

# The EU and pharmaceutical parallel trade: an actor-based analysis of EU-level policy outcomes

By  
Lídia Szabó

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Supervisor: Professor Annabelle Littoz-Monnet

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## ***Abstract***

My research project attempts to show why the pharmaceutical manufacturers have not been able to impose their preferences at the EU level in the policy-process of parallel trade. Pharmaceutical manufacturers have well-organized interest representation in Brussels, and the lobby power of the industry is high. Therefore, it is a puzzle why the voice of the manufacturers has not been heard yet in the policy process, why they cannot achieve the elimination of the parallel trade of medicines. Additionally, theoretical analysis about the role and contribution of interest groups in the policy-process of parallel trade is missing, which could be edifying for the stakeholders.

I use the Policy Network Approach in my research. First, I investigate the positions of the interest groups and their allies. Next, I discuss and explain the policy outcomes, and I analyze the lobby strategy of the pharmaceutical manufacturers with the help of the literature of interest groups. Next, I add the approach of Scharpf on negative integration to my explanation to get a broader understanding of policy outcomes.

My research concludes that the Policy Network Analysis is a constructive approach to the study of the EU policy making, as it can shed light on the fact that the activity of interest groups has influenced deeply the policy-process of parallel trade. However, the lobby strategy of manufacturers lacks efficiency. Furthermore, they aim at positive integration, which is difficult to reach at the EU level.

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# INTRODUCTION

The phenomenon of parallel trade is well-known in the pharmaceutical market within the EU. A debate about the legacy and constraints of the parallel trade has emerged within the European Commission since 1982<sup>1</sup>. According to the Commission, pharmaceutical parallel trade is a lawful form of trade within the EU<sup>2</sup>. The pharmaceutical markets in the member states are differently regulated because of the different health care systems. Furthermore, the level of GDP is also different in each European state. Thus, there are price differences between member states regarding medicines. Parallel trade is based on the different price level of EU member states, under the principle of free movement of goods in the internal market. Parallel trade covers the activity of firms which buy original pharmaceutical products produced genuinely under intellectual property right protection<sup>3</sup> in a lower price country, and sell them in a higher price country in parallel with the manufacturer's normal distribution channel. Parallel import decreases the profit of the pharmaceutical manufacturer, and the latter are therefore interested in forbidding the activity.

## Research question

My research project will attempt to show why the voice of pharmaceutical manufacturers has not been heard yet in the policy-process of parallel trade. The research question is very interesting knowing that the goals of the Lisbon Strategy emphasize the need to increase competitiveness within the EU, where the well-running pharmaceutical sector should play an important role. Therefore, the pharmaceutical sector is considered as

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<sup>1</sup> COM (1982) Pharmaceutical Parallel Trade, OJ C 115 of 6.5.1982

<sup>2</sup> COM (2003) 839, Pharmaceutical Parallel Trade, [http://eur-lex.europa.eu/LexUriServ/site/en/com/2003/com2003\\_0839en01.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/com/2003/com2003_0839en01.pdf), 12. 03. 2006

<sup>3</sup> Enemark, U. And others, 'The economic impact of parallel import of pharmaceuticals', CAST - Centre for Applied Health Services Research and Technology Assessment (2006), [http://www.cast.sdu.dk/pdf/Parallel\\_import\\_rapport\\_13\\_06\\_1430\\_opdateret\\_final.pdf](http://www.cast.sdu.dk/pdf/Parallel_import_rapport_13_06_1430_opdateret_final.pdf), 10.11.2006, p. 10

strategically important in the EU, thus the lobby power of pharmaceutical manufacturers is expected to be high. Furthermore, manufacturers of the pharmaceutical sector have a well-organized lobby organization in Brussels. Additionally, theoretical analyses of the role and contribution of interest groups in the policy-process of parallel trade is missing. Thus, it is interesting to analyze why the voice of the pharmaceutical manufacturers has not been heard yet in the policy process of parallel trade.

