



***Changing Policy Focus
through Organisational Reform?***
*The case of the pharmaceutical unit
in the European Commission*

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Abstract

This article demonstrates how organisational structure may systematically tip the scales in the direction of certain actors, solutions, interests and concerns in a decision process. The article reports from a case study of an organisational reform in the European Commission, i.e., the move of the pharmaceutical unit from DG Enterprise to DG SANCO in 2010. To what extent, how and why did the reorganisation of the pharmaceutical policy field affect decision behaviour within the pharmaceutical unit? The empirical findings show that balancing contact, interests and concerns are important to the officials in the unit, independent of DG affiliation. At the same time, however, they tend to favour actors, solutions, interests and concerns pertaining to their own DG and sector. Hence, after the reform priorities changed: public health actors partly replaced industry actors in the unit's network, and public health interests and concerns replaced pharmaceutical industry and business interests and concerns.

Keywords

Decision Behaviour, European Union, Organisational Structure, Organisational Theory, Pharmaceutical Policy

Introduction

What is the relative significance of organisational structure in explaining administrative behaviour? This article sheds light on this question as it investigates how rearranging an organisation's structure impacts on how the organisation works. The article reports from a case study on the effects of a reorganisation of the pharmaceutical policy field in the European Commission (the Commission). In March 2010, the unit responsible for pharmaceutical policy was moved horizontally from the Directorate-General (DG) for Enterprise and Industry (DG Enterprise) to DG Health and Consumer (DG SANCO). The reform thus constituted a change in the DG affiliation of the officials in the pharmaceutical unit. The two DG's have different purposes and constitute different frameworks for pharmaceutical policy-making: while DG Enterprise's task is to promote the single market and to ensure favourable framework conditions for European industry, DG SANCO's task is to empower consumers and protect and improve public health. The following question is asked: To what extent, how and why did the reorganisation of the pharmaceutical policy field affect decision behaviour within the pharmaceutical unit?

The decision behaviour of the officials in the pharmaceutical unit, defined as their attention patterns, was studied in the process of developing a legislative framework on information to patients. The process took place simultaneously with the reform. The empirical findings show that throughout the process and independent of DG affiliation, the officials were continuously exposed to multiple competing actors, solutions, interests and concerns. Balancing these was central to the officials, but it was also important to prioritise their own DG and sector. The substance of the officials' priorities – who and what was attended to – thus depended on their DG affiliation. Consequently, the reorganisation affected which actors that were perceived as important, which solutions that were preferred, as well as whose interests and which concerns that were emphasised in the decision process under study. The case study thus demonstrates the relative significance of organisational structure in tipping the scales in favour of certain actors, solutions, interests and concerns in a decision processes.

The analytical tools applied in this article are drawn from organisational and institutional perspectives. The organisational perspective is useful as it unpacks the components of the organisation under study, and highlights the importance of organisational structure, demography and locus in explaining administrative behaviour. In addition, the institutional perspective highlights the importance of informal norms and values (culture) in explaining administrative behaviour. These perspectives will be further elaborated below.

The next section provides an overview of relevant literature focussing on the impact of organisational structure on decision behaviour. Then follows an outline of the analytical tools, and thereafter a description of the methodological tools applied in the article. The empirical findings of the case study are then presented, and finally, the findings are discussed in a concluding section.

The impact of organisational structure

Why study the impact of organisational structures, or more specifically, rearranging these structures, on decision behaviour? When organisations act, it is basically individuals who act, and it is therefore essential to understand the significance of individuals' organisational position, and changes in this position, for their decision behaviour. Studies of reforms are common, but often concentrated on explaining the causes of and/or the reform process itself. How reform may impact on the activity of an organisation has been given less attention in the public administration literature (Egeberg 2012a). Reorganisations are frequently carried out at different levels of governance, and may be viewed as a tool or a deliberate strategy for achieving particular goals. However, 'students of organisational decision-making observe that reforms often fail. Change takes place without explicit decisions and decisions to change follow after change has already occurred. Decisions to change often do not lead to change, or they lead to further unanticipated or unintended change' (Olsen 1997: 205-6). Thus the importance of understanding effects of reforms generally, but also the relation between the each of the organisational factors outlined above and decision behaviour specifically. The present study observes behaviour subsequent to a reorganisation of organisational structure, and if behavioural changes can be traced under these circumstances, it increases the likelihood that a cause-effect relationship really exists between the variables that have been outlined (Egeberg 2012a: 162).

