legislative framework on information to patients from March 2004 to October 2011. The study compares decision behaviour before and after the reorganization in March 2010, and in addition to official documents and secondary literature, the study builds extensively on 18 semi-structured interviews with one national official; nine former and current Commission officials (permanent and seconded staff); five representatives of stakeholder organizations; and three representatives from the European Medicines Agency (EMA). Consequently, the empirical material covers how unit officials' themselves perceive their own behaviour as well as how their decision behaviour is perceived by actors in their close environment. The extent to which decision behaviour reflects formal (or informal) structures of the Commission is established based on these perceptions of the officials' distribution of attention.

There are some methodological challenges to measuring reform effects, concerning data and timing. Ideally one would want data gathered at two points of time (dynamic data), before and after the

reorganization. However, the data material is gathered after the reorganization took place and qualifies only as 'quasi-dynamic'. Furthermore, one faces the attribution problem (Christensen et al. 2007: 150); as time passes, the probability of revealing lasting reform effects increases, but so too does the difficulty of isolating the effects of a specific reform and changes that have occurred concurrently in the meantime (Askim et al. 2010: 234). In this study, the possibility of isolating (short term) effects is prioritized, meaning that the effects revealed might be temporary. Yet, this gave the opportunity to explore and exclude potential variation and impact of other explanatory factors. Four independent factors were constant: unit structure, professional composition, location and culture; and one factor varied, DG affiliation. Operationalizing organizational structure, demography and locus is relatively straight forward, as it requires knowledge about the Commission's organizational chart, the unit's professional composition and its location. Organizational culture is more difficult to operationalize, but was identified as the sum of existing informal norms, values and beliefs in the organization that the interviewees accounted for during the interviews.

Changing pharmaceutical policy focus? The pharmaceutical policy field in the Commission

Pharmaceuticals are 'peculiar' (Permanand 2006: 3) given they are industrial manufactured products with wide-ranging influence on public health. Consequently, pharmaceutical policy is connected to both the industry sector and the health sector. This dual aspect makes it a highly complex policy field to regulate as a heterogeneous group of actors (consumers, patients, industry, member states) are affected by pharmaceutical policy and have interests that are not easily reconciled (Permanand and Mossialos 2005: 690; Permanand 2006: 6).

Although a long-standing aim of EU pharmaceutical policy, there is no common European market for prescription drugs. This can be explained as a consequence of the 'clash' between the supranational free movement rules for goods and the subsidiarity principle (Permanand and Mossialos 2005). The health policy field is decentralized; as the member states are in charge of their own health policy, the Commission has, from the outset, had limited competence within this field. Although the health aspect was always significant in

the pharmaceutical legislation,[4] policy remained the responsibility of DG Enterprise, which promotes the internal market, favourable framework conditions for European industry, economic growth, innovation and job creation (Sabathil et al. 2008: 145-8).[5] This organization became over the years an issue of conflict. Patients' and consumers' groups, as well as MEPs and member states, advocated a reorganization to DG SANCO, which seeks to empower consumers, to protect and improve public health and to ensure that the EU's internal market works for the benefit of consumers.[6] EU pharmaceutical policy was perceived as 'captured' by industry, that is, being dominated by industry actors and interests, and focussed on developing a single market and a globally competitive pharmaceutical industry. The regulatory framework was described as favouring the pharmaceutical industry at the expense of health and consumer concerns (Abraham and Lewis 2000; Permanand and Mossialos 2005; Permanand 2006; Boessen 2008; Carboni 2009; Baeten 2010; Geyer 2011). It was questioned whether a reorganization would actually impact on EU's pharmaceutical policy (Boessen 2008: 139) as 'simply passing the brief to DG SANCO would be too simplistic a solution' (Permanand 2006: 193). The formal transfer of the portfolio, which took place in March 2010 in connection to the launch of the Barosso II Commission, received great attention and was welcomed by many.[7]

The pharmaceutical unit

The administrative subunit with particular responsibility for pharmaceuticals was established in the mid-eighties (Hauray and Urfalino 2009: 435). The unit's amount of tasks has steadily increased over the years and in October 2011, approximately forty people staffed the unit, including 25 Administrators with backgrounds in

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[4] The first directive on pharmaceuticals, EEC/65/65, (Council, 1965) aimed at harmonizing the member states' authorization of pharmaceuticals (Permanand 2006: 2), and established the principle of medicine approval to be based on efficacy, safety and quality (Hauray and Urfalino 2009: 435).

[5] See also DG Enterprise's web page <http://ec.europa.eu/enterprise/dg/objectives/index_en.htm>; and annual activity reports (2003-2010): <http://ec.europa.eu/enterprise/dg/annual-activity-report/index_en.htm>, accessed October 2013.

[6] See DG SANCO 2011, <http://ec.europa.eu/dgs/health_consumer/about_us/who_we_are_en.htm>, accessed October 2013.

[7] See for instance <http://www.europeanvoice.com/article/imported/change-in-administration-of-pharma-policy-welcomed/66678.aspx>, acccessed October 2013.

pharmacy, chemistry, biology, human and veterinary medicine, law and economics. The unit carries out tasks such as initiating, preparing, and revising pharmaceutical legislation, decision-making on marketing authorizations, monitoring of member state implementation of pharmaceutical legislation, managing of infringement procedures, and supervising the European Medicines Agency (EMA). DG Enterprise and DG SANCO differ widely in purpose and hence constitute very different frames for pharmaceutical policy. Yet, the reorganization mainly constituted a change in DG affiliation for the unit, its structure, tasks, size, multidisciplinary professional composition and physical location remained the same.

The unit culture is characterized by the special position between two sectors. Interviewees emphasized the importance of performing tasks effectively and being objective. A DG SANCO official pointed out 'if you look at the objectives of the legal framework, it has always had the purpose of securing safety, quality and efficiency. This was always the basis [and] this has always been taken seriously by the pharmaceutical unit' (#5). The unit is referred to as an 'island', both in DG Enterprise and DG SANCO, due to the large staff and its professional composition, the high technical level and comprehensive amount of the tasks and the legal portfolio they are responsible for. In DG Enterprise, the unit stood out because 'you can't compare medicines to cares' (#4). In DG SANCO, the unit stands out because 'Pharmaceuticals is an area where we really have competences under the treaty. It is of course protection of public health, but it is internal market as well' (#4).

The policy process: information to patients

Advertisement of medicinal products in Europe is currently regulated by Directive 2001/83/EC, banning advertising for prescription products (Council/Parliament, 2001). The rationale behind the ban is that advertising would boost healthcare expenditure, without necessarily contributing to health gains, and that the needless consumption of drugs can be harmful to health (Baeten 2010: 174). DG Enterprise proposed to relax the ban on

advertising in 2001, [8] following pressure by the European pharmaceutical industry (Boessen 2008: 104; Baeten 2010:175; Hancher and Földes 2011: 5). The proposal was rejected in 2004, but the European Parliament (EP) and the Council asked the Commission to present a report on the current practice of information provision in member states, and, if appropriate, put forward a proposal setting out an information strategy to ensure good, quality, objective, reliable and non-promotional information on medicinal products (Hancher and Földes 2011: 5-6; Council/Parliament 2004). A report, developed by the pharmaceutical unit and presented in December 2007, concluded that rules and practices on information provision differed widely among the member states (European Commission 2007a), especially with regard to content, public access to information, information channels and control mechanisms (European Commission 2007b). Consequently, the pharmaceutical unit developed a legislative proposal on information to patients (European Commission 2008a; European Commission, 2008b; 2008c).[9] During spring 2008, a public consultation was held on the key ideas of the forthcoming legal proposal. In addition to the aim of harmonising practices on information provision in member states, the consultation paper stated:

> A major part is to present a clear distinction between advertising of and information provided on prescription medicines. This distinction as well as the quality criteria, the content and means of the information provided, together with the proposed structure for the monitoring of the quality of the information, should create a framework for the industry to provide certain information on their medicines to the public. The proposal should enable EU citizens to get objective information from reliable sources
>
> (European Commission 2008a: 5-6)

The proposal presented in December 2008 reflected the major aims and objectives stated in the consultation paper, but was rejected by the Council in 2009 due to fear of increased health expenditures and

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[8] The proposal was part of the first so-called pharmaceutical regulation package, tabled by the Commission in 2001, adopted by the Council in 2004 and in force from 2005.

[9] A directive (European Commission, 2008b) and a regulation (European Commission, 2008c), as part of the so-called pharmaceutical package two.

circumvention of the advertising ban (Council 2009a). The Council was unwilling to move forward with the proposal before the Commission made considerable changes (Council 2009b; #1, #2, #6). In November 2010, the EP adopted a series of amendments to the proposal.[10] In the pharmaceutical unit, the work with the proposal was put on hold after the Council rejection in 2009, and was not resumed until spring 2011 (#6). A revised proposal was tabled in October 2011 (European Commission 2011a; European Commission 2011b).

Problems and solutions

Which problems did the pharmaceutical unit focus on during the policy process, and what solutions were prioritized? Throughout the process, the main conflict issue concerned the role of industry as a (neutral) source of information. In addition, disagreement centred on the distinction between advertisement and information, what channels should be allowed for information provision and what monitoring and control arrangements should be introduced. Conflict clearly followed sectorial lines within the Commission with DG SANCO strongly opposing the 2008 proposal through the inter-service consultation. 'I think it is well known that there were quite some struggles within the Commission at that time.' […] DG Enterprise wanted a more active role for the industry, while DG SANCO was more sceptical (#1).

External interest groups roughly made up a 'health coalition' opposing the proposal, with an 'industry coalition' in favour of the proposal. The first group included healthcare professionals and organizations, patient and consumer groups, and social insurance organizations; the latter group consisted of pharmaceutical industry associations and companies (Carboni 2009: 27-8). The health coalition argued that information provision is a task for regulators and health professionals, and that the role of industry should be limited due to their commercial interests. The industry coalition argued that the pharmaceutical industry possessed essential knowledge and should have a central role in providing information about their prescription products.

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[10] See the Official journal of the European Union: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:099E:SOM:en:HTML>, accessed October 2013.

From the beginning, the pharmaceutical unit was convinced that a better framework was necessary. The existing regulatory framework was perceived as inadequate, defining advertising only vaguely and not regulating provision of non-promotional information, leaving the borderline between advertising and information unclear (European Commission 2008a: 5-6). In addition, the 2007 report had uncovered that information provision in the EU was not harmonized. The legal framework caused some disagreement between the unit and the DG leadership. Although the proposal in legal terms would not remove the ban on advertisement for pharmaceuticals, there was ambivalence in the pharmaceutical unit regarding whether industry could be a neutral source of information.

> Is the industry really able to give – which also was something we gave many thoughts as well – neutral information? Isn't it kind of inherent, that when you want to sell a product, you present it in the most favourable way? Can the industry be a source of information to the general public? That was one of the major points for SANCO. Not only for SANCO – that was the overarching doubt for all discussions.
>
> (#9)

Despite the uncertainties, the unit aligned with the industry coalition and prioritized solutions that would generally secure a strong role for the pharmaceutical industry in information provision when they drafted the 2008 proposal. The 2007 report emphasized the public health gains of revising the legal framework, but clearly stated that 'the pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available' (European Commission 2007a: 9), implying that a key role for industry as a source of information was envisioned.

> The basic idea was that the pharmaceutical industry […] has certain information on medicinal products because they have done all the studies […], they have the data, and why should they not be a source of information to the public? And enabling the public to judge by themselves what kind of information they want and to give them the entire picture of what is available in terms of information
>
> (#9)

After the reorganization, conflict continued to follow sectoral lines. The unit was still convinced of the need to revise and improve the existing legislative framework, and this was accepted more broadly in relation to the 2011 proposal than the 2008 proposal – also by DG SANCO, the member states and the health coalition. As a result of the reorganization the unit chose a different approach to the main problem: it was no longer a question of enabling the pharmaceutical industry to give information about their products, it was about how to strengthen patients' and consumers' rights to receive information about medicines. The industry would still have a role in information provision, but the basic premise was no longer that industry could be a neutral source. The reorganization therefor resulted in substantial changes in the focus of the regulatory framework. In revising the proposal, the unit concentrated on patients' and consumers' right to receive information as opposed to companies' rights to give information. The 2011 proposal introduced restrictions on industry's latitude, establishing pre-control arrangements and restricting what kind of information that could be provided as well as which channels that could be used (#6). The 2011 proposal, therefore, became more in line with the demands promoted by DG SANCO and the health coalition earlier in the process.

> The information must be asked by the patients in order to be delivered. It is the 'pull' principle against the 'push' principle, and this is very well defined now in the proposal. Patients should get information when they ask for it, not get it when they do not want it. This is the difference
>
> (#6)

The change of perspective in the pharmaceutical unit after the reorganization is confirmed by respondents outside the Commission as well. 'The medicinal product is not seen as the goal […], it is more an element that contributes to the overall EU objectives of public health. There was a shift in mind-set on how the medicinal product should be considered' (#10).[11] Despite the change of focus, it was underlined by several of the interviewees that the unit was undergoing a process of adapting to DG SANCO. The legal framework still regulates the pharmaceutical industry, and the

[11] Se also: <http://haieurope.org/wp-content/uploads/2011/12/Dec-2011-DTCA-Chronology-update.pdf>, accessed October 2013.

officials also need to take this into account when they consider problems and solutions.

Interaction and coordination

Who did the unit interact and coordinate with in the process of developing a framework on information to patients? Whose interests and arguments did the officials emphasize in the policy process? Unit officials emphasize that horizontal and vertical contact and co-ordination within the pharmaceutical unit itself and its own DG as most important, independent of DG affiliation. Relations within the unit remained stable throughout the process, which is not so surprising since the unit was moved intact. However, an important implication of the reorganization was that intra- and inter-DG interaction changed. The unit's closest contacts in DG Enterprise were replaced by DG SANCO contacts and DG Enterprise replaced DG SANCO as an external DG with interests but less influence in the policy process.

Politico-administrative signals were reported to be imperative throughout the process, and the reorganization caused a change of substance in the political interests and arguments that the unit was exposed to and emphasized during the policy process. For example, in DG Enterprise it was a pronounced political wish to use the legislative framework to facilitate the pharmaceutical industry (#2, #9, #8), whereas in DG SANCO there was a clear political aim in restricting the role of the industry and strengthening the rights of consumers and patients (#1, #2, #5, #6, #7).[12]

> Clearly, this DG [SANCO] has less responsibility for promoting European industry than DG Enterprise. I believe in the longer term the overall public health perspective will, as it already has in this case [the information to patients process], show a stronger overtone than earlier. And this is logical, because at the inter-service consultations, we would earlier be able only to comment on that we were critical, whereas now it is our

[12] After the reorganization, the Commissioner of DG SANCO early signalized a new approach to the legislation and an explicit wish to bring patient considerations into the process of reassessing the legal proposals. See also the verbatim of EP hearing of designate Commissioner Dalli on 14 January 2010 (at p. 7), <http://www.europarl.europa.eu/hearings/static/commissioners/cre/dalli.pdf>, accessed October 2013.

> responsibility to actually prepare it – and then others can be critical if they perceive it as to little suitable for the pharmaceutical industry.
>
> (#5)

When it comes to contacts external to the Commission, the unit interacted with a range of actors such as the other Community institutions and interested parties. Continuous contact with the EP and the Council was central and the interests of the member states and the arguments of the EP in connection to the amendments were important throughout the process. With regard to interest groups, all the officials interviewed underlined that a broad, cross-sectorial network of external contacts is highly valued. This was evident in that they routinely organized consultations and participated in meetings and different forums: '[I]t is an on-going dialogue' (#6). The officials also underlined the importance of considering all the different views involved in the process. '[T]he legislative process in the Commission is always to balance the interests, to listen to everybody' (#4). However, actors sharing their sectorial affiliation were perceived as particularly affected parties that should be favoured with regards to access. In DG Enterprise, therefore, contact with the pharmaceutical industry was prioritized.

> We were contacted by both consumer protection groups […] and got feedback from them as well as from the industry. […] Industry was quite favourable, and consumer protection groups and association groups were less favourable, to put it like that. Since normally Enterprise worked or was in touch more with companies, it is their primary stakeholder.
>
> (#9)

> Well, we listened to all. Lots of comments were received, and everybody was
> heard. But in the end of the day it was clear that the idea of industry being able to provide information should be maintained. It was more a question about how to go about to do this […]. There was a clear view that 'we want to pursue this project, we see a value in it'.
>
> (#9)

After the reorganization, the scope of contact with the pharmaceutical industry decreased. '[T]here is definitely less contact with the industry. They might not be happy about it, that is another thing' (#4). The network was still significant in the sense that DG SANCO has a broader network of contacts in the health sector than DG Enterprise, implying that new actors from the health sector gained access after the reorganization. Consumers and patients were regarded as most important among interested parties, and the salience of the interests and arguments of health sector groups increased.

