Networked Health Care Governance in the European Union

Dorte Sindbjerg Martinsen
Reini Schrama
University of Copenhagen

Abstract The European Union (EU) increasingly resorts to new forms of governance to establish unified health and welfare policies without member states having to transfer their sovereignty to a supranational level. European Administrative Networks are important instruments in the toolbox of new forms of governance, dealing with rulemaking, rule monitoring, and rule enforcement. Operating beyond, but not above, the state, European networks of national administrative units allow for interaction and exchange to coordinate national responses to increased interaction across their borders. The authors use social network analysis to uncover the pattern of interaction among national representatives in two central EU health care networks. Their analysis finds not only that the network in the area of pharmacovigilance has more competences, resources, and capacity to improve the enforcement of EU rules than the network regarding cross-border health care but also that the driving forces behind network interaction appear to differ quite a bit as well. While the supranational character becomes apparent in the former network, network interactions in the latter seem aimed at mitigating the impact of patient mobility rather than improving cross-border health care take up.

Keywords health care governance, European administrative networks, cross-border health care, pharmacovigilance

Health Care Governance in the European Union

Over time, the European Union (EU) has increased its regulatory welfare function, including health care regulation. Although the organization and substance of welfare policies are national competences, EU welfare regulation stands out (Levi-Faur 2014). As figure 1 demonstrates, binding

Journal of Health Politics, Policy and Law, Vol. 46, No. 1, February 2021
DOI 10.1215/03616878-8706627

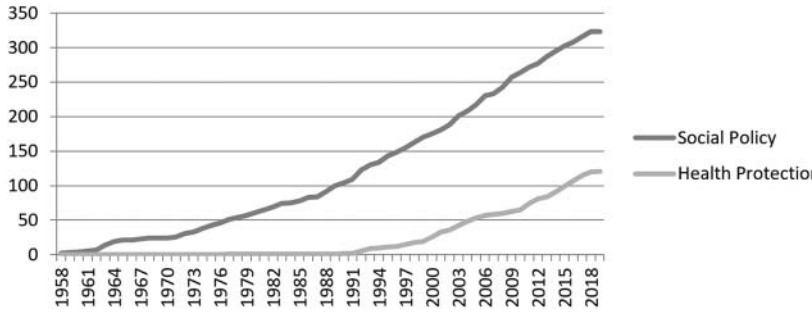

Figure 1 Total EU legislation in the welfare area, including health care, 1958–2019.

Source: Authors' compilation of EU regulations and directives classified on the basis of adoption dates.

Notes: The data has been compiled by means of EUR-Lex's advanced search function with the search codes 05.20 (social policy) and 15.30 (health protection). We excluded decisions, recommendations, and delegations from the compilation as well as acts based exclusively on the Euratom Treaty; acts that addressed statistics, surveys, financial provisions; and acts that addressed only one member state. We are grateful for research assistance from Søren Lund Frandsen.

social policy and health care regulation has increased considerably over time. In 1958 a few social provisions were inserted in the Rome Treaty, addressing coordination of social security for migrant workers and equal pay for equal work between men and women. One of the first European Community regulations, regulation no. 3/58 (now regulation 883/2004), was adopted on the basis of the treaty's article on coordination of social security. This regulation first gave migrant workers and then all EU citizens (as well as their family members) a right to coordinated health care services among other welfare benefits. In 1993 the Maastricht Treaty introduced a separate section, article 152 (now article 168 TFEU) on public health. In this way, the EU got its own independent treaty basis for the regulation of health. As shown in figure 1, health protection regulation expanded significantly after this point, and it is today a considerable part of EU binding regulation.

The key institutions deciding on binding health care provisions are the European Commission, European Council, European Parliament, and the Court of Justice of the European Union (CJEU). In fact, when discussing the development of EU health care governance, the CJEU plays a prominent role and is regarded as a fundamental driver of health care integration. While its importance is undisputable, it is the EU legislative institutions

that determine the scope and content of directives and regulations. Moreover, numerous smaller EU agencies and committees are also a major aspect of EU health care governance, assisting the commission, producing European standards, and monitoring national implementation practices. Their role and impact on EU health care regulation, however, remain largely unexplored.

This article examines the role of European administrative networks dealing with implementation or enforcement of EU legislation. European administrative networks (EANs) composed of national administrative units (such as agencies, ministries, or civil servants) are alternative means through which national implementation and enforcement of EU rules are addressed. In EU health care governance, we know little about their extent or function. To investigate the role of EANs in health care governance, we conducted an online survey[1] among all national representatives and asked them to rank five other members with whom they were most frequently in contact. Based on this new survey data, we were able to map out who interacts with whom when dealing with the coordination of health care policy, who is the most central in the network, and what kinds of organizational attributes relate to activity in the network. Our comparative cases are two networks that were both established by the commission in 2012 but reflect different levels of political support. Whereas the Pharmacovigilance Risk Assessment Committee was established as part of the European Medicines Agency, in a field where both national and European actors warrant more collaboration, the Cross-Border Healthcare Expert Group was kept rather isolated from supranational steering and operates in an area of high national stakes.

Below we provide an overview of EANs in EU health policy. Then we examine two specific networks in more detail: the Pharmacovigilance Risk Assessment Committee (PRAC) and the Cross-Border Healthcare expert group (CBHC). These two networks are part of a broader picture in which administrative networks are increasingly part of EU health care governance but vary in role and competences.

Networked Health Care Regulation

The literature on EU agencies and regulatory networks concludes, overall, that agencies and networks have regulatory impact in developing standards, and that they are able to promote harmonized rules at a

1. Surveys were conducted in 2019, and the response rates were 87% for the Cross-border Healthcare Expert Group and 97% for the Pharmacovigilance Risk Assessment Committee, which allows us to paint a rather accurate picture of the pattern of interactions.

