

n° 1 / November 2009

# research Observatoire social européen paper

**Advocacy Groups in  
the Multilevel System  
of the European  
Union: a Case Study in  
Health Policy-Making**



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## **Advocacy Groups in the Multilevel System of the European Union: a Case Study in Health Policy-Making**

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## Abstract

Health policy is basically Member States' competence. However, the European Union has recently raised a number of key questions facing both (pharmaceutical) industries and public health interests. A crucial element of health policy making in the EU is the balance between public health and health-care on the one hand, and industrial policy on the other. By a public policy approach the paper analyses the problems, the actors and resources involved, the patterns of interaction in EU health policy, trying to figure out the ground for a European or a National battle. The main research questions are: how does decision and policy making on health issue take place? Who are the key actors in the process? What is the role of interest groups in health care-related policies? How do national governments and EU institutions interact in the health policy making process and governance? The analysis is based on a case-study strategy. Two different processes, both part of the pharmaceutical policy, are analysed. The "Pharma Forum" and the "Pharma Package". The Pharma Forum for the first time in Europe gathered all healthcare stakeholders, Commission, Members States and representatives of the Parliament to discuss key issues about health care. The Pharma Package is the popular name for a series of measures recently proposed by the European Commission impacting the pharmaceutical industry. In the end, this case study illustrates both the strategic role of the Commission and the relevance of advocacy groups in the EU policy making process.

Keywords: lobbying, pharmaceutical policy, health policy-making, advocacy coalition framework, European Union

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## 1. INTRODUCTION

The main goal of this study is to give evidence of the EU policy-making process dynamics<sup>1</sup> by empirical accounts of lobbying in health care related issues.

“The study of interest representation in the EU can help explain how European public policies emerge, how they are framed and processed, why they take the character they do, and how they might contribute to our understanding of the course of European integration” (Greenwood, 2003).

Policies are the result of an interactive process between many actors having their own interests and strategies. This study concentrates on the actors, resources, pattern of interaction involved in health policy making at the EU level by focusing on the way advocacy groups lobbying EU institutions. Two case studies, the “Pharma Forum” and the “Pharma Package” will provide insights into the political game of health policy making, in order to determine what resources and venues of influence actors use to come to policy change on issues where actors’ preferences conflict.

By applying the Advocacy Coalition Framework (ACF) as a theoretical basis for understanding both EU policy-making process and intergovernmental relations<sup>2</sup> within health policy field, this paper analyzes the policy subsystem-wide dynamics with multiple actors who structure their relationship into advocacy coalitions moved by policy beliefs, and try to influence policy by multiple resources and venues. The ACF is often used to explain stakeholders behaviour and policy outcomes in conflicting political contexts, with two or more coalitions pursuing different policy objectives (Sabatier and Weible, 2005). This is the case of EU health policy making, where divergent interests stand in opposition, public health and health-care on the one hand, and industrial policy on the other.

The paper is structured as follows: first we outline the conceptual framework (ACF) and methodology for the analysis; second we define the boundary of the policy field (EU health policy and pharmaceuticals); third we focus on the role of advocacy groups at the EU level; third, we analysed the two case studies (the Pharma Forum and the Pharma Package); fourth, we apply the ACF by sketching out the main actors and their respective roles, the resources involved, the venues of influences, the patterns of interaction in EU health-care policy making process; finally, we draw some conclusions about the findings of the case study.

## 2. THEORETICAL FRAMEWORK

The ACF (Sabatier and Jenkins-Smith 1993, 1999; Sabatier 1998) views the policy process as a competition between coalitions of actors who advocate beliefs about policy problems and solutions. This competition takes place within *policy subsystems*, defined as the set of actors who are actively concerned with an issue and regularly seek to influence public policy related to it. Actors in a policy subsystems include local and state government officials, advocacy groups, non-governmental organizations, community groups, researchers and academics, media, etc.

Following works in cognitive and social psychology, the ACF argues that actors perceive the world and process information according to a variety of cognitive biases which provide

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1. The focus of the analysis is on EU level policy-making, activities at the Member States level are not included.

2. Studies involving both the horizontal and vertical relations between sub-national, national and/or supranational governments may all be categorized under the field of IGR. Some of these studies might well be conceptualized as (and this is the case) European Multi-Level Governance.

heuristic guidance in complex situations. In the case of public policies, such guidance is provided by *belief systems* about how a given public problem is structured, and how it should be dealt with. The belief system is what makes coalitions hold together and builds the basis for their coordination and internal organization. Sabatier and Jenkins-Smith (1993) distinguish three levels of beliefs in the belief system of a coalition:

- *deep core*: normative and ontological axioms that define a vision of the individual, society and the world;
- *policy core*: causal perceptions and policy positions for achieving deep core beliefs in a given policy subsystem,
- *secondary aspects*: empirical beliefs on how to implement the policy core.

Coalitions, the ACF argues, form around beliefs, and particularly around policy core beliefs. In order to realize the goals generated by their beliefs, advocacy coalitions try to make governmental institutions behave in accordance with their policy cores. In this, they are assumed to be instrumentally rational, for instance using venues provided by the constitutional structure through which they can exert influence in an efficient way. Based on these premises, the ACF perceives *policy change* as a transformation of a hegemonic belief system within a policy subsystem<sup>3</sup>, whereas *policy learning* as a process which is most likely to concern only secondary aspects of a belief system, leaving the policy core of a coalition intact, and bringing to minor policy changes (Sabatier, 1988). Minor policy changes<sup>4</sup> are the result of two processes: learning within and learning across coalitions. The second case is where *policy brokers* may intervene. Learning across two coalitions happens when their respective belief systems and opinions about policy domain defer. When the two coalitions are in conflict and it is difficult to have a dialogue between them, policy brokers mediate the conflicting belief systems looking for some reasonable compromise which will reduce conflict intensity. For that, policy brokers have to be able to relativized the believes and preferences of the competing coalitions to facilitate policy solution. In addition, they must be linked to decision makers or have access to decision-making points.

Within the ACF, we refer to the components of the approach more useful for our analysis:

- a) the identification of advocacy coalitions, policy core beliefs, resources and available political venues;
- b) the role of information and knowledge;
- c) the role of policy broker;
- d) the factors of success necessary to produce policy change.

Furthermore, we aim to look for more insights about the role of policy broker and the definition of policy change at the EU level. The ACF seems not to explain several important aspects of policy changes, neither does the model provide a useful framework to examine in detail how policy brokers accomplish their tasks (Smith, 2000).

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3. The ACF takes into account also the influence of exogenous variables on the policy subsystem. Two sets of external factors frame and constrain the activities of advocacy groups, the one quite stable, the other more dynamic. Stable parameters include the basic constitutional structure, socio-cultural values, and natural resources of a political system; dynamic influences include external changes or events in global socioeconomic conditions (Sabatier, 1998).

4. The ACF defines minor policy change as a modification of specific beliefs about causal connections and stakes of the world that have bearing in the policy issue area (changes in secondary aspects of the policy subsystem); in contrast, the ACF defines major policy change as an alteration of the policy core beliefs. Policy learning rarely results in major policy change, as it is secondary aspects which tend to be modified by endogenous learning whereas it is wholesale shifts in dominant policy core belief which are associated with major policy change (Smith, 2000).

### *Methodology*

The ACF approach is tested by using a qualitative research strategy - namely a case study design. Two case studies, the "Pharma Forum" and the "Pharma Package" have been selected since they both involve diverging interests (public health and social protection vs. industrial interests). A certain level of conflict is necessary in order to study the interplay between multiple actors in the policy-making process. Moreover, they both concern *information to patient*, a controversial policy issue at the crossroad of competing pressures.

The fieldwork has relied mostly on documents analysis, semi-structured interviews, and personal observation. The main sources were governmental documents (Commission communications, speeches, minutes of the plenary meetings of the European Parliament and minutes of Council working groups meeting, positions papers by interest groups, national governments publications and press releases, etc.). The information collected by documents was combined with semi-structured interviews, which were carried out during April-June 2009. The sample of interviewees was made of the key actors we identified by both relevant documents and the snowball technique. Starting with suggestions from preliminary interviews, a snowball-sampling technique<sup>5</sup> generated a list of stakeholders (n=30). This method suits the case of health policy, since it allows to catch one specific network of interconnected people. By snowball method we managed to cover all the different types of actors involved in the process: consumers and patients groups, umbrella organizations of providers and payers, individual companies, pharmaceutical industries and civil society groups, policy officers from the European Commission, members of the European Parliament, Health attachés from the Permanent Representations in Brussels (tab. 1).

Finally, visiting the Observatoire Social Européen (OSE) in Brussels for three months has allowed us to take part to events and conferences about the research topic.

### **3. THE EU HEALTH POLICY: COMMUNITY VS. MEMBER STATES COMPETENCIES AND POWERS WITHIN THE PHARMACEUTICAL SECTOR.**

Health policy is generally not considered as a policy area of the Community, because there is no legal Union competence for that (Lamping, 2005: 19). This is basically due to the successful resistance of national governments to transfer substantial health policy competencies to the supranational level.

In detail, the European Union did not have policy mandate in the field of public health until 1999, when the public health article was amended and renumbered by the Treaty of Amsterdam as the current Article 152 (Mossialos et al., 2009). Treaty Article 152 defines the role of the EU as complementing national policies, sets out procedures by which the EU institutions may act in the health field, and delineates the types of measures that may be enacted, but explicitly bars the use of harmonization: "Community action in the field of public health shall fully respect the responsibilities of the Member States for the organization and delivery of health services and medical care" (Art. 152, no 5). Thus, the EU is limited to establishing public health programmes and incentives in the health policy field.

It was not until 2002 that the European Council of Ministers agreed that health care systems share common principles of solidarity, equity, and universality, but chose not to take any further concrete actions. After the health sector's exclusion from the *EU Services*

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5. Snowball sampling may simply be defined as "a technique for finding research subjects. One subject gives the researcher the name of another subject, who in turn provides the name of a third, and so on" (Vogt, 1999).

*Directive*<sup>6</sup>, which aims to break down barriers to cross-border trade in services between EU Member States, health and long-term care were formally added to the Open Method of Coordination (OMC)<sup>7</sup> procedures conducted by the Social Protection Committee (SPC) in 2005.