As regards the impact of organisational structure on decision behaviour, empirical studies have contributed to substantiating the theoretical hypotheses about the impact of horizontal specialisation (Egeberg 2012a: 161). The Commission has been depicted as a heterogeneous organisation with competing DGs (e.g., Cram 1994; Christiansen 1997; Cini 1997). DG affiliation has been pointed out as crucial for understanding decision behaviour within the Commission, 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). Studies have also indicated that the sectorial specialisation of the Commission has had implications for its relations to external interested parties, as each DG has become associated with

particular client groups, and the respective relations seems to differ in nature from DG to DG (Mazey and Richardson 2006; Bouwen 2009).

As regards studies of effects of horizontal reorganisation, Hult (1987) found in a study of bureaucratic merger that it may foster shifts in policy direction, as well as impact on relations to interest groups, by making networks more differentiated and diluting established 'iron triangles'. Similar patterns have been found in studies focussing on the importance of venues and changes in venues for agenda-setting (Princen 2007; 2010; 2011); and studies on how framing and reframing have consequences for how issues are processed, which interests play a role during policy drafting and deliberation and what type of political conflicts and coalitions that are likely to emerge as a result (Daviter 2007). Common to these studies is that they deal with policy areas that touch upon several sectors, where (changing) policy images interact with (changing) institutional venues (Baumgartner and Jones 1991) in one way or another. Daviter (2009) described how these dynamics played out and contributed to shifts in biotechnology policy in the EU. Mörtz (2000) found that reframing the defence equipment and industry issue in the Commission activated other perspectives, actors and knowledge, and also that it affected (strengthened) the relationship to particular external actors. Harcourt (1998) described how reorganising the DG responsibility of a portfolio affected the process of developing a regulation on media ownership; it impacted on the choice of solutions and policy instruments, the aims and the argumentation of the legal framework and the actor alliances. The present study supports the findings of the above-mentioned studies concerning the importance of horizontal specialisation in explaining decision processes in the Commission. The present study contributes to this literature as it specifies the relative importance of horizontal specialisation in shaping and reshaping the policy focus of a policy area in the Commission by systematically tipping the balance in a particular direction.

Concerning the pharmaceutical field in the Commission, it has been questioned whether a reorganisation would impact EU's pharmaceutical policy, which has been regarded as 'captured' by the pharmaceutical industry (Boessen 2008) and described as mainly focussed on developing an integrated market and a globally competitive pharmaceutical industry (see Permanand and Mossialos 2005; Permanand 2006; Carboni 2009; Baeten 2010; Geyer 2011). The present study does not support the hypothesis of regulatory capture, but contributes to the understanding of EU's pharmaceutical policy as complemented with concerns beyond market and industry interests.

Analytical tools

The article combines an organisational perspective and an institutional perspective. According to the perspectives, an organisation may influence (although not determine) the decision behaviour taking place within the organisation. Decision behaviour is understood as the many choices and decisions the officials make as they perform their tasks during the different phases of the policy cycle. This means that the decision process is understood as more than the formal decision that is made – it includes also agenda-setting, policy formulation, decision-making, policy implementation and evaluation (Howlett *et al.* 2009). The theoretical connection between the organisational components and decision behaviour is based on the mechanism of bounded rationality (Simon 1997). When choosing between different action alternatives, individuals are not able to attend to all concerns at one time. The organisational context surrounding individuals serves to simplify decisions that might otherwise be complex and incomprehensible by sorting some alternatives into the decision process and some alternatives out of it (Egeberg 2012a: 157). It is thus argued that how participants distribute their attention – how they think and act, what and who they attend to as they perform their daily tasks – is shaped by their organisational context. When ‘unpacking’ the organisational context, four factors that may impact decision behaviour are singled out. Variation in one of these factors is expected to cause variation in decision behaviour.