### **Debate and gap**

This dissertation aims to explain why the lobby of the manufacturers could not impose its preferences at the EU level. Therefore, in the literature of interest groups I look for an answer how an interest group can successfully influence. The Policy Network Approach provides a useful theoretical framework for analyzing the activity of interest groups and their contribution to the policy processes. It is the appropriate framework to analyze policy communities within the EU as it views the EU policy model through an actor-based stakeholder perspective emphasizing the role of ideas, knowledge and expertise besides the importance of the interests of the actors. It highlights the role of informalities within the interactions, where public and private actors aim to solve problems of collective action. In the policy process of the pharmaceutical parallel trade, informal communication, ideas and economic interests play an active role besides of the opinion of experts, which strengthen the position of the interest groups.

The literature of interest groups states that the multi-level governance of the EU created a multi-layered system of interest groups. Successful interest groups have to be well-organized and possess human, political-economic, financial and informational resources<sup>4</sup>. Additionally, the group has to deal with a strongly communitarized and narrow focused policy by influencing policy formation. Interest groups have to be actively involved in the whole

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<sup>4</sup>Lehmann, W. 'Lobbying in the European Union: Current rules and practices', *Working Paper, Constitutional Affairs Series, AFCE 104 EN*, Directorate-General for Research (2003)

policy process to reach beneficial policy outcomes. However, as Greenwood states, ‘The EU political system is one in which no one type of interest can routinely dominate.’<sup>5</sup> The multiple level of EU policymaking and the diffusion of power between institutions create a complex system, where different policy issues define the dominant groups.

Although the lobby of pharmaceutical manufacturers is a well-organized interest organization, the group of manufacturers could not reach their objective during the policy-process of the pharmaceutical parallel trade; thus, parallel trade is still a legal activity in the EU.

## **Methodology**

I will rely on different sources consisting of background papers, conference papers, speeches, action plans, and articles of the pharmaceutical manufacturers’ interest group and of the policy network which is promoting pharmaceutical parallel trade. At the same time, an important part of my research will focus on analyzing primary sources of the EU Law, such as informal Commission guidelines and case law<sup>6</sup> in order to understand the principles on which decisions are made related to parallel trade. Since theoretical analyses of the role and contribution of interest groups in the policy-process of parallel trade is missing, I will base my analysis on the materials published by interest groups and EU institutions mainly on their websites.

The content analysis and the comparative text analyses are the best approaches to answer my research question because the research will be based on the formal and informal expressions of lobby activity of two opposing coalitions. Furthermore, the cases of the ECJ require content analyses to understand the decisions of the Court and to make predictions why the voice of the manufacturers’ groups has not been heard yet.

## **Limitations**

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<sup>5</sup>Greenwood, J. *Interest Representation in the EU*. Basingstoke: Palgrave Macmillan, (2003)

<sup>6</sup> ECJ rulings on parallel trade, [http://www.paralleltrade.pl/orzeczenia\\_ets.php?lang=en](http://www.paralleltrade.pl/orzeczenia_ets.php?lang=en), 04. 04. 2007

The primary shortcoming of the method is that there might be overstated arguments in the documents and press releases of interest groups. To gain an insight into the role of interest groups in the policy-process, I will use the triangulation technique.

### **Contribution**

The research will make a worthwhile contribution to the field in several ways. First, I will shed light on interesting aspects of policy-making process in the field of parallel trade. It is a field that was never looked at the policy network approach. Second, it will contribute to the literature on the role of interest groups in the EU policy-making process. The research will conclude that the activity of interest groups has influenced deeply the policy-process of parallel trade, but the voice of the manufacturers' interest group has not been heard yet because their lobby strategy lacks of efficiency since they could not establish an enough powerful policy network. Furthermore, the group of manufacturers aims to set up more binding rules of trade within the EU, which is not easy to reach at the EU level.