Despite lack of direct legislative authority, the EU health policy has been considerably developed over recent years. Within the public health field the EU has tackled the issues of the quality and safety of blood, blood products and human tissues, and recently organ transplantation. The Community has also engaged in several strategies to detect and control communicable diseases and to reduce the negative health impacts of hazardous products such as tobacco, alcohol, and illicit drugs. Another important area of EU public health policy is the establishment of regulatory agencies to provide expert opinions and advice, collect and disseminate information, and generally support European institutions, such as the European Monitoring Centre for Drugs and Drug Addiction, the European Agency for Safety and Health at Work, the European Medicines Agency (EMA) and the European Food Safety Agency. Furthermore, an area of policy that has seen the most recent major developments is the free movement of patients (*Cross-boarder Health Care Directive*). The ECJ has developed most of the Community law in the area of patients' mobility. In 1998, the famous *Kohll and Decker cases* gave the Court its first opportunity to apply the free movement of persons provisions to the health sector. The Court found that Community nationals had the right to obtain medical treatment in any Member State without prior authorization and also to be reimbursed consistent with the tariffs of the state in which they are insured.

One of the most controversial aspects related to health governance in Europe is properly the clash between the supranational free movement rules and national healthcare policy competencies. This is especially relevant to pharmaceutical sector. Although pharmaceuticals represent a policy domain where outcomes are mainly related to market and industrial policy goals, they must also achieve healthcare interests - such as keeping healthcare costs down and ensuring the safety, efficacy and quality of medicines -, and the Commission has only competence over the former (Mossialos and Permanand, 2005b). While the Commission can, for instance, promote the crossborder movement of medicines by pushing harmonization, according to the *Single European Market*; the Member States have the power to decide their own healthcare policy priorities, under the principle of *subsidiarity*. It means that the Commission must balance industrial and public health concerns, and reconcile wider social and political interests within the context of market harmonization. As a consequence, EU pharmaceutical policy has reached something of a deadlock "*stemming primarily from a dissonance between the principle of subsidiarity and the free movement goals of the Single Market - under which medicines are treated as an industrial good*" (Mossialos and Permanand, 2005b: 49). Nevertheless, the Commission has been able - for instance, by employing soft law mechanisms such as the OMC - to establish a wide-ranging Community regulatory framework<sup>8</sup>, even if a single medicines market remains a faraway goal.

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6. A wide variety of health related lobbying groups opposed the application of the Services Directive by claiming that health care services are 'unique' and should not be treated as any other commercial service; and that Member States would have difficulty managing their health systems with the additional EU oversight.

7. The EU's relatively new "open method of coordination" is characterized by an intergovernmental form of policy-making. Under this open method, Member States co-operate with each other on legislating reforms by establishing common timetables, indicators and policies, with greater emphasis on consensus and mutual learning among Member States. Under the traditional, so-called "community method" of EU governance, more power was held by bodies such as the European Commission and the European Court of Justice than by the Member States.

8. For a chronological overview of the development of EU pharmaceutical policy see: Mossialos and Permanand, 2005b, pp. 50-53.

In conclusion, although any harmonisation of the laws and regulations on health policy in the Member States is excluded, the impact of the EU upon health matters is increasing (Leibfried and Pierson, 2000):

*“Health policy is a challenging example of how to make a formal non topic one of the Union’s major future policy fields - despite the treaty” (Lamping: 2005, 21)*

However only limited attention has been focused on the process of health policy making at the EU level, missing the dynamics and the interactions among different governmental and private actors (Mossialos and Permand, 2005a).

#### 4. THE ROLE OF ADVOCACY GROUPS AT THE EU LEVEL

Interest groups are cast as potential agents to support the *output* legitimacy of EU public policy, concerned with the supply of information, ideas and expert resources for the technical quality of such policies, and the legitimacy which derives from *inputs*, concerned with the support for public policy deriving from the ability to participate in it and confidence in the means used to formulate and implement it (Greenwood, 2007).

Much of the distinctiveness about the roles and character of EU interest intermediation has its origins in the nature of the EU’s multi-level governance transnational system. Ernest Haas first outlined how European integration arose from the relationship between organized interests and the EU central institutions as a result of their mutual interests in the transfer of competencies to the European level. In this account, private and public interests, nurtured by the Commission, act as forces upon Member States to seek EU-level solutions for particular desired outcomes (Haas, 1958). The multiple levels of EU policy-making, the diffusion of power between and within its constituent parts, and its sheer scale and complexity, also results in an orientation towards *consensus politics*. The EU is not a majoritarian system of government in which a ‘winner takes all’, but a delicate balance of power between and within multiple levels, institutions and actors, carefully crafted to ensure that none of its principal stakeholders are left with only losses and no gains.

Table 1 - Sample of interviewed organizations (N. interviews = 30)

Consumers/ Patients Organizations	Health Professional and Provider Organizations	Pharmaceutical Industry Associations	Health and Social Protection Organizations	Institutions
The European Consumers' Organisation (BEUC)  The European Patients' Forum (EPF)	The European Federation of Nurses Associations (EFN)  The Standing Committee of European Doctors (CPME)  The Pharmaceutical Group of the European Union (PGEU)  The European Hospital and Healthcare Federation (HOPE)	The European Generic Medicines Association (EGA)  The European Federation of Pharmaceutical Industries and Associations (EFPIA)  The European medical technology industry association (EUROMED)  The European Self - Medication Industry (AESGP)  The European Association of pharmaceutical full-line wholesalers (GIRP)  The representation offices in Brussels of "Merck Sharp & Dohme" and of "Novartis" companies	<a href="#">European Public Health Alliance</a> (EPHA)  Association Internationale de la mutualité (AIM)  European Social Insurance Platform (ESIP)  European Regional and Local Health Authorities (EUREGHA)	EP: - Committee on Industry, Research and Energy; - Committee on the Environment, Public Health and Food Safety  Commission: - The Directorate General for Health & Consumers (DG Sanco); - The Directorate General for Enterprise (DG-Enterprise); - The Internal Market and Services Directorate General; (DG MARKET)  Council: Permanent representations of Italy and of Czech Republic to Europe  Czech Republic EU Presidency

An environment where outcomes are so open provides opportunities for a wide variety of organized interests to operate in and to become institutionalized mechanisms for locating and creating consensus.

EU political institutions have played an active role in using interest groups in pursuit of essentially pluralistic system goals, open and accessible to all, with widely distributed benefits. Most public policy outcomes have to reflect the interests of a wide variety of stakeholders in such a broadly constituted political system in order to retain continued legitimacy. Using interest groups as part of a system to achieve this requires structural support for them, such as funding, and elaborate procedures designed to ensure equality of political access. If business interests have a naturally privileged position in policy-making as generators of resources which governments need in order to survive, then political institutions need to be active in creating a level playing field for other types of interests (Lindblom, 1977). For this reason, and in a wider search for democratic legitimacy, the European political institutions have been active in designing procedures and systems to support the engagement by other types of interests. In a political system which lacks a 'public space' of participation, there is a heightened reliance upon interest groups to play the systemic accountability roles which is performed in other comparative political settings by an active and interested media, and by political parties in adversarial systems.

There is a wide variety of interest groups at the EU level. They differ in size, power, strategies and relationships with formal policy-makers (Greenwood, 2003)

### *Organizational Structure*

Advocacy groups have a standard structure. The Secretariat in Brussels has a two fold function: 1) providing members with information about EU agenda; 2) representing and promoting members' interests at the EU level. Beside the permanent structure of the Secretariat, there are the representative and decision making bodies. The General Assembly is the supreme organ of the organization which decides on all important matters including policy decisions and the annual budget. Policy proposals are then developed by [Working Groups](#) in collaboration with the Secretariat. The working groups provide additional technical expertise to the Secretariat in developing policy proposals, which are then presented by the Executive Committee to the General Assembly for approval. The Presidency is exercised by the national delegations on a rotational basis. The President is chosen by the representatives of his/her country.

As far as the membership, it depends on the features of the interest organization. In the case of umbrella associations, advocacy groups have a multilayered membership: national associations, individual companies, associations at the European level, etc.

The organizational structure is functional to the working methods of the interest groups. Advocacy organizations at the EU level are clearly oriented towards their national member associations' needs and interests. Therefore, all the decision making processes are consensus-based:

*"The working principle is consensus. However, member organizations are very independent at the national level"* (Lobbyist, Health professional organization).

*"The articulation of interests is a bottom up more than a top down process. We get input from national members and then we try to find common positions on which elaborate lobbying strategies"* (Lobbyist, Consumer organization).

### *Functions*

The main function of advocacy groups is to lobby EU institutions. The Commission defines lobbying as "activities carried out with the objective of influencing the policy formulation and decision-making processes of the European institutions". Rule 9(4) in the Rules of Procedure of the European Parliament says lobbyists are "persons who wish to enter Parliament's premises frequently with a view to supplying information to Members within the framework of their parliamentary mandate in their own interests or those of third parties".

There are two different types of lobbying: *reactive* and *pro-active*. The first one consists of replying to EU institutions initiatives by defending the represented interests, while the second one is of promoting interests and pushing new issues and ideas on the EU policy agenda.

Advocacy groups use a set of tools in doing their lobbying activities. Networking is the first step to get contacts with the key actors in the field.

*"Building relationships is very important. It allows you both to be updated about what is going on and to be visible to people"* (Lobbyist, Health professional organization).

Joining public debates, round tables, forum, key events, meetings and conferences, workshops, etc, is another way to promote and defend interests. Being part of the "Brussels environment" is a key factor for successful lobby:

*"You need to know what is going to happen, before it becomes official. The earlier you are in the process, the more chances you have to be successful"* (Lobbyist, Pharmaceutical industry)

In that, it is strategic to build alliances with other stakeholders:

*“Where you cannot be, your ally may be and defend your interest”* (Lobbyst, Health professional organization)

*Last, but not least*, providing institutions with the information they need is helpful in building stable and reliable relationships with decision makers, as one of the interviewed lobbyist from a pharmaceutical industry association said to us.

### *Resources*

One of the major difference between national interest groups, and those at the EU level, lies in the resources at their disposal. EU-level groups operate on a much more restricted resource base than national groups, largely as a result of their restricted functions and specialization on political representation:

*“The more interested interest groups are to money, the closer they go to Member States. The more interested they are to scientific issues, the closer they go to the EU level.”* (Policy Officer, DG Enterprise).