In an organisational perspective, organisational structure is key to understand and explain decision behaviour in organisations. It is normally illustrated in an organisational chart and expresses role expectations and norms for action: who should do what, how and when in the everyday work, including which interests and goals that are to be pursued (Egeberg 2006b: 33). As argued by Gulick (1937), how the organisational structure impacts decision behaviour depends on how it is organised. The horizontal specialisation of an organisation refers to the way tasks are distributed at one level. This affects information exchange and co-ordination processes as well as the horizons of the individuals within the organisation, and increases the likelihood that behavioural patterns will follow particular lines. Which lines behaviour follows depends on the specialisation principle chosen: organising according to the principle of purpose is supposed to foster sectorial co-operation patterns and perspectives among decision makers (Egeberg 2012a: 159). Thus, a horizontal reorganisation – displacing a policy field horizontally – could lead to a reorientation of individual perspectives.

Two further key organisational factors are demography and locus. Demography refers to the personnel composition in terms of different personal attributes, and signifies the socialisation of certain values, norms and

role expectations belonging to a particular profession that individuals internalise during their education (Egeberg 2012a: 160). Variation in this organisational factor would imply a change in the professional composition of the organisation. Organisational locus – 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). Variation in this factor would imply changing the location of the organisation. Finally, an organisation's degree of institutionalisation may be an essential factor in explaining decision behaviour. Institutionalisation refers to the process of which informal norms, practices and values evolve and become important for the activities of an organisation (Christensen *et al.* 2007: 37). This implies the classical understanding by Selznick (1957) of how an organisation may grow into an institution as informal structures are gradually developed and infused with meaning over time, and a high degree of institutionalisation can make an organisation robust towards change. Individual decision behaviour may thus be guided by informal norms, values and beliefs that dominate the organisation. Variation in this factor would imply a de- and/or re-institutionalisation of informal values and beliefs in the organisation (Olsen 2009).

Methodological tools

To answer the research question, the decision behaviour of the officials in the pharmaceutical unit was studied within the process of developing a regulative framework on information to patients about prescription medicines from March 2004 to October 2011. This process thus overlapped with the organisational reform in 2010. Answering the research question required observations at two points in time, i.e., both before and after the reorganisation. Covering these requirements, the study builds extensively on nine semi-structured interviews with one national official and eight former and current Commission officials (both permanent staff and seconded national experts). A complete list of these interviews can be found at the end of the paper. It is important to note that the behavioural patterns studied are the officials' *perceptions* of their own behaviour. In addition, the study builds on official documents and secondary literature.

The theoretical perspective outlines four independent factors that may impact on decision behaviour. Operationalising organisational structure, demography and locus requires knowledge about the Commission's organisational chart, the unit's professional composition and its location. Institutionalisation was defined as the existence of informal norms, values and beliefs of the organisation that were detected through interviews (Christensen *et al.* 2007: 38).

As regards variation in these factors, organisational structure is seemingly the only factor that has changed. The location of the unit and the professional composition of the personnel were not changed in connection to the 2010 reform. In addition, the unit structure itself remained intact, and the interviews did not uncover any signs of de- or re-institutionalisation of informal norms and values. Thus, demography, location and institutionalisation were treated as constant factors.

As noted above, the dependent variable decision behaviour is understood as the many choices the officials make as they perform their tasks during the different phases of the policy cycle. In line with the theoretical argument, the organisational context influences what and whom they pay attention to as they make these choices. Decision behaviour is therefore operationalised as attention patterns. Three indicators are outlined to study the attention patterns of the officials in the pharmaceutical unit:

- Network: includes mapping the unit's contact network (internal and external relationships), and who the officials perceive as important in the decision process.
- Conflicts and solutions: includes mapping conflict issues and disagreements, and what solutions the officials consider valuable.
- Interests and concerns: includes mapping whose interests and what concerns the officials are exposed to and which are ultimately emphasised in the decision process.

Studying the pharmaceutical unit's distribution of attention in the process of information to patients as it unfolded first in DG Enterprise, and in DG SANCO after the reform, will indicate whether there have been any changes in who and what the officials attend to. The following expectations were formulated for the present case:

- As the Commission is horizontally organised according to the purpose principle, it is expected that the officials in the pharmaceutical unit is influenced by their DG affiliation. Consequently, as DG Enterprise and DG SANCO are organised according to different purposes, it is expected that the horizontal reform – variation in DG affiliation – lead to variation in who and what the officials attended to.
- As the pharmaceutical unit's structure, professional composition, location and its organisational culture remained constant, these factors were expected to contribute to stability in who and what the officials attended to.