> Maybe the NGOs and [consumer] organizations and so forth were more used to working with SANCO […] because SANCO was their main interlocutor […] Protection of public health is the primary goal, and there is more reluctance to have too many contacts with the industry
>
> (#4)

Representatives of the interest groups confirm these changes in behavioural patterns: whereas patients' and consumers' groups experienced easier access after the reorganization, industry groups found it more difficult to interact with the unit. Industry interest groups express discontent with this development. '[S]ince the reorganization, things have become more opaque and less transparent' (#10). A consumer/patient group representative explained it this way:

> The people in DG Enterprise are concerned about the single market, about innovation, about competition, about boosting the economy and about employment, first and foremost. Health for them is a secondary concern. […] So after the pharma move, we noticed that it became easier to work on information to patients because the people were in DG SANCO and not in DG Enterprise
>
> (#9)

Concerns

Which concerns did the pharmaceutical unit emphasize? Throughout the process there were numerous concerns to be considered. Some overall concerns were central, independent of DG affiliation, such as

harmonizing information provision in the EU and improving the quality of the existing regulatory framework. At the same time, some concerns were ranked higher than others in the process of developing the regulatory framework. In DG Enterprise, the unit prioritized industry sector concerns, including, a clear and simple legal framework for the pharmaceutical industry, equal obligations and opportunities for all companies, legal certainty for marketing authorization holders with cross-border activity and sustaining the European pharmaceutical industry's competitiveness (European Commission 2008a: 2).

> DG Enterprise is focussed on enterprise […] So there is a different focus, although you are talking about the same thing. You're talking about medicinal products, but there are different facets to everything. It is more the enterprise side, and of course that came into play here'
>
> (#9)

After the reorganization, however, industry sector concerns was less emphasized. 'In DG SANCO, the focus is on public health' (#6). When revising the legal proposal, the unit focussed on concerns such as strengthening patient rights, the rational use of medicines, ensuring equal access to neutral, quality information (especially on the internet) and preserving the initial ban on advertisement. 'It is obvious that the amended proposals are more oriented towards the patients' (#6). Also respondents outside the Commission confirm that they have observed a change in what concerns the unit focus on after the reorganization, both in the case of information to patients and in general (#10-#14, #16-#18). It is underlined by the officials in the unit that although they are in DG SANCO and public health comes first, industry and market concerns still have to be taken into account.

> I can say from the point of view of myself, and many of my colleagues, I believe, that the change is not very dramatic notably because the legal framework is still the same. And this is what I keep repeating. I am still doing the same thing […]. However, there is a change in emphasis
>
> (#4)

Concluding discussion

This article takes as point of departure the theoretical debate on the potential for deliberate design and redesign of public policy. While perspectives highlighting the importance of informal factors for decision-making behaviour have dominated previous research, this article contributes by showing the value of organizational structure in explaining decision behaviour. The analysis demonstrates the extent to which decision behaviour, and eventually policy outcomes, can change after reorganization. Supporting the structural-instrumental perspective, behavioural patterns clearly reflected the DG structure of the Commission both before and after the reorganization. The reorganization of DG affiliation changed how the pharmaceutical unit perceived and prioritized problems, solutions, actors and concerns. The pharmaceutical unit went from mainly prioritising industry actors, interests and concerns to emphasising public health actors, interests and concerns. The main consequence of the reorganization was a change in policy focus in the process and eventually a change in focus and content of the (second) legislative proposal. The short time that had passed since the reorganization took place implies that behavioural patterns may change and develop further and new patterns arise (the officials in the unit are clearly still in a process of adapting to the new DG). Yet, the fact that the behavioural change took place relatively short time after the reorganization strengthens the structural-instrumental perspective. The perspective is further strengthened considering how limited the reorganization actually was, confined to the unit's external organizational environment. The unit was moved intact from DG Enterprise to DG SANCO, the unit structure (the officials' primary organizational affiliation) and its multidisciplinary staff retained. In addition, their physical location in DG Enterprises' building remained the same.

Other factors as well were central in changing the direction of the policy process and its outcome, such as the dissatisfaction of the Council, and the amendments suggested by the EP. In addition, the empirical material revealed behavioural patterns that were *not* affected by the reorganization. In addition to listening to leadership, some concerns were considered crucial independently of DG affiliation and throughout the policy process, for instance the general issue of harmonising the pharmaceutical legislation and its practice, improving the legislative framework and balancing the relative

attention paid to the different actors, interests, and concerns involved. It is likely that this continuity in decision behaviour can be explained by the organizational factors that were not reorganized: the multi-disciplinary staff, its location, structure and unit culture remained stable. In many ways the officials continued to carry out their daily tasks after the reorganization in the same manner as before. Professional expertise was key to the officials during the processes. In addition, a strong unit culture seemed to be connected to the 'peculiarity' of pharmaceuticals: indifferent of DG affiliation, the unit was still 'island'. Furthermore, values and norms of neutrality, equal treatment, transparency and loyalty to leadership seemed prominent to the officials throughout the process. This supports the cultural-institutional perspective.

Besides showing the significance of rearranging organizational structure for administrative decision behaviour in the Commission, the findings support earlier studies showing that DG affiliation is an important supplier of conditions when it comes to choices in decision processes: not only who gets access to processes in the Commission, but also how problems are perceived and solved and whose interests and concerns are emphasized (Mörth 2000; Mazey and Richardson 2006: Bouwen 2009; Egeberg 2006a; Suvarierol 2008; Trondal et al. 2008; Trondal et al. 2010; Trondal 2012; Egeberg 2012b). In the larger perspective, the findings support the hypothesis that the Commission as an executive is becoming more *normalized,* indicating that a transformation of the European executive system is taking place (Egeberg 2006a; Trondal 2010: Wille 2013). It can be argued that the move of pharmaceutical policy to the 'health department' and its strengthening of the public health perspective in pharmaceutical policy has increased the Commission's pharmaceutical policy administration resemblance with similar administrations at member state level.

The study leaves little explanatory power to the hypothesis of regulatory capture in the pharmaceutical field in the Commission (Abraham and Lewis 2000; Permanand and Mossialos 2005; Permanand 2006; Boessen 2008; Carboni 2009; Baeten 2010; Geyer 2011). Although the pharmaceutical field was dominated by industry before the reorganization, this article shows that this was due to the characteristics of the Commission's organizational structure. Demonstrating the importance of organizational structure, this study

also refutes the assertions that a reorganization would not make a difference to EU pharmaceutical policy (Permanand 2006: Boessen 2008). The reorganization seems to have strengthened the public health perspective in pharmaceutical policy.

The process on information to patients is special in the sense that it goes to the core of the 'clash' between the subsidiarity principle and the supranational free movement rules (Permanand and Mossialos 2005), and perhaps created more conflict than other policy processes in the Commission. The change of policy focus might thus be particularly clear in this process. However, it is likely that the change of focus applies to the general behaviour of the officials in the pharmaceutical unit and to other policy processes and outcomes as well, given the clear perceptions in both the unit itself and its organizational environment. Although further research on reform effects is necessary, it is likely that corresponding reorganizations in other DGs and national ministries will have similar effects. Generally, the comprehensive change in decision behaviour and policy outcome after the reorganization strengthens the theoretical hypothesis of the significance of organizational structure for decision behaviour: the gap between organizational structure and actual decision behaviour is not as large as is often argued in the theoretical debate.

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Article 2

Exploring EU Commission-agency relationship
Partnership or parenthood?

Abstract

This article sheds light on the importance of agencification at the European level for balance of politico-administrative and scientific/technical considerations in decision-making processes through a case study of the relationship between the EU Commission and the European Medicines Agency (EMA). The article explores what characterises the relationship in terms of how close the two organizations are and to what extent there is mutual influence. The findings show that policy phase, politicization and organizational capacity in both organizations contributes to a close relationship where the Commission is more in the position to impact on EMA's operation than vice versa. It is argued that despite Commission control of agency activities through informal hierarchical structures, it does not annul the effect of creating an agency in the pharmaceutical area.

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Introduction

Contributors to the literature on European agencies seem to agree that agencies have become part and parcel of the EU system, but the role and status of these agencies remain unsettled.[1] Much of the debate in the literature concerns the extent to which EU agencies can operate autonomously and who their main superior body is. Recent studies indicate that the European Commission (European Commission) is a main interlocutor and partner in the agencies' lives. The Commission has, more or less reluctantly (Curtin and Dehousse, 2012), been central in the creation of most agencies. Over the years, it has proposed Community strategies arguing for stronger Commission control (European Commission, 2001) and more autonomous agencies (European Commission, 2005; Trondal and Jeppesen, 2008, 420). In 2012, the Commission proposed measures that can be interpreted as an attempt to standardize, clarify, and strengthen the role of the Commission vis-à-vis agencies (European Commission, 2012).[2] However, few studies have explicitly examined and conceptualized the relationship between the Commission and the European agencies or identified factors that condition such a relationship.

Why is it important to study this relationship? Theoretically, the topic taps into the question of implications of 'agencification' at European level for decision behavior, that is, the balance of politico-administrative and scientific/technical considerations in decision-making processes. Although the status of EU agencies is unsettled with regards to a 'superior' body, the idea of 'building executive power' (Egeberg et al., 2012) by establishing separate and specialized agencies is based on a desire to separate certain decisions from

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[2] The background was a call by the Commission for a 'common understanding between the EU institutions of the purpose and role of agencies' in 2008 (European Commission 2008: 2), and the following inter-institutional working group's conclusions and the common approach presented in 2012 (Parliament, Council and Commission 2012).

political considerations and on an assumption that it is possible to do so (Christensen and Lægreid, 2006, 30). This resembles the motivation for creating agencies at European level (Busuioc, 2013, 4). Separate and specialized organizations may contribute to a clearer demarcation of responsibilities and distribution of functions (Christensen and Lægreid, 2006 4). Such divisions can, however, be more difficult in practice than in theory, and the actual relationship may not necessarily reflect formal provisions (Busuioc, 2013; Christensen and Lægreid, 2006; Groenleer, 2009; Martens, 2010; Yesilkagit, 2004). Given that in practice the Commission is close to the agencies, it should be established whether such a close relationship implies that political considerations dominate decision processes and annul the effect of creating agencies in the first place. The Commission's dominance in such a relationship would resemble parenthood, whereas more equal positions would resemble a partnership.

Furthermore, 'there is an immediate question with regard to how they [agencies] relate to the core of the Commission powers and tasks and thus the institutional balance overall' (Curtin and Dehousse, 2012, 197). A close, dependent relationship could indicate that a transformation and centralization of the European executive system is taking place, in the sense that it may contribute to the Commission's capacity and independence vis-à-vis national governments (Egeberg, 2006; Egeberg and Trondal, 2011; Trondal, 2010; Wille, 2013). At the same time, it may indicate a 'normalization' of the Commission in the sense that although it started out in the 1950s as a technocratic international body, it is increasingly evolving into an executive body, with organizational and behavioral patterns typical of national level (Curtin and Egeberg, 2008).

The article explores the relationship between the Commission and the European Medicines Agency (EMA). The two organizations are structurally connected by both being central parts of the EU pharmaceutical policy administrative system, administering policy across organizational boundaries. The primary aim is to investigate what characterizes the relationship in terms of distance – how close they are – and of impact – whether there is a mutual or a unidirectional influence. A second aim is to identify factors that condition distance and impact the relationship. In order to do so, I study the interaction between the two organizations on a day-to-day

basis: the level and nature of contact, coordination, and conflict. The article is organized as follows. Firstly, I take a closer look at how one can understand the department–agency relationships and outline some expectations regarding the Commission–EMA relationship. Next, a short description of method and data collection is given, and then the case study is presented. Finally, findings and implications are discussed in a concluding section. The study shows that the policy stage, politicization, and organizational capacity in both organizations contribute to a close relationship, where the Commission is more in a position to impact on EMA's operation than vice versa. It is argued that despite strong Commission control of agency activities through informal hierarchical structures, this does not annul the effect of creating an agency in the pharmaceutical area.

Understanding department–agency relationships

The EU administrative system is composed of different organizational components. In such a system, an inter-institutional relationship can be understood as 'structural connectedness' between the components (March, 1999, 135; Olsen, 2007, 95). This is also the case for European agencies and their surroundings – they are structurally connected to the other institutions that make up the EU institutional architecture. Arguably, however, what the 'structural connectedness' constitutes is rather ambiguous, for example whether it can be understood as horizontal or vertical. Agencies are rarely 'orphans', or free in an absolute sense (Christensen and Lægreid, 2007, 7). At national level, they are often explicitly linked to a ministry. Findings from studies of relationships between ministries and agencies at national level have recently been summarized in a review article (Egeberg, 2012). Clearly, external vertical specialization and the division of labor across hierarchical levels reduce the possibilities for political control. Officials in agencies exercise discretion relatively isolated from political processes at ministry level and have relatively little contact with the political leadership of the ministry and with ministries other than their 'own' (and parliament). At the same time, the distance in the relationship also reduces the agency's possibility of impacting on the ministry. In addition, agency officials prioritize differently to officials at departmental level; they emphasize expert and user/clientele concerns before political interests, whereas officials in the superior body emphasize political concerns before expert and user concerns. However, structural capacities at both levels may impact on the relationship. The superior

body's ability to exert political influence depends on its organizational capacity, while agency autonomy is positively correlated with agency size.

At European level, however, it is unclear who the main superior body of agencies is. On the one hand, agencification at European level is in many cases about transferring action capacity from the constituent states to a new center (Curtin and Egeberg, 2008; Egeberg et al., 2012, 20; Trondal and Jeppesen, 2008). Some authors have concluded that the agencies are subject to substantial intergovernmental control, with the Council/member states overseeing EU agencies through representation on management boards and networks of national agencies (Christensen and Nielsen, 2010; Kelemen, 2002; Kelemen and Tarrant, 2011). On the other hand, institutional links to other Community institutions are also established when a European agency is created. In the absence of a clearly defined superior body, it has been suggested to be a multiple principal relationship (Dehousse, 2008).

At the same time, research indicates that the Commission plays an important role vis-à-vis EU agencies. For example, the Commission is important in European issue-specific networks, where European agencies make up the hub (Busuioc, 2009, 2013; Gornitzka, 2009; Groenleer et al., 2010; Martens, 2010; Schout, 2008). Well prepared and informed, the Commission has also been shown to play an important role on EU agency boards (Busuioc, 2013; Busuioc et al., 2012; Groenleer, 2009). Moreover, findings indicate that EU agency officials find themselves closer to the Commission than the Council and national ministries and that the Commission is perceived as influential and important in the daily lives of the agencies. The Commission is important in policy implementation, but even more so in policy formulation, indicating that the policy stage matters. In addition, the politicization of tasks or issues can increase the impact of political actors (Egeberg and Trondal, 2011). Ongaro et al. (2011, 408) find extensive arrangements in place for EU institutions to scrutinize and control EU agencies, but that the extent to which these are utilized can be low in the face of good agency performance. Taken together, this has raised questions as to whether the agencies increasingly relate to particular 'parent' DGs and whether the Commission may have more actual control over agencies than can be

inferred from their formal provisions (Egeberg and Trondal, 2011; Egeberg et al., 2012; Groenleer, 2009).

An important premise in this article is that organizations structure the decision behavior that takes place within and between organizations (Egeberg, 2012). Organizing through specialization and decentralization is expected to create organizational boundaries that reduce inter-organizational coordination and influence (Gulick, 1937). The above-mentioned review identifies some factors that have consequences for the distance and impact in department–agency relationships. In the case of the Commission and EMA, as a starting point one would expect that specialization would create organizational boundaries that contribute to distance in the relationship, and that the possibilities for mutual influence are rather low. One would expect EMA to act relatively isolated from the political leadership and processes of the Commission and for the two organizations to have little contact and different priorities. At the same time, the Commission is expected to be more important to the agency than the Council and national ministries. Distance and impact are expected to depend on the extent to which the Commission has the organizational capacity to follow up on EMA's activities and also on the extent to which EMA has the capacity to act on its own. Moreover, the Commission is expected to dominate policy formulation processes, but less so in policy implementation. Furthermore, it is expected that the relationship would become closer when issues are politicized. Finally, good agency performance may contribute to distance by reducing Commission scrutiny and control.

Data and method

Three sources of data have been important to this study. Firstly, the study builds on 16 interviews. Interviews with five Commission officials, four EMA officials, one management board member, and one EMA committee member give a picture of the relationship between DG SANCO and EMA as they themselves perceive it. In addition, the interviews include five stakeholder organizations that observe the relationship from the outside. All interviewees were promised full anonymity. Secondly, official EMA and Commission documents are important sources of priorities and objectives. For example, EMA's founding regulation will give an impression of the formal relationship, while work programs, annual reports, and roadmaps reflect its interpretations of priorities, tasks, and objectives. Commission white papers, roadmaps, and other official documents

reveal its overall strategies toward agencies. Thirdly, secondary literature, including evaluation reports of EMA and of European agencies, has served as an important data source.

Exploring the inter-institutional relationship

The organization of the EU pharmaceutical policy area

EU pharmaceutical policy formulation and implementation mainly involves the Commission, EMA, and the network of member states' competent authorities (NCAs). The Commission is in charge of policy formulation, but draws on the expertise of EMA and NCAs. The same actors cooperate on risk regulation on the implementation side. EMA and NCAs are in charge of technical-scientific risk assessment, whereas the Commission adopts the final decision (following a comitology procedure).