For instance, EU business associations do not undertake the range of functions that national business associations undertake, such as the provision of business services and advice, industry training, discounted financial services, and so on, because their members, which are national associations and large firms, do not require these functions (Greenwood, 2007). Rather, they are looking to their EU associations to provide for their political representation in EU public affairs. This means that they are dependent upon membership subscriptions for resources, rather than having their own independent resource streams derived from the supply of business services.

Financial disclosure is one of the most controversial aspects of advocacy groups, especially of groups representing public interests. The way interest groups find grants is not transparent all the time. In the majority of Member States there are no detailed rules on lobbying at the parliamentary or governmental level. On the other hand, in the US a lobbyist needs to read a 577 page manual to get everything right. The EU is somewhere in between. The European Parliament, for example, has a voluntary register of lobbyists, mainly for security purposes. The Commission’s register<sup>9</sup> has rules on disclosing financial data. Professional consultancies and law firms, for example, are required to declare the turnover linked to lobbying EU institutions, plus the relative weight of major clients. “In-house” lobbyists and trade associations have to estimate the costs associated direct lobbying of EU institutions. NGOs and think-tanks need to disclose their overall budgets and a breakdown of their main sources of funding.

*“The Commission believes that this sort of financial disclosure will indicate the level of influence that a lobby group can be expected to have. This might be true, but we should avoid the misconception that money equals influence. NGOs with limited resources can be as effective as rich multinational companies”* (Lobbyst, Pharmaceutical company)

Beside *financial resources*, Weible (2006) identifies others five main resources at disposal of advocacy groups:

1. *Access to decision makers*: when an advocacy coalition has close contacts to decision makers or has members in position of formal authority is favoured in getting policy objectives;

<sup>9</sup> In 2005 Commissioner Kallas launched “The European Transparency Initiative” (or ETI) to further strengthen public trust in the EU Institutions through increased openness and accessibility:

[http://ec.europa.eu/Commission\\_barroso/kallas/work/eu\\_transparency/index\\_en.htm](http://ec.europa.eu/Commission_barroso/kallas/work/eu_transparency/index_en.htm)

2. *Public Opinion*: stakeholders use public support to increase the legitimacy for their lobbying actions.
3. *Information*: the use of policy analyses, reports, and scientific and technical information is an advantage in lobbying institutions.
4. *Mobilizing troops*: public demonstrations, campaigns and other supporting activities help advocacy groups in influencing government decisions.
5. *Skillful leadership*: coalition leaders can help in both driving coalitions' action and attracting additional resources to their coalition.

Advocacy groups strategically use their resources to influence policy in multiple venues. Venues are institutional arenas within which stakeholders have the chance to influence policy-making process (Weibe, 2006: 101). Advocacy groups spend a lot of time in venue shopping, looking for institutional access where they can have strategic advantage for their interests.

At the EU level, venues of influence are mainly represented by the key institutions involved in the policy-making process, that are the Commission, the Parliament and the Council of Ministers.

To exert successful influence, advocacy groups need to adopt different strategies in approaching institutions:

*"To be successful you need to understand the languages key actors speak. This is because EU institutions have different styles and languages"* (Lobbyist, Pharmaceutical industry association).

*"Commission is looking for data. EP is driven by political emotional issues. Council cares about relationship building: here, the trick is the relationship between national member associations and the permanent representatives by which we can understand both what is going on in the Council and what Member States think."* (Lobbyist, Health organization)

## Lobbying EU institutions: venues of influence

Taken as a whole, the EU is highly accessible to advocacy groups because its multilevel nature provides for easy access, and because of its needs for political participation. Each of the political institutions in any political system has different relationships with organized interests, depending upon functions and properties.

### *Venues to the European Commission*

Commission plays an important agenda-setting role within EU policy-making process. All deliberations are initiated by a Commission proposal, which is prepared by the competent DG, supported by both external consultants and horizontal coordination with other DGs (Nugent, 2003). Once the proposal is drafted it has to be approved by a simple majority of the College of Commissioners. It means that Commissioners have to build alliances within the College in order to make the proposal approved.

*"You should be inside Commission's head before it thinks...It means to be proactive in order to influence EU agenda"* (Lobbyist, Consumer organization).

Organized interests provide a predictable range of policy benefits to the European Commission in the roles it undertakes. These are: a source of support for drafting legislation; a means of 'testing out' proposals among stakeholders, and the ways they are likely to be received in different national settings ahead of the Council of Ministers; and, in the Commission's role as guardian of the Treaties, information about the

implementation of measures, and their impact. These can be summarized as the function of acquiring information, ideas, intelligence, specialist knowledge and input.

*"The Commission has always been an institution open to outside input. The Commission believes this process to be fundamental to the development of its policies. This dialogue has proved to be valuable to both the Commission and to interested outside parties. Commission officials acknowledge the need for such outside input and welcome it"<sup>10</sup>.*

At the same time, there are incentives for the European Commission to pursue a system of privilege for certain preferred partner organizations. All public administrations need to seek solutions to input overload, and like to find ways to simplify their consultative lives. They prefer to engage with those who keep to the rules of the game, rather than aggressive outsiders who create conflict beyond the confines of bureaucratic capacity to deal with it. (Greenwood, 2007)

*"We are not interested in those groups who behave as 'ayatollah'. We need scientific arguments, not dogmatic ones....NGOs sometimes do 'religious battles'. They do not want to talk to industries as principle"* (Policy officer, DG Sanco)

*"I think that NGOs are not able to make compromises, they are used to shout and make noise, that's it. I strongly believe that radical positions cannot change policy. We do not take into account aggressive attitudes"*(Policy officer, DG Enterprise)

The small size of the Commission relative to its functions can make it dependent upon the expertise that outside interests bring for drafting workable and technically feasible policy proposals. These circumstances carry the potential for the 'privatization' of policy-making, that is that those able to fill the resource deficits of the Commission by supplying information for policymaking purposes would find their perspectives reflected in policy proposals.

*"We closely work with advocacy groups who produce evidence based arguments. After a proposal is draft we usually have public consultation and impact assessment. We get many comments by advocacy groups. The best for us are the ones which produce knowledge...if we learn from that, it means they are good arguments"* (Policy officer, DG Enterprise)

Lobbying the Commission takes place at two levels: the Service and the Cabinet ones.

*"We usually receive emails, phone calls, letters asking for a meeting. Advocacy groups representing industries usually privilege face to face contacts, while NGOs send us position papers."* (Policy officer, DG Internal Market)

*"We represent industries. Different type of industries, not only the pharmaceutical ones. So, at the end there is a balance in representation I think. Our stakeholders are industries, but also patients groups and what I call the Greenpeace of healthcare. We try to listen to all of them, but I admit that sometimes voices from small groups are missed. We deal not only with umbrella associations, but also directly with single companies. You know, the big pharmaceutical industries have their own office in Brussels and they lobby on their own"* (Policy Officer, DG Enterprise).

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10. [http://ec.europa.eu/civil\\_society/interest\\_groups/approche/communication\\_en.htm](http://ec.europa.eu/civil_society/interest_groups/approche/communication_en.htm)

### *Interests groups lobby the Cabinet as well*

The role of the Cabinet is to guarantee that the political ideas of the Commissioners are reflected in the policy proposals. When the proposal is at the College of the Commissioners to be approved, advocacy groups strongly exert pressures to the political level of the Commission. At the same time, the Commissioners' Cabinet exploits interest groups to influence Member States.

Finally, not only interest groups influence Commission's actions, but also Commission influences advocacy groups' behaviour and strategy:

*"We influence lobbies by passing messages. It means we try to make it clear what we want and what we do not want...It sometimes happens that interest groups asked me to join their members meeting as a speaker, in order to explain their members what Commission does"(Policy officer, DG Sanco)*

*"Commission not only waits for inputs but ask for inputs as well; we impact on the policy agenda and interest groups shape their strategy according to our aims and proposals" (Policy Officer, DG Enterprise)*

### *Venues to the European Parliament*

In the field of health policy, passing legislation is covered by the co-decision procedure<sup>11</sup> which provides for joint decision-making and negotiations between the Council and the EP and the possibility for the EP to reject draft legislation (Nugent 2003). The EP is based on committee structure, with one or more committees appointed for drafting amendments to the Commission proposal. The key actors in the Parliament are the draftperson - the rapporteur - and the political groups who are responsible for interest aggregation. Advocacy groups usually lobby both the rapporteur<sup>12</sup>, and the shadow rapporteur<sup>13</sup>. The process is usually as follows: once the Commission's proposal comes to the Parliament, there is a meeting of the presidents of the 20 parliamentary committees for appointing the committee and the related rapporteur responsible for the dossier. The lobbying starts already at this stage, when the political group is appointed. First, lobbyists go to the coordinator of the political group; second, they ask MEPs for an appointment; third, they take part to the public debates, the committee meeting, etc. since the EP is a very open and transparent institution: all the meetings, included the plenary sessions, are accessible to the public.

*"At the EP level, we are used to hold receptions, where we invite MEPs. We try to link our national member associations with the MEPs of their country" (Lobbyist, Patient organization)*

The role of lobbyists in the EP is an important one. They try to influence MEPs by giving them information, and MEPs regard them as a source of information for understanding key points in the policy making process:

*"The advocacy groups do both promoting their interest and providing information. The last one is a very important function by which MEPs are educated on issues". (MEP, Committee on the Environment, Public Health and Food Safety)*

11. A flow chart representing the co-decision procedure is on the EU Commission website ([http://ec.europa.eu/codecision/stepbystep/diagram\\_en.htm](http://ec.europa.eu/codecision/stepbystep/diagram_en.htm))

12. During the monthly Plenary sessions certain MEPs present reports which have been adopted by one of Parliament's committees. These reports contain proposals for resolutions or legislative amendments to be voted on by the entire Parliament. The reports are known by the personal names of the MEPs who draft and present them i.e "the Spinelli report". This role is highly important in Parliament and the MEPs who write the reports are known by the French term "rapporteur". Rapporteurs are elected by fellow MEPs when one of Parliament's committees is assigned to draft up a report on a legislative proposal, another document from the European Commission or a particular subject. The rapporteur's key task is to analyse the project, consult with specialists in the particular field and with those who could be affected, discuss with other members within the committee and recommend the political "line" to be followed. All of these considerations flow into the report they submit to the Committee.