Although this is a single case study, it could be argued that it sheds light on larger class of similar events (George and Bennett 2005). Knowledge about the relative importance of rearranging a policy field horizontally for the decision behaviour within a policy field is relevant for public administration more generally, including the national level. The findings of this study should thus be of interest to most academics studying organisations as well as high-level practitioners in position to carry out organisational reforms.

Case study: changing policy focus in the commission?

The pharmaceutical policy field

Pharmaceuticals are ‘peculiar’ (Permanand 2006: 3): they are industrial manufactured products with wide-ranging influence on public health. Consequently, the pharmaceutical policy area is connected to both the industry sector and the health sector. This dual aspect makes it a highly complex policy field to regulate, characterised by a heterogeneous group of actors that are affected by pharmaceutical policy and have interests that are not easily combined: consumer and patient interests organisations 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; and member states face the parallel challenges of ensuring access to quality medicines, cost containment and (in some cases) providing support for a local (high employment) industry (Permanand 2006: 6). There is no single market in prescription drugs, and this has been explained as a consequence of a ‘clash’ between the supranational free movement rules and national health policy competencies (Permanand and Mossialos 2005). As the member states are in charge of their own health policy, the Commission has from the outset had limited competence within this field. The health aspect has always been present in the pharmaceutical legislation,¹ but the fact that pharmaceutical policy was the responsibility of DG Enterprise and not DG SANCO became over the years an issue of conflict, due to the different purposes of DG Enterprise and DG SANCO. DG Enterprise 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). The DG works to ensure the smooth functioning of the internal market for goods, including pharmaceutical products (Sabathil *et al.*

¹ The first directive on pharmaceuticals, EEC/65/65, (Council, 1965) aimed at harmonising the member states’ authorisation of pharmaceuticals (Permanand 2006: 2), and established the principle of medicine approval to be compulsory and based on efficacy, safety and quality (Hauray and Urfalino 2009: 435).

2008: 145-8).² DG SANCO is in charge of consumers and public health. It works to ensure that the EU's internal market works for the benefit of consumers, and 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'.³

The pharmaceutical unit

The administrative subunit with particular responsibility for pharmaceuticals was developed in the mid-eighties (Hauray and Urfalino 2009: 435). In DG Enterprise, the pharmaceutical unit was organised within Directorate F Industry, within the area of Competitiveness of the Internal Market for Goods and Sectorial Policies (Sabathil *et al.* 2008: 152). It was located in the Breydel building together with the rest of DG Enterprise. In DG SANCO, the pharmaceutical unit is organised within Directorate D Health Systems and Products. The unit's size and amount of tasks have steadily increased over the years, and in October 2011, approximately forty people staffed the unit. Among these were about 25 Administrators, with background in 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 authorisations, monitoring of member state implementation of pharmaceutical legislation, managing of infringement procedures, and supervising the European Medicines Agency (EMA). The reorganisation – the formal transfer of the pharmaceutical unit to DG SANCO – took place in March 2010. The unit was moved as a block, and the unit's main tasks, its structure, size, professional composition and location remained intact. As regards the existence of a unit culture, some informal values and norms seem to characterise the unit. The officials seem to be united by their high workload and the strong focus on effectively performing their tasks. They also seem to be bound together by the awareness of the unit's special position between two sectors due to the peculiarity of pharmaceuticals. One interviewee illustrated this by referring to the unit as an island both in DG Enterprise and DG SANCO.

² 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 April 2012.

³ See DG SANCO 2011,

<http://ec.europa.eu/dgs/health_consumer/about_us/who_we_are_en.htm>, accessed April 2012.