In exploring the Commission–agency relationships, there is no organizational chart that can be consulted. According to the Commission,[3] the role of the Commission vis-à-vis the agencies is mainly governed by the agencies' constituent acts. In addition, agencies must follow the Commission's budgetary and financing provisions as well as adopt the staff regulations of Officials of the European Communities. This is also the case with EMA, although EMA is self-financed by more than 80 per cent through fees. EMA's founding regulation (Regulation (EC) No 726/2004 of the European Parliament and of the Council) stipulates the composition of the agency and the formal division of tasks and responsibilities, but does not explicitly establish a hierarchical 'command line' between the Commission and EMA. The Commission can consult the agency on a number of scientific issues; request information and attend meetings; approve committee procedures and propose appointments and/or the removal of the Executive Director; and initiate evaluations of the agency. In addition, annual reports and work plans are forwarded to the Commission (although little is said about what happens afterward).

[3] Analytical Fiche No 31 (2010). Part of a number of 'detalied analytical papers' published in relation to the inter-institutional working group's '2012 overhaul'. Available at <http://europa.eu/agencies/regulatory_agencies_bodies/>.

EMA's main function is to issue scientific opinions on applications for marketing authorizations (premarketing risk assessment) and to coordinate pharmacovigilance (post-marketing surveillance of products). The agency is composed of a secretariat, a management board comprising member states' representatives, and seven committees made up of experts from the NCAs. The committees have 'exclusive responsibility for preparing the agency's opinions' (EC726/2004). The secretariat is situated in London and headed by the Executive Director. The system consists of three procedures for issuing marketing authorizations. In the decentralized procedure, companies can apply for simultaneous authorization in more than one EU country. In a mutual recognition procedure, companies that have a medicine authorized in one EU member state can apply for this authorization to be recognized in other EU countries. In the centralized procedure, EMA receives and validates applications from pharmaceutical companies, coordinates the NCA's assessment work and the scientific committees, and submits the opinions to the Commission. For each product application, EMA appoints a team that works closely with the NCA evaluators. The centralized procedure is mandatory for some research-based products (such as biotechnological products) and voluntary for others. Once the Commission receives the scientific opinion, it is transformed into a draft decision on marketing authorization and approved by the member states in the comitology procedure (#2). The Commission then issues a final decision. If the decision is not in accordance with the opinion of the agency, the Commission has to annex a detailed explanation of the reasons for the difference (Art. 10, Regulation (EC) No 726/20). The Commission can also suspend the procedure and send the opinion back to the agency if the member states' written observations raise important questions.

The development of the European medicines regulatory system has been characterized by path dependency: the system as it is today has been built gradually and has become increasingly centralized since it was triggered by the thalidomide scandal in the 1960s (Groenleer 2009; Krapohl 2008). From the start, there were two main goals: safeguarding public health and the free movement of pharmaceutical products (Abraham and Lewis, 2000, 83). In the beginning, the system was mostly focused on premarketing measures, while pharmacovigilance came later. The first directive (65/65/EEC) established the general authorization requirement for new

pharmaceuticals (Krapohl, 2008, 70). Secondly, a community procedure for mutual recognition of authorizations and an expert committee, the Committee for Proprietary Medicinal Products (CPMP), was established. The committee comprised representatives from the member states' regulatory agencies, and gave scientific advice on the safety, efficacy, and quality of products to facilitate mutual recognition in case of disagreements among member states (Krapohl, 2008, 72).

The 1980s saw two important developments. In 1987, the Commission was given competence to change requirements regarding the substantive criteria for safety, efficacy, and quality. Simultaneously, a comitology procedure was established: the Standing Committee on Medicinal Products for Human Use was composed of representatives of member states' governments (ministries) that would oversee the Commission's actions with regard to the substantive authorization criteria (Krapohl, 2008, 72). However, an enduring obstacle to a single market was the member states' reluctance to recognize each other's authorizations. In particular, considerations on the desired balance in the cost-benefit analysis differed widely among the member states. This analysis is at the core of the product evaluations: the more therapeutic effects pharmaceuticals have, the more they carry the risk of adverse side effects (Krapohl, 2008, 74). Due to the shortcomings of the system, in the early 1990s the Commission (DG Enterprise) proposed further centralizing of the system by establishing the agency and a centralized procedure with binding outcomes. The regulatory framework was adopted in 1993 and came in force in January 1995. According to Abraham and Lewis (2000), this constituted a transition from a weak to a strong regulatory regime (Abraham and Lewis, 2000, 113). The system was further centralized in 2004 by an expansion of the centralized procedure's application area, following an evaluation of the system which showed that the centralized procedure could become more effective and that mutual recognition was still not functioning optimally (CMS Cameron McKenna and Anderson Consulting, 2000, 11). A new evaluation in 2010 reported that the system was considered legitimate and effective by stakeholders (Ernst and Young, 2010, 10–11). In addition, the EMA secretariat was reported to strongly contribute to the effectiveness of the system by providing experts with administrative and regulatory assistance, as well as increasingly scientific assistance in some fields.

The 2010 evaluation also noted the strong organizational growth EMA had gone through in terms of increased number of committees (seven) and staff (700). Although the secretariat's formal role is rather anonymous, the secretariat has grown into a comprehensive organization in its own right. By comparison, DG SANCO has approximately 960 employees.

Over time the agency has become renowned for dominating the decision-making procedure and is often referred to as a quasi-regulatory agency despite its formal advisory role (Permanand and Mossialos, 2005, 698). EMA's impact on the Commission has been interpreted as fairly extensive, given its status as an expert organization and the fact that the Commission never has any objections to its scientific opinions. As Gehring (2012) notes, 'in practice the EMA dominates the authorization procedure, while political authority is almost negligible' (Gehring, 2012, 113). EMA has thus built up the reputation of strong de facto decision-making powers (Gehring and Krapohl, 2007; Groenleer, 2009; Krapohl, 2008). Its relationship with the Commission has been described as balanced by mutual dependence, as it is in neither the Commission's nor EMA's interest to risk the legitimacy of the system (Dehousse, 2008; Groenleer, 2009).

In recent years, the agency and the system have become increasingly subject to negative public attention. EMA has been criticized for serving the industry while disregarding consumer and patient interests, for too close connections to the industry (both committee experts and secretariat employees), and for having an inadequate framework to deal with conflicts of interest (European Court of Auditors, 2012). The European Parliament also postponed its discharge of EMA's budget for 2009 and 2010 due to issues related to the management of procurement, transparency, and conflicts of interest (EMA Management Board, 2011a, 7; EMA Management Board, 2011b, 2; EMA Management Board, 2012a, 6; EMA Management Board, 2012b, 2; European Parliament, 2011; European Court of Auditors, 2013). The Mediator case, where a drug was available in France and caused great harm despite previous reports of adverse side effects already in 1998, also contributed to negative attention. Simultaneously, however, the agency has taken measures to deal with these challenges; for example, it has revised its agency transparency policy and conflict of interest guidelines and has

reorganized the organizational structure of the secretariat (Court of Auditors, 2012; EMA Management Board, 2011b). The recently established Patients' and Consumers' Working Party (PCWP) has proven successful in improving relations with patent and consumer groups (#12, #13, #14, #15, #16).

In 2010, the pharmaceutical policy field in the Commission was moved from DG Enterprise and Industry to DG Health and Consumers (DG SANCO). As a consequence, EMA was 'added to DG SANCO's responsibilities' (DG SANCO, 2010, 3), a DG that until then had been one of EMA's greatest critics (#3, #4, #11). In the beginning, the relationship was characterized by tension, but started to improve after EMA's new Executive Director Guido Rasi was appointed in 2011 (#3, #11). In 2012, DG SANCO reorganized its unit in charge of pharmaceutical policy into two units, in order to improve its organizational capacity.

A tight informal hierarchy

EMA interviewees report that among the Community institutions, the Commission is EMA's most important contact (#6, #7). Officials both in the Commission and in EMA perceive DG SANCO as the agency's natural main interlocutor in the Commission.[4] The intention is that all contact between the agency and the Commission should go via the two units in charge of pharmaceutical policy in DG SANCO, but mainly EMA's primary contact in the Commission, which is Unit D5 'Medicinal products – authorizations, European Medicines Agency'. This includes contact between EMA and other DGs as well as contact between EMA and other units in DG SANCO. This implies that there is little contact between EMA and other DGs (although there are some exceptions) and suggests that sector affiliation determines 'parent DGs'.

On the agency side, it is mainly the EMA secretariat that is in contact with the Commission. One EMA employee describes the degree of contact with DG SANCO as '[d]aily, all the time. At all the levels of the organization; in fact people will interact with them directly from

[4] See also for instance DG SANCO's management plan 2013 (DG SANCO 2013: 50): 'DG SANCO will achieve further coordination and coherence in the supervision of the four Regulatory Agencies for which it is the Commission's interlocutor'. See also DG SANCO's annual activity reports for 2010 (DG SANCO 2010) and 2011 (DG SANCO 2011).

the operational units.' At higher levels, EMA's Executive Director has annual meetings with the Commissioner, Director-General, and Directors in DG SANCO. At lower levels, there is a high frequency of informal contact supplementing the official contact channels between officials in the pharmaceutical units and in the EMA secretariat through meetings, teleconferences, e-mails, and phone calls. The Commission has two representatives (DG SANCO and DG Enterprise) on EMA's management board, where DG SANCO plays an active role; and a representative from DG SANCO is present at all EMA Committee meetings, where they are reported to be mostly observing (#1, #10, #11). However, it cannot be compared in scope to the interaction with the secretariat: the Board meets three to four times every year, and the committees meet once a month.

Coordination between the pharmaceutical units and the EMA secretariat is viewed as important by officials in both organizations: to EMA it is important that DG SANCO is continuously updated on agency activities, whereas to DG SANCO coordination is important in order to monitor and supervise the agency's activities. In order to be efficient, EMA depends on DG SANCO to approve its opinions, and thus it has become increasingly important for the agency to be attentive to DG SANCO's perspectives. This means paying careful attention to DG SANCO's signals with regard to information and clarifications.

> We really have to make sure that what we give to the Commission meets all their requirements so that it will reach the patient. In that sense, in that exercise, they [DG SANCO] are indeed very important
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> (#6, EMA official)

The frequency of coordination changes in the policy stage. When it comes to policy formulation, DG SANCO may ask EMA's advice when there is a specific need for technical expertise in developing legislation; and DG SANCO believes that EMA makes a valuable contribution in this connection (#1, #3). DG SANCO also makes use of the agency's competence by consulting it on technical issues in special cases, such as the recent horsemeat issue, but also at all stages of the process of preparing new or revising existing legislation as well as negotiating about it in the Commission and discussing it at the Council or the EP (#6, #7).

However, there is clearly more coordination when it comes to the implementation phase, where the level of coordination varies in relation to the task being implemented. There is little coordination regarding pharmacovigilance tasks, where the agency acts fairly independently. This seems to be the only area that EMA works relatively isolated from DG SANCO. Coordination is especially important in the centralized procedure – at all stages from when the EMA secretariat receives and validates applications, up until the scientific opinion is handed over to the Commission. Coordination is crucial when it comes to potentially controversial issues arising during the procedure. Regular meetings are held prior to the meetings in the scientific committees, in order to ensure that DG SANCO is fully updated on difficult discussions and on how the agency is progressing. Also, once the scientific opinions are transferred to DG SANCO, they are often sent (by letter) back to the committees accompanied by a request for better argumentation and justification for the scientific opinions. The overall aim is to be proactive. Interaction follows formal procedures, but there are also different informal routines. The EMA secretariat involves DG SANCO as much as possible during the procedure in order to make sure that 'the end result is something that is not a challenge or is going to cause any issues' (#7).

The level and nature of contact and coordination has increased in recent years, in particular following the transfer of the pharmaceutical area from DG Enterprise to DG SANCO (Vestlund, forthcoming). DG SANCO puts more resources into supervising and overseeing agency activities than DG Enterprise did (#1). The reorganization into two pharmaceutical units has also increased DG SANCO's steering capacity (#4). Together this indicates that the Commission's organizational structure has significance for the character of the relationship. Furthermore, the level and nature of conflict have also changed in the same period. The two organizations have conflicting perspectives on how to interpret the legislative framework, and DG SANCO seems to be less attentive to EMA's views in this regard. The founding regulation serves as starting point for most of the interviewees when they are asked to describe the relationship between EMA and the Commission, but they display differing interpretations regarding the respective roles the two organizations should play in the system. The formal division of labor and responsibility is perceived as clear, but it is acknowledged that

the roles are not always clear-cut and that role interpretations may differ in both the Commission and EMA.

> It very clearly says what the tasks of the agency are with regard to the Commission, and that's how the agency was built up effectively. I think that underpins most of the relationship – 'this is what we have to do, this is what they have to do, and how can we make it work together'.
>
> (#6, EMA official)

> Automatically you talk about tasks. There are two distinct roles here. It is clear that the Commission is responsible for the legal aspects of the work, the policies, the common approaches; they deal with other agencies as well. We are more an implementing, technical scientific agency that gives technical scientific input to the Commission that they can take into account for their decisions. Yet in a way, we are an independent European agency, we are not an agency of the Commission, we are an agency of the European Union. Most of our task is indeed giving advice to the European Commission, but I think our relationship in general is like it is our partner DG in the Commission.
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> (#7, EMA official)

> Well, the official term is that we are the partner DG […]. We used to use the French term *DG de tutelle*, but agencies don't like it. In the inter-institutional group's report I have noticed that they use the term DG partner, which is probably a more politically correct term
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> (#3, DG SANCO official)

The fact that DG SANCO closely monitors and supervises the agency's activities is in itself a source of tension. DG SANCO justifies the comprehensive involvement in the agency's activities by the fact that they are ultimately legally responsible for the decisions that are made, and that they would have to defend the decisions in court cases (#1, #2, #3, #4). DG SANCO underlines that they focus on the legal dimension of the scientific opinions and scrutinize in order to ensure consistency and robustness in marketing authorizations. The agency is an independent agency and its scientific opinions should be based on the work of independent experts. They acknowledge,

however, that things are never black and white, and that the lines between risk management and risk assessment are sometimes blurred (#1, #2, #3).

Officials in DG SANCO signal that EMA could avoid scrutiny by being more legally consistent in its work. The output of the committees is not always consistent, which is particularly the case with the work of the Committee on Human Medicinal Products (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC) (#1, #10). Also, in light of the large amount of resources EMA receives, it is to some degree seen as underperforming: it does not focus sufficiently on core tasks but undertakes actions in areas where it is not delegated competence, such as creating new working groups or taking new initiatives in international affairs. Over the years EMA has become active in international cooperation: it has bilateral relations, for example with the American Food and Drug Administration and the Japanese Pharmaceutical and Medical Devices Agency, and participates in various international forums (EMA, 2010, 7; EMA, 2011, 11; Ernst and Young, 2010, 13). From DG SANCO's point of view, EMA has exceeded its mandate and authority in international relations. According to the founding regulation, the agency 'shall act upon request of the Commission' in international affairs. DG SANCO does make use of EMA's expertise, such as in trade negotiations, but perceives EMA's role mainly as a support to DG SANCO in this field (#1). There is also an element of competition between the two organizations with regard to representing the EU internationally. In the view of DG SANCO, EMA has to some extent been taking on the role as the 'EU regulator', whereas that is formally the Commission's competence. EMA has also the time and resources to go to conferences and so on, whereas DG SANCO has less capacity to do so. Since it is DG SANCO that negotiates the budget in the Commission on behalf of the agency, it perceives the agency as undermining its own position by not sticking to its core tasks (#1, #3). The agency, however, views the supervision as interference with its work that is outside the mandate of DG SANCO (#10, #11).

From EMA's viewpoint, this use of resources is a natural consequence of the responsibilities that have been added by the Commission over the years, such as increased demands on efficiency and transparency, a new and wider span of tasks, and the growth in

the number of committees (#6, #7, #8, #11). Furthermore, there is conflict regarding which concerns are important and which considerations should form the basis for decisions. On the one hand, DG SANCO and EMA share many concerns: they are generally both strongly committed to public health, to medicines reaching patients and consumers, and to quality and consistency in the output of the scientific work. On the other hand, the two organizations differ in their views on how these concerns are best promoted, and DG SANCO has increasingly challenged the opinions of the agency (#4). The Orphacol case serves as a good example of this. DG SANCO disagreed in this case on the validation of an application for marketing authorization and refused (twice) to issue marketing authorization. This was despite the twice unanimously adopted decision by the scientific committee and its support by the comitology committee (#3). In addition, DG SANCO and EMA differ in their views on the risk-benefit analysis that constitutes the basis for positive or negative opinions on marketing authorizations. Basically, the EMA committee experts base their opinions on the principle that if the benefit outweighs the risk, the product can be granted marketing authorization (although it also depends on patient groups, and so on). DG SANCO, however, requires not just that the benefit outweigh the risks, but that it does so to a great extent. This means that DG SANCO practices a stricter risk-benefit analysis than the scientific experts do in their evaluations (#10, #11). However, according to the interviews, EMA has not yet made any changes to the scientific opinions following comments from the Commission, but rather has tried to specify the foundations on which it has reached its conclusions.

Finally, DG SANCO issues guidelines for the appointment of experts. Recently, these guidelines were made stricter regarding the background of EMA experts, demanding five years' quarantine for experts that have worked in the pharmaceutical industry. The strict guidelines came as a response to public concerns raised as to the independence of EMA's experts and assertions of too close cooperation with the pharmaceutical industry. For EMA, this has complicated the process of getting experts, since the best experts often possess their expertise as a result of experience from working within the industry and from developing medicines (#6, #7, #8, #11).