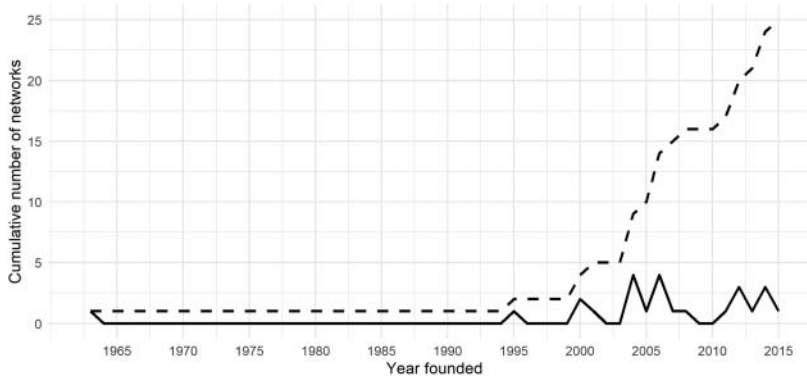

Figure 2 Development of European Administrative Networks dealing with implementation or enforcement of EU health legislation since 1958.

national level (Eberlein and Newman 2008; Maggetti 2007, 2014). It also finds that the commission plays an active role in networks and agencies, using these as a "back road" to both the informal harmonization of regulatory practices and a strategy for solving compliance problems (Martens 2008).

Seven of the decentralized and executive EU agencies deal with health-related policies: the European Environment Agency, the European Agency for Safety and Health at Work, the European Centre for Disease Prevention and Control, the European Monitoring Centre for Drugs and Drug Addiction, the European Food Safety Authority, the European Medicines Agency, and the Consumers, Health, Agriculture, and Food Executive Agency. Of these agencies, the European Medicines Agency (EMA) enjoys the most considerable regulatory competence, as it is responsible for the scientific evaluation and approval of applications for the authorization of medical products. Pharmaceutical companies must submit a single authorization application to the EMA, and, once granted, the authorization is valid in all EU member states as well as in the European Economic Area countries. Most of the agency evaluation work is carried out by its seven scientific committees: the Committee for Medicinal Products for Human Use (CHMP), the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee for Medicinal Products for Veterinary Use (CVMP), the Committee for Orphan Medicinal Products (COMP), the Committee on Herbal Medicinal Products (HMPC), the Committee for Advanced Therapies (CAT), and the Paediatric Committee (PDCO).

Table 1 European Administrative Networks Dealing with Implementation or Enforcement of EU Health Legislation, by Name and Abbreviation

Name of network	Foundation
European Pharmacopoeia Network	1963
European Information Network on Drugs and Drug Addiction (REITOX)	1995
General European OMCL Network (GEON network)	2000
Committee for Orphan Medicinal Products (COMP)	2000
Health Security Committee (HSC)	2001
Heads of Medicines Agencies	2004
Competent Bodies (CCB)	2004
Clinical Trial Facilitation Group (CTFG)	2004
Committee for Medicinal Products for Human Use (CHMP)	2004
Competent Authorities on Substances of Human Origin Expert Group (CASOHO)	2005
Competent Authorities for Tissues and Cells	2006
Expert Group on Health Information (EGHI)	2006
Global Health Security Action Group (GHSAG)	2006
Medical Devices Experts Group (MDEG)	2006
High Level Group on Nutrition and Physical Activity	2007
Network of Competent Authorities for Pricing and Reimbursement	2008
Expert Group on the Delegated Act on Safety Features for Medical Products for Human Use	2011
European Union Network for Patient Safety and Quality of Care (PaSQ)	2012
The Cross-border Healthcare Expert Group (CBHC)	*2012*
Pharmacovigilance Risk Assessment Committee (PRAC)	*2012*
Health Technology Assessment Network (EUnetHTA)	2013
Expert Group on Safe and Timely Access to Medicines for Patients (STAMP)	2014
Health Systems Performance Assessment (HSPA)	2014
Clinical Trials Coordination and Advisory Group (CTAG)	2014
European Workforce for Health Expert Group	2015

The EMA's impact on health integration has been examined to some extent. Findings are, however, quite mixed when evaluating its impact. Despite decades of EU regulation and the considerable mandate of the EMA, a single European market for pharmaceuticals and medical devices has faced substantial obstacles (Altenstetter and Permanand 2007; Permanand and Mossialos 2005). The impact of the EMA suffers from the constitutional asymmetry of EU health care integration, in which EU free

movement principles clash with member states' insistence on preserving national health care competences (Altenstetter and Permanand 2007; Permanand and Mossialos 2005). Furthermore, there is little information regarding which other networks assist with the implementation and enforcement of EU health care regulation, what kinds of roles they play in health care governance, and how their roles and relationships are structured.

To provide an overview of the EANs that assist in EU health care governance, we systematically mapped the establishment of health care networks playing a role in the implementation or enforcement of European legislation over time.[2] We identified 25 such networks, established over time. Figure 2 demonstrates European Administrative Networks dealing with the implementation or enforcement of EU health care legislation. Table 1 lists the networks by names, abbreviations, and the year of establishment.

The Pharmacovigilance Risk Assessment Committee (PRAC)

The Pharmacovigilance Risk Assessment Committee was set up in 2012 as part of the European Medicines Agency (EMA) to discuss medicinal product–related safety issues on a European level. The committee meets every month at the EMA, and its task is to detect, assess, and prevent adverse effects of medicines on the European market. This entails the monitoring of medicine use under normal conditions for previously undetected adverse effects, after medicines have taken entry on the market and are administered to the general population (postauthorization). All reported safety issues need to be scientifically assessed and acted on to improve the safe use of medicines across the EU (Borg et al. 2011). To ensure the

2. The mapping is part of a larger research project examining European Administrative Networks across five policy areas: health, social welfare, environment, immigration and asylum, and internal market. We conducted our mapping of the networks on the basis of a comprehensive search for networks across different data sources: the Register of Commission Expert Groups, EUR-LEX, the webpages of the relevant directorates-general as well as the EU agencies, council presidency meeting agendas, general web searches, and searches in the existing literature. To search for EANs, we used the following keywords: *network*, *association*, *system*, *group*, *forum*, *committee*, and *partnership*. Subsequently, to denote implementation and enforcement activities, we used the search terms *implementation*, *enforcement*, *application*, *monitoring*, and *compliance*. All compiled networks were subsequently cross-validated by different members of our research team. Finally, we ensured external validation of our included networks by means of interviews held with key respondents from the five policy areas in the responsible ministries in two member states as well as with the responsible directorates-general in the EU Commission. Figure 2 and table 1 compile networks in EU health policy only.

Table 2 PRAC Membership

Groups represented	PRAC membership
National regulators	One member and an alternate nominated by each of the 28 EU member states, Iceland, and Norway*
Scientific experts	Six independent scientific experts nominated by the European Commission after consulting the European Parliament
Patient organizations	One member and one alternate representing patients' organizations nominated by the European Commission, after consulting the European Parliament
Health care professionals	One member and an alternate representing health care professionals nominated by the European Commission after consulting the European Parliament

*Liechtenstein had delegated its tasks related to the PRAC to Austria.

safety of medicines on the European market, national regulators, as well as scientific experts, health care professionals, and patient organizations need to act in concert. The PRAC is composed of representatives of each group (see Table 2).