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 this 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). The issue of revising the legislation came on the European agenda in the end of the 1990s. After rejecting a Commission proposal⁴ relaxing the ban on advertising, the EP and the Council asked in 2004 the Commission to present a report on the current practice of information provision in member states within three years (Hancher and Földes 2011: 5-6). If appropriate, the Commission were to put forward a proposal setting out an information strategy to ensure good, quality, objective, reliable and non-promotional information on medicinal products (Council/Parliament, 2004). This request serves as starting point of the process under study. The requested report was presented in December 2007, concluding that rules and practices on information provision differed widely among the member states (Commission, 2007a), especially with regard to information channels, public access to information, content of information, and who could provide and control information (Commission, 2007b). Hence, the pharmaceutical unit developed a legislative proposal on information to patients, a directive (Commission, 2008a) and a regulation (Commission, 2008b), that was presented in December 2008 as part of the pharmaceutical package two. The proposal was rejected by the Council in 2009, as the member states feared increased burdens on health expenditures and national competent authorities as well as circumvention of the ban on advertising (Council, 2009a). The Council was unwilling to move forward with the proposal before the Commission made considerable changes in it (Council, 2009b; Interview). The work with the proposal was put on hold, and was not resumed until the unit had moved to DG SANCO. Due to the difficulties involved, the proposal on information to patients was not a priority until spring 2011 (Interview). In the meantime, in November 2010, the EP adopted 78 amendments to the proposal. A revised proposal was tabled in October 2011 (Commission, 2011a; Commission, 2011b), which is currently being discussed in the Council (Interview). Below, the pharmaceutical unit's attention patterns in the process of developing the legislative framework on information to patients are presented.

⁴ The proposal was part of the first so-called pharmaceutical regulation package, tabled by the Commission in 2001.

Contact network

The reorganisation affected which contacts that were perceived as important and influential by the pharmaceutical unit in the process of developing a legal proposal on information to patients. In that sense, both their internal and external relationships were affected by the reform. Concerning internal relationships in the Commission, horizontal and vertical contact and co-ordination within the unit and their own DG was perceived as most important in the process. This was central to the officials independent of DG affiliation, but the reorganisation thus implied that many of the unit's closest contacts changed. When the unit was in DG Enterprise, it interacted and co-ordinated most frequently with contacts in DG Enterprise, while after the reform, the unit interacted mostly with contacts in DG SANCO. To some extent, the unit also interacted with other DGs during the process, informally and through the inter-service consultation procedure.

When it comes to external contacts, the reorganisation affected the diversity of the network and the frequency of contact with particular external interested parties. Throughout the process of developing a proposal on information to patients, the unit was in contact with a range of actors such as the other Community institutions and affected parties. As regards the community institutions, the unit interacted with the EP and the Council, independent of DG affiliation. As regards affected parties, the officials valued a broad, cross-sectorial network of external contacts. Depending on capacity, the unit organised or participated in meetings, consultations, and different forums, and this seems to have been unaffected by the reorganisation; 'it is an on-going dialogue' (Interview). However, there was also a perception that actors sharing their sectorial affiliation are particularly affected parties and therefore to some extent should be favoured. When the unit was in DG Enterprise, contact with the pharmaceutical industry was prioritised.

We were contacted by both consumer protection groups and associations and got feedback from them as well as from the industry. So basically, industry was quite favourable, and consumer protection groups and association groups were less favourable, to put it like that. Since normally, Enterprise worked or were in touch more with companies, it is their primary stakeholder, I would say so. But it does not exclude that we of course got responses and feedback from other groups.

(Interview)

After the reorganisation the diversity of the external network and the scope of contact with the pharmaceutical industry decreased. The unit's network of contacts was now primarily within the health sector. '[T]here is definitely less contact with the industry. They might not be happy about it, that is another thing' (Interview). The network was still broad in the sense that DG SANCO has a broader network of contacts in the health sector than DG Enterprise had, but consumers and patients were regarded as most important among interested parties and thus the contacts that should be favoured (Interview).

Maybe the NGOs and [consumer] organisations and so forth were more used to working with SANCO [...] because SANCO was their main interlocutor. Maybe they are more active now. I also think that there is less contact with the industry now. That is also something I think is a bit in the SANCO culture. Protection of public health is the primary goal, and there is more reluctance to have too many contacts with the industry.