Concluding discussion

The establishment of the agency in the pharmaceutical field in many ways resembles vertical specialization in the sense that tasks initially administered by the Commission became increasingly specialized and decentralized until the establishment of the agency with a permanent secretariat and a management board. In light of established knowledge on department–agency relationships, showing that external vertical specialization tends to reduce interaction and possibilities for mutual impact, the two organizations are perhaps surprisingly close. Despite the absence of a clearly formulated formal hierarchical structure, the relationship between the Commission and EMA is now arguably characterized by an informal hierarchy, with the Commission influencing the agency's activities more than vice versa. Whereas EMA perceives the relationship as a 'partnership', the perceptions expressed by DG SANCO are more in line with 'parenthood', in the sense that it sees it as its responsibility to supervise and monitor the agency. The findings thus support previous studies showing that the Commission is close to agencies and that agencies relate to certain 'parent' DGs in the Commission. Although the agency questions the legitimacy of this 'parenthood', the de facto decision-making power that EMA is renowned for seems currently to be under pressure.

However, the findings show that inter-institutional distance and influence vary according to several factors: the policy stage, the implementation task and politicization, and the organizational structure of EMA and the Commission. As expected, the relationship is much closer in the policy implementation stage than the policy formulation stage. In the formulation stage, the Commission makes use of EMA's expertise when needed. In the implementation stage, the relationship is closer with regard to premarketing tasks than post-marketing tasks. Also, as expected, the relationship becomes closer when issues are politicized. Furthermore, DG SANCO's reorganization of its pharmaceutical unit into two units strengthened its capacity to follow up the agency. The informal hierarchy has also mainly developed after the move of the pharmaceutical portfolio from DG Enterprise to DG SANCO. These findings indicate that the Commission's organizational structure impacts on the relationship. DG SANCO may conduct a stronger steering of EU agencies belonging to its portfolio than DG Enterprise, but this can also indicate a general Commission trend of strengthening agency

steering and relations. This would not be surprising in light of the new approach to agencies introduced in 2012 (European Commission, 2012).

Additionally, how close the relationship is and how influential DG SANCO is varies according to the agency's organizational structure. Whereas the EMA secretariat is very open to influence from DG SANCO and prepared to adjust its activities accordingly, the scientific committees are less attentive to Commission views. DG SANCO and EMA differ in their considerations as to what should be the foundations for decisions. Although DG SANCO scrutinizes EMA opinions to a greater extent than previously, scientific-technical decision making in the committees still seems to be safeguarded from political interference. The position of the secretariat between DG SANCO and the scientific committees seems to be significant in this sense. One implication is that in the longer term, the impact of the Commission on the EMA secretariat can threaten the scientific-technical decision making if the trend of assigning more scientific tasks to the secretariat continues.

Commission–agency relationships may take different forms, depending on the agency and the DG involved. All in all, the case study shows how the Commission indeed can be close to and impact on the operation of an agency without necessarily annulling the effect of 'agencification' at European level. The study illustrates that the EU-Commission relationships may face similar challenges tensions as ministry-agency relationships at the national level. Furthermore, the study contributes to answer the question referred to in the introduction of how agencies relate to the core of the Commission powers and tasks and thus the overall EU institutional balance (Curtin and Dehousse, 2012, 197). EU agencies that are close to the Commission arguably contributes to the Commission's executive capacity and ability to act independently from the member states. The case study thus supports the hypotheses of normalization and executive center formation at European level.

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Interviews

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#3 Official, DG SANCO
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#5 Official, DG SANCO
#6 Official, EMA
#7 Official, EMA
#8 Official, EMA
#9 Official, EMA
#10 CHMP member
#11 Management Board member
#12 Policy officer, EFPIA
#13 Policy officer, EPHA
#14 Policy officer, EPF
#15 Policy officer, AESGP
#16 Policy officer, BEUC

Article 3

The quest for order
Unravelling the relationship between the European Commission and European Union agencies

Abstract

Over the past couple of decades a considerable number of European Union (EU) agencies have been established. Research has so far shown that they have become more than mere facilitators of transnational regulatory networks, arenas for the exchange of information on 'best practice', and vehicles for member state governments. Task expansion has taken place, e.g. by taking up (quasi-) regulatory tasks. However, the jury is still out as regards exactly where in the political-administrative landscape EU agencies are situated. Benefiting from novel data sources, this study sheds light on so far undocumented relationships between EU agencies and the European Commission. The study shows that EU agencies have become integral components in the policy-making and – implementation activities of Commission departments. Secondly, this development is accounted for by an organizational approach that

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specifies a set of organizational factors. The study argues that such tight relationships between Commission departments and EU agencies signify a centralization of EU executive power.

Introduction

Especially since the early 1990s, a wide range of (semi-) regulatory, monitoring, and coordination tasks have been centered to a quickly growing number of agencies in the European Union (EU).[1] This EU-level agencification has happened not only in numbers but also in terms of their powers, some of which are novel and far-reaching. This process of agencification has also accompanied a quantum leap in the study of EU agencies (e.g. Busuioc et al. 2012; Rittberger and Wonka 2011). A majority of studies on EU agencies focuses on institutional formation, institutionalization and intra-agency governance. However, our understanding of where these agencies 'belong' in the European political-administrative space remains incomplete, discussed among practitioners, and contested among scholars (Vestlund 2015). This study documents thus far undocumented terrain of the relationship between these agencies and the European Commission (European Commission). The ambition is to offer new empirical observations about what characterizes this relationship and what can explain it. Two sets of data are presented, offering observations about how the Commission-agency relationship is assumed to work and how it works in practice.

Research has so far shown that EU agencies have become more than mere facilitators of transnational regulatory networks and arenas for the exchange of information on 'best practice' (Egeberg and Trondal 2011a). Task expansion has taken place, e.g. by taking up (quasi-) regulatory tasks. However, the jury is still out as regards exactly where in the political-administrative landscape EU agencies are situated. Benefiting from novel data sources, this study sheds light on so far undocumented relationships between EU agencies and the Commission. The study examines this relationship and offer causal explanation of how EU agencies might have become parts of Commission departments' portfolios. The article argues that tight

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relationships between Commission departments and EU agencies signify centralization of EU executive power and a quest for executive order.

The European political-administrative system is characterized by unsettled and poorly understood institutional ties. This state of affairs is intriguing since it renders the European political order a living laboratory for study (Olsen 2007). The growing role of EU agencies has caused the Commission to re-launch the debate on 'the role of agencies and their place in the governance of the EU' (European Commission 2008: 2). This article contributes to this debate by showing the emergence of rather intimate relationships between the Commission and EU agencies. The study offers two observations. First, EU agencies have become integral components in the policy-making and –implementation activities of several Commission departments. Secondly, this development is facilitated by certain organizational factors: first, the Commission and EU agencies are sharing the *function* of being executive bodies. Second, Commission and agency personnel have both an EU institution as their *primary affiliation.* Third, among EU institutions only the Commission disposes over the necessary *administrative capacity* to monitoring EU agencies in their daily work. Fourth, and finally, *legitimized templates* of department-agency arrangements drawn from national settings point towards the Commission as the most appropriate parent organization.

The article is presented in the following steps. The next section outlines a theoretical tool-kit consisting of one classificatory map on EU agencies and their relationships towards the Commission, and secondly an organizational approach that supplies variables that may explain why EU agencies have gravitated towards some institutions (Commission departments) more than towards others. The succeeding section empirically examines this relationship in two steps: First, by probing how the Commission-EU agency relationship is *framed* by relevant actors, and secondly by illuminating how this relationship is *practiced*. A concluding discussion suggests that the empirical observations signify that tight relationships between Commission departments and EU agencies signify centralization of EU executive power.

Theoretical perspectives and previous studies

This section is presented in two steps. The first section offers a catalogue of the most common images or claims about the relationship between EU agencies and the Commission available in contemporary literature. The second section introduces an organizational approach that supplies factors that may explain variation in the relationship between EU agencies and the Commission.

Images of the relationship between the Commission and EU agencies

The intergovernmental image

In the view of intergovernmentalists, EU-level administrative bodies are set up to implement or monitor the implementation of policies agreed upon by national governments. Such bodies (or 'agents') are expected to do this in an impartial manner, thus enhancing the credibility of government commitments (Moravcsik 1998). Regarding EU agencies, powers entrusted to them seem to have been delegated more often from national governments than from the Commission (Dehousse 2008: 793). Also, several EU agencies have in fact evolved from pre-existing transnational networks of national agencies (Thatcher and Coen 2008; Thatcher 2011). Thus, governments have insisted on keeping EU agencies under their control; most apparently expressed in the composition of their management boards on which national delegates usually constitute an overwhelming majority (Kelemen 2002; Dehousse 2008; Christensen and Nielsen 2010). 'Far from representing new supranational structures which could threaten the authority of national regulators, European agencies are rather viewed as the heart of a network, bringing together the various government agencies active in a given policy area' (Dehousse 1997: 257). Fourteen years later Kelemen and Tarrant (2011: 942) drew the same conclusion: 'EU policy-makers have not created a centralized, hierarchical Brussels-based bureaucracy'. Recently, Kassim et al. (2013: 131-32) highlight the establishment of EU agencies as one of the factors that might contribute to a weakening of the Commission in relation to national capitals. Hence, the intergovernmentalist expectation is that EU agencies will, for the most part, remain within the remit of national governments and have week ties towards the Commission.

The Communitarian image

EU agencies may also be depicted as integral components of the Commission and its departments. Agency autonomy as well as member-state control is sacrificed for the Union's need for integrated and uniform administration (Olsen 2003). According to this second image, the ties between the Community institutions (notably Commission departments) and EU agencies are close. Most EU agencies are vertically specialized outside the Commission, although they may be *de facto* integral components of the Commission when measured by their activity and by actors' perceptions. EU agencies are authorized to make individual decisions based on existing secondary legislation. Such agencies may thus be 'instruments of centralisation' of regulatory functions at the Union level (Majone 2005: 97). According to Hofmann and Turk (2006: 592), EU '[a]gencies integrate national and supranational actors into a unitary administrative structure…'. Similarly, Everson and Joerges (2006: 529) claim that 'European agencies … remain firmly ensconced within the institutional umbrella of the Commission'. According to this image we should expect to see strong signs of extensive relationships between the Commission and EU agencies, particularly relationships that may indicate a hierarchy with the Commission at the helm.

The epistemic image

Transnational regulatory networks may be seen as 'communities' endogenously driven by expert knowledge and professional values (Haas 1992). This model sees EU agencies as porous and transparent institutions, penetrated by webs of external actors and institutions (Everson et al. 1999: 58). Agency governance is thus disaggregated by seamless webs of actors that challenge the relationships between the Commission and EU agencies. Eberlein and Grande (2005) describe what they call the 'informalization' of regulatory politics, characterized by 'best-practice' and information exchange (cf. Majone 1997), activities not subject to any classical democratic control. Consistent with this, a survey of EU-agency personnel unveiled that their attitudes were overwhelmingly technocratic although sensitivity to stake-holder concerns was also present (Wonka and Rittberger 2011). Elaborating on a 'multi-principals model' on EU agencies, Dehousse (2008: 803) concludes that 'none of the existing agencies can be depicted as a mere instrument in the hands of any one of the 'political' institutions' (see also Curtin and Dehousse 2012). Thus,

since transnational regulatory networks, from an epistemic community perspective, are 'floating in-between' levels of governance, we do not expect to find clear steering and accountability arrangements in any direction, including vis-à-vis the Commission.

Accounting for the relationship: An organizational perspective

Theoretically, the agency literature has been, and still is, biased towards a rational choice approach generally and the principal agent (PA) perspective in particular. The PA model demonstrates how the formal design of agencies may reduce 'agency losses' and the possibility of 'runaway bureaucracy' (Calvert et al. 1989; Geradin et al. 2005; Thatcher and Stone Sweet 2003). However, by assuming that the principal-agency relationship may be ambiguous, shifting and at times contested, this study offers an organizational approach that give explanatory primacy to organizational factors. Seen from this perspective, existing organizational (normative) structures affect actual behaviour, both in terms of daily decision processes and in terms of processes aiming at changing structures, procedures, and arrangements themselves. The argument is not that structure provides an exhaustive explanation of behaviour, or determines policy output in any detailed manner. The idea is rather that organization structure tends to intervene in a systematic and understandable way in decision-making processes, making some choices more likely than others (Christensen et al. 2007; Egeberg 2012; March and Olsen 1989). Insights from this perspective lead us to expect that EU agencies are actually less under the control of national governments and more under the control of the Commission.

Although EU-agency management boards are numerically dominated by national delegates, those delegates are not necessarily acting primarily as government representatives. Most board members come from national (regulatory) agencies, not from ministerial departments (Suvarierol et al. 2013). Due to such agencies' organizational detachment from ministries ('vertical specialization'), national agency officials tend, in practice, to be more sheltered from political (ministerial) steering than officials in ministerial departments. This finding seems to be relatively consistent across time and space (Egeberg 2012). Concomitantly, Buess (forthcoming) observed that only a minority of government representatives on EU-agency management boards brought instructions from the national

capital when attending meetings. Thus, they seem to be loosely coupled to their political masters. Moreover, in (formal) organizational terms, national delegates' membership on EU-agency boards makes up a highly *secondary* organizational affiliation: the frequency of board meetings are in general low and the demands imposed on their time and energy by their national agency (*primary* affiliation) are considerably more burdensome. Accordingly, studies have documented that government representatives attending EU-agency management boards often meet relatively ill-prepared. Combined with few board meetings and considerable size of the meetings (often more than 40 attendees), management boards are deemed not that effective in overseeing and controlling the activities of EU agencies (Busuioc 2012; Busuioc and Groenleer 2012).

On the other hand, one could think of several organizational factors that might be conducive to a closer cooperation between EU agencies and the Commission. Firstly, EU agency personnel and Commission personnel share their primary affiliation (formally) to EU-level bodies. As might be expected from an organizational perspective then, studies show that both groups of staff actually direct their loyalty and attention primarily inside their respective supranational organizations (Suvarierol et al. 2013; Trondal and Jeppesen 2008; Trondal et al. 2010). Secondly, taking the functional specialization among EU institutions into consideration, we see that EU agencies and the Commission also share the same (executive) functions in the EU polity: they are both in charge of rule implementation and rule development. This stands in contrast to the Council and the EP which have mainly legislative functions. And, thirdly, and partly as a consequence of the latter point, it is reason to believe that the Commission, compared to the Council and the EP, disposes over considerably more and relevant organizational capacity that might be mobilized for incorporating EU agencies into its realm.

Finally, 'institutionalized environments' may contribute to push the Commission and EU agencies into a more typical 'ministry-agency relationship'. This argument rests on the 'Stanford Institutionalist School' and not on the structural-instrumental approach outlined above. 'Institutionalized environments' mean that there exists organizational templates 'out there' which are deemed legitimate, modern or successful. These organizational models represent a normative pressure on organizations to adapt accordingly in order to

enhance their own legitimacy (Meyer and Rowan 1977). Arguably, the dominant and 'legitimized' way of situating regulatory agencies in the political-administrative space is found at the national level. The main template there consists of agencies allocated among various ministries according to issue area. Agencies are structurally separated from their respective ministerial departments and enjoy some autonomy in their daily operations; e.g. when adopting individual decisions. However, agencies usually operate within framework legislation and political executives have ultimate political responsibility for their activities (Verhoest et al. 2012: 3). One could imagine that 'a quest for order' at the EU level (cf. Olsen 2007), becomes 'inspired' by the way of doing things at the national level. If so, this would exclude the possibility of subordinating EU agencies to political bodies at the level *beneath*, i.e. national institutions. In a European context, linking agencies directly to legislative bodies, in this case the Council and the EP, does not sound harmonious either (Schapiro 1997).

Data and method

This study draws empirically on Commission and EU-agency documents and, to some extent, on interviews. One primary source is the Annual Activity Reports (AARs) with appendices of all Commission DGs for the years 2005 and 2012.[2] The ambition is to offer a synchronous study and no diachronic study. Using data from two years simply adds validity to the measured relationships between the Commission and EU regulatory agencies, and does not aim to systematically measure change over time. In addition to the AARs, Commission opinions on EU agencies' work programmes are part of the data material. These documents are searchable at the Commission's website, but access needs to be requested. All Commission comments for the years 2005 (three) and 2012 (13) were requested. In addition, in order to avoid a Commission bias in our data, we investigated the potential for obtaining AARs from the DGs of the Council's General Secretariat as well. Council DGs do not systematically produce AARs, however, and since there existed only three AARs from 2005 and one from 2012, the foundation for comparison was limited.