# I. THEORETICAL INTRODUCTION

## 1. *The Policy Network Approach*

### 1.1. ORIGINS OF THE POLICY NETWORK APPROACH

The policy network approach originated in the UK<sup>7</sup>. With the growing complexity of EU policy processes political scientists have begun to use the approach in order to better understand the nature of policy processes in the EU since 1970's. According to Peterson, the policy network approach has been applied for the study of the EU because the development of the political system of the European Union 'gave rise to new and different forms of governance, in which power was increasingly shared horizontally'<sup>8</sup>. To understand non-hierarchical forms of governance where the informalities of the policy process become key, the policy network approach seems to be the appropriate framework to analyze the nature of policy processes within the EU.

The emergence of policy network approaches also came along with the acknowledgement that grand theories of European integration had failed to ask all of the questions which have emerged in contemporary European integration, because 'neofunctionalism and intergovernmentalism were not able to capture the sheer complexity of the emerging European polity'<sup>9</sup>. The added value of the policy network analysis to the study of the EU is that it can focus on singular moments of changes, and it

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<sup>7</sup> Richardson, J. 'Policy-making in the EU, Interests, ideas and garbage cans of primeval soup', in Richardson, J. (ed.) 2007. *European Union, Power and Policy-making*, Routledge (2007), p. 3-27. pp. 4

<sup>8</sup> Peterson, J. 'Policy Networks' in Wiener, A. and Diez, T. (eds.) in *European Integration Theory*, Oxford University Press (2004) pp. 123

<sup>9</sup> Rosamond, B. 'Theorizing the 'New Europe'', *Theories of European Integration*, Palgrave (2000), p. 98-128, pp. 105



can describe the dynamics of integration, unlike grand theories of International Relations, which neglect the day-to day patterns of politics<sup>10</sup>. As Hix argues, it is absurd to look for a general theory of the EU, one has to make a distinction between macro-level and middle-range theories<sup>11</sup>, which might supplement each other. Therefore, the policy network approach with its focus on the daily policy-making is a meso-level theory; unlike grand theories, it does not focus on integration but on European governance. According to Majone, the study of the EU turned from the integration studies towards the European governance<sup>12</sup>, the application of the policy network approach to the study of the EU supports his view. In sum, there was a need to create a new theoretical approach in order to grasp a better understanding of policy-making within the EU.

## 1.2 CRITIQUE OF THE POLICY NETWORK APPROACH

The policy network approach has been mainly criticized for not being a theory. However, as Peterson states, theorizing about policy networks is in an early stage, that is the reason for it cannot answer important questions about EU governance. At least, the approach can highlight the fact that the answers related to EU governance might be found in the subsystems of policy-making<sup>13</sup>.

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<sup>10</sup> Rosamond, B. 'Theorizing the 'New Europe'', *Theories of European Integration*, Palgrave, (2000), p. 98-128, pp. 106

<sup>11</sup> Hix, S. 'Comparative Politics, International Relations and the Study of the EU', *West European Politics*, 19 (1996), p. 386-402, pp. 390

<sup>12</sup> Majone, G. *Dilemmas of European Integration*, The Ambiguities and Pitfalls of Integration by Stealth, Oxford University Press, (2005), p. 1-257

<sup>13</sup> Peterson, J. 'Policy Networks' in Wiener, A. and Diez, T. (eds.) in *European Integration Theory*, Oxford University Press (2004) pp. 123

Kassim forms serious criticism towards the policy network approach, stating that there is 'little continuity and much fragmentation' in the EU policy process, thus the policy network approach might not be a useful tool for the analysis of EU policy outcomes because it is based on the continuous activity of groups in the policy processes<sup>14</sup>. However, stability is not assumed as a condition of the approach. Peterson states that the policy network approach aims to identify the nature of fluidity<sup>15</sup>. The continuous activity of the groups on different policy stages enable to get a more detailed view about the complex nature of policy making. The fluidity is reflected in the different forms of the policy networks during the policy process, where interest groups aim to maximize their power of influence.

Furthermore, Kassim claims that the policy network approach neglects the role of formal institutions<sup>16</sup>. His statement might be rejected if we consider the policy network approach as a meso-level theory which aims to describe the dynamism of day-to-day politics, the role of the subsystems seems to be also very important besides the formal institutions. The added value of the approach is that it focuses on informal institutions and subsystems besides of the formal way of decision-making.