The committee is part of new European pharmacovigilance legislation. Directive 2010/84/EC and regulation no. 1235/2010 revamped the old pharmacovigilance framework establishing the EMA to harmonize the work of existing national medicine regulatory bodies. The legal updates were driven by the "Mediator" case in France, exposing weaknesses in the European pharmacovigilance legislation. Mediator was a medicine for diabetes and obesity originally licensed by the French regulator that led to a number of deaths across Europe. While adverse effects were observed by several health professionals and flagged by regulators in Spain and Italy, it was not appropriately signaled, assessed, and acted on by the French regulatory authority (Mullard 2011). The commission even stress-tested the new legislation to avoid such scenarios and set out to remedy regulators acting in disharmony and to increase proactive regulatory action on safety issues (Borg et al. 2015). Key to the new pharmacovigilance framework, with the PRAC at its center, is to clearly define the roles and responsibilities of all involved parties, reduce administrative burdens, systemize the collection of safety signals in a single EU database, and harmonize pharmacovigilance procedures.

The commission was remarkably successful in getting their proposal for the directive and the regulation adopted (Borg et al. 2011). However, both the council and the Parliament wanted to see the role of the new PRAC strengthened to ensure harmonized responses to safety concerns across Europe. First, through an amendment of the council,[3] all member states are to be represented equally in the committee. Second, the new legislation takes a new direction in that the EMÁs Committee for Medicinal Products for Human Use (CMPH) now has to rely on the assessments made by the PRAC (which previously was not the case with the Pharmacovigilance Working Party). The PRAĆs decisions on regulatory action are not legally binding on itself, as they first have to go through the CMPH. However, both the council and the Parliament[4] wanted to see included in the texts that the CMPH needs to explain and justify their position vis-à-vis the PRAC recommendation whenever they deviate. This is also to ensure that regulatory actions on safety issues are decoupled from decisions to authorize market access. The independence of the PRAC is therefore essential to avoid this potential conflict of interest (Garattini and Bertele' 2011).

PRAC Tasks and Outputs

Crucially, the new pharmacovigilance legislation treats member states as a network of assessors and resources. This should reduce duplication of regulatory action, enabling national regulators to share their workload. Interaction between the members is supported and coordinated by the EMA. Based on expertise on substances of medicinal products, national regulators across the EU can take the lead and take over responsibilities to monitor and assess safety signals of other countries. This mode of work sharing in the network of member states is part of the strategy to reduce administrative burdens. It has become even more essential than before, as the withdrawal of the United Kingdom from the EU now requires redistributing the work currently performed by the United Kingdom across other EU countries (EMA 2018: 5). The United Kingdom was in fact one of the countries with the most responsibilities; there is now, however, a broad distribution of their workload across the rest of the network.

Apart from lead member states, the network now also makes use of multinational assessment teams (32). Rather than assigning all responsibilities to a single member state, the rapporteur and the corapporteur gather

3. 2008/0257(COD) 30/11/2009.
4. 2008/0257(COD) 22/09/2010.

a team of experts from several national agencies. This allows for a broad-based involvement of national authorities, including the smaller member states and those that joined in 2014, and optimizes the use of national resources (5). The committee appoints the rapporteurs in question, based on their expertise on the relevant medicinal product. Essentially their role is to write assessment reports and prepare recommendations or advice to the CMPH. In doing so, the PRAC rapporteurs closely collaborate with the CMPH rapporteurs as well. Whereas the multinational team structure may encourage broader involvement, the appointed rapporteurs and co-rapporteurs still largely come from northern and western European member states. (Sweden, the Netherlands, Germany, the United Kingdom, and Denmark provide almost 60% of the PRAC rapporteurs.)

The PRAC is responsible for the monitoring, assessment, and assignment of regulatory actions in case of safety risks. The pharmacovigilance network is in charge of three main assessments, namely, the assessment of Risk Management Plans (RMPs), Periodic Safety Update Reports (PSURs), and Post-Authorization Safety Studies (PASS). First, the committee needs to assess all updated RMPs submitted by marketing-authorization holders. These plans are detailed descriptions of activities related to the identification, prevention, or minimization of risks related to the medicine. The PRAĆs output with regard to RMPs takes the form of advice to the CMPH. Second, together with the lead member state and other scientific EMA committees, the PRAC continuously assesses the information in PSURs to decide whether the benefit-risk balance has changed and whether the marketing authorization needs to be updated. The PRAC sends its recommendations concerning PSUR assessments to the CMPH, whose decisions become legally binding once transmitted to member states and the commission. Third, the PRAC needs to assess the protocols designed by marketing-authorization holders for imposed PASSes as well as their results. These compulsory safety studies are to be set up by marketing-authorization holders if there is a suspected adverse effect of the medicine requiring more research. The PRAC output following assessments of safety protocols of PASS becomes directly applicable. Overall, the PRAC predominantly discusses safety issues in their assessments of PSURs, followed by RMP assessments.

Ultimately, the PRAC needs to prioritize and evaluate safety signals. These signals need to be detected by the EMA, national regulatory authorities in the member states, and the marketing-authorization holders and are maintained in a centralized monitoring system (EudraVigilance). The PRAC assesses whether the reported adverse events are caused by the

medicine. Based on this assessment, the PRAC may recommend an update of product information to ensure the safe use of the medicine.

The Cross-border Healthcare Expert Group (CBHC)

The Cross-border Healthcare Expert Group is mandated by article 16 of the Patients' Rights Directive (directive 2011/24/EU) in 2012. Its stated task is to assist the European Commission with the implementation of the directive. The expert group provides the commission with advice and expertise, and national authorities with a forum to exchange their experiences of the directive. The members of the network are health care representatives from all EU countries, plus Norway and Iceland. The commission chairs the network. The network meets approximately twice a year. According to the meeting agendas, members exchange views on the implementation of the directive, discuss recent implementation reports from the commission, and listen to different presentations on relevant themes. Such themes include how to improve citizens' information on the directive, health care cooperation in border regions, and implementation experiences in selected member states.