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[2] AARs 2004-2011 are available at: <http://ec.europa.eu/atwork/synthesis/aar/aar2010/index_en.htm> [last accessed 13 May 2014]. AARs 2012 are available at: <http://ec.europa.eu/atwork/synthesis/aar/index_en.htm> [last accessed 13 May 2014]

The Commission DGs' AARs were systematically searched through electronically in order to detect and extract text concerning EU agencies. The aim was to map to what extent and how such agencies are mentioned and agency activities reported on by each DG. The AARs for both 2005 and 2012 were accessed through the Commission's official website. For the purpose of reducing the amount of undiscovered text, the document search included keywords based on agency names and acronyms (*agenc*, *authorit*, *office*, *centre*, *foundation*, *institute*, *college*, *unit*, *control*, *body*, *parent*, and *partner)*. The 2012 information was coded according to the categories given in Table 4.2. The 2005 reports were standardized only to a certain extent, leaving it up to each DG how detailed information that was provided. The 2012 reports followed a more common template, but there seems to be few strict guidelines for the extent to which and how regulatory (decentralized) agencies and their activities should be commented on. Thus, an important caveat in the material is that the reports might be subject to over and/or under reporting. The years 2005 and 2012 were chosen due to the availability of data. Full sets (including all DGs) of AARs were accessible only from 2004. Furthermore, many of the 2004 reports were scanned documents and not electronically searchable. 2005 were thus chosen out of cost and time considerations. The data sources also consist of other Commission documents such as 'analytical fiches'[3], opinions, communications and reports. In particular, the so-called 'analytical fiches' are used to tap the EU's policy on its agencies. Authored by the Commission, these papers may come to over-emphasize the role of the Commission. However, it is, after, all the Commission that has been assigned the task to prepare the policy documents in this area, leading up to an inter-institutional agreement or understanding.

Supplementing Commission documents, annual activity reports of the 32 EU regulatory (decentralized) agencies[4] were also searched through in order to map how and when the Commission, Council

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[3] A series of analytical papers published at the Commission's website, available at: <http://europa.eu/about-eu/agencies/overhaul/index_en.htm> [last accessed 13 May 2014].

[4] ACER, BEREC, CdT, CEDEFOP, CEPOL, CPVO, EASO, EASA, EBA, ECDC, ECHA, EEA, EFCA, EFSA, EIGE, EIOPA, EMA, EMCDDA, EMSA, ENISA, ERA, ESMA, ETF, eu-LISA, EU-OSHA, EUROFOUND, EUROJUST, EUROPOL, FRONTEX, GSA, OHIM, FRA.

and Parliament were mentioned and referred to by the agencies themselves, thereby counteracting some of the imbalance that may follow from building solely on Commission documents. The following keywords were included in the search: *commission*, *directorate*, *general*, *council*, *secretariat*, *parliament*, *parent*, *partner*, *DG*, *EP*, and *EC*. The frequency in the AARs of the words *commission*, *DG*, *EC*, *council*, *presidency*, *parliament* and *EP* is reported in Table 4.3. First, the frequency was registered electronically by using the Adobe Professional (and controlled for in Word Frequency Counter). All hits were manually controlled for context and irrelevant hits filtered out. We are fully aware of the methodological limits of such counting alone. Nevertheless, used in combination with, *inter alia,* content-analysis of the AARs of Commission DGs, one gets a more balanced picture of the Commission - EU agency relationship. Additional information was acquired through five phone interviews followed up by emails with representatives of the EP Directorate for Presidency Service of the Parliament, the Council General Secretariat, and the Commission's Secretariat General. Two final caveats should be mentioned. First, the data presented are slightly biased towards the Commission. Secondly, the data offers a mix of self-reporting and perceptional data on this relationship. Conclusions are drawn with these concerns in mind.

Unveiling the Commission-agency relationships

The first section frames the Commission-agency relationship by discerning (i) how the organizational arrangement between the Commission and EU agencies is set out (frame structure), and (ii) how this relationship is planned, foreseen and endorsed (frame policy).The second section presents how this relationship works in practice, as perceived mainly by the Commission and EU agencies, respectively.

Framing the Commission-agency relationship

(i) Frame structure

The frame structure is not the result of a grand institutional design from the Commission headquarter. Initially, the Commission was hesitant to the emergence of parallel administrations outside the Commission. During the last decade, the Commission has indeed changed basic ideas about EU agencies - from viewing them as a 'tolerated anomaly' (European Commission 2001: 16) towards seeing them as 'part of the institutional landscape of the Union' (European

Commission 2009: 2). As the Commission experienced that the agencification process advanced momentum, their major response has been to rein EU agencies into the orbit of the Commission. At the end of the decade – after several evaluations of EU 'decentralised agencies' - the Commission now 'concludes positively on several aspects of the agency system' (Analytical Fiche Nr. 29: 3).

Most of the current EU agencies share some generic organizational features: they are specialized bodies outside the key Community bodies, they have limited mandates and formal powers, they are led by a Director and a Management board, and they are horizontally organized fairly similarly to the Commission DGs. The management board's main functions are usually to decide on the agency's budget, the work programme, and the appointment of its executive director, subsequent to the Commission's nomination of a candidate. Management boards are typically composed of a large majority of member state representatives and a couple of Commission representatives; more seldom accompanied by EP and interest group representatives. Finally, a vast majority of the budgets of EU agencies are financed by the EU budget, sometimes with additional contributions coming from fees and payments from services. Moreover, the financial discipline by the Commission's Financial Controller has become gradually stricter (Dehousse 2008: 19). '[...] [T]he Commission remains responsible for the execution of the budgetary lines dedicated to the agency [...]' (Analytical Fiche Nr. 2: 5). Thus, the frame structure priorities the Commission.

(ii) Frame policy

Facilitated by this frame structure, the Commission's frame policy endorses EU agencies as 'partners' of the Commission and its DGs. EU agencies are seen as integral parts of the Commission. One early testimony of this integral policy frame was the 'White Paper on Governance' issued in 2001 which called for the Commission to control and monitor EU agencies. As one illustration, the White Paper emphasized that agency staff should fall under the same staff regulations as ordinary Commission Administrators (see also European Commission 2005: 20). Agency autonomy was sacrificed for the Union's need for integrated and uniform administration. The White Paper appealed for Commission control of EU agencies while also underlining the limited roles played by such agencies. During the discussion of this White Paper the Commission seemed

increasingly reluctant to grant autonomy to EU agencies by suggesting that EU agencies in general 'reinforce [...] the capacity of the European executive as a whole [...]' (Secretariat General 2001: 3). Yet, the Commission recognized that it lacked sufficient capacities to control EU agencies (Secretariat General 2001: 24). This experience triggered the Secretariat General (2001: 25) to call for the creation of 'appropriate infrastructure' in the Commission for steering and monitoring EU agencies. At present, however, the Commission may be hesitant to intervene on a case-by-case basis in EU agency affairs. Illustrative of this, 'the Commission [claimed it] cannot give instructions to the agencies or oblige them to withdraw certain decisions' (Szapiro 2005: 4).

The 'Analytical Fiches' reveals the Commission's policy frame of close integration of the Commission DGs and 'their' agencies. The semantic twins applied by the Commission are 'partner' and 'parent', where 'partner' suggests a more equal role between the agencies and the Commission while 'parent' advises a more superior role of the Commission vis-à-vis EU agencies. The Commission even argues that the 'parent' role of the Commission has become greater than envisaged (Analytical Fiche Nr. 31: 4). 'The Commission is often requested to take responsibilities in relation to agencies in a way which is not proportionate to its institutional role and influence in respect of agencies (Analytical Fiche Nr. 31: 4). The parental role of the Commission 'often takes place on an informal, operational basis' (Analytical Fiche Nr. 31: 4). Interestingly, informants in the Commission report that some DGs ask 'their' agencies for input when writing the Analytical Fiches. These DGs seem to be advocates for 'their' agencies inside the Commission – for example vis-à-vis other DGs in annual budgetary processes.

Whereas the relationship between EU agencies and the Commission is described in great detail in the 'Analytical Fiches', the corresponding relationship between EU agencies and the EP and the Council is described with less rigor. This difference illustrates a policy frame favouring the Commission-agency relationship. This variation was already envisaged in the 'Inter-institutional Agreement' on EU agencies presented by the Commission in 2005. The EP's role in the preparation of agencies' annual work programmes as well as in the nomination of executive director is described as 'formal hearing', 'exchange of information' and 'views',

etc. (Analytical Fiche Nr. 32). However, the EP has particular responsibilities on deciding agencies' annual budgets. Also, responsible EP committees assign a 'standing rapporteur' or 'contact person' for agencies 'under the committee's responsibility' (Analytical Fiche Nr. 32: 5). The role of the Council is described as that of 'political supervision' by discussing annual activity reports and 'hearings' (Analytical Fiche Nr. 33). 'The Council is centrally involved when the basic regulation is discussed. When an agency is established, the Council's role is limited' (Analytical Fiche Nr. 32: 4). By contrast, the role of the Commission in dealing with the annual work programmes of agencies is described in great detail:

> 'Experience shows that the work programme has proved to be a valuable tool in order to enhance coherence and complementarity of agencies' activities vis-à-vis EU policies, since the work programme is generally submitted to a process of consultation with the Commission. However, the way this consultation takes place is quite uneven across agencies, as in some cases the Commission is consulted at DG level, in others the annual work programme is adopted after receiving the Commission's opinion …, while for a couple of agencies the Commission agreement is necessary before the annual work programme can be adopted'.
>
> (Analytical Fiche Nr 13:2)

Also, 'most agencies have to receive the Commission's opinion before adopting the multi-annual staff policy plan' (Analytical Fiche Nr. 31: 2). Finally, 'the Commission is also responsible for executing the Commission budget line related to the contribution to the agency' (Analytical Fiche Nr. 31: 3).

The Commission has placed evermore emphasis on developing a *coherent* policy frame on EU agencies (Szapiro 2005: 4). The first initiative in this regard was the 'Interinstitutional Agreement' proposed in 2005, followed up with 'The way forward' in 2008. The next step was the launch of a 'detailed *Roadmap* for setting up agencies issued by the Commission in the autumn 2009. This Roadmap aims at helping the parent DGs in the Commission with the set-up of their new agencies [...]' (Analytical Fiche Nr. 2: 5). Indicative of this is the parent DG's role in the creation and staffing of EU agencies: 'Before the adoption of the founding regulation by the legislator,

certain elements of the selection of the core administrative staff may be initiated by the parent Directorate General of the Commission [...]' (Analytical Fiche Nr. 12: 2). The set-up process may be facilitated when experienced Commission personnel is seconded to the newly created agency (Analytical Fiche Nr.2: 5). Moreover, 'the basic regulation normally foresees that a Commission official may be appointed as an interim director to facilitate the start-up of an agency' (Analytical Fiche Nr. 12: 1-2). And, 'before acquiring decisional autonomy, the agency exists only as a project in the work programme of the Commission responsible service' (Analytical Fiche Nr. 12: 4). As expressed in a recent evaluation of EU agencies, 'whereas the connection with the parent DG often comes naturally, several agencies express concern that it is more difficult to maintain a close working relationship [...] with other DGs' (Rambøll et al. 2009: 74).

Also, the Commission has launched the idea to develop a 'common approach' together with the EP and the Council in July 2012 (Joint Statement 2012). Together these policy documents reflect an emergent policy frame – an 'agencification policy'. These non-binding blueprints aim towards 'greater coherence in the way agencies function' (European Parliament, Council, European Commission 2012; European Commission 2012: 2). The Roadmap issues 'concrete timetables for the planned initiatives' (European Commission 2012). The Roadmap (European Commission 2012) also states that Commission representatives' on the agency management boards 'will be more closely involved in the monitoring of the agencies' activities [...]'.

The Commission quests for order by quasi-monopolizing interactions with the agencies is substantiated by the Roadmap's launch of an 'alert-warning system': 'The Commission is now formally entrusted with the responsibility to warn the European Parliament and Council in case it has serious reasons for concern that an agency's Management Board is about to take decisions which may not comply with the mandate of the agency […]' (European Commission 2012: 1-2).The Commission's new Roadmap thus aims to develop common standards that may be issued vis-à-vis EU agencies – for example in the preparation of annual work programmes.

Following up the 'common approach', the Commission has recently established an inter-service group of agency correspondents that meets twice a year to discuss Analytical Fiches, the 'common

approach', new initiatives, best practices, and so on. This inter-service group typically consists of desk officials from all 'policy DGs' who have sub-ordinated EU agencies, plus horizontal DGs with a coordinating role (Analytical Fiche Nr. 31: 5). Still, most capacities for supervising EU agencies exist within Commission DGs. The expected consequences of a coordinated policy from the Commission vis-à-vis EU agencies thus remain embryonic.

In sum, the Commission offers a structural and policy frame that pictures tight relationships between Commission DGs and 'their' EU agencies. The Commission frames EU agencies as integral to Commission activities, not as free-floating bodies.

Commission-Agency relationships in practice

A first sign of whether an organized relationship between the Commission and EU agencies exists is the extent to which agencies are seen as 'belonging to' *particular* Commission departments (DGs). Table 4.1 shows indeed how the Commission itself has neatly allocated the so-called regulatory (or decentralized) agencies among certain DGs.

This registration is based on the 32 DG Annual Activity Reports (2012) in which the various DGs report on their activities *inter alia* in relation to 'their' respective agencies. The only exceptions observed are ECHA's connection to DG ENTR as well as to DG ENV, and EMCDDA's link to DG SANCO as well as to DG JUST. However, such 'double-hatted-ness', which may reflect unresolved tensions between interests (such as industrial and environmental), is also known within national governments.

Tables 4.2 and A4.2 (Appendix, p. 135) register DG-Agency activities and language use by content-analyzing DG Annual Activity Reports (2012). In 29 of the 32 agency cases (i.e. 91 per cent), the DGs mention 'supervision' and 'monitoring' of 'their' agencies as part of their

Table 4.1: Commission DGs and EU (decentralized/regulatory) agencies, 2012

Commission DGs 2012	Agencies 2012	
Agriculture and Rural Development (AGRI)		
Budget (BUDG)		
Climate Action (CLIMA)		
Communication (COMM)		
Communications Networks, Content and Technology (CNECT)	ENISA	European Network and Information Security Agency
	BEREC	Body of European Regulators for Electronic Communications
Competition (COMP)		
Economic and Financial Affairs (ECFIN)		
Education and Culture (EAC)	CEDEFOP	European Centre for the Development of Vocational Training
	ETF	European Training Foundation
Employment, Social Affairs and Inclusion (EMPL)	EU-OSHA	European Agency for Safety and Health at Work
	EUROFOUND	European Foundation for the Improvement of Living and Working Conditions
Energy (ENER)	ACER	Agency for the Cooperation of Energy Regulators
Enlargement (ELARG)		
Enterprise and Industry (ENTR)	ECHA	European Chemicals Agency
	GSA	European GNSS Agency
Environment (ENV)	ECHA	European Chemicals Agency
	EEA	European Environment Agency
EuropeAid Development & Cooperation (DEVCO)		
Eurostat (ESTAT)		
Health and Consumers (SANCO)	EMA	European Medicines Agency
	ECDC	European Centre for Disease Prevention and Control
	EFSA	European Food Safety Authority
	CPVO	Community Plant Variety Office

Home Affairs (HOME)	EASO	European Asylum Support Office
	EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
	FRONTEX	European Agency for the Management of Operational Cooperation at the External Borders of the Member States and the EU
	CEPOL	European Police College
	EURO-POL	European Police Office
	eu-LISA	EU Agency for large-scale IT systems
Humanitarian Aid and Civil Protection (ECHO)		
Human Resources and Security (HR)		
Informatics (DIGIT)		
Internal Market and Services (MARKT)	OHIM	Office for Harmonization of the Internal Market
	EBA	European Banking Authority
	EIOPA	European Insurance and Occupational Pensions Authority
	ESMA	European Securities and Markets Authority
Interpretation (SCIC)		
Joint Research Centre (JRC)		
Justice (JUST)	EIGE	European Institute for Gender Equality
	EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
	FRA	European Union Agency for Fundamental Rights
	EURO-JUST	The European Union's Judicial Cooperation Unit
Maritime Affairs and Fisheries (MARE)	EFCA	European Fisheries Control Agency
Mobility and Transport (MOVE)	EASA	European Aviation Safety Agency
	EMSA	European Maritime Safety Agency
	ERA	European Railway Agency
Regional Policy (REGIO)		

Research and Innovation (RTD)		
Secretariat-General (SG)		
Taxation and Customs Union (TAXUD)		
Trade (TRADE)		
Translation (DGT)	CdT	Translation Centre for the Bodies of the European Union

Source: Annual Activity Reports of the 32 Commission DGs (2012).

activities during the year.In 23 cases (72 per cent), the DGs speak of themselves as 'parent DG' or 'responsible DG'. Together, these observations indicate that there exists, or should exist in the eyes of the Commission, a kind of hierarchical relationship between the DG and the agency. The term 'partner DG', on the other hand, which signals a more horizontal relationship, only appears in a minority of cases (9). Moreover, only in relation to four agencies', the DG is considered solely as a 'partner DG'. Interestingly, and most commonly, the term 'partner DG' operates in tandem with 'parent DG'. This linguistic ambiguity probably reflects some power ambiguity as regards the governance structures surrounding EU agencies.

According to Table 4.2, the DGs report *regular* meetings or other contacts with an overwhelming majority of the agencies (26 of 32 agencies, or 81 per cent). Meetings provide opportunities for giving a steer on behalf of the Commission, e.g. related to the agency budget or work plan. However, meetings are also arenas in which agencies may try to get their own arguments across. Table 4.2 reveals that it is quite common that DGs comment on agencies' annual work programme: this takes place in half of the cases (16). We registered 13 Commission Comment Letters on agency work plans in 2013. These seem to be highly formal letters signed by the respective Commissioners. The number of Commission Comment Letters on the work programmes of EU agencies has increased significantly; from only one in 2003 to 13 in 2012, thus becoming a more regular activity over time. Interestingly, Table 4.2A also shows that former 'intergovernmental agencies' are all subject to the Commission's supervision and involvement in their work programmes. They take part in regular meetings with the Commission, and the term 'parent DG' is used across agencies.