### 1.3. DEFINITIONS OF THE POLICY NETWORK

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<sup>14</sup>Rosamond, B. 'Theorizing the 'New Europe'', *Theories of European Integration*, Palgrave (2000), p. 98-128, pp. 124

<sup>15</sup>Peterson, J. 'Decision-Making in the European Union: Towards a Framework for Analysis', *Journal of European Public Policy*, 1995 2:1, p. 69-93.

<sup>16</sup>Kassim, H. 'Policy Networks, Networks and European Union Policy-Making: A Skeptical View', *West European Politics*, 1994 17, 4, p. 15-27.

According to Rhodes, the EU is a ‘differentiated polity’<sup>17</sup>, where different policy issues are handled by different decision rules and with the participation of different dominant actors. The complex nature of the EU policy process requires the involvement of a large number of actors ‘persuading them to move from the status quo to a new policy settlement’<sup>18</sup>. The high density of interactions of the numerous actors within different policy issues creates policy networks. As Kohler-Koch states, policy communities emerge on behalf of the deep segmentation of policy process and the highly specialized nature of policy issues which require close cooperation among the experts<sup>19</sup>. Negotiations within one policy process take a long time, thus the continuous interactions contribute to the emergence of policy networks.

According to Peterson, a policy network is ‘an arena for the mediation of the interests of government and interest groups’<sup>20</sup>. As Rosamond emphasizes, policy networks are mainly ‘understood as venues for the pooling and exchange of information and resources’<sup>21</sup>. Additionally, Peterson and Bomberg state that a policy network is a ‘cluster of actors, each of which has an interest, or ‘stake’ in a given policy sector and the capacity to help determine policy success or failure’<sup>22</sup>. However, Börzel uses the a broader definition of policy network, saying that networks are ‘relatively stable

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<sup>17</sup>Rhodes, R. A. W., Ian Bache, and Stephen George. ‘Policy Networks and Policy Making in the European Union: A Critical Appraisal’, in Hooghe, L. (ed.) 1996. *Cohesion Policy and European Integration: Building Multi-Level Governance*, Oxford: Oxford University Press (1996), p. 367-387

<sup>18</sup>Richardson, J. ‘Policy-making in the EU, Interests, ideas and garbage cans of primeval soup’, in Richardson, J. (ed.) 2007. *European Union, Power and Policy-making*, Routledge (2007), p. 3-27, pp. 6

<sup>19</sup>Kohler-Koch, B. ‘Organized Interest in the EC and the European Parliament’, *European integration online Papers*, Vol. 1 (1997) No. 009., pp. 7

<sup>20</sup>Peterson, J. ‘Decision-Making in the European Union: Towards a Framework for Analysis’, *Journal of European Public Policy*, (1995) 2:1, p. 69-93.

<sup>21</sup>Rosamond, B. ‘Theorizing the ‘New Europe’, *Theories of European Integration*, Palgrave (2000), p. 98-128, pp. 124

<sup>22</sup>Peterson, J. and Bomberg, E, *Decision-Making in the European Union*, New York: St. Martin Press (1999), pp. 8

relationships which are of non-hierarchical and interdependent nature linking variety of actors, who share common interest with regard to a policy and who exchange resources to pursue these shared interests acknowledging that cooperation is the best way to achieve common goals'<sup>23</sup>. In this dissertation I will use the definition given by Börzel. The essential characteristics of policy networks, according to her definition, are the interdependent nature of the actors, the ability of actors to cooperate in order to reach commonly beneficial goals, and the fact that the members of a network are not only experts and EU officials but can consist of a variety of interested actors.