The Patients' Rights Directive (as described in more detail in other articles in this special issue) regulates when patients in the EU (plus Norway and Iceland) have a right to planned cross-border health care, when health care treatment can be provided in other member states without prior authorization from the competent health authorities, and the conditions under which member states are obliged to issue a prior authorization. The scope and limits of EU cross-border health care have been quite disputed over time (see, e.g., de Ruijter 2015; Greer and Jarman 2012; Hatzopoulos and Hervey 2013; Hervey and McHale 2015; Martinsen 2015; Obermaier 2009; Palm et al. 2000). In the political negotiations leading up to adopting the directive, member states in the council and members of the European Parliament disagreed considerably on the scope and limits of the Patients' Rights Directive; and the resulting compromise adopted considerable more national control (specifically regarding financing of cross-border health care by the insuring member state) than originally interpreted by the CJEU and proposed by the commission (Martinsen 2015). One of the issues negotiated was the extent to which the commission or the member states should decide on which health care treatments could be defined as non-hospital and thus not to be authorized beforehand, and which would count as hospital care, highly specialized, or cost-intensive and thus requiring prior authorization.

Central in these political negotiations was the question of which networks were to assist the commission in negotiating these issues (and with what structure and mandate). The commission originally proposed article 8.2, according to which the treatments defined as highly specialized and cost-intensive care should be included on a specific list, created and regularly updated by the commission with the assistance of a committee under the comitology procedure.[5] In this way, the commission would gain considerable control of what could be classified as "highly specialized and cost-intensive" care. Most member states, however, opposed this part of the proposal. The member states found that the formulation of article 8.2, and the mandate here assigned to the commission and the Comitology Committee, would not allow them sufficient control, thus endangering the sustainability and steering capacities of national health care systems (Martinsen 2015: 166). In the final version of the directive, the commission's proposal of article 8.2 was abolished, meaning that the commission's central role in controlling what was defined as "specialized and cost-intensive" had been removed, as had the envisioned committee under the comitology procedure. The final agreement established that, for hospital care, highly specialized care, and cost-intensive care, a national system of prior authorization was justified; and what constituted such type of care should properly be defined by the member states. Instead of the envisioned comitology committee, article 16 of the adopted directive laid down that a committee consisting of national representatives was to assist the commission on implementation, but without further specification of its role and tasks. The political adoption of the directive thus leaves the purposes and the function of the CBHC open, to be filled as members convene and interact.

CBHC Tasks and Results

Perhaps the most central issue in the application of the directive has been whether member states have implemented a system of prior authorization permitting patients to access cross-border health care. A related issue is the extent to which such authorization is granted. The primary task of the CBHC network has been to exchange information on these points. External presenters and stakeholders also attend meetings to present user experiences of the process. This exchange of information and experiences may ultimately improve EU citizens' ability to effectively take advantage of cross-border health care legislation.

5. June 23, 2011; COM (2008) 414, 15–16, recital 30 and article 8.2.

Despite the legislative aim of the Patients' Rights Directive "to establish rules for facilitating access to safe and high-quality cross-border health care in the Union and to ensure patient mobility" (directive 2011/24/EU, recital 10), very few EU citizens make use of the directive. Only the Czech Republic, Estonia, Finland, Lithuania, the Netherlands, and Norway did not adopt a system for prior authorization. In 2017 1864 cross-border treatments were authorized beforehand, and 203,553 treatments in other member states were subsequently reimbursed without requiring prior authorization (European Commission 2017). Cross-border health care varies notably across member states. Together, four member states—Ireland, Luxembourg, the United Kingdom, and Slovakia—issued 1,706 of the 1,864 prior authorization, whereas France had the highest number of reimbursements without prior authorization at 130,070.[6] However, France noted that it was not possible to distinguish the care provided under the regulation coordinating social security across borders (i.e., regulation 883/2004, which also covers acute health care treatment under the European health card) and the directive. Denmark also has a relatively high number of reimbursements without prior authorization (25,183 in 2017). However, the large majority of these concerned dental treatment, which could already be reimbursed in Denmark before the directive was adopted and implemented. In general, therefore, the numbers of both prior authorizations and reimbursements without prior authorization as a result of the directive remain modest.

As part of our survey conducted with the CBHC members in 2019, we asked the member state representatives to give their perception of the result of the network. Figure 3 presents the different responses, showing that the large majority of member state representatives find that the network only moderately improves the ability of patients to access health care in other member states.

In sum, despite the task of the network to assist the commission on the implementation of the directive, the task fulfilment is arguably moderate, when assessed against the aim of the directive to establish rules facilitating and improving cross-border health care.

Comparing PRAC and CBHC

The fact that the PRAC and the CBHC vary considerably both in their role and their competences when it comes to the application of EU health

6. Germany, Cyprus, Netherlands, Sweden, and Iceland were not able to return any data on patient mobility. This means that approximately 21% of the potential population of traveling patients are not reflected in the data.

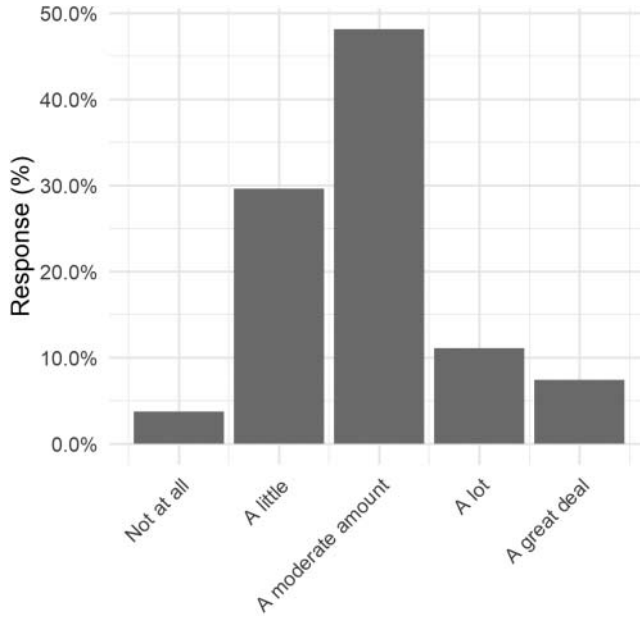

Figure 3 Response to the survey question, "In your view, to what extent does the Cross-border Healthcare Expert Group facilitate/improve the possibility to take up health care in another member state?"