The DGs' Annual Activity Reports from 2005 contain relatively little substance on EU regulatory (decentralized) agencies. Moreover, the information given was not systematized to the same extent as in 2012. Thus, tables comparable to Tables 4.2 and 4.2A have not been possible to build. Typically, the 2005 reports dealt with administrative assistance to agencies and training efforts, e.g. financial training courses (DG BUDG), guidelines on procedures for selecting the heads of agencies and for personnel policy more generally (DG ADMIN), etc.

Table 4.2: Commission DG – Agency relationships as described in DG Annual Activity Reports (2012)

	Frequency	**Percentage**
DG supervises/monitors agency	29	91
Regular contacts between DG and agency	26	81
DG sees itself as parent DG of agency	23	72
DG gives opinion on agency work programme	16	50
DG sees itself as partner DG of agency	9	28

Note: The table shows the frequency and percentage of agencies (N=32) about which the following was said.

It is harder to find documentation as regards EP-agency relationships. This may indicate a less intimate relationship. For example, while the Commission is entitled to request information from EU agencies all the time, the EP does not have the right to address 'parliamentary questions' directly to agencies (although the EP may invite the agency director for informal hearings): questions regarding agencies have to go via the Commission. All questions follow the route from the Unit for Parliamentary Questions in the EP the Commission's Secretariat General, which forwards the questions to the responsible DG. Where the question concerns 'mixed competences' of the Commission and the agency, the responsible DG sends the question to the agency asking it to draft the answer for that part of the question for which it is competent and to return it to the DG, which sends the reply to the EP.

In cases where the question concerns a matter for the agency's sole competence, the responsible DG forwards the question to the agency

asking it to draft the answer and to return it to the DG. The DG then replies the MEP. In addition, MEPs may ask for informal meetings with agency personnel (Source: interviews in the Commission and EP).

With regards to Council-agency relationships in practice, we have found no written, systematic documentation. This does not at all mean that such connections are non-existent. However, the fact that the EP, in important respects, deals with EU agencies via the Commission and *not* via the Council indicate s that Council-agency relationships represent weaker ties than those between the Commission and the agencies (see also Font and Pèrez 2014).

Table 4.3: References to the Commission, Council and Parliament in the Annual Activity Reports of 32 EU agencies (2012).* (word count/hits)

EU institution	Frequency	Percentage
Commission	2806	73
Council	619	16
European Parliament	397	10
Total	3822	99

* ACER, BEREC, CDT, CEDEFOP, CEPOL, CPVO, EASO, EASA, EBA, ECDC, ECHA, EEA, EFCA, EFSA, EIGE, EIOPA, EMA, EMCDDA, EMSA, ENISA, ERA, ESMA, ETF, EU-LISA, EU-OSHA, EUROFOUND, EUROJUST, EUROPOL, FRONTEX, GSA, OHIM, FRA.

Based on the agencies' annual activity reports (2012), we have quantified the distribution of references herein to the Commission, Council and Parliament respectively. Thus, we might limit the bias stemming from only looking at the annual activity reports of the Commission DGs. Table 4.3 confirms the pivotal role of the Commission compared to the two other key institutions: an overwhelming majority of 'hits' (73 per cent) concerns the Commission, while only 16 and 10 per cent respectively relate to the Council and the EP.

Concluding discussion

This study's point of departure is the growing role of EU regulatory (decentralized) agencies. Not only have they increased in number and got more staff resources; they have also taken on (quasi-)regulatory tasks that clearly reach beyond their role as network facilitator or 'best practice'-mediator. However, our knowledge has remained incomplete on where these agencies 'belong' in the

European political-administrative space. This study documents fairly strong relationships between these agencies and the Commission (administration). These observations support a 'communitarian image' of the Commission-agency relationship. This observation moreover signifies centralization of EU executive power and a quest for executive order.

To account for this observation, this article has introduced an organizational perspective. From an organizational perspective, the following factors are conducive to the development of relatively close relationships between Commission DGs and EU agencies: First, both are sharing the *function* of being primarily executive bodies. Second, at both places personnel, from the bottom to the top, have an EU institution as their *primary organizational affiliation*. Third, compared to the Council and the EP, only the Commission disposes over administrative *capacity* to follow up work at the policy implementation stage. And fourth, and finally, *legitimized templates* of department-agency arrangements found at the national level point in the direction of assigning agencies to particular departments within the executive rather than to legislative chambers. This seems to be the case at least in a European context.

The study reveals that the EU has developed an 'agencification policy' which now seems to be anchored in common understandings and agreements across the EU's key institutions. The Commission stands out as the driving force behind this policy development, and has given itself a prominent place in the area. Moreover, the Commission has created its own administrative infrastructure within the affected DGs as well as across such DGs in order to follow up its agencification policy in practice. Concerning practice, we have demonstrated how the Commission has systematically allocated the agencies among its DGs according to issue area. In an overwhelming majority of cases, the DGs supervise, have regular meetings with, and consider themselves to be *parent* DGs rather than partners of their respective agencies. It is also quite common for DGs to comment on the annual work programme of 'their' agencies, and increasingly so. Finally, we have shown that agency attention is directed significantly more towards the Commission than towards the Council or the EP. In sum, our interpretation is that although agencification tends to de-concentrate executive power (Egeberg 2012), it nevertheless may indicate centralization of executive power at the EU level since powers may

have been delegated to agencies more often from national governments than from the Commission (Dehousse 2008). The fact that agencies are geographically spread and located outside the political center, does not seem to affect the center's actual control over agencies (Egeberg and Trondal 2011b).

In addition, steps in the direction of a parliamentary system at the EU level may reinforce such a development. The EP, having achieved enhanced access to Commission decision-making through a range of formal and informal tools (cf. Egeberg et al. 2014; Wille 2013), may thus attain *indirect* control over agencies provided that they are subordinated to the Commission. The EP's support of a vertically integrated EU executive makes sense on this background. (Otherwise in a system based on the separation of powers, as in the USA, the legislator, having little control over the political executive will itself aim at reining in agencies directly (Shapiro 1997)). The EP may find its dealing with agencies via the Commission's Secretariat General (e.g. as regards parliamentary questions) highly convenient compared to dealing with the 32 agencies on an individual basis. A kind of order has emerged.

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Appendix

Table A4.2: Commission DG – Agency relationships as described in Annual Activity Reports of 32 Commission DGs (2012)

EU agency	Supervision/ Monitoring of Agency	Opinion on work programme of agency	Regular contacts/ meetings	'Parent DG'/ responsible DG	'Partner' DG
EEA	x		x		x
BEREC	x				
ENISA	x	x			
ETF	x	x	x	x	
Cedefop	x		x	x	
EUROFOUND	x			x	
EU-OSHA	x			x	
ACER	x	x*	x	x	
ECHA	x		x	x	x
GSA	x	x	x	x	
CVPO	x		x	x	x
ECDC	x		x	x	x
EFSA	x		x	x	x
EMA	x		x	x	x
FRONTEX	x	x	x	x	
Cepol	x	x	x	x	
Europol	x	x	x	x	
EASO	x	x	x	x	
EMCDDA	x	x	x	x	
eu-LISA	x	x	x	x	
EBA	x		x		x
ESMA	x		x		x
EIOPA	x		x		x
OHIM					
FRA	x	x	x	x	
Eurojust	x	x	x	x	
EIGE	x	x	x	x	
EFCA		x	x		
ERA	x		x	x	
EMSA	x	x*	x	x	
EASA	x	x*	x	x	
CdT					

**According to Commission Comment Letters on the annual work programmes of EU agencies.*

Article 4

Pooling administrative resources through EU regulatory networks

Abstract

This article presents new insights on how national agencies (NAs) interact and pool resources in EU regulatory networks. The findings show that in addition to exchanging information, knowledge and best practices through consultation, NAs routinely share workload and expertise by mutually adapting to and complementing each other in the network. It is argued that pooling of resources is facilitated and reinforced by lack of agency steering by national ministries, shared sector affiliation and professional backgrounds among network actors, lack of NA administrative capacity, as well as the coordination by a strong EU agency. Overall, this may imply improved agency performance, but also increased interdependence. The study underlines the importance of including the European administrative space in the study of national agencies and argues that NAs pooling resources through EU regulatory networks indicates administrative integration and centralization.

Introduction

Agencies have increasingly become important building blocks in national administrations, supporting their parent ministries in policy

formulation and implementation.[1] In parallel, research interest in these organizations has grown. Despite the fact that national agencies (NAs) are increasingly involved in transnational networks where executive EU-level bodies constitute hubs, most research on NAs has focussed on their autonomy in national administrations and relationships to ministries, leaving out potential influence of the European administrative space (Egeberg 2008; Trondal 2014). This could be due to the conventional understanding of EU policy administration as indirect, i.e. channelled through national central governments, and of NAs primarily as governments' agents. There are some exceptions to this deficiency, however, indicating that EU policy administration also can take place more directly between EU level actors and NAs (Hofmann and Türk 2007). Recent studies show that NAs may be part of a multilevel EU administration in addition to their national administrations (acting 'double-hatted'), and that NAs gain resources through networks that may strengthen their autonomy and regulatory powers in national administrative systems (Egeberg 2006; Newman 2008; Yesilkagit 2011; Bach and Ruffing 2013; Danielsen and Yesilkagit 2013; Maggetti 2014; Bach et al. 2014). However, little attention has been paid to how network participation influence members (Maggetti 2014) and intra-network dynamics – what kind of interaction takes place that allows agencies to gain resources? Hence, this article asks: how and why do NAs interact and pool resources through EU regulatory networks?

Network interaction may be more or less extensive for NAs, differing with regard to who agency officials interact with (officials from the Commission, EU agency, and/or sister agencies in other countries), the frequency of interaction, the 'content' of interaction (exchange of views, information and best practice, cooperation, and/or coordination), the type of tasks interaction relates to (formulation, transposition and/or application of EU policy) and the importance attributed to interaction (actors, agreements, arguments). The article

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maps intra-EU network interaction along these dimensions and presents new insights on agency behaviour. NAs not only consult and exchange information, knowledge and best practice, but also routinely share workload and expertise by mutually adapting to and complementing each other in the network. This enables NAs to focus on fewer tasks and fields of expertise. This implies that NAs can improve their performance, but also that they (and to some extent their parent ministries) increasingly depend on the network to fulfil their functions. The article illustrates the significance of including the European administrative space in addition to national administrative systems when studying NAs.

'NA' refers to an administrative body that is formally separated from a ministerial level, staffed by public servants, financed mainly by the state budget, and subject to public legal procedures, that carries out public tasks at the national level on a permanent basis. Agencies have some autonomy from their respective ministry in policy decision-making and over personnel, finance and managerial matters, but are not completely independent because political executives have ultimate responsibility for their activities (Christensen and Lægreid 2006: 12). The article presents a case study of the medicines agencies in Slovakia and Norway, which participates in the European medicines regulatory network (EMRN) together with sister agencies, the European Commission (the Commission), and the European Medicines Agency (EMA).

The article draws on an organizational approach, and it is suggested that NAs pooling resources through EU regulatory networks is facilitated and reinforced by certain organizational factors at the national and European levels. First, vertical specialization and loose ministry steering at the national level enables NAs to operate relatively independent in the network, without ministry interference. This allows NA officials to focus on scientific-technical concerns rather than national, political concerns, when they interact in the network. Additionally, horizontal specialization at the EU and national levels (shared sector affiliation) and the demographic composition of the network (shared educational backgrounds) facilitate end reinforce focus on common, sector-specific issues, challenges and solutions, as well as professional standards and values among officials. Furthermore, lack of administrative capacity in several agencies and the coordination capacity of the EU level

agency contribute to resource pooling among NAs. Arguably, NAs pooling administrative resources according to an EU level agency's coordination signifies administrative integration and centralization of the EU's administrative system, and can be seen an indication of an emerging multilevel union administration (Egeberg 2006: Trondal 2010).

The article is organized as follows: first, an analytical framework is developed in two steps. The next section presents the relevant literature on NAs and outlines empirical propositions regarding how NAs may interact in EU networks, based on a state-centric view and a multilevel union administration view. Thereafter, a theoretical argument is developed based on the organizational approach, suggesting that factors in the NAs' organizational environment can help us understand why pooling takes place. After a description of methods and data, the empirical study is presented. First, the NAs under study and their relationships to parent ministries are presented, showing that they are able to operate relatively independently in relation to network tasks. Second, it is shown how NAs pool administrative resources through the network and interaction is characterized by sectorial and professional dynamics. The contributions to and the importance of the resource pool seems to differ among small and large agencies, which seems to be related to their administrative capacity in terms of work force, expertise and experience. Finally, it is shown how resource pooling is administered and facilitated by a strong EU agency at the centre of the network. The article ends with a concluding discussion.

Agencies in national and European administrations

Agencies have increasingly become important parts of national administrative systems over the last decades (Christensen and Lægreid 2006: 21-2). In the wake of this, research interest in agencies has grown but mainly focussed on the role of agencies in national government settings and autonomy versus control in relationships to ministries. Despite the fact that national agencies (NAs) are more and more involved in transnational networks where executive EU-level bodies constitute hubs, the European dimension in agency studies has largely been neglected (Egeberg 2008; Trondal 2014). The deficiency in the literature may be related to the conventional understanding of EU policy administration, i.e., that it is dominated by the member states (Hofmann 2008: 663). From this state-centric

point of view, administration is in the hands of coherent and autonomous member states and agencies are understood as government's agents. Administration is 'indirect' in the sense that activities of national administrations related to the formulation and implementation of EU policies are channelled through national central governments (Hofmann 2008). Public administration and its operation have traditionally been perceived as a core state power (Genschel and Jachtenfuchs 2013), and formulating and implementing public policy in Europe a prerogative of national administrations (Trondal and Peters 2013: 295). Although the Commission has been entrusted with a broad range of tasks, they have not been matched by increase in resources and capacity for independent action or ability to pursue its own preferences. The Commission has been weakened post-Maastricht, and executive power in the EU is understood as decentralized, i.e., firmly in the hands of member states (Kassim 2003; Kassim and Menon 2010; Kassim et al. 2013). EU agencies and networks contribute to this since it allows member states to closely monitor EU policy administration (Bickerton et al. 2014). From this point of view, one would expect to find medicines agencies operating as part of the national government's apparatus and mainly coordinating views with 'parent' ministries as they carry out their tasks. EU level bodies will play a modest role vis-à-vis NAs – interaction with EU executive bodies and other NAs in the network would mostly be indirect via ministries and thus less extensive. Agency activities related to EU policy administration and participation in EU networks would be highly synchronized with parent ministries, and network interaction characterized by agencies instructed by national governments and promoting national health policy views.

However, this picture is challenged by recent research. In a multilevel union approach, NAs operate not only as part of their national administrations, but also as central building blocks in an integrated, European multilevel administration where the Commission is core executive (Egeberg 2006: Trondal 2010). Studies of NAs that include the European administrative space indicate that administration of EU policy is not merely indirect via national ministries. NAs may link up to sector specific networks and cooperate with EU level bodies and sister agencies in other member states, in particular in relation to implementation tasks. NAs may operate as 'double-hatted' (Egeberg 2006) or even 'multi-hatted' (Egeberg and Trondal 2009a), acting on

behalf of a second master or centre, or a transnational network in which the EU executive constitutes a node, in addition to parent ministries. Through networks NAs exchange information and best practice with actors conducting similar scientific-technical tasks and focussing on comparable professional concerns (Egeberg 2006; Støle 2006; Barbieri 2006; Ugland and Veggeland 2006; Nørgård 2006; Martens 2006; Sverdrup 2006; Gulbrandsen 2011). Also, by connecting to networks NAs gain capacity and expertise and strengthen their autonomy vis-à-vis their national superiors and challenge ministries in specific policy issues, even in the policy formulation phase (Newman 2008; Yesilkagit 2011; Bach and Ruffing 2013; Danielsen and Yesilkagit 2013; Bach et al. 2014). Networks may also have a positive effect on the reinforcement of NAs' regulatory powers in national administrative systems (Maggetti 2014), and impact domestic adoption of standards (Maggetti and Gilardi 2011). From this point of view, one would expect medicines agencies operating as part of a multilevel union administration in addition to their respective national administrations. Interaction with EU executive bodies and sister NAs in the network would take place directly and be more extensive. Agency activities related to formulation and implementation of EU policy would be less synchronized with parent ministries, and more synchronized with network participants.

The organizational perspective

In order to understand why NAs pool resources through EU networks the article draws on an organizational perspective, which allows us to take into account the interplay between the national and European organizational contexts in the study of NAs, and to 'unpack' these organizational contexts to search for explanatory factors. The point of departure is that particular organizational factors systematically lead daily decision processes in certain directions, making some choices more likely than others (Egeberg 2012). A key assumption is that individuals are bounded rationally and not capable of overseeing all alternatives and possibilities when they make decisions (Simon 1997). This means that when choosing between different action alternatives, an individuals' organizational context can work to simplify complex problems by narrowing down and sorting both feasible and unfeasible policy options (Egeberg 2012). The argument is thus that certain organizational dimensions of

the national and European administrations are conducive to NAs pooling resources through EU networks.