#### 1.4. TYPOLOGY OF THE POLICY NETWORKS

Policy networks can take different shapes. The most stable form of policy network is the policy community (Richardson and Jordan, 1979)<sup>24</sup>. According to Peterson, a 'continuum emerges with tightly integrated policy communities on one end', which are more easily capable for collective action, and 'loosely affiliated issue networks on the other'<sup>25</sup>, which are not easy to mobilize for collective action. One can distinguish policy communities from issue networks (Heclo, 1978)<sup>26</sup> by comparing the membership of the two networks. Namely policy communities have a limited number of members, whereas issue networks are larger and more fluid. Furthermore, in the policy communities all

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<sup>23</sup>Börzel, T. 'What's So Special About Policy Networks? – An Exploration of the Concept and Its Usefulness in Studying European Governance', *European Integration online Papers* Vol. 1 (1997) No. 016, pp. 1

<sup>24</sup> Richardson, J. and Jordan, G. *Governing under Pressure: The Policy Process of a Post-Parliamentary Democracy*, Oxford: Martin Robertson (1979)

<sup>25</sup>Peterson, J. 'Policy Networks' in Wiener, A. and Diez, T. (eds.) in *European Integration Theory*, Oxford University Press (2004) pp. 120

<sup>26</sup> Heclo, H. 'Issue Networks and the Executive Establishment', in A. King (ed.) *The New American Political System*, Washington DC: American Enterprise Institute (1978)

participants share basic values and accept the legitimacy of outcomes; however, in the issue networks a measure of agreement exists but conflict is ever present. Therefore, the structure of the policy network will have an impact on policy outcomes; well-organized policy communities reach their goals more easily, and they have more resources to control policy agenda.

Additionally, Haas identifies another type of policy network, which is based on the uncertainty of policy-making, where a knowledge-based network of experts can influence policy processes<sup>27</sup>. According to Haas, these ‘epistemic communities may consist of professionals from a variety of disciplines and backgrounds’, they share intersubjective understandings, values and practices, and members of the community ‘have a shared commitment to the application and production of knowledge’<sup>28</sup>. Epistemic communities might be an important source of knowledge towards the decision-makers. Additionally, their activity helps to legitimize the decisions, and influences the policy-processes.

Sabatier works with another type of policy networks, he imagines policy communities as advocacy coalitions. The advocacy coalition framework is also based on the knowledge-interest relationship<sup>29</sup> as in Haas’s approach; but unlike the epistemic communities, advocacy coalitions are more focused on reaching certain policy goals. As he argues, ‘actors can be aggregated into a number of advocacy coalitions composed of people from various organizations who share a set of normative and causal beliefs and

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<sup>27</sup>Haas, P. ‘Introduction: Epistemic Communities and International Policy Coordination.’ *International Organization*, (1992) 46(1): 1-37.

<sup>28</sup>(ibid.)

<sup>29</sup>Rosamond, B. ‘Theorizing the ‘New Europe’, *Theories of European Integration*, Palgrave (2000) p. 98-128, pp. 125

who often act in concert'<sup>30</sup>. Peterson states that it is possible to form coalitions between advocacy coalitions and epistemic communities to shift the policy agenda to a more advantageous direction<sup>31</sup>.

Independent of the nature of the policy network, there is a common understanding about the degree of influence by which a policy network can affect policy processes. The degree of influence depends on the stability of the network, the relative insularity of group, and the strength of resource dependencies<sup>32</sup>. If the network consists of interdependent actors regarding resources, it is more likely that the network can reach its goals. However, if the network has self-sufficient actors, and they can act individually, the motivation for collective action will be smaller.

## 1.5. THE APPLICATION OF THE POLICY NETWORK APPROACH

According to Börzel, the authors of the policy network literature use the approach in four different ways for the study of the EU. Major distinctions can be put between authors who use the policy network as an analytical tool, and who consider the policy networks as a theoretical approach. Furthermore, the literature differs according to whether they treat European governance as a dependent or an independent variable. Table 1 shows the clear distinctions between the different applications of the approach.