Source: Authors' survey material, compiled 2019.

policy is reflected in our comparative analysis. While there is considerable political support for the PRAC, there is much less for the CBHC. This also shows in the importance network members ascribe to different network functions. As part of our survey, we asked the national representatives of both networks how important they considered their network to be for improving application, exchanging information, or issuing opinions regarding the relevant policy domain. Figure 4 illustrates the differences in how national representatives in the network perceive its functioning. Overall, members of the PRAC think of their network as more important than members of the CBHC do theirs. And, while the PRAC members find "issuing opinions" is the most important task, for the CBHC members the most important function is "information exchange." This confirms that the CBHC is in fact more a network of information exchange rather than for solving problems, whereas the competences of the PRAC go much further.

The PRAC is, notably, better staffed than the CBHC. However, when asked how many staff members each member state are in one way or

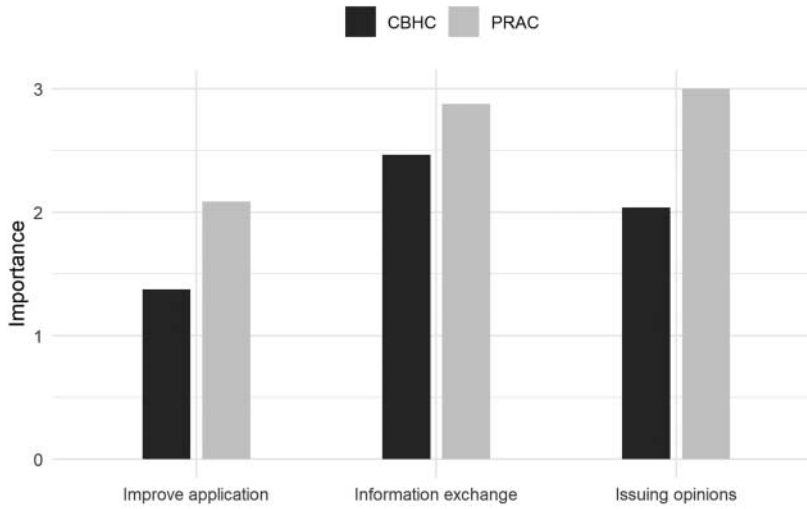

Figure 4 Response to the survey question, "How important would you say the [network in question] is for improving application, exchanging information, issuing opinions?"

Source: Authors' survey material, compiled 2019.

another involved in the activities of the network, the difference in answers is considerable between networks as well as between member states. While for the CBHC is particularly skewed toward low staff levels, both networks exhibit strong differences among members in terms of staffing available for tasks related to the network (see fig. 5). Discrepancies between staff levels among members will likely impact the degree to which members can interact with one another on an equal footing, resulting in a less horizontal network structure.

Besides competences and resources, there is also a notable difference in the relationship network members maintain with supranational actors (see fig. 6). First, the PRAC members are more frequently in contact with the commission than the CBHC members are. These differences are predominantly due to a much higher degree of contact for the purpose of improving administrative capacity of the national bodies represented in the PRAC. This demonstrates a much greater supranational influence on the PRAC than on the CBHC. Moreover, as the PRAC is part of a European agency as well, the commission is not their only principal. Even though the PRAC members are closer to the commission than the CBHC members, their contact with the EMA is even more frequent. Similar to the purpose of

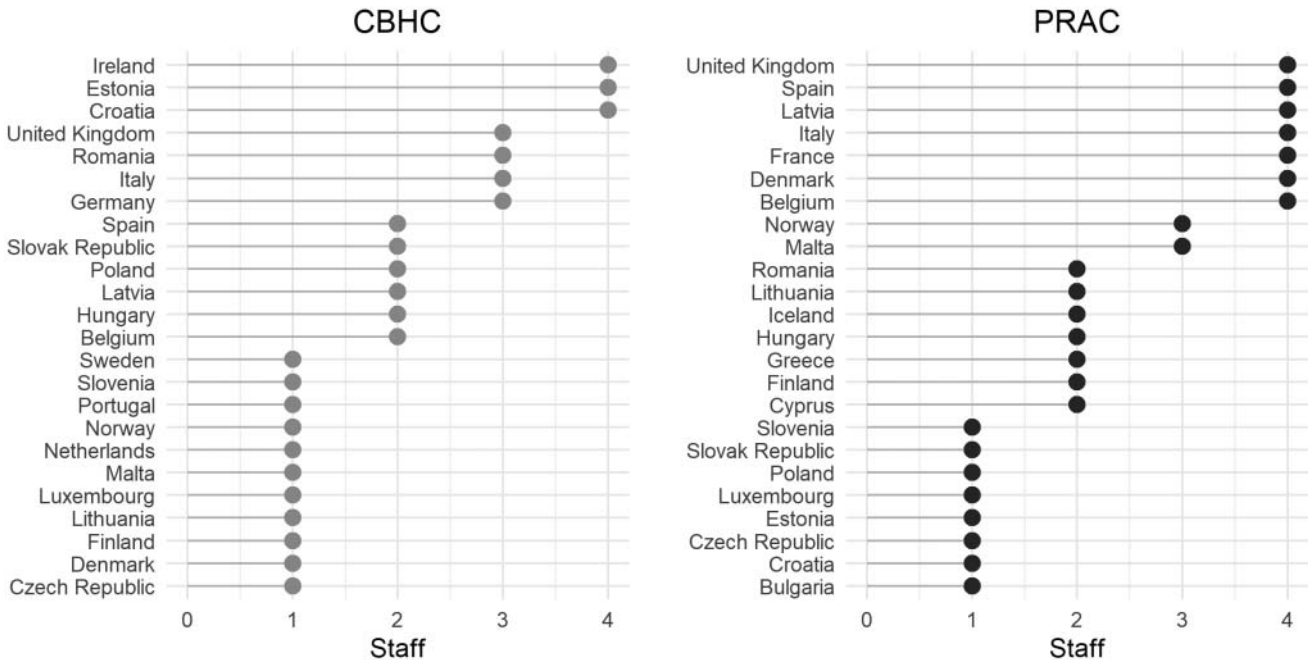

Figure 5 Response to the survey question, "How many staff members of your member state are in one way or another involved in the activities of the [network in question]?"

Source: Authors' survey material, compiled 2019.