(Interview)

Conflicts and solutions

The officials' view on conflicts and solutions changed after the reorganisation, and the level of conflict within the Commission and with external parties seems to have decreased. Throughout the process of developing a legal framework on information to patients, conflict mainly revolved around the role of the industry as a neutral source of information. In addition, conflict centred on the distinction between advertisement and information, what channels should be allowed for information provision and what monitoring and control arrangements that should be introduced. Also, the need of revising the framework at all was questioned early in the process.

When the unit was in DG Enterprise, there was some conflict inside the Commission regarding the role of the industry. First of all, DG SANCO opposed to the 2008 proposal in the inter-service consultation, which was referred to as being quite difficult, and in the end was resolved politically at

leadership level. Secondly, there was disagreement inside DG Enterprise. Although the proposal in legal terms would not remove the ban on advertisement for pharmaceuticals, there was some ambivalence in the pharmaceutical unit towards whether the industry could be a neutral source of information. And 'apparently, there was not a strong will in the unit to push this proposal through, and definitely not in that direction' (Interview).

Well, basically it was the advertising issue and the general question of 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.

(Interview)

As regards external interested parties, they roughly made up a 'health coalition' opposing the proposal and an 'industry coalition' in favour of the proposal. The first group included healthcare professionals and organisations, patient and consumer groups, and social insurance organisations, the latter consisted of affiliations with pro-industry beliefs, including pharmaceutical industry associations and companies (Carboni 2009: 27-8). The health coalition (and DG SANCO) questioned from the outset the need to revise the proposal, and argued mainly that information provision is a task for regulators and health professionals, and that the industry's role should be limited due to their commercial interests involved. Furthermore, the health coalition criticised the decision process in general, and the 2008 proposal in particular for establishing the industry as main source of information; for not establishing a clear distinction between advertising and information; for extending the types of information that could be disseminated and the channels to be used; and for not establishing satisfactory monitoring arrangements (Hancher and Földes 2011: 7-10). The industry coalition argued that the pharmaceutical industry has the essential knowledge and should have a role in providing information about their prescription products.

When the unit was in DG Enterprise it mainly aligned with the industry coalition on the conflict issues. The 2007 report focussed on the public health gains of revising the legal framework, but also 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 role of the 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.

(Interview)

After the reorganisation, however, the unit's perceptions on conflict issues and solutions changed, and the level of internal and external conflict decreased. The question of revising the legislative framework was no longer a conflict theme, as most actors involved agreed that there was a need to revise the existing legislative framework. Within DG SANCO and the unit, there seems to have been little disagreement in the process of revising the proposal. The professional backgrounds of the unit's staff are perhaps more compatible with DG SANCO than with DG Enterprise.

I think it is nicer, it is more logical that we are part of DG SANCO than DG Enterprise [...] In DG SANCO you have more people with scientific background [...]. So there is greater interest in the scientific part that we are doing, which we did not have so much in DG Enterprise'.

(Interview)

It is underlined that the unit is still adapting to DG SANCO, in particular with regard to the legal framework, but when revising the proposal, the unit focussed on restricting the role of the industry and strengthening the public health perspective. The revised proposal is thus more in line with the demands promoted by DG SANCO and the health coalition earlier in the process.

It is more defined now what information could be given to the patient. It is not only that the industry has the right to give information, the industry will have the obligation to provide certain information [...] And then there are many restrictions with regard to how to make the information available, which channels: printed information would not be allowed. To make it a little bit simpler, 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. One important element is the pre-control of the information before it becomes available. This is very clear-cut in the amended proposal.

(Interview)

Interests and concerns

Throughout the process of information to patients there were numerous interests and concerns to be considered. In general, the officials highlight the importance of balancing all interests and concerns involved, independent of DG affiliation. At the same time, however, they need to give something precedence in the decision process, implying that some interests and concerns are ranked above others. In both DGs, the interests and concerns of their own DG, the DG's target sector and actors belonging to the DG's target groups were prioritised in the decision process. Thus, the reorganisation affected whose interests and which concerns that were emphasised.

Some overall concerns were central throughout the process, such as harmonising information provision in the EU and solving the main challenges regarding information provision. The existing regulatory framework was perceived as inadequate, defining advertising only vaguely and not regulating provision of non-promotional information, thus leaving the borderline between advertising and information unclear (Commission 2008a: 5-6; Interview). Another main concern was to balance the different concerns involved, including both public health and industry concerns. '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' (Interview).