Organizational structure expresses impersonal role expectations and norms for action. From an organizational perspective, structural designs are expected to 'route' information exchange, coordination processes and conflict resolution (Egeberg 2012: 161). First, external vertical specialization is a structural dimension that expresses the intended division of labour across hierarchical levels (Egeberg 2012: 159). Establishing agencies outside ministries indicates that some separation of political and scientific-technical decision-making is intended, but is not in itself a guarantee for *de facto* agency autonomy. Studies indicate that agency officials exercise discretion differently from their colleagues in ministries, by attaching more importance to professional and expert considerations and to user or client interests than to political concerns. External vertical specialization may thus reduce political control and give more leeway for expert-based decision-making. At the same time, agencies' possibility to impact on ministerial decisions seems to be reduced (Egeberg 2012). Ministerial control and steering of agency activities can be increased if the ministry strengthens the capacity of relevant units in the ministry ('duplication'). Politicization of cases may also increase ministerial control and steering of agency activities (Egeberg 2012). However, studies show that NAs that are not only formally but also in practice partly decoupled from direct political steering may constitute an administrative infrastructure open for re-coupling into new organizational configurations, partly by-passing their parent ministries (Trondal 2014: 547). Integrated ministries would not be conducive to such a development (Egeberg and Trondal 2009b: 686). Thus, vertical specialization and NAs being loosely steered enable them to link up to networks and promote expert-based views rather than the ministry's political views.

Furthermore, horizontal specialization at the EU and national levels contributes to an infrastructure that facilitates resource pooling. Horizontal specialization refers to how tasks are distributed at one level, and as maintained by Gulick (1937), this can be according to territory, purpose, function or clientele served. The principle chosen has implications for what is emphasized and paid attention to by individuals, and consequently what is de-emphasized and paid less attention to. Organizing according to purpose focuses individual

decision-makers' attention and behaviour along sectoral lines (Egeberg 2012). Horizontal specialization may facilitate interaction and identification among units that are organized according to similar principle, even though they are located at different levels and in different countries (Egeberg 2006). Networks bring together officials from units (in the Commission, EU agencies and NAs) with compatible organizational structures. The fact that officials share sector affiliation implies that they focus on similar concerns, tasks, issues, problems and solutions, and pay less attention to for instance territorially based concerns and problems. This shared focus facilitates and encourages pooling of resources.

Moreover, organizational demography is a relevant organizational factor, referring to the composition – in terms of different personal attributes such as nationality and education – within the social entity under study (Egeberg 2012: 159). Studies have shown that different types of 'epistemic' dynamics are evoked in EU administrative settings (Trondal et al. 2008; Trondal 2010). During their education, individuals may internalise certain values, norms and role expectations belonging to a particular profession, which condition their perspectives and guide their behaviour. Agency officials participating in networks may be 'pre-packed' with images and attitudes acquired over the years in particular educational settings (Egeberg 2012: 160). The fact that officials share professional backgrounds and view themselves as expert representatives rather than national representatives constitutes a common foundation for an epistemic community, in which officials have a shared set of normative and principled beliefs, shared causal beliefs, shared notions of validity and a common policy enterprise (Haas 1992). Being guided by professional standards, values and role expectations, it is important to officials to achieve the best possible results from a scientific expert point of view, through peer review, learning, and mutual adaptation. This facilitates and reinforces pooling of resources.

Finally, a relevant organizational factor is administrative capacity. The size of an organization, or the number of roles to be filled, may indicate capacity to initiate policies, develop alternatives, or to implement final decisions (Egeberg 2012: 159). Administrating a policy area requires a minimum measure of organized attention, organizational autonomy and capacity for gathering area-relevant

information as well as preparing decisions, actions and proposals and implementing actions, programmes and policies (Gornitzka 2009: 110). The building blocks of administrative capacity are policy expertise, professional staff, financial resources and some degree of organizational continuity (Martens 2008b). Studies show that interaction in networks and the views and input of EU level bodies may be more important to NAs that have little administrative capacity and are newcomers in the EU system (Martens 2008b). Engaging in resource pooling may thus be more important to agencies that lack manpower and/or professional experience and expertise. Also, administrative capacity at the EU level may facilitate resource pooling. Studies show that EU executive bodies with large administrative capacity may play an important role vis-à-vis NAs, influencing their actions and choices related to EU policy implementation and interpretation (Martens 2008a: 95). The Commission and EU agencies have 'captured' both NAs and networks due to capacities and assets such as expertise and overview (Martens 2006; Martens 2008a; 2008b; Levi-Faur 2011), even where the legal basis for Community action is weak (Gornitzka 2009). EU agencies integrate national administrative bodies into their operation by providing structures for cooperation between the supranational and national level, and between national authorities (Hofmann and Türk 2007: 258). They embody executive capacity for action and execution of policy (Egeberg et al. 2012; Egeberg et al. 2014). Situated at the centre of regulatory networks they may be directly involved in NAs' work (Egeberg et al. 2012; Versluis 2012), reduce room for national adaptation of EU policies and feed supranational concerns into national-level decision-processes (including at the policy formulation stage). EU level bodies' strength is related to its centrality in European decision-making procedures and unique position as permanent nexus, positions that are difficult to fill by national administrative actors (Gornitzka 2009: 124). Thus, an EU executive body that possess policy expertise, professional staff, financial resources and some degree of organizational continuity facilitates and reinforces pooling.

Methods and data

The article presents an intensive study of how and why NAs interact in a EU regulatory network. The reason for choosing two agencies was to increase the number of observations and obtain rich data material about NAs' network relationships and dynamics rather than

cross-case comparison. The aim was to identify factors that may lead to specific outcomes by providing convincing empirical information, such as comprehensive storylines, information on spatial-temporal distance and proximity between causes and consequences as well as on perceptions and motivations of important actors (Blatter and Haverland 2012: 110-19). This implies that the potential for empirical generalization is limited, but that the findings may be valuable in developing propositions in further studies of network interaction (Yin 2014).

Medicines agencies in Slovakia and Norway were chosen out of practical concerns (access to rich data) and due to their theoretical relevance for the research question (Blatter and Haverland 2012: 99-105). The pharmaceutical field is relatively institutionalized and centralized. Implementation is partly centralized with the Commission making decisions on marketing authorizations (MAs) on certain products, and a European agency was established to coordinate member states' scientific input to MA decisions and facilitate mutual recognition in the field. Lack of harmonization in this field is normally explained by referring to an asymmetry between EU single market interests and member states' nationally sensitive health interests (Permanand 2006; Permanand and Mossialos 2005; Greer 2013; Hauray 2013; Lamping 2013), but this asymmetry might have been reduced after the Lisbon Treaty explicitly mentioned pharmaceuticals under the health article and the portfolio was moved to the Commission DG responsible for Health and consumers (DG Sanco) in 2010. In addition, pharmaceuticals are often considered a more technical area than other health policy fields, potentially reducing politicization and strong ministry steering. Moreover, it has been suggested that in time, the system would develop in a direction a number of member states acquires leading roles when it comes to supplying expertise for the centralized procedure. The other member states would merely follow decisions made while delivering expertise in very specific areas. Such work sharing could again lead to the development of 'centres of excellence' as part of a more integrated and homogenous organizational system of market authorization with EMA as central authority (Groenleer 2009: 168). Thus, medicines agencies can be seen as most likely cases for linking up to and interact extensively in the European regulatory network. At the same time, centralized decision-making and Treaty changes are not necessarily followed up in practice, and the EMRN

has been characterized by controversies in recent years, revealing that member states and Community institutions may have different approaches to pharmaceutical regulation (Vestlund 2015). One can thus not exclude the possibility of finding national administrations under strong governmental control, less able to and/or interested in interacting in EU regulatory networks.

Although cross-case comparison was not a primary aim, there are some interesting similarities and differences between Norway and Slovakia that may influence their network relationships. Norway and Slovakia are small European countries of roughly the same size, but while Norway can be classified as a mature, stable and rich democracy Slovakia may be characterized as a transitional democracy with a struggling economy. Furthermore, Norway shares a Nordic political culture imbued with an egalitarian spirit and a protestant ethic, while Slovakia belongs to the Central European sphere with a predominantly Catholic tradition and more widespread acceptance of power distance compared to Norway (Batora and Baldersheim 2012: 6). National administrative traditions may therefor differ, for instance with regard to ministry steering of agencies. Also, the two countries have different affiliations to the EU: while Slovakia became member in 2004, Norway is not a member but connected to the EU through the Agreement on the European Economic Arena (EEA) since 1994. Through the agreement Norway has access to the single market and has committed itself to implement EU legislation.

The article builds on interview data gathered in several rounds since 2008 and include 32 interviews with officials at the Norwegian and Slovak medicines agencies, the Norwegian Ministry of Health and Care Services and the Slovak Ministry of Health, as well as Commission and EMA officials (listed under references). The interviewees are utilized as informants rather than respondents (Grønmo 2007), implying that they provide information about other actor's background, status, actions, meanings, processes or general social conditions. The study builds mainly the perceptions of officials that participate in the EMRN. The informants represent different actors at both the EU and national levels. Ensuring that data are not collected from only one source or one type of source contributes toward the research goal of triangulation, where collected data is cross-checked through multiple sources. This is assumed to strengthen the robustness and credibility of the findings (Tansey

2007: 766). The interviewees in the two agencies being studied cover several hierarchical levels and all sections/departments of the organizations are included in the study except for HR, IT and Finance. Officials were asked about who and what is important to them as they perform tasks in relation to EU policy administration: contact, cooperation and coordination in the European and national administrative systems, and the relative importance of the respective actors, different concerns and arguments.

The agencies under study: SIDC and NOMA

The competent authority in Slovakia is the State Institute for Drug Control (SIDC), organized under the Slovak Ministry of Health. SIDC has 170 employees with educational backgrounds from pharmacy, chemistry and biology as well as human and veterinary medicine. SIDC obtained full access to the EMRN when Slovakia became EU member in 2004. Preparations for adopting EU regulations and standards as well as participation in the EU pharmaceutical administrative system began in 1997, when SIDC obtained observer status in the Pharmaceutical Committee and an EMA working group (WHO 2002).

The Norwegian Medicines Agency (NOMA) is organized under the Ministry of Health and Care Services. NOMA has 250 employees with similar backgrounds as SIDC staff. Norway is not a member of the EU but connected to the EMRN through the EEA agreement, and thus has the same obligations and rights in the system as EU member states (except for voting rights in decision-making). NOMA had observer status in committees and working groups under the Commission and EMA from 1998, and full access to the EMRN from 2000 (Dyrdal 2004: 15).

The two agencies have similar responsibilities in their national administrations related to EU policy administration. While ministries are formally responsible for policy formulation and transposition, the agencies are responsible for policy application and activities related to the EMRN. In addition to serving their parent ministry with technical and scientific support, the NAs ensures pre- and post-market surveillance of the quality, efficacy and safety of medicinal products and provides scientific and regulatory advice and information to the public. Both agencies are financed through state budgets via their respective ministries, and according to inter-

viewees, this is the most important influence the ministry has on their daily work.

The actual ministry-agency relationships are relatively similar in Slovakia and Norway: they are characterized by a fairly low degree of political steering, leaving SIDC and NOMA able to operate quite independently in EMRN activities. Ministry officials in both countries report that they to a high degree rely on agency expertise and capacity in relation to EU policy formulation and transposition tasks. In practice, the ministries may ask the agencies to conduct these tasks due to lack of capacity, but this is more common in Norway than in Slovakia. Also, NOMA officials accompany ministry officials in meetings in the Pharmaceutical Committee,[2] which is not the case in Slovakia. The Slovak Ministry of Health is generally more oriented towards working groups and decision-processes in the Council (the Norwegian ministry do not have access to Council decision processes). Agency officials confirm the importance of coordinating with their parent ministries in relation to formulation of formal national positions to and transposition of EU legislation, and report that although they experience that the ministries take their views into account and depend on their capacity, they would like to contribute more in the formulation phase (especially SIDC). At the same time, both the Commission and EMA are perceived as central alternative channels for input to EU policy-making in cases when there is little coordination of views with the ministry (i.e., if the ministry does not listen). When it comes to policy application, neither of the agencies experience involvement in decision-making by the ministry except for when controversial issues arise. In general, officials in both agencies report that their ministries are more oriented towards the financial aspects of medicines and rarely interfere in scientific-technical decision-making, but are kept informed through various reporting routines (annual, biannual and weekly reports as well as meetings).

[2] The Pharmaceutical Committee is a committee under the Commission that brings together member states representatives (ministry officials) to give input and receive information on policy processes.

The European medicines regulatory network (EMRN)

Since the mid-sixties, a comprehensive administrative system has developed in the EU pharmaceutical policy field through institutionalization of formal and informal structures, in terms of rules, norms and standards as well as EU level bodies (Hauray and Urfalino 2009). The result is the complex structure of the European medicines regulatory network (EMRN), including the Commission, EMA and national medicines agencies. The EU regulatory framework on pharmaceuticals has grown steadily since the first directive in 1965 established that medicines must receive a marketing authorization (MA) before entering the market, based on the evaluation of safety, therapeutic efficacy and quality of the medicinal product (Krapohl 2008: 70). It now covers the complete life cycle of a medicine from product development, testing and manufacturing to approval for sale by MA and post-market monitoring of adverse effects (Hauray 2013). Initially, the system was based on national MAs that could be made valid in other member states through mutual recognition. Mutual recognition did not work very well, however, due to member states differences in health policy and professional evaluations. This was the reason for introducing a centralized procedure (CP) for certain products with the Commission as decision-taker, and for establishing EMA to coordinate it. The new system was in function from 1995 (Krapohl 2008). EMA provides scientific s support to the Commission in EU policy formulation and administers the CP as well as arbitration in procedures based on mutual recognition of nationally issued MAs. Also, the NAs initiated a more informal network in 1996, the Heads of medicines agencies (HMA), in order to facilitate mutual recognition of nationally issued MAs. EMA contributes to the HMA as secretariat, and if mutual recognition fails, the case goes to EMA and eventually to the Commission for a binding decision.

The main function of NAs in the network is to provide scientific expertise: experts from NAs meet in EMA committees, and within their specified fields of expertise[3] they agree on and deliver scientific opinions to the Commission. This relates to product assessments that constitute the basis for (MAs) as well as recommendations and advice

[3] Human medicines, veterinary medicines, pharmacovigilance, orphan products, herbal products, advance therapies and paediatric medicines.

on guidelines, policy development and international affairs. For each case that concerns product assessments, two *rapporteurs* are appointed among the NAs to evaluate applications and provide scientific assessment reports. Scientific opinions are agreed on and ratified by votes in committees (Hauray 2013: 86), and submitted by the EMA secretariat to the Commission for final decisions.

Network interaction: pooling administrative resources

Agency officials from both NOMA and SIDC underline the importance of continuous interaction with sister agencies in relation to formulation, transposition and application tasks. A number of contact points exist, related to committees and working groups under the Commission, EMA and HMA, and national officials spend much of their time participating in network-related meetings and working with network-related issues. There is also frequent use of e-mails, phone calls and teleconferences. The fact that officials share sector affiliation, and work with similar tasks and issues, face similar actors, and needs to solve the same problems, seems to be important in facilitate pooling of resources. In addition, the fact that they share professional backgrounds and perceptions of professional standards, values and role expectations, seems to facilitate mutual adaptation and acceptance of other NAs' considerations and decisions.

The pooling of resources that takes place in the network can be summarized in two inter-related points: sharing of workload, and sharing of expertise. With regard to the first point, interviewees in both agencies underline that they would not be able to conduct the same amount of work on their own, due to lack of capacity in terms of personnel. Since they participate in EMA, they are able to introduce more products faster into their national markets. This implies that the agencies can prioritize to concentrate on fewer tasks.[4]

> Through EMA we benefit from the resources of the competent authorities in all member states and receive a faster and more thorough evaluation of new drugs […] Without participating in the system we would have had to evaluate all medicines

[4] The CP has become very popular among pharmaceutical companies due to its predictability in terms of guidelines and time limits (national procedures are often less effective). The number of applications is thus increasing.

> ourselves. It would be very resource intensive and we would have lost much information on the adverse effects and safety of products.
>
> (NOMA)

With regard to the second point, sharing of expertise has two aspects. The first aspect is that through constant interaction in the network, officials feel that they develop their competence and improve the quality of their own decisions. Discussing issues and challenges either with another expert or in plenary provides opportunities for learning through consultation and exchange of information, practices and experiences. This is in relation to all kinds of tasks, indifferent of policy phase or whether it is a national or EU matter (a distinction that is not always easy to make), and pertains to general problem solving as well as handling of individual cases (such as product evaluations and complaints issued by companies), court cases and advice to ministry (such as development of new legislation or transposition of specific rules to national legislation). Although one not always agree with other officials' considerations, it is helpful to see a specific case from several angles. In addition, officials report that they get new ideas and inspiration by being part of a bigger professional environment. Some officials have their closest colleagues in other NAs, because there are so few working on the same topic in their own agency. Committee discussions are focussed on scientific-technical aspects of pharmaceuticals, and there is little promotion of what can be interpreted as national or political views. 'It is more about discipline than nationality. I would say that the collaboration follows scientific lines' (NOMA).