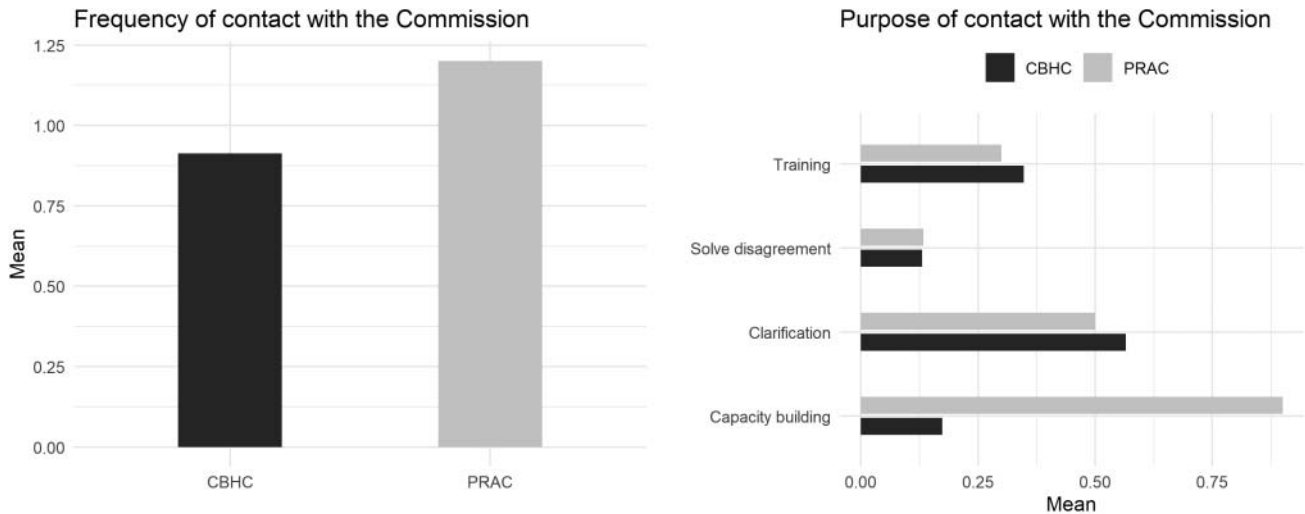

Figure 6 Response to the survey question, "How often is your organization in contact with the European Commission/EMA concerning matters addressed in the network? What is the purpose of these contacts?"

Source: Authors' survey material, compiled 2019.

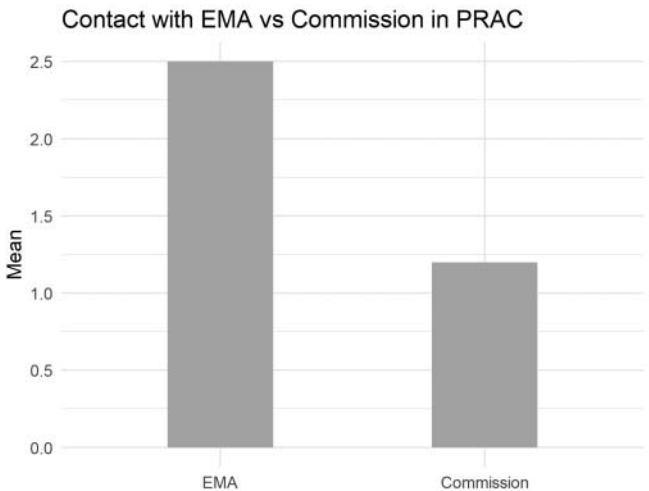

Figure 6 (*continued*)

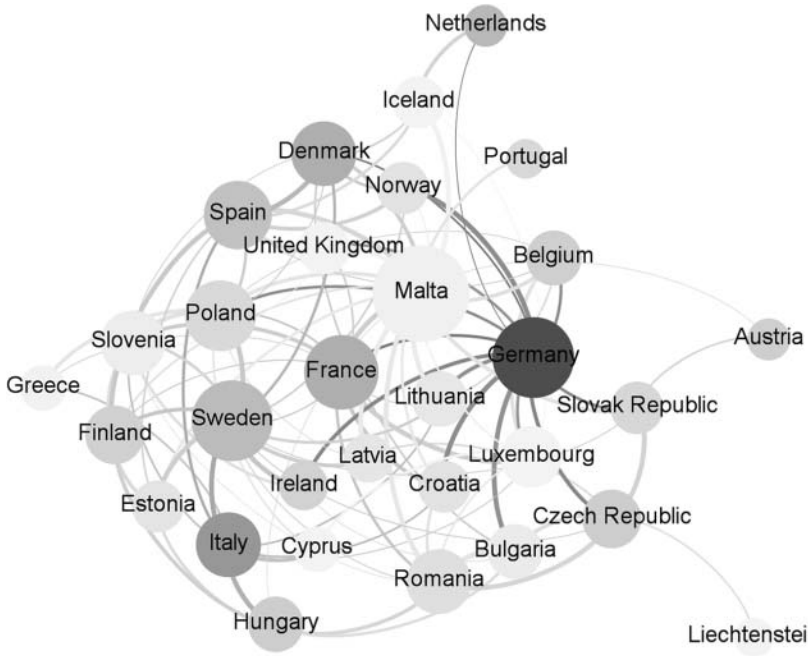

Figure 7 Response to the survey question, "What five other network members is your organization most frequently in contact with?"

Source: Authors' survey material, compiled 2019.

Notes: Interactions in the PRAC. The larger the node, the higher the degree centrality. The thicker the tie, the more frequent the contact. The darker the node, the more rapporteurs and leading roles are assigned to the network member.

contact with the commission, capacity building is the most prominent objective. However, disagreements between members and public authorities are discussed with the EMA rather than with the commission.

Mapping out the interactions among network members for both the PRAC and the CBHC provides insight into network structure and the position of the various member states in the respective networks. In our survey of national representatives in both networks, we asked them to rank five other network members their organization was most frequently in contact with. Contact could mean general discussions, exchange of views, as well as informal advice. This data was mapped out in network graphs (see figs. 7 and 8), in which member states were represented as nodes, and their named interactions as undirected ties, allowing us to do a social network analysis.