13. Mep who monitors a dossier for political groups other than that of the rapporteur

*"In writing the report we usually contact stakeholders for getting info, opinions, etc. At the same time we receive a lot of opinions, ideas, critics by Member States national governments, patients groups, industries, etc."* (MEP, Committee on Industry, Research and Energy)

Back in the 1970s, most members of the European Parliament were only too pleased when a lobbyist dropped in for a chat. Now that the Parliament has real legislative clout, its corridors are packed with professionals trying to win MEPs over to their way of thinking. For some people, the term "lobby" still has negative connotations. They think it's a shady activity carried out in smoke-filled rooms. This image is unfair and outdated. Today, most lobbyists are experts in their field and represent their clients' interests in a professional manner. They keep MEPs informed on subjects they might otherwise lack adequate knowledge about. Unlike Commissioners, with their army of officials, or government ministers who have national civil servants to brief them, MEPs have to get by with the help of only a couple of assistants. Lobbyists provide vital information and expertise. It is up to Europe's elected decision-makers to listen, learn and then make up their own minds.

*"Our work is to listen to them. They help us to have a global idea about the issue we are appointed for preparing reports. However, you must have the talent to listen to them not to talk. Lobbies come to complete the picture"* (MEP, Committee on the Environment, Public Health and Food Safety)

Lobbying at the EP level is more and more increasing compared to the past. This makes very hard for MEPs, which usually have one or two parliamentary assistants, to manage the complex world of lobbies. Today, Brussels hosts around 15,000 lobbyists from 2,500 organisations, up from around 400 lobby groups in the 1970s (Stubb, 2008). There are law firms, think-tanks, international companies and non-governmental organisations. There are lobbyists for producers and consumers, industrialists and green campaigns.

*"Advocacy groups do now a lot of pressures compared to the past. For instance, as far as the Pharma Package I met more than 20 groups/ companies"* (MEP, Committee on the Environment, Public Health and Food Safety)

The EP has contacts not only with advocacy groups, but also with the Commission, which takes part to the parliamentary committee meetings, and with national experts within the Council. These are usually informal contacts but they allow coordination along the co-decision procedure, a process which may take years to be concluded.

### *Venues to the Council*

The Council can be represented as a hierarchical pyramid. At the apex there is the Council of Ministers, followed by the Committee of Permanent Representatives (Coreper), while the base is made of a large number of working groups. Work in the Council usually starts at the working group level, where national experts examine Commission proposals according to instructions from their respective governments.

The representatives in the working groups are technicians, while the permanent representatives, EU ambassadors and their deputies are politicians.

Advocacy groups usually lobby Council by their national member associations. They pass the message to their membership and encourage them to contact their national MEPs, who in turn can exert pressure on the Permanent National Representatives in the Council.

*"We usually receive visit from industries representatives, while we have few contacts with NGOs. Industries come to us in order to have information and to explain their positions; NGOs sometimes write us email, but they generally are active at the EP level, by being linked to MEPs the most of the time"* (Health attaché, Italian Permanent Representation)

On the one side permanent representations in Brussels guide interest groups in the complex decision making process; on the other side interest groups support them, since permanent representations have very few resources to spend:

*"We help them and they help us". (Lobbyist, pharmaceutical company)*

However, compared to the other EU institutions there is much less involvement of advocacy groups at the Council level. It is still a virgin landscape for lobbies.

*"Interest groups have not understood yet how to lobby the Council level. They start lobbying the Presidency too late. They miss a big chance to exert pressure"*  
(Health Attaché from Czech Republic EU Presidency)

The health attaché from Czech Republic EU Presidency claims that lobbying is too much focused on the Commission. Advocacy groups have not developed yet a professional approach to the Council. They start lobbying Presidency too late. Furthermore, she says that a considerable weakness of the EU political system is that institutions are not able to work at the same time. The policy-decision making process at the EU level is too long and complex and cannot respond efficiently to the input side. The co-decision procedure could take two or three years sometimes to be ended, and it involves so many institutional players all with their own agenda.

*"It happens sometimes that the results of your lobbying activity is completely different from it was at the beginning. EU legislation is the output of a very long process and at the end you could get a totally different legislative outcome"*  
(Lobbyst, Pharmaceutical industry association)

Council strictly works with the Commission (to find agreements), but also with the EP (to be updated about the political debate) in the decision making process. However, it seems a very hard process to get common positions across the working groups at the Council level:

*"As far as the Pharma Package, we were three people at the table - the Permanent Representation, the National Health Ministry, the Italian pharmaceutical agency. We try to elaborate a common position to be addressed within the Council meeting, by involving also national administrations such as ministries and regions. It is very difficult to work together and get compromises. For example regions sometimes act on their own by avoiding coordination with us". (Health attaché, Italian Permanent Representation)*

Finally, a speaker for a pharmaceutical industry association about the difficulty of lobbying Council said:

*"Council is the most not transparent institution. It is very hard to get information from it, to know the state of the discussion"* (Lobbyst, Pharmaceutical industry association)

Finally, according to the most of the interviewees, in order to successfully lobbying EU institution: a) you have to know who are the key players; b) you have to translate the message into the right language: if your target is the EP you should bring emotional arguments, a simple and clear message, while if it is the Commission, you need to provide technical information; as far as the Council, you have to be able to use both emotional and technical languages; c) you have to use the language they speak and reply to their needs; d) you have to be reasonable and credible; e) you need to learn where to go and how to provide concrete arguments, which allows others to advocate for you.

## 5. LOBBYING IN THE EU HEALTH POLICY-MAKING: A CASE STUDY ON PHARMACEUTICAL POLICY

In the following paragraphs we will focus on two different processes both part of the pharmaceutical policy. The first examines the High Level Pharmaceutical Forum, a three years process of stakeholders' consultation about health care related issues. The second concentrates on a series of measures recently proposed by the European Commission impacting the pharmaceutical industry ("the Pharma Package"). Although it dates back to several Commission attempts to review pharmaceutical legislation in order to increase competitiveness of the EU pharmaceutical industries vis-à-vis US industry, it has not yet been concluded. Reaching agreement on this issue is difficult, because it involves conflicting interests among public health and social protection groups on the one side and industries on the other side. In other terms, it refers to the clash between Member States social protection and public health policy objectives and the Commission industry policy goals.

### Background

In 2001<sup>14</sup> the Commission's Directorate General Enterprise<sup>15</sup> proposed a five-year trial relating to article 88 of Directive 2001/83/EC during which the pharmaceutical industry could direct to a limited extent information to the general public about medicinal products used for the treatment of aids, asthma and diabetes ("Review of the EU Pharmaceutical Legislation").

The European Parliament and Council rejected the proposal. In its report of 9 October 2002 the EP objected to direct-to-consumer advertising and considered that the Commission's proposal would lead to that. Member States were against the proposal as well. Loosening the ban would influence national healthcare systems, since demand is stimulated for those medicines that are most advertised. Being healthcare organization and financing a national competence, the Commission should have known that Member States would probably block its proposal.

The Parliament was also worried about the circumstance that patients would obtain information about medicinal products but not about other treatments. Therefore, through the same Directive, the Commission was called upon by the EP to analyze the different processes in European countries and to draft proposals, in order to define useful strategies to get good quality, reliable and non promotional information. In the end, the pilot study was rejected and replaced by the request for a report.

Parallel to the preparation stage of the review process, the Commission was pursuing also alternative routes for discussion to ensure that the topic remained on the agenda. In 2001 the Commission set up the G10 High Level Group<sup>16</sup> on innovation and the provision of

14. The pressure from pharmaceutical industry to promote direct information to patients actually dated from the mid 1990s.

15. DG Enterprise is responsible for drafting pharmaceutical legislation.

16. The High Level Group on Innovation and Provision of Medicines - The G10 Medicines Group - was set up following a symposium on Pharmaceutical Industry Competitiveness held in December 2000. The objective of the Group was to review the extent to which current pharmaceutical, health and enterprise policies could achieve the twin goals of both encouraging innovation and competitiveness and ensuring satisfactory delivery of public health and social imperatives. The membership of the Group consisted of representation at the highest level from different administrations and organisations: from the Member States, the Swedish Minister of Industry, together with the French, German, British and Portuguese Ministers of Health; from the industries, EFPIA, EGA, AESGP; from health organizations, AIM and a patient representative from the Picker Institute. It was evident the overrepresentation of the pharmaceutical industry. The G10 recommended the need for a workable distinction between advertising and information. Furthermore a collaborative public-private partnership involving a range of interested parties should have been established ([http://ec.europa.eu/health/ph\\_overview/Documents/key08\\_en.pdf](http://ec.europa.eu/health/ph_overview/Documents/key08_en.pdf))

medicines, which recommended a public-private partnership on patients information; in 2005 then it established the Pharmaceutical Forum which again covered the information to patients issue.

After the first meeting of the Pharma Forum in 2006, the Commission increased pressure through various public consultations plus impact assessment. Two general web-based public consultations were carried out respectively in 2007 and 2008. The first formal public consultation was about a Draft report on practices with regard to the provision of information to patients on medicinal products, summarising the current state of play without presenting yet any political orientations or proposals; the second public consultation specifically addressed the key ideas of the forthcoming legal proposal on information to patients. Contributions were asked from all stakeholders and interested parties dealing with medicines or with provision of information on medicinal products to citizen. This covered for example information providers, healthcare providers and regulatory authorities. All citizens, civil societies and organisations were also welcomed to contribute to the consultation. The first part of the consultation received 73 responses, the second one 185 contributions from the range of relevant stakeholder groups (tab. 2).