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.

(Interview)

Emphasising the interests and arguments of its own DG and DG leadership was central to the unit throughout the process. In DG Enterprise, there was a pronounced political wish in DG Enterprise to allow and enable the industry to give information about prescription medicines: [T]here was no doubt that Commissioner Verheugen [...] politically wanted such a proposal to open up for allowing and enabling the industry to a greater extent to give information about prescription medicines' (Interview). As regards external affected parties, the general perception among the officials was that it was important to listen to all affected parties, but that the interests and arguments of actors sharing their sectorial affiliation should be favoured in decision processes. In DG Enterprise,

[w]ell, 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".

(Interview)

The main industry sector concerns that were emphasised were including the pharmaceutical industry as an information source in the system for information provision; to ensure equal obligations and opportunities for marketing authorisation holders; to provide a clear and simple legal framework for the pharmaceutical industry and avoid that divergence in rules and practices have a negative impact on the legal certainty for marketing authorisation holders with cross-border activity; and to sustain the competitiveness of European pharmaceutical industry (European Commission 2008b: 2; Interview).

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'.

(Interview)

After the reorganisation, the interests and concerns of DG SANCO, the public health sector and its target groups became imperative. The Commissioner of DG SANCO, John Dalli, early signalled a new approach and an explicit wish to bring patient considerations into the process of reassessing the legal proposals:

‘We believe that patients should have access to information on prescription drugs that are on the market. The inclusion of pharma in the health portfolio gives us the opportunity to reassess the proposal on the table and to inject a stronger patient perspective’.⁵

After the unit moved to DG SANCO, it focussed in particular on reducing the role of the industry. ‘In DG SANCO, the focus is on public health’ (Interview). The main public health concerns that were emphasised was to strengthen the rights of the patient and ensure equal access to neutral, quality information (especially on the internet); to strengthen the rational use of medicines; and to preserve the initial ban on advertising of prescription medicines. This was to some extent complicated, as the legal framework is supposed to regulate the behaviour of the pharmaceutical industry, but at the same time, ‘[i]t is obvious that the amended proposals are more oriented towards the patients’ (Interview).

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

(Interview)

Concluding discussion

The findings of the present case study suggest that rearranging an organisational structure may impact on policy processes and ultimately, reshape policy outcomes. A multiple set of actors, solutions, concerns and interests competed for attention in the process of developing a legislative framework on information to patients, illustrating the complex role of the pharmaceutical unit. The findings show that structural reorganisations may have limited impact on certain attention patterns. The unit’s own DG was the officials’ key contact, and political guidelines were essential, independent of DG affiliation. Some concerns were considered crucial independently of DG

⁵ 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 8 May 2012.

affiliation, for instance the overall concern of harmonising the pharmaceutical legislation and balancing the relative attention paid to the different contacts, interests, and concerns involved. At the same time, the officials tend to favour 1) contact with their own DG and actors sharing their sectorial affiliation; 2) solutions preferred by the sector they are affiliated with; 3) the interests and arguments of actors sharing their sectorial affiliation; and 4) the concerns of the sector they are affiliated with. It is suggested that these stable attention patterns may be explained by the organisational and institutional factors that remained constant: the unit structure, its locus, professional composition, and institutionalised norms and values. The unit was established in the eighties and a particular 'unit culture' seems to have developed, connected to the unit's high workload and its special position due to the peculiarity of pharmaceuticals. In addition, the fact that the unit was moved to DG SANCO as block, with its multidisciplinary staff and its physical location in DG Enterprises' building intact, may explain that some attention patterns were unaffected by the change in DG affiliation, especially the officials' focus on balancing the different concerns and interests involved in the process. In most ways, the officials carry out their day-to-day tasks in the same manner as always, and the pharmaceutical field is still a complicated area where a multiple set of actors, interests, and concerns are competing for the attention of the officials. In this sense, the change in DG affiliation may be seen as a rather limited reform, confined to the external organisational environment of the unit.