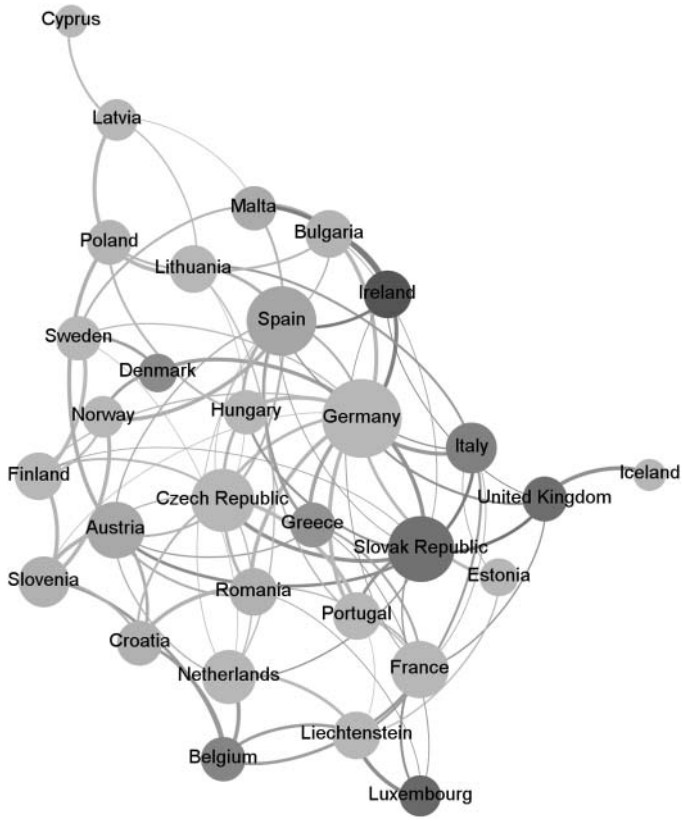

Figure 8 Response to the survey question, "What five other network members is your organization most frequently in contact with?"

Source: Authors' survey material, compiled 2019.

Notes: Interactions in the CBHC. The larger the node, the higher the degree centrality. The thicker the tie, the more frequent the contact. The darker the node, the more patients were authorized to take up health care in another member state with prior authorization.

Figure 7 displays the network of most frequent interactions among national representatives in the PRAC. The network contains 30 nodes and 106 ties, which adds up to a relatively dense graph (density = 0.24). The density of interactions echoes the complexity of pharmacovigilance, demanding continuous activity and the handling of many emerging technical issues. On average, each member has approximately seven (more frequent) contacts. However, the Netherlands (20 contacts), the United Kingdom (17 contacts), and Germany (16 contacts) have more than double the average degree, making them more central to the network. Interestingly,

we observe that member states that hold the most specialized expertise in pharmacovigilance within a country, in terms of rapporteurs and leads on substances, are more active in the network. This suggests that both expertise influence over the network is concentrated in the western and northern member states. Additionally, the network exhibits a significant centralized structure,[7] meaning that the power of members varies considerably. Factors other than technical expertise may come into play as well, when it comes to network influence, such as connectedness to other EMA bodies. This is demonstrated by the central role of both the Netherlands and the United Kingdom, from which the EMA operates (pre- and post-Brexit). This finding is in support of our other findings that the PRAC has a more supranational character than the CBHC.

As seen in Figure 8, the interactions in the network of the CBHC are slightly less dense. Similarly to the PRAC, it contains 31 nodes, but it only counts 97 ties, adding up to a density rate of 0.21. The relatively low interaction level reflects a different context in which the CBHC is operating. Meeting only every six months and dealing with implementation in a relatively stable environment may not require as dense and continuous interaction as the PRAC. The CBHC members on average interact more frequently with six other members each. When it comes to cross-border health care, Germany (16 contacts), but also Spain (13 contacts) and Slovakia (12 contacts), are the most active networkers. Similar to the PRAC, the network structure of the CBHC is centralized,[8] with an unequal distribution of contacts across members.

Interestingly, the members that we find to be most active in the network are themselves not convinced the network improves the ability to take up health care in another member state. National representatives of Germany thought this was not at all the case, while Spain and Slovakia believed the network's contribution was only small. Still, Slovakia's activity could be explained by its relatively high number of patients that were granted approval to take up health care elsewhere in the EU. While we do not have any numbers on patient mobility in Germany, Spain authorized cross-order health care for a total of only 16 patients (6 with prior authorization and 10 without), indicating that not all active members seem to have more experience with the application of the directive. Furthermore, those

7. We used conditional uniform graph tests to compare 20,000 random replications with networks of a similar size and density to the observed network and found the observed centralization score to be significantly higher than expected (0.48, $p < 0.001$).

8. We used conditional uniform graph tests to compare 20,000 random replications with networks of a similar size and density to the observed network and found the observed centralization score to be significantly higher than expected (0.47, $p < 0.001$).

members indicating that the CBHC network was in fact improving cross-border health care take-up a great deal (Ireland, Greece) or a lot (United Kingdom, Italy, and Croatia) are located rather to the periphery of the network with moderate to average levels of interaction. Thus neither perceived effectiveness nor experience with granting patients to take up health care in another member state seems to affect active participation in the network. Interestingly, Germany (receiving patients mostly from France and Denmark), Spain (receiving patients mostly from France and Norway), and the Czech Republic (receiving patients mostly from Poland and Slovakia) are on the receiving end of patients taking up care in their health care systems. As most of their interactions do not directly reflect these patient flows, the sheer impact of the directive on their health care systems may have caused them to become more active in the network.

Conclusion

While there is an increasing use of European Administrative Networks to improve the implementation and enforcement of EU rules in the health policy domain, the role and competences of these networks vary to a high degree. Diving deeper into the functioning and interactions in two networks, established in 2012 by the commission to coordinate a uniform application of health policy, we find striking differences.

The PRAC operates in the area of pharmacovigilance in which political support for more collaboration is shared by both national and European actors. This has led to a network that is much more supranational in character, being part of a European agency and having a strong connection to the commission. As a consequence, the network has the mandate to go beyond information sharing and is considered important enough to issue recommendations to be taken up by other EMA bodies and that become binding decisions across the union. Despite differences in capacity and resources across members, capacity building has been a focus by both the commission and the EMA and has led to an increasingly active and effective network. Since the network seems to be driven by technical and medical expertise and resources, which is mostly concentrated in Western and Northern Europe, interactions do not reflect the intended goal by the council that all member states are represented equally. Additionally, members' integration in the European Agency seems to be an important factor for network activity, demonstrating the supranational character of the network.