Table 2 - Overview of the public consultation responses regarding pharmaceutical industry as an information provider about prescription-only medicines (%)

	Yes	No	Mixed	No Comment
Healthcare professionals and organisations	7	70	15	8
Patient organisations	25	50	10	15
Consumer Organizations	0	56	44	0
Pharmaceutical industry organisations and companies	96	0	0	4
Regulators <sup>a</sup>	11	46	29	14
Media and patient information organisations	72	14	0	14
Social insurance organisations	0	100	0	0
Research and others	20	30	0	50
<b>Total</b>	<b>26</b>	<b>48</b>	<b>14</b>	<b>12</b>

*"Yes" refers to opinions that highlighted the role of a pharmaceutical company as an information provider, because, for example, nobody knows the product better than its producer*

*"No" refers to opinions that declined the role of a pharmaceutical company as an information provider, because, for example, the information that comes from the producer can not be neutral*

*Mixed" refers to responses that accused that there is a lack of a coherent distinction between advertising and information*

*"No comment" refers to responses that did not take out this issue*

a. Austrian Ministry of Health, Family and Youth, Dutch authorities; European Medicines Agency (EMA); Federal Agency for Medicines and Health Products, Belgium; Federal government, Germany; German Federal Environment Agency; French authorities; Icelandic Medicines Control Agency; Infarmed, Portugal; Irish Medicines Board (IMB); Italian Medicines Agency; Medical Products Agency (MPA), Sweden; Ministerio de Sanidad y Consumo, Spain; Ministry for Health and Prevention, Denmark; Ministry of Health of the Republic of Latvia; Ministry of Health, Hungary; Ministry of Health, Welfare and Sport, The Netherlands; Ministry of Social Affairs and Health, Finland; National Health Service (NHS), UK; Non-EEA Regulatory Agency; Norwegian Medicines Agency; Regional Drug and Therapeutic Committee in Stockholm (Läksak), Sweden; Regionala läkemedelsrådet i Västra götlandsregionen, Sweden; Senate Department for Health, the Environment and Consumer

Protection of the land of Berlin, Germany; State Institute for Drug Control of the Czech Republic; Swedish Associations of Local Authorities and Regions; Swedish Council on Technology Assessment in Health Care; UK Government.

Source: Summary of the responses to public consultation on the key elements of a legal proposal on information to patients was launched by the Commission on 5 February, 2008 :

[http://ec.europa.eu/enterprise/pharmaceuticals/patients/docs/summary\\_publ\\_cons\\_220508.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/patients/docs/summary_publ_cons_220508.pdf)

As we see in detail in the next sections, DG Enterprise increased pressure until it finally managed to move from High Level discussions requiring consensus to a draft legal proposal on patients information, which was released in December 2008, within the "Pharmaceutical Package".

**Table 3 - Chronological overview of the Commission's policy proposal on Information to Patients**

Date	Policy Development
2001	Commission's proposal for loosening ban on direct-to-consumer advertising of prescription drugs
2001 - 2002	Commission set up the G10 High Level Group on innovation and the provision of medicines
2002	EP and Council rejected the Commission's proposal
2005 - 2008	Commission established the High Level Pharmaceutical Forum
2007 - 2008	Public consultations + Impact assessment
2008	Commission legislative proposal on information to patients included in the Pharma Package

### The High Level Pharmaceutical Forum

The official aim of the Pharmaceutical Forum was to improve the competitiveness of the pharmaceutical industry and its contribution to social and public health objectives. The main role of the Forum was to provide strategic direction, a political mandate and momentum as well as a platform for discussion on competitiveness and related public health issues. By exchanging best practices and examining efficiency gains within a European high level platform, it had to contribute to ensuring patients access to medicines within a sustainable healthcare budget, and to discussing the competitiveness of the European pharmaceutical industry and related public health considerations.

Table 4 - Composition of the Pharma Forum

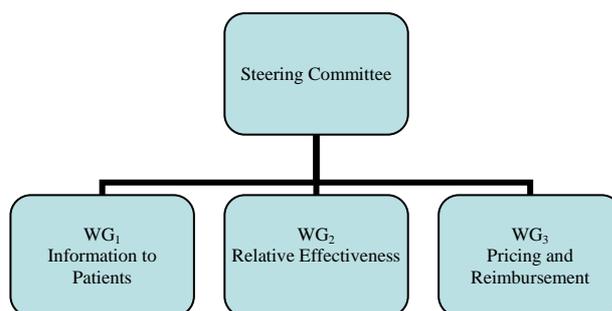
Governmental participants	Patients, Providers, Payers and public health groups
<i>Two Commissioners: Enterprise &amp; Industry, Health &amp; Consumer Protection.</i>	<i>Five representing business: EFPIA (European Federation of Pharmaceutical Industries &amp; Associations), AESGP (European Self-Medication Industry), EGA (European Generic medicines Association), EuropaBio (European Association for Bioindustries), GIRP (European Association of Full-Line Wholesalers)</i>
<i>Ministers from each of the 27 Member States were invited</i>	<i>Five patients and social protection - public health groups: European Patients Forum (NGO funded by industry), PGEU (Pharmaceutical Group of the European Union representing community pharmacists) CPME (Standing Committee of European Doctors representing all medical doctors in the EU), AIM (Association Internationale de la Mutualité), ESIP (European Social Insurance Platform)</i>
<i>Three Members of European Parliament (ALDE, EPP, PSE)</i>	
Tot. 32	Tot. 10

The Forum was set up as a follow-up to the “G10 Medicines”, which discussed the balance of health objectives and industry competitiveness in Europe, as we saw in the previous paragraph. Compared to the G10, the High Level Pharmaceutical involved an higher number of stakeholders. The Forum was composed by at least 40 members, more than half of which were Member State representatives (tab. 4). Out of the 10 non-governmental participants, five represent pharmaceutical and biotech businesses, and five represent non-business interests. However, these other organisations include the European Patients Forum, whose legitimacy has been questioned because of its close ties with industry and its lack of transparency.

The Pharma Forum aimed to discuss three main issues: a) *relative effectiveness*: increasing the quality and quantity of available data and analysing current assessment processes; b) *pricing and reimbursement*: developing solutions for access, and trade-problems, to ensure timely and equitable access to pharmaceuticals for patients, to enable control of pharmaceuticals expenditure by Member States and to reward valuable innovation that also encourages research & development; c) *information to patients*: improving the quality of information to patients about diseases and treatment options.

Three working groups focusing on the above topics formed in 2006 (Fig. 1), and the first full Forum met and adopted a progress report in September 2006. In spring 2007, the Commission organised a public consultation on the work of the Pharma Forum’s Information to Patient Working Group. A second meeting of the Forum took place in June 2007 and another progress report was adopted. The third and final meeting was held in October 2008, when a set of conclusions and recommendations were adopted.

Fig. 1 Structure of the Pharma Forum



The Forum's working methods were based on the following principles:

1. Building a shared understanding: gathering of data and facts; identify and exchange (good) practices.
2. Create awareness about problems for patients, Member States/payers and industry.
3. Build proposals to address identified problems.
4. Involvement of available expertise: academic knowledge, existing networks.

The consultation lasted three years and it was depicted as not an easy process by our interviewees:

*"During the first year we established common perspectives and shared best practices; the second year was very critical: dealing with different interests on the same board was very painful. At the end we tried to identify common interests and a balanced approach. But you know, we have the shortcoming that we could not legislate about those topics. Given that, the results were "weak". However weak is better than nothing"* (Policy officer, DG Enterprise)

*"It was a very difficult process. The idea was to have a consensus based process. However, you work with different stakeholders, but first with individuals having conflicting interests. It is sometimes not clear to identify who is behind the interest group"* (Policy officer, DG Sanco)

*"Consensus and support on certain issues by both industries and patients groups were very hard. We all start from a common perspective on the problem, but then everybody shows different positions. The role of the Commission was very important in finding a compromise among different positions"* (Lobbyist, Pharmaceutical company)

There has also been strong criticism of the composition of some of the individual working groups, especially the working group on information to patients. During a public consultation in spring 2007, several organisations such as the European consumer organisation (BEUC) and Health Action International (HAI) strongly criticized the methods and outcomes of the Information to Patients Working Group (tab. 5 resumes success and failure factors of the Pharma Forum according to the sample of interviewees). BEUC said there were major flaws in the structure of the group, that it was the wrong type of forum for such a project, and that the methods were "not appropriate, do not bring added value and are not the way to develop information for patients...It was appointed in a selective manner without transparency or clear criteria, and with a composition that was bound to politicize the issues under discussion." (Friends of the Earth Europe, 2008)

Table 5 - Pharma Forum: an assessment by the participants

+	-
<p>- "all stakeholders together for the first time" (Lobbyst, Health professional organization)</p> <p>- "understanding other points of view" (Lobbyst, Patient Organization);</p> <p>- "all the interests were represented and had the chance to raise their own voice" (Lobbyst, Pharmaceutical Company)</p> <p>- "spreading knowledge" (Policy officer, DG Sanco)</p> <p>- "exchange of best practices" (Policy Officer, DG Enterprise)</p> <p>- "Member States and stakeholders working together" (Lobbyst, Pharmaceutical Company)</p> <p>- "the Pharma Forum was very well organized. Moreover, the role of the Commission was really helpful in favouring the exchange of practices". (Lobbyst, Pharmaceutical Industry Association)</p>	<p>- painful process: <i>the more people you have around the table the more difficult is to achieve consensus</i> (Policy officer, DG Sanco)</p> <p>- outcome not transparent: <i>"the process was not at all transparent. Commission synthesized the results of the meetings without making clear who contributed to what"</i> (Lobbyist, Health organization)</p> <p>- "it was very time consuming process" (Lobbyst, Pharmaceutical Industry Association)</p> <p>- criteria for selecting participants were not clear: <i>"We did not understand why some key stakeholders were not invited to the forum"</i> (Lobbyist, Health professional organization)</p> <p>- the process was driven by the Commission: <i>"Commission did not make circulate our point of view among the other stakeholders. It decided what or what not to include in the results"</i> (Lobbyist, Social Protection organization)</p> <p>- "the mountain who has given birth to the mickey mouse" (Health attaché, Italian Permanent Representation)</p> <p>- "The Pharma Forum was a way for industries to lobby the Commission" (Health attaché, Czech Republic Permanent Representation)</p>

A policy officer from DG Sanco replied to our question about the criteria used in inviting advocacy groups to join the Pharma Forum, as follows:

*"We usually invite stakeholders who have expertise in the topic we discuss. As far as the Pharma Forum we invited 10 stakeholders - half from the private sector, half from the civil society - whom we think they have expertise in that topic. BEUC, for example, was not very active on that issue at that time. Expertise in lobbying is a moving process. Stakeholders are invited to join policy making process according to the topic and the expertise they have"* (Policy Officer, DG Sanco)

A policy officer from DG Enterprise added:

*"We tried to cover all the different interests, but it was clear for us that in inviting stakeholders we did not want people shutting at the at the table"* (Policy Officer, DG Enterprise)

In June 2007, the Association Internationale de la Mutualité (AIM) and the European Social Insurance Platform (ESIP) issued a position statement expressing their dissatisfaction with

the Pharma Forum way of working and substance. They objected to the use of the word “partnership” to describe the procedures followed so far in the working group. It read: “ESIP and AIM still have concerns about the lack of transparency of the processes, procedure and methodologies in the Forum, in particular the Working Group on information to patients.” The statement also indicated that suggestions put forward by ESIP and AIM were not being taken into consideration in the information process and debate: “ESIP and AIM strongly regret that their constructive proposals made during this process, in particular the request for a survey for existing patient information practices and the use of an EU quality label to identify high quality information, have not been taken up for further discussion”<sup>17</sup>.