However, the case study also illustrates the relative significance of organisational structure (DG affiliation) in tipping the scales in a particular direction when it comes to weighing priorities in a decision process. As mentioned, the officials tend to favour actors, solutions, interests and concerns pertaining to their own DG and sector. Who and what the unit prioritised during the process of developing a legal framework on information to patients thus depended on their DG affiliation. First of all, the case demonstrates that reforms affect which contacts that are attended to. The unit's closest contacts changed from DG Enterprise to DG SANCO when the DG affiliation changed. As regards external network, the unit had less contact with the pharmaceutical industry, and the network was primarily health sector based after the reorganisation. Secondly, the case illustrates that reorganisations may affect how decision makers perceive conflict issues and solutions. After the reform the unit switched from co-ordinating mainly with the industry coalition to aligning with the health coalition on the main conflict issues. The unit went from suggesting solutions based on the assertion that the pharmaceutical industry could have a valuable role in information provision to solving the main challenges by reducing the role of the industry. Therefore, the revised proposal to a greater extent reflected the demands of the health coalition. Finally, the case shows that reorganisations may affect which interests and

concerns that are emphasised during a decision process. Although health concerns were weighty to the unit when it was in DG Enterprise, they ranked industry sector concerns and interests highest; and although pharmaceutical industry concerns and interests were important to the unit after the reorganisation, public health was the main priority.

In light of these findings, it seems fairly reasonable to argue that structure to some extent affects the certain kind of prioritising that officials are obliged to do in their daily work. These findings are also in line with the previous findings mentioned above. Not surprisingly however, the study demonstrates the limitations of organisational structure as explanatory variable for decision behaviour. The importance of culture is more diffuse and difficult to 'measure', but it seems fair to argue that informal values and norms have some explanatory value as regards the unit's work on information to patients. Culture was treated as a constant in this study, as the interviewees did not report of any changes in unit culture in connection to the reorganisation. However, there is always possibility that a de- or re-institutionalisation, making the unit culture more compatible to DG SANCO, had taken place in advance of the reorganisation. For instance, it seems to have been easier for the unit to work with the information to patients issue in DG SANCO than in DG Enterprise. The educational composition of the unit might also have been important in this regard, as many of the officials have background in health related professions. The degree of conflict decreased after the reorganisation, and the professional argumentation of the officials seemed to resonate more in DG SANCO than in DG Enterprise. Other organisational factors could be relevant explanatory factors in a broader study, such as an overall Commission culture and the inter-institutional setting and co-operation with the Council and the EP. Also, as DGs have been shown to have different cultures (Cini 1997), this may have significance for the unit over time.

The process of agreeing upon a legislative framework for information to patients is still on-going, and the reception among stakeholders of the 2011 proposal was ambiguous. The process embodies one of the main challenges associated with pharmaceutical policy in particular, and EU health policy in general, i.e., the challenge of striking a balance between health and market concerns (Mossialos *et al.* 2010; Hancher 2010). This study challenges the regulatory capture hypothesis and shows that it is possible to change the focus of a particular policy field. In the larger perspective, the findings support the hypothesis that the Commission as an executive is becoming more *normalised*, in the sense that it increasingly resembles an executive body as we are used to see it at the national level as regards organisational and behavioural patterns. This is one development that indicates that a transformation of the European executive system is taking place (Egeberg 2006a; Trondal 2010). For instance, political steering of the services seems to be common, relations between the

services seem to be characterised somewhat by rivalry and the different DGs seem to have 'their' respective stakeholders in the external environment. In addition, pharmaceutical policy is now organised within the DG responsible for health and consumers, a way of organising that is common at the national level.

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Annexe

Interviews

Former official, DG SANCO, 25.10.2011

Former official, DG Enterprise (Pharmaceutical unit) 23.11.2011

National official, 6.12.2011

Official, DG SANCO (Pharmaceutical Unit), 8.12.2011

Official, DG SANCO, 8.12.2011

Official, DG SANCO, (Pharmaceutical unit), 8.12.2011

Official, DG SANCO (Pharmaceutical Unit), 19.4.2012

Former official, DG Enterprise (Pharmaceutical Unit), 10.5.2012

Former official, DG Enterprise (Pharmaceutical Unit), 28.5.2012

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