In contrast, there has been limited support for European collaboration in the area of cross-border health care, which is reflected in a network that is considered to be important for information sharing at most and limited in its contribution to improve cross-border health care utilization. Interestingly, members that do think highly of the network's effectiveness are not that well connected in the network, while those that are rather skeptical about its impact are among the most central in the network. Compared to the PRAC, in the CBHC there is less of a continuous demand for dense interactions as it operates in a relatively stable environment and meets approximately twice a year. Even though the density of network interactions is not much lower than in the PRAC, it is unclear what drives interactions in the CBHC. Not only is the propensity to access health care in another member state under the directive rather moderate, but also the network interactions do not reflect the numbers on patient mobility either. Rather than functioning as a network to improve cross-border health care utilization, the network seems to be more useful for members to mitigate the impact of the directive on their health care systems.

In sum, our analysis first demonstrates that varying levels of political support for further European collaboration is reflected in differences in networks' competences, resources, and capacity to implement and enforce EU rules. This is perhaps predictable. More intriguingly, it also shows the way in which these small administrative bodies perform not only an integrative function within the EU but also a protective function for national interests. In other words—and somewhat paradoxically—member states sometimes enthusiastically participate in supranational bodies with the main intention of limiting supranational activity on domestic health care systems.

■ ■ ■

Dorte Sindbjerg Martinsen is a professor of political science at the University of Copenhagen. Her research focuses on EU welfare policies, investigating integration, and national implementation of and compliance with EU social policies, including health care. Together with Ellen Mastenbroek (Radboud University) and Reini Schrama (University of Copenhagen), she is currently undertaking a research project on the role of European Administrative Networks in the implementation and enforcement of EU legislation.
dm@ifs.ku.dk

Reini Schrama is a postdoctoral researcher in the Department of Political Science at the University of Copenhagen. Her expertise is in the implementation and enforcement of EU policy and networked governance in the social and health policy domain. In her research, she applies social network analysis to uncover the structure and drivers of network interaction. Currently, she is working on a project to study the functioning, establishment, and role of European Administrative Networks in the implementation of EU policy by national authorities (together with Ellen Mastenbroek of Radboud University and Dorte Sindbjerg Martinsen).

Acknowledgment

The research for this article was funded by the Danish Council for Independent Research, grant number DFF-7015-00024.

References

Altenstetter, Christa, and Govin Permanand. 2007. "EU Regulation of Medical Devices and Pharmaceuticals in Comparative Perspective." *Review of Policy Research* 24, no. 5: 385–405.

Borg, John-Joseph, George Aislaitner, Michal Pirozynski, and Stephen Mifsud. 2011. "Strengthening and Rationalizing Pharmacovigilance in the EU: Where Is Europe Heading To?" *Drug Safety* 34, no. 3: 187–97. doi.org/10.2165/11586620-000000000-00000.

Borg, John-Joseph, Amy Tanti, Dimitrios Kouvelas, Calin Lungu, Michal Pirozynski, Anthony Serracino-Inglott, and George Aislaitner. 2015. "European Union Pharmacovigilance Capabilities: Potential for the New Legislation." *Therapeutic Advances in Drug Safety* 6, no. 4: 120–40. doi.org/10.1177/2042098615591802.

de Ruijter, Anniek. 2015. "A Silent Revolution: The Expansion of EU Power in the Field of Human Health: A Rights-Based Analysis of EU Health Law and Policy." PhD diss., University of Amsterdam.

Eberlein, Burkard, and Abraham L. Newman. 2008. "Escaping the International Governance Dilemma? Incorporated Transgovernmental Networks in the European Union." *Governance* 21, no. 1: 25–52.

European Commission. 2017. "Member State Data on Cross-border Patient Healthcare Following Directive 2011/24/EU: Year 2017." ec.europa.eu/health/sites/health/files/cross_border_care/docs/2017_msdata_en.pdf (accessed August 17, 2020).

EMA (European Medicines Agency). 2018. "Annual Report 2017." February 5. www.ema.europa.eu/en/documents/annual-report/2017-annual-report-european-medicines-agency_en.pdf.

Garattini, Silvio, and Vittorio Bertele. 2011. "Anything New in EU Pharmacovigilance?" *European Journal of Clinical Pharmacology* 67, no. 11: 1199–1200. doi.org/10.1007/s00228-011-1052-1.

Greer, Scott, and Holly Jarman. 2012. "Managing Risks in EU Health Services Policy: Spot Markets, Legal Certainty, and Bureaucratic Resistance." *Journal of European Social Policy* 22, no. 3: 259–72.

Hatzopoulos, Vassilis, and Tamara Hervey. 2013. "Coming into Line: The EU's Court Softens on Cross-border Health Care." *Health Economics, Policy, and Law* 8, no. 1: 1–5.

Hervey, Tamara, and Jean McHale. 2015. *European Union Health Law: Themes and Implications*. Cambridge: Cambridge University Press.

Levi-Faur, David. 2014. "The Welfare State: A Regulatory Perspective." *Public Administration* 92, no. 3: 599–614.

Maggetti, Martino. 2007. "De facto Independence after Delegation: A Fuzzy-Set Analysis." *Regulation and Governance* 1, no. 4: 271–94.

Maggetti, Martino. 2014. "The Politics of Network Governance in Europe: The Case of Energy Regulation." *West European Politics* 37, no. 3: 497–514.

Martens, Maria. 2008. "Administrative Integration through the Back Door? The Role and Influence of the European Commission in Transgovernmental Networks within the Environmental Policy Field." *European Integration* 30, no. 5: 635–51.

Martinsen, Dorte Sindbjerg. 2015. *An Ever More Powerful Court? The Political Constraints of Legal Integration in the European Union*. Oxford: Oxford University Press.

Mullard, Asher. 2011. "Mediator Scandal Rocks French Medical Community." *Lancet* 377, no. 9769: 890–92. doi.org/10.1016/s0140-6736(11)60334-6.

Obermaier, Andreas. 2009. *The End of Territoriality? The Impact of ECJ Rulings on British, German, and French Social Policy*. Surrey, UK: Ashgate.

Palm, Willy, Jason Nickless, Henri Lewalle, and Alain Coheur. 2000. "Implications of Recent Jurisprudence on the Co-ordination of Health Care Protection Systems." Association Internationale de la Mutualite, May. ec.europa.eu/employment_social/soc-prot/disable/synt_en.pdf.

Permanand, Govin, and Elias Mossialos. 2005. "Constitutional Asymmetry and Pharmaceutical Policy-Making in the European Union." *Journal of European Public Policy* 12, no. 4: 687–709.