A major contentious issue in the Information to Patients Working Group was a proposal to weaken the ban on direct-to-consumer advertising of prescription drugs<sup>18</sup>. BEUC, HAI, AIM and ESIP objected that their concerns over the conflicts of interest for pharmaceutical companies providing information for patients between independent information and product marketing were not taken seriously. They argued that public health interests should not be mixed or even over-ridden by commercial interests - ie. information to patients should not come directly from those who produce medicines because the main goal of pharmaceutical companies is to maximise sales. Similarly, the Pharmaceutical Group of the European Union (PGEU) argued that health professionals, including pharmacists and doctors, should remain the primary source of easily accessible and reliable information about medicines, and that the pharmaceutical industry should not be given more scope to “push” information to patients.

In the final conclusions, the Pharmaceutical Forum recommended retaining the ban on advertising prescription medicines to the general public, but at the same time also recommended that “all the relevant players, including national competent authorities, the Commission, public health stakeholders and industry, should ensure high quality information”<sup>19</sup>. A footnote explains that AIM expressed some reserves concerning the involvement of industry in providing information to patients.

The draft proposed that industry should be allowed to publish written information about prescription medicines in newspapers and magazines and on the internet. Companies should also be allowed to prepare the information leaflets issued with medicines in a different way and to present their products “in the context of the condition to be prevented or treated”. No approval would be required before publication. Public health campaigners condemned these proposals as damaging to patients and health professionals. Resistance from a wide range of public interest organisations and disagreement within the Commission itself has led to the delay of the package, which was initially expected to be launched in October 2008, but was delayed to November and then finally launched in December 2008. In the final package as we see in the next paragraph, the Commission had pulled back on some contentious issues by including for example prior approval of all information, and excluding ‘general’ printed media (newspaper, magazines etc...) from the list of media where companies would be allowed to publish information.

To recap, the reactions from the non-industry stakeholders in the Pharma Forum show that, although the overall composition of the Forum was not significantly biased in favour

17. ESIP&AIM Joint Statement [http://ec.europa.eu/enterprise/phabiocom/docs/pf\\_20070626\\_esip\\_aim\\_joint\\_statement.pdf](http://ec.europa.eu/enterprise/phabiocom/docs/pf_20070626_esip_aim_joint_statement.pdf); all contributions to the consultation:

[http://ec.europa.eu/health/ph\\_overview/other\\_policies/pharmaceutical/results\\_consultation\\_en.htm](http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/results_consultation_en.htm); an overview of comments regarding information to patients can be found here: <http://www.haiweb.org/28102007/ManyConcerns.pdf>.

18. In the EU advertising of drugs is regulated by Directive 92/28/EEC banning advertising of prescription-only drugs to the general public. In 2001 the Commission proposed a partial lifting of the ban giving manufactures the chance to inform patients on their medical products for HIV/AIDS, diabetes and asthma.

19. Commission synthesized the results of three years consultation process in a 11 pages report: [http://ec.europa.eu/pharmaforum/docs/final\\_conclusions\\_en.pdf](http://ec.europa.eu/pharmaforum/docs/final_conclusions_en.pdf)

of industry, crucial areas such as information to patients were dominated by industry interests. The European Public Health Alliance (EPHA) states that the “Pharmaceutical Forum, as it stands, and the outcomes of its work cannot be considered as indisputable, unbiased and reliable.” and that “Non-industry positions were sidelined and ignored.” One of the most contentious issues – the weakening of the ban on advertising of prescription medicines – was fiercely opposed by a wide range of non-industry stakeholders. While the final recommendations keep the current ban in place, they also propose allowing the industry to act as a source of information for patients.

This creates a loophole which finds its way into the Commission’s draft “Pharmaceutical Package”, allowing industry to publish written information about prescription medicines in newspapers and magazines and on the internet, weakening the advertising ban. It was only because of strong resistance from public health campaigners (and Member States) that some degree of protection against advertising of prescription medicines was inserted into the pharmaceutical package.

### The Pharmaceutical Package

The “Pharma Package”, is the popular name for a series of measures proposed by the European Commission impacting the pharmaceutical industry. It contains three important initiatives plus a Commission communication: a proposal for a directive on how to modernize *pharmacovigilance* in order to improve safety of medicines; a proposal to improve patient safety by reducing the infiltration of counterfeit medicines into the supply chain (*fighting counterfeits*); and a directive on the future direction of the supply of health information to patients (*the informed patient*). Among the three legislative proposals, our analysis will especially focus on the information to patients. This proposal was a very controversial issue as it emerged in the Pharma Forum, and which dates back to the Commission’s attempts to review the EU pharmaceutical legislation (see tab. 3 for a chronological overview). As we have seen in the previous section, throughout all the process DG Enterprise had a clear agenda: allowing the pharmaceutical industry to communicate information to patients.

*“The Commission doesn’t set out an information strategy but it just provides the pharmaceutical industries greater flexibility to provide information directly to the public on prescription medicines” (Lobbyist, Consumer organization)*

*“We are very much concerned by the Commission legal proposal. It gives priority to industrial commercial interests rather than to public health concerns and consumer protection interests” (Lobbyist, Health Organization)*

Before the Pharma Package was released, twenty organizations in the field of health representing patients, consumers, health professionals and social health insurers sent a joint-letter<sup>20</sup> to both the Health Commissioner Vassiliou and the President of the EU Commission Barroso, to express their fears about the draft proposal relating the pharmaceutical package, in particular the role it would have given to the pharmaceutical industry concerning information to patients on prescription-only medicines.

*“The proposed changes to the existing legislation will have a substantial impact on European patients, consumers and national health care systems. Any attempts to alter the current legislative framework should be guided by and based on an in-depth assessment of patients’ and consumers’ needs...The signatories of this letter*

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20. Joint open letter to Commissioner Vassiliou on the pharmaceutical package  
[http://www.epha.org/IMG/pdf/Open\\_joint\\_letter\\_Commissioner\\_Vassiliou\\_9\\_November\\_2008.pdf](http://www.epha.org/IMG/pdf/Open_joint_letter_Commissioner_Vassiliou_9_November_2008.pdf)  
 Letter to EC President Barroso on Pharmaceutical Package November 2008  
[http://www.age-platform.org/EN/IMG/pdf\\_pharmaceutical\\_package.pdf](http://www.age-platform.org/EN/IMG/pdf_pharmaceutical_package.pdf)

*ask you to continue to lead in defending patients and consumer in the pharmaceutical package and to ensure that public health considerations supersede industrial interests” (Joint Letter to EC President Manuel Barroso, November 2008)*

Member States did not welcome the Commission’s proposal as well. Many ministers expressed their concerns over the regulation and directive on the provision of information on medicines by marketing authorisation holders. On 9 June, during a Health Council meeting in Luxembourg, it became clear that over 20 Member States do not see the proposal as a solid base for negotiations:

*“While agreeing that there is a need to improve the information to the general public on prescription-only medicinal products, many delegations fear that the suggested system could be overly burdensome for competent authorities without leading to significant improvements in the quality of the information provided to patients. In addition, many delegations hold that the distinction between ‘information’ and ‘advertising’ was not sufficiently clear. So they fear that the proposals will not provide adequate guarantees, and that the prohibition of advertising of prescription-only medicinal products to the general public will be circumvented” (Council Meeting, June 2009)<sup>21</sup>.*

This is a controversial issue, as the EP’s information to patients rapporteur says, because: *“Many Member States believe that they have the perfect system and they think that more information will drive up health care costs...the Member States are afraid of the costs of the enforcement of the legislation [cfr. the ex-ante checking of the medicine information by health authorities]” (Europolitics, 26 October, 2009)<sup>22</sup>.*

The Committee of the Regions (CoR) was on the same critical wave, blaming that the information to patients proposal was *“biased in favour of pharmaceutical companies and would put consumers at risk” (Europolitics, 30 June 2009)<sup>23</sup>.* According to CoR rapporteur Susanna Haby (EPP-ED, Sweden), the fact that the package was drafted by Directorate-General Enterprise and Industry and not by DG Health *“tells you all you need to know about who is likely to benefit from them” (ibidem)*. Moreover, she emphasised that the Commission neglected the role of independent local health care professionals when it comes to information to patients on prescribed medicines; in its proposal, the Commission allows pharmaceutical companies to take the lead on patient’s information, but the CoR suggests that this should be done by independent local health care professionals.

Coming back to the advocacy groups, the most of them hardly criticized the not transparent process by which Commission was preparing the legislative proposal about information to patients. It seemed that the Commission had used soft instruments such as consultation platforms to divert public interest advocacy groups’ attention away from the legal proposal drafting process:

*“It was very bad. Commission was preparing the package while we were engaged in the Pharma Forum. Therefore, it was not very clear whom contributed to it. Only one result of the Pharma Forum - the quality criteria - was partially included in the package” (Lobbyst, Health organization)*

There was actually no link between the topics discussed in the Pharma Forum (relative effectiveness; pricing and reimbursement; information to patients) and the legislative policy issues proposed in the Pharma Package (pharmacovigilance, fake medicines, information to patients). Only the information to patients issue was partially recalled in the Commission legislative proposals.

21. <http://www.consilium.europa.eu/uedocs/NewsWord/en/Isa/108380.doc>

22. <http://europolitics.abccom.cyberscope.fr/social/council-should-start-discussing-full-pharma-package-artb252293-26.html>

23. <http://www.europolitics.info/social/cor-considers-executive-s-proposals-biased-art242180-26.html>

When we asked the Commission policy officers involved in the process the reasons why the Pharma Forum and the Pharma Package were not linked to each other, and especially why the Pharma Forum was not used to discuss the upcoming Commission legislative proposals, the common answer was that *"The Pharma Forum and the Pharma Package were moved by different political mandates. Commission is a very fragmented policy house: each DG has its own political mandate and communication is not very easy among different Units"*. That is to say that the two DGs involved in the policy making process - DG Enterprise and DG Sanco - had respectively their own policy agenda. But not only, within each DG there are different units and each unit has its own mandate as well.