> I always get very good and useful responses when I need something. [...] It is important for me that I know them and can ask them anything. I can discuss problems with them at the meetings or in breaks […] It is important if I want to know something about medical products, the situation in Europe.
>
> (SIDC)

> It has clearly been important for both my personal and professional development. You travel quite a lot and get impetuses from other countries, from scientists that have other views than your own. You get a broader perspective than if you

> were working isolated in Norway. You develop more nuanced views and get professional corrections.
>
> (NOMA)

The second aspect of sharing expertise is that by coordinating with sister agencies through the network, SIDC and NOMA benefit from scientific expertise that their own agency does not possess, but that other agencies contribute to the resource pool.

> We cannot have equal expertise in everything, and this collaboration is very important to get access to the best professional assessments in all fields of expertise. The evaluations of EMA constitutes the foundation of NOMA's authorization of medicines in Norway.
>
> (NOMA)

This implies that SIDC and NOMA can prioritize to concentrate their capacity and specialize in particular scientific areas, and lean on other agencies for expertise in other areas. In NOMA's case, this means that they have downscaled their activities in relation to the CP and decided to focus on four particular scientific fields.

> NOMA has, and so have most of the other countries, selected priority areas. […] We seek to work only with these products when tasks come up; we submit applications and show that we have experience with the products or similar products.
>
> (NOMA)

The specific areas were chosen based on existing expertise and aims of improving it. Earlier NOMA contributed in several fields, but 'Now we never apply outside those areas. And then you become more competent, you do a good job, the quality is good, you submit in time and get good feedback from EMA' (NOMA). In SIDC's case sharing expertise implies that they can narrow their focus in the process of building expertise. SIDC has until recently relied on external experts but is now in the process of building up in-house expertise. The aim is to specialize in specific scientific areas so they can contribute more to the EMRN and influence scientific decision-making. In this process SIDC is actively seeking advice and has been assisted by sister agencies on which areas to specialize in and how.

> We try to focus on specific processes. Our aim is not to be experts in every field, but we try to focus on specific aspects and we try to use the resources and expertise of other medicines agencies […].
>
> (SIDC)

According to SIDC and NOMA officials, NAs are increasingly adapting to each other and complementing each other in the EMRN. The other side of this is greater dependence on the network.

> Committee participants have different areas of expertise. Some agencies are good in certain areas, and we appreciate that the committee covers different disciplines and that members complement each other. We might be concerned that we have slightly different points of view, but we also proactively try to calibrate ourselves in relation to each other.
>
> (NOMA)

> There are more and more products coming, and member states concentrate on various aspects in order to save resources. […] Everybody cannot do everything in the network. Some member states are perfect experts within specific fields, and some are not. Therefor some differentiation and focussing of work is necessary.
>
> (SIDC)

> There used to be big differences between these countries in how they assessed drugs […] However, these traditional differences are becoming more and more indistinguishable. After the new system came into place in 1995 the countries have become more and more coordinated.
>
> (NOMA)

The significance of NAs' administrative capacity

The importance of the resource pool differs among agencies, based on agency administrative capacity in terms of staff size, expertise and experience. The larger agencies in the system are able to contribute more to the resource pool and are perhaps less dependent on it than small agencies. Especially the Dutch, Swedish, British and German agencies are mentioned as 'big sisters'. These agencies have resources in terms of personnel. This implies that they are able to specialize in a

broader range of fields of expertise, can be more active in discussions, take on a more tasks in the system and generally involve themselves more in network activities by for instance scrutinizing and commenting on the work that is done by other agencies. In comparison, SIDC and NOMA are small agencies, and officials do not have the capacity to involve themselves to the same extent, but need to focus on the tasks and activities where they have direct responsibility.

> Of course there are still big differences between the large agencies, for example the British, Swedish, and Dutch agencies, and small agencies, such as ours. In our department there is just four people in pharmacovigilance. It is really impossible to do the same as the large agencies do and we participate much less than the other agencies.
>
> (SIDC)

Moreover, due to their positions in the network, 'big sisters' have more influence on scientific decisions. Yet, SIDC and NOMA officials experience that scientific knowledge is the most important currency in a network where the focus is of a scientific-technical nature. 'If you provide qualified input, and have skilled professionals in the pharmaceutical area, what is said will be taken into account. […] The key is to provide good input' (NOMA). Although large agencies have more resources, contribute more to the resource pool and consequently may be less dependent on the network, they may nevertheless benefit from resource pool and the expertise of smaller agencies (EMA 2014b). For instance, pooling resources has allowed NOMA to specialize in cancer medicine and develop advanced expertise that is not necessarily found in a larger agency. In general, an enduring topic at EMA management board meetings is that the functioning of the EMRN is under pressure due to a general lack of resources among NAs, and that fees for conducting tasks in the network should be increased (some tasks are not compensated at all).[5]

[5] Minutes from EMA Management Board meetings since 2009 are available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000104.jsp&mid=WC0b01ac0580028c31 (accessed 2 October 2014).

Sharing of workload and expertise is clearly valuable to both SIDC and NOMA, but has an extra dimension to officials in SIDC, related to lack of professional experience and newcomer status in the EU system. Due to poor accessibility to innovative drugs during communism (Szalay at al. 2011; Badescu 2005), SIDC has more experience with generic than innovative drugs. Since accession to the EMRN, however, Slovakia has built a new regulatory system for pharmaceuticals. The Commission, EMA and sister agencies have all been vital to develop administrative, legal and scientific expertise; EMA and sister agencies (especially the Dutch agency) in training administrative and scientific staff, and the Commission in connection to transposition and application of the EU pharmaceutical legislation.

> It is really important that we are part of the European network […] In this cooperation we can share knowledge and share work, which makes it easier to deal with limited resources. It is important for transfer of knowledge and skills, because we have been member of the EU for just ten years. [W]e took over all the legislation and regulations concerning medicines, so it is really nice that we have had the other agencies to learn from, their experiences and their skills. We also had some projects that helped us to start and implement this knowledge here.
>
> (SIDC)

> Without the network, without EMA's role, EMA training and EMA setting guidelines and rules, it would be impossible for us as a newcomer to the EU.
>
> (SIDC)

EMA: administering resource pooling

The EMA secretariat has an important role in administering the pool of resources. Officials in both agencies report that they are more or less continuously in contact with EMA officials through regular meetings (committees, working groups, the Management board and informal networks), procedures, e-mails and phone calls. From the start EMA was a small agency with two scientific committees (Groenleer 2009: 145), but today EMA consists of seven scientific committees, 26 working parties, 9 scientific advisory groups and several ad hoc advisory groups, in addition to the Management board (where NAs' directors meet) and the EMA secretariat (EMA 2014a). Agency officials perceive EMA as a hub and as a 'primus inter

pares' in the network. EMA owes this status to its key position in all network activities, processes and procedures, information and unique overview, and knowledge of legal framework. EMA facilitates network interaction by organizing and hosting all meetings at their premises in London (including booking flights and hotels for committee participants), serving as secretariat for all committees, receiving MA applications from pharmaceutical companies and finalizing and submitting scientific opinions to the Commission. In addition, the EMA secretariat distributes network tasks among NAs (for instance scientific assessments and inspections) and formulates guidelines, standards, templates and best practices. EMA's administrative capacity is a debated topic in network due to its high costs. The secretariat has grown significantly since 1995 and now has 785 employees (EMA 2014a; Groenleer 2009).

With eighty per cent of EMA's funding coming from industry fees, the expansion of the secretariat has taken place gradually in accordance with increased application activity. Interviewees underline that without its resources, the EMA secretariat would not be able to play its important role in the EMRN.

The EMA secretariat's initial task was to 'provide technical, scientific and administrative support for the committees and ensure appropriate coordination between them' (EC726/2004). It has built up a reputation for being a strong, quasi-regulatory EU agency, organizing efficiently the coordination of national expertise and ensuring high-quality scientific decisions (Gehring and Krapohl 2007; Krapohl 2008; Groenleer 2009: 170; Hauray 2013: 92). The secretariat's centrality is illustrated by how it distributes tasks among NAs. MA applications are submitted directly to EMA, who appoints a product team and a team leader to follow each case. The product team leader (PTL) is the contact point for the applicant (pharmaceutical company), coordinates the process with the two *rapporteur* agencies and ensures that evaluations proceeds according to written procedures (procedures are for instance subject to strict timelines). The PTL also provides the assessments teams with relevant information on a product available at the agency, which in some cases dates back several years (EMA 2014b). To become *rapporteur* NAs submit written applications to the EMA secretariat, which takes the decision in cooperation with Committee chairs. What is important is NAs' ability to deliver scientific assessments in time and expertise

in the subject matter.[6] Although NAs receive fees for *rapporteurships*, they are not necessarily proportional to the expenses of the task, and some assignments are more popular than others. If none of the NAs volunteer, EMA personnel will approach NA representatives at committee meetings and ask them directly.

Furthermore, EMA ensures legal consistency between scientific decisions through advice and establishment of standards, and officials report that the legal support of EMA is valuable when they take on assignments in the network. EMA increasingly also provides scientific support. For example, applications within the orphan area are scientifically assessed by the EMA team before the evaluation process by NAs.

> They are definitely a special agency. EMA provides not only coordination of scientific expertise, but is also a driver for training, harmonizing procedures and setting standards. This has influence on the member states, I would say. […] I can provide you with one example – transparency is a topic in the EU at the moment. EMA is setting the rules for transparency and declaration of interests and the general strategy in that area.
>
> (SIDC)

> There is close cooperation with EMA. The EMA coordinator is part of the team and will always be central to discussions, dialogue and process: technically as contact persons, but they are also central in academic discussions. They are scientific coordinators, not merely administrative coordinators. […] And useful in the regulatory area – many committee representatives don't have regulatory experience.
>
> (NOMA)

The Commission, contributes to the network with legal expertise, but has otherwise a modest role. Agency officials report that they interact frequently with the Commission in a range of expert committees and working groups (Commission officials participate in all forums connected to EMA and HMA). Officials in both agencies perceive the

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[6] Also, applicants can indicate preferences with regard to *rapporteur* agencies (Hauray 2013: 90).

Commission as a central source of legal expertise in relation to transposition and application of legislative framework (especially SIDC officials). Also, as mentioned, the Commission is a key channel for input on new legislative initiatives and a useful information source on EU legislative processes when coordination with the ministry is limited. If necessary, contacting the Commission is 'as easy as calling the ministry' (NOMA). However, in relation to day-to-day processes, communication with the Commission normally goes via EMA, which keeps the Commission continuously updated on network activities (Vestlund 2015).

Concluding discussion

The point of departure of this article was the assertion that the significance of the European administrative space is often left out in studies of NAs, due to an understanding of EU policy formulation and implementation as indirect, with NAs operating under strong ministry control and consequently limited network interaction. Recent research has challenged this picture, showing that national agencies can have independent interaction with EU executive bodies and sister agencies and gain resources through EU networks. Given the development of a comprehensive EU regulatory system in the pharmaceutical field (Hauray and Urfalino 2009), medicines agencies seemed like most likely cases for extensive network interaction and resource pooling.

An examination of ministry-agency relationships in Slovakia and Norway showed that ministries are in the driver's seat when developing formal national input to EU policy formulation and in the transposition phase. They may also be involved in implementation issues if cases are politicized. This supports a state centric view. At the same time, the ministries have little capacity, and the agencies under study can in practice operate relatively independently in network activities related to both EU policy formulation (providing input via the Commission and EMA) and implementation of EU policies, without coordinating with the ministry. The fact that NAs interact with network actors in the application phase is in line with previous studies that have included European administrative structures, and supports a multilevel union administration view. It is perhaps more surprising that NAs independently give input to EU policy formulation directly without synchronizing views with the ministry. This might be less controversial given that the input is

scientific-technical in nature, but what this bypassing of ministries in policy formulation actually implies should be further substantiated in future research. Nevertheless, vertical specialization of national administrative systems and loose ministry steering of agencies enable NAs to link up to the EMRN to interact with the Commission, EMA and sister agencies from other countries, as well as promote views that are expert-based rather than political. Strong ministry steering could potentially hamper pooling in a network where scientific arguments carry most weight.

Furthermore, supporting a multilevel administration view, the study shows how NAs interact and pool resources through the EMRN. NAs exchange information, knowledge and best practices through consultation in relation to all kinds of activities, indifferent of policy phase or whether it is EU-related. More importantly, however, is it that NAs routinely share workload and expertise through mutual adaptation, allowing them to focus on fewer tasks and specialize in certain fields of expertise. This represents new insight into how NAs interact in networks. Network participation thus not only has consequences for NAs and their roles in national administrative systems (Egeberg 2006; Newman 2008; Yesilkagit 2011; Bach and Ruffing 2013; Danielsen and Yesilkagit 2013; Maggetti 2014; Bach et al. 2014), but also behaviours vis-à-vis other NAs. Network interaction is clearly focussed around sector-specific issues and mutual adaptation seems to be facilitated by shared professional considerations and standards. Thus, pooling of resources seems to be facilitated and reinforced by shared sector affiliation and professional backgrounds among participants.

However, the most important factors contributing to NAs pooling resources seem to be NA and EU agency administrative capacity. Large NAs contribute more, have more to say, and are less dependent on the resource pool. Small agencies contribute less and are more dependent on the resource pool. Resource pooling is also slightly more important to SIDC, due to its novice status in the EU (cf. Martens 2008b). At the same time, the resource pool allows small agencies to develop advanced expertise that can be valuable also to large agencies, implying that also large agencies can benefit from pooling. Thus, lack of agency administrative capacity in terms of manpower, experience and/or expertise seems to facilitate and reinforce pooling.

Furthermore, the existence of a strong EU agency is important to pooling. The EMA secretariat constitutes a permanent hub that coordinates all processes, controls all procedures and distributes tasks among the NAs. Its administrative capacity is key to EMA's role as main coordinator, task distributor and *primus inter pares* in the network, a position that would be difficult to fill by any of the NAs. Also, although the Commission is important regarding policy formulation and interpretation of legislation, EMA most of the time serves as intermediary between the Commission and NAs. Compared to studies showing the Commission's strong role vis-à-vis NAs and networks in other policy fields, EMA seems to fill this function in the EMRN (Martens 2006; Martens 2008a; 2008b; Levi-Faur 2011; Versluis 2012; Egeberg et al. 2012). At the same time, recent studies have shown that the EU agencies are integral parts of the Commission's administration (Egeberg et al. 2015; Vestlund 2015), indicating that the Commission keeps close overview network activities. In sum, the highly institutionalized and centralized pharmaceutical policy administration at EU level seems to be conducive to routinized division of labour that signifies more than mere harmonized behaviour. Although pooling of resources implies that NAs overall can improve their performance, it also means that they (and to some extent their parent ministries) may increasingly depend on EU networks to fulfil their functions. Even though mutual adaptation so far pertains mainly to the CP and the application phase, it may in the long run have consequences for NAs' ability to support to ministries in developing national policy positions, given for instance the development of 'centres of excellence' (cf. Groenleer 2009). The study thus illustrates the significance of including the European administrative space in studies of NAs. Arguably, NAs pooling resources through EU networks according to EU agency coordination indicates administrative integration and centralization of executive power in the EU, contributing to an emerging multilevel union administration (Egeberg 2006: Trondal 2010).

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Interviews

#1 Official NOMA, November 2008
#2 Official NOMA, November 2008
#3 Official NOMA, November 2008
#4 Official NOMA, November 2008
#5 Official NOMA, November 2008
#6 Official NOMA, November 2008
#7 Official NOMA, November 2008
#8 Official NOMA, November 2008
#9 Official NOMA, December 2008
#10 Official NOMA, December 2008
#11 Official NOMA, December 2008
#12 Official NOMA, December 2008
#13 Official, Norwegian Ministry of Health and Care Services, 2008
#14 Official, Norwegian Ministry of Health and Care Services, 2011
#15 Official EMA, April 2013
#16 Official EMA, April 2013
#17 Official EMA, May 2013
#18 Official DG SANCO, 2011
#19 Official DG SANCO, 2011
#20 Official DG SANCO, 2013
#21 Official NOMA, April 2013
#22 Official NOMA, May 2013
#23 Official SIDC, April 2014
#24 Official SIDC, April 2014
#25 Official SIDC, April 2014

#26 Official SIDC, April 2014
#27 Official SIDC, April 2014
#28 Official SIDC, April 2014
#29 Official SIDC, April 2014
#30 Official SIDC, April 2014
#31 Official, Slovak Ministry of Health, April 2014
#32 Official, Slovak Ministry of Health, April 2014

What characterizes decision-making in the EU administrative system? This report studies decision behaviour within an emerging multilevel European Union (EU) administration, composed of the European Commission, a growing number of EU agencies and national regulatory authorities. These actors are increasingly connected and integrated across levels of governance and national borders. There is disagreement among scholars as well as practitioners on the effects of these institutional developments, and whether they contribute to preserving executive power as decentralized and anchored within member states, or if they contribute to centralizing executive power at the EU level.

The report finds indications that decision-making in the system is gradually becoming normalized, in the sense that it increasingly embodies many of the organizational and behavioural patterns that are highly typical of executives from national settings. Furthermore, the findings show that executive decision-making behaviour is gradually becoming more centralized, with the European Commission as a core executive. The findings of this report thus challenge existing images that portray the European administrative system as *sui generis* and executive power as being mainly decentralized.

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