Finally, most of interviewees claimed that the *"The Pharma Package was clearly the result of a very strong lobbying, especially from industries. The Commission made the draft proposal circulating before it became official, therefore lobbying started very early in the process."*

As a member of the DG Enterprise Cabinet commented, Commission is like *"a house of glass. Proposals go out too easily"*. The closer you are to the DG responsible for drafting policy proposal, the more chance you have to influence EU policy making process.

## 6. THE POLICY SUBSYSTEM: ACTORS, BELIEFS, RESOURCES

### Advocacy coalitions and policy core beliefs

The ACF assumes that stakeholders are primarily motivated to convert their beliefs into policy and then seek allies to form advocacy coalitions to pursue the identified policy objectives. Advocacy coalitions include actors of similar core beliefs who engage in a nontrivial degree of coordination (Sabatier and Jenkins-Smith 1999, 120). Looking at the advocacy groups' policy positions on the press releases and on the organisations' website, we can broadly identify<sup>24</sup> two main coalitions in our case studies. For instance, Table 2, which gathers the results of the public consultation about info to patients carried out by the Commission in 2008, shows at least two coalitions. Coalition A consists of affiliations with pro-industry beliefs (pharmaceutical industry as *an information provider*), including pharmaceutical industry associations and companies, media and patient information organisations. Opposing the pro-industry coalition is Coalition B, clearly supporting public health/social protection interests<sup>25</sup>, that include healthcare professionals and organisations, patients and consumers groups, regulators, social insurance organizations. Among anti-industry affiliations, the strongest alliance is between health professional and social insurance organizations and consumers groups. Research and patient organizations do not show so clear-cut percentages opposing the role of industry as info provider. As many patients groups are industry-sponsored, they cannot be totally in opposition with it.

### Advocacy coalitions and usable resources

The pro-industry coalition controls a sizable amount of resources. First, coalition A affiliations could count on the financial resources provided mainly by pharmaceutical industries. Among coalition A members, there are considerable multinational pharmaceutical companies able to do effective lobbying on their own. The pro-industry

24. We decide to polarize advocacy groups in their preferences in order to simplify the analysis. However, we are aware that more than two coalitions could be identified according to the different degree of convergence/divergence between actors' policy preferences.

25. Its policy core belief is "that public health considerations supersede industrial interests", as it was stated in the joint letter about the "Pharma Package" to both the European Commissioner for Health and the President of the EU Commission President Barroso.

coalition's beliefs systems is also supported by the Directorate Enterprise and Industry of the Commission, which clearly aims to increase European pharmaceutical industry competitiveness vis-à-vis US industry and harmonize pharmaceutical market in Europe<sup>26</sup>. In having access to legal authority, Coalition A can offer two relevant resources: skilful leadership and information. Within Coalition A there are advocacy groups driven by charismatic lobbyists, which have been able to build longstanding collaborative and trust-based relationship with the Commission. Commission needs technical information and pharmaceutical industry associations/companies have the resources to provide EU institutions with data, reports, policy analyses and especially evidence-based arguments.

Compared with coalition A, coalition B controls fewer resources. At the individual level, coalition B members engage in lobbying activities with varying degrees of financial support. They globally have fewer financial resources than their counterparts, but many of them usually get grants and funds from Commission and EU projects.

Coalition B has also access to mobilizable members from the health community and Member States. As we have seen in the Pharma Package case study, twenty health organizations sent a [joint letter to Commissioner Androulla Vassiliou](#); the letter was intended to encourage the Commissioner to stand firm with her position towards the Information to Patients part of the Pharmaceutical Package. Following this, EPHA, working with several EPHA members and other partner organisations, co-signed and sent another letter related to the launch of the Pharmaceutical Package to [the President of the European Commission Barroso](#) and the press. The letter warned the College of Commissioners that various parts of the Pharmaceutical Package (Counterfeit Medicines, Pharmacovigilance and Information to Patients) should be reconsidered. It called for the different parts of the Pharmaceutical Package to be unbundled, as the separate parts should be considered individually given that they deal with different issues.

More than financial and informational resources, coalition B affiliations base their strength on public and health community support to apply political leverage to the process.

### Advocacy coalitions and accessible venues

Coalition A and Coalition B have been active in several routes. Members of both coalitions were pressuring all the available venues - Commission, EP, Council -, but each one seems to have its own preferred channel according to policy preferences, resources, relationship pattern, etc. Whereas industry and some patient groups had good access to DG Enterprise, public health and consumer organizations were considered stakeholders of DG Sanco. Thus, Coalition A and Coalition B have been respectively oriented to Directorate of Enterprise and Industry (DG Enterprise) and Directorate for Health & Consumers (DG Sanco). Bearing in mind that the proposals were developed by DG Enterprise<sup>27</sup>, Coalition A had a privileged access to the process. DG Sanco was not completely able to counterbalance the industry-oriented proposals of DG Enterprise. It was only created in 1999 with a very limited mandate and without a strong culture compared to the experienced DG Enterprise.

26. "This Communication outlines the Commission's vision to ensure that European citizens will benefit from a competitive industry that generates safe, innovative and accessible medicines..The pharmaceutical industry contributes to the well-being of citizens through the availability of medicines, economic growth and employment. Europe has been losing ground in pharmaceutical innovation. It is important to slow down or even reverse this trend"  
(Commission Communication on the Pharmaceutical Sector, 2008)

[http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack\\_12\\_2008/communication/citizens\\_summary\\_communication.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_12_2008/communication/citizens_summary_communication.pdf)

27. In the joint letter sent by 20 NGOs to EC President Barroso, there was a claim for shifting competence on medicines from DG Enterprise to DG Sanco: "Finally, in order to better ensure that public health considerations are put before industrial interests, we call for competence on medicines to be transferred from DG ENTERPRISE to DG SANCO, and to become a responsibility of the EU Health Commissioner". [Letter to President Barroso on Pharmaceutical Package November 2008.](#)  
[http://www.age-platform.org/EN/IMG/pdf\\_pharmaceutical\\_package.pdf](http://www.age-platform.org/EN/IMG/pdf_pharmaceutical_package.pdf)

Then, pro-industry advocacy coalition was lobbying the Commission more than the EP; conversely anti-industry coalition members were pressing MEPs more than Commission's policy officers.

Council is still an undiscovered land for both coalitions, since advocacy groups are actually in the stage of learning how to approach this institution, as outlined in the previous paragraphs.

In sum, Coalition A has a comparative advantage in terms of organisational capacity, financial resources and expertise. The position of industries is strengthened by their ability to lobby at all levels of the EU institutional system and by their close relationship to the Commission, who plays a central and strategic role in the policy making process as we will see in the next section.

### Policy broker and policy change

The pharmaceutical policy subsystem is polarized between a pro-industry advocacy coalition and a public health/social protection advocacy coalition. These coalitions are mainly divided in their policy preferences: coalition A aims to increase and protect pharmaceutical industry interests, while coalition B cares that public health considerations supersede industrial interests. The conflict is mainly driven by normative beliefs, making policy change extremely difficult. Although pro-industry coalition is closer to policy change than coalition B, neither advocacy coalition is getting what it really wants until now. It is just too early in the process<sup>28</sup> to assess whether stakeholders have exhausted all the available venues and resources. The best option for both coalitions is a consensus-based approach.

In the case examined here, policy learning is observed, as it is predicted by the ACF. Policy learning within and between coalitions is an important aspect of policy change. *In this policy subsystem, policy learning globally consists of the widespread of knowledge, scientific and technical information, relationship building, willingness and capacity to compromise.*

Learning process is most likely to concern only secondary aspects of a belief system, leaving the policy core of a coalition intact, and bringing to minor policy changes (Sabatier, 1988). Minor policy changes are the result of two processes: learning within and learning across coalitions. The second is more interesting in this case as it is where policy broker may intervene. When the two coalitions are in conflict and it is difficult to have a dialogue between them, policy brokers mediate the conflicting belief systems looking for some reasonable compromise which will reduce conflict intensity. Policy brokers play a crucial role within consensual decision-making systems: they mediate between conflicting interests during political negotiations, control information, and translate divergent opinions into compromises.

This was mainly the role played by the Commission in these case study:

*"Commission has played an important role in achieving consensus among different interests. Commission is aware it needs to involve more and more stakeholders in the process. While it is true that everybody has its own interest and it is not neutral (Commission included), the more inclusive the EU process becomes, the more objective it will get"* (Lobbyist, Pharmaceutical Industry)

The position of broker in policy negotiations depends on the features of the political system and on specific context factors: the higher the degree of consensus required, the

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28. On 1 September 2009 the Commissioner for Enterprise and Industry in presenting the Pharma Package to the new elected EP (the Environment, Public Health and Food Safety Committee), said that the Czech and the current Swedish Presidencies had refused to discuss the information to patients issue, and that it would be passed on the Spanish Presidency in 2010.

more norms of compromise create incentives for broker's action across coalitions. In the EU context, the policy making process combines aspects of intergovernmental negotiations and supranational centralisation. The Commission draws up the proposal and a decision has to be taken by Member States in the Council, and in the case of co-decision with the EP. The Commission has to search for consensus, trying to avoid decisions that violate Member States interests. Policy proposals without consensus can be blocked by intergovernmental haggling (Scharpf, 2000). Therefore Commission has to strategically pursue all the venues and resources available in order to avoid deadlock. Commission tries to maximize its room to maneuver in the policy process, while attempting to avoid direct conflict with the Member States. By favouring the exchange of information and opinions among stakeholders, building supportive networks, promoting public consultations the Commission can indirectly influence the policy direction of Member States. In addition, by attending all the meetings in the Council and in the EP, the Commission knows the bottom lines of the actors involved in the process: the formal and informal institutional avenues leave room for strategic behaviour. In this case, policy broker takes an important position, where it can channel information among advocacy groups and influence the final output, behaving as a strategic actor. The role of the policy broker can rest on a continuum ranging from brokerage to advocacy and actors performing this function may intermittently switch towards more advocacy oriented - behaviour (Sabatier 1993, 27). Therefore, the Commission not only has played the role of broker in the process, but it has also confirmed to be able of being both a *policy entrepreneur*<sup>29</sup> (Cram, 1997, Heritier 1999) and a *purposeful opportunist*<sup>30</sup> (Cram 1993, 1997).

The role of the Commission as a policy entrepreneur should not be ignored. In the case of information to patients, the Commission has been able to frame and keep the policy issue on the EU agenda for almost 10 years. Although the Commission's proposal was initially unsuccessful, the Commission has managed to find a way out of the political impasse (the EP and Council rejection to Commission proposal) by using alternative routes (i.e. the G10 and the Pharma Forum) as a platform to keep issues that were not agreed upon in the review on the political agenda.

Despite lack of substantial competencies, health has been emerging as a European policy field through many creative avenues (Greer, 2006). *This case study shows how EU integration can result from the ability of institutions - especially the European Commission - to use the "material constitution"*<sup>31</sup> *to influence the structure of politics at the EU level.* Even though the Member States provided the EU with limited health competencies, excluding harmonization of their laws and establishing the subsidiarity principle for health services and medical care, it does have numerous responsibilities relevant to health.

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29. Commission behaves as a policy entrepreneur who "propose[s], lobb[ies] for, and 'sell[s]' a policy proposal to a decision-making body" (Pollack, 1997, p. 125) in order to increase its competencies. Pollack argues that the Commission has the potential to act as a policy entrepreneur since it embodies all Kingdon's characteristics of a successful policy entrepreneur, i.e. the Commission has "expertise, brokering skills, and the institutional persistence and has the additional advantage of the formal right of initiative and well- developed policy networks" (Pollack, 1997, p. 126).

30 Many studies have demonstrated that EU institutions, as purposive actors, play a critical role in influencing the agenda setting, policy formulation and implementation processes. "Crucially, a purposeful opportunist knows where it wants to go but it is fairly flexible about how it gets there" (Cram, 1997: 34). "Purposeful, because it very rarely tries to reduce its own potential role (even if, like any rational, autonomous, organization, it is willing to forego involvement on a case by case basis). Opportunistic, because it will react quickly to substantive policy ideas (such as "centres of reference") and opportunities." (Greer, 2008: 6). From its early days, the Commission sought to create a constituency of support for its actions in areas where it lacked legal competence. Particularly in areas where its powers were limited, the involvement of a broad range of actors was used to identify salient issues and to generate grounds to push for the extension of the Commission's competence (Cram, 1993, 1997).

31. The constitution in the material sense must be distinguished from the constitution in the formal sense, namely a document called "constitution", which, as written constitution, may contain not only norms regulating the creation of general norms, but also norms concerning other politically important subjects.

The two case studies are clearly the example of how the Commission is able to shape advocacy groups' strategies and to exploit stakeholders' resources and critical junctures among institutions.

To sum up the Commission's action in the process, plans for reform pharmaceutical legislation had started to take shape inside the Commission already in 2002, following the reject by the EP and the Council. The Commission Directorate General - DG Enterprise initiated and fostered EU high level debates between experts, professionals and Member State governments on patient information. The not transparent approach in inviting stakeholders resulted in an overrepresentation of industrial interests. Furthermore various and simultaneous routes pursued by the Commission and overlapping consultations created confusion. It was clear that DG Enterprise had its own agenda - giving patients information by industry - and successfully lobbied for that. By creating and fostering high level debates, the Commission not only favored policy learning such as sharing experiences, exchange of knowledge, but also managed to create commitment for its goal as building of supporting coalitions. In many policy areas the Commission generally tries to build trust through the creation of supportive and consultative networks with advocacy groups or through increasing (sometimes *apparently*) the level of transparency and legitimacy by public consultation procedures (Cram, 1977; Héritier, 2000).

In conclusion, the key to understand the EU policy making dynamics in health care seems to be the relevant role played by the European Commission throughout all the policy process. Commission as policy broker has favoured policy learning and as part of the advocacy coalition has exerted pressure for policy change as well.

Beside the role of policy broker in influencing policy change, the ACF allows us to get some interesting insights about the factors of success necessary to produce policy change within the multilevel system of the EU. Bearing in mind that EU policy making is a consensus-based process, which first of all requires agreement between the institutional players (Commission, EP, Council and Member States), the policy analysis suggests that policy change at the EU level is especially fostered by the following factors<sup>32</sup> (fig. 2):

a) *Accessible venues*

The institutional setting<sup>33</sup> with the Commission, the EP and the Council each playing a specific role in the legislative process offer advocacy groups access points differentiated according to organizational and informational cost of lobbying. By facilitating or conversely hindering some courses of actions institutions define opportunities and constraints for actors' involvement, influencing the success or failure of the political game.

This study shows the central role played by Commission as both policy broker and policy entrepreneur in the policy-making process. Access to policy broker is a strategic venue especially when it takes authority position. However, Commission results in a very fragmented body. Each DG represents a world with its own language and network. It means each DG comes with different treaty bases, different cultures, different stakeholders and consequently different interests to push on the policy agenda. In our case, the fact that DG Enterprise controlled pharmaceutical policy instead of DG Sanco resulted in an industry oriented agenda and an easy access to policy making for pro-industry coalition.

As far as the EP, it seems to be the most vulnerable institution: MEPs are much more exposed to manipulation than Commission policy officers or Council members, because they are not in a position (they only have a couple of assistants for dealing with many lobbyists) to check the information that has been provided to them.

32. We take into account the influence of endogenous variables, controlling for external factors.

33. Despite of the increasing role of the ECJ in EU health policy development, we have not included it in the analysis since it has not played a relevant role in the selected case-studies.

Finally, Council members are bound by the instructions they receive from their national governments, which makes it more difficult to lobby them. If there is lobby work to do, it is probably at the national level, in the ministerial headquarters, not with the Permanent Representatives in Brussels.

#### b) *Available resources*

Advocacy coalitions' resources are important elements in shaping and developing EU health policy. The financial resources, information, public support, leadership skills, which interest groups have at their disposal, all influence to some extent the strategies and the chance of success in achieving policy change.

Above all, interest groups' expertise and capacity to generate knowledge play an important role at the EU level. The analysis has clearly shown the favouring of certain types of knowledge over others: while it is difficult to determine the exact impact of knowledge on the policy change process, the two cases demonstrate that different types and uses of knowledge are essential to achieve policy change outcomes. It is evident that the key to successful lobbying (that is to advocate for policy change) is strongly based on reputation of providing reliable information and knowledge-based arguments according to institutions demands, more than emotional issues.

#### c) *Belief System*

This analysis shows that industrial interests prevailed over the interests of others. This case makes clear how much European Commission controls legislation. The European agenda for pharmaceuticals is a DG Enterprise agenda. The policy core beliefs of DG Enterprise and of the pharmaceutical industry both had a strong focus on creating a competitive European pharmaceutical industry vis-à-vis US industry. Since individuals' identities are closely tied to their beliefs, they tend to filter or ignore dissenting information or events that challenge their belief and readily accept information that bolsters their beliefs. The DG with the competence to draft legislation selectively offered access to advocacy groups whose policy preferences were in line with those of the DG. In both the two analysed processes, DG Enterprise gave access and listened to pharmaceutical companies and associations, more than to public health and consumer groups. The Commission pursued its own agenda without taking into account all the interests. It invested in network building and creating alliances with *like-minded* advocacy groups.

In other terms, the case studies illustrate that the political ideology of the institutions influence the receptivity towards the knowledge and evidence brought in the process by advocacy coalitions. In the end, Commission was willing only to knowledge and evidence supporting its ideological perspective. Such findings have serious implications for all policy fields. Advocacy groups/ coalitions should be aware of the current dominant policy paradigm and the barriers to change that it may present. As our analysis shows, it may be difficult to persuade decision makers of the value of public health interests in developing policy, when the dominant paradigm in health care policy is industries competitiveness. The dominant advocacy coalition in the health policy community such as pharmaceutical industries benefit from Commission's legal proposal to review pharmaceutical legislation and have the ears of government (the Commission). Similarly pro-industry governments will not be totally receptive to knowledge concerning the social determinants and objectives of health policy, whatever the empirical evidence could be.

## 7. CONCLUSIONS

This study presents a rich picture of the intergovernmental praxis in EU health policy. While the findings of the study cannot simply be generalized to all the policy areas, this research presents a detailed account of the nature and way policy-making takes shape at the EU level in a significant policy field.

Above all, the empirical analysis has showed how relevant is lobbying in producing policy outcomes at the EU level. Lobbying in the multilevel system of the EU is a strategic activity concerning not only the traditional advocacy groups, but even institutions. It is evident from this study that *lobbying is a two-way street relationship*, a relationship of give and take, a relationship which can be a mutually-beneficial for both sides. Advocacy groups seek to influence outcome in the policy making process by persuading decision makers to support or even champion their cause that would not have done so otherwise. But governmental actors want something from lobbyists too. In order to be successful, you need to lobby institutions giving them what they need. They need expertise and technical information for policy development, they press advocacy groups to do campaign contributions for them. They ask lobbyists for assistance in attracting support from other institutions, from the public or others. These are all cases that emerge from our study. The Commission especially exploits stakeholders' resources and strategies to exert pressure on national governments and expand its competencies in policy fields, such as health policy, traditionally under Member States subsidiary principle. It is evident from the policy analysis how the *"material constitution" gives the chance to EU actors, especially Commission, to change the structure of politics in the long run*. In this case, the Commission has been able to bypass formal legislative veto points by using informal avenues or practises (stakeholders' consultation processes, public debates, informational platforms, etc.). This is a manner to further EU integration process, expanding the EU's role in fields of Member States' authority by "ways of doing" rather than "hard law".

Moreover, in this case the Commission has been able to act as "successful lobbyist" in promoting its own policy interest. It has effectively "lobbied" not only public health and business interest groups, but also the European Parliament and the Council (and Member States) to different degrees. Since almost 10 years from its failed attempt to review EU pharmaceutical legislation, the Commission has managed to bring its policy proposal back in the EU legislative agenda.

In conclusion, lobbying results in a "successful" way to articulate intergovernmental relations in the multilevel system of the EU, where the European Commission plays a pivot role in making a national policy issue the central core of a European battle.

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