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<sup>30</sup>Sabatier, P. 'Advocacy Coalition Framework: Revision and Relevance for Europe', *Journal of European Public Policy*, (1998) 5/1: 93-133. pp. 133

<sup>31</sup>Peterson, J. 'Policy Networks' in Wiener, A. and Diez, T. (eds.) in *European Integration Theory*, Oxford University Press (2004) pp. 121

<sup>32</sup>(ibid.) pp. 123

Table 1. Börzel's approach<sup>33</sup>

	Policy network as <i>analytical tool</i>	Policy network as <i>theoretical approach</i>
<b>European governance as dependent variable</b>  Bottom-up perspective	<b>A.</b> Forms of interest intermediation/ policy outcomes/ policy changes/ processes/ structures of European policy-making  <i>(intergovernmental vs. supranational policy-making)</i>	<b>C.</b> EU as a system of governance without government  <i>(policy networks as a mode of European governance; EU as a new form of modern statehood vs EU as a system of governance beyond the state)</i>
<b>European governance as independent variable</b>  Top-down perspective	<b>B.</b> Impact of European policy-making on the domestic structures of the member states  <i>(strengthening vs. weakening the state)</i>	<b>D.</b> Impact of European integration on the domestic structures of the member states  <i>(transformation do the state from the actor into arena)</i>

The present paper will use the policy network approach as an analytical tool, with the European governance as a dependent variable. The reason for this is that this paper aims to explain a policy outcome of the policy process of the pharmaceutical parallel trade. Furthermore, the majority of authors (Mazey, Richardson, Peterson, Sandholtz)<sup>34</sup> of the policy network approach use the approach in this way: they are mainly interested in the relation between formal institutions and interest groups and the influence of the interest groups on policy outcomes, which is the topic of this paper.

<sup>33</sup>Börzel, T. 'What's So Special About Policy Networks?—An Exploration of the Concept and Its Usefulness in Studying European Governance', *European Integration online Papers* Vol. 1 (1997) n. 016, pp. 29

<sup>34</sup>(ibid.) pp. 11

European governance as an independent variable enables us to analyze the impact of European policy making or European integration on domestic structures, which is not the topic of our analysis. Finally, the policy network analysis will not be used as a theoretical approach, for several reasons. First, it gives too much importance to policy networks, neglecting the role of institutions like the European Commission or national governments in the policy process. Neglecting the role of institutions would overlook crucial aspects of the EU decision making process. Jachtenfuchs shares the view of the authors using the policy network analysis as a theoretical approach, and he argues, ‘if governance of by negotiation is possible, the notion of governance is no longer linked exclusively to the state’<sup>35</sup>. However, the decision rules of the EU secure an important role for the Council and for the Commission.

According to the above stated analytical framework, I highlight the view of different authors of the policy network literature about the lobby activity within the EU. As Mazey states, interest groups exploit new structures to maximize their capacity to their advantage at the EU level, and a ‘dual strategy’ is required to efficient interest representation, which means that lobby activity is needed on both national and supranational level<sup>36</sup>. According to Kochler-Koch, there is a multi-level system of governance in the EU, in which ‘authoritative allocation is a matter of joint decision-making based on multi-lateral organizations’<sup>37</sup>. Therefore, Mazey emphasizes that efficient lobbying requires a multi-track strategy, and multiple access points are needed

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<sup>35</sup> Jachtenfuchs, M. ‘Theoretical Perspectives on European Governance’, *European Law Journal*, (1995), 1, 2: 115-133, pp. 125.

<sup>36</sup> Mazey, Sonia and Jeremy Richardson, ‘Interest groups and the EU policy making: organizational logic and venue shopping European Union’, *Power and Policy-Making*, ed. Richardson, Routledge, (2001), p. 208-227

<sup>37</sup> Kochler-Koch, B. ‘Organized Interest in the EC and the EP’, *European Integration Online Papers*, (1997) Vol. 1, No. 9.



to the venues that the complex EU policy process provides<sup>38</sup>. The multiple access points and continuous interactions among actors enable the formation of policy networks which consist of the members of interest groups and other actors from different institutions EU institutions.

The complexity of the decision-making process and the multiple access points require the cooperation of the interested actors. As Coen argues, successful lobbying might be based on four strategic capacities: the interest group has to identify clear and focused goals; it has to develop relationships and credibility; the nature of the policy process within the EU has to be understood; and the interest group has to look for allies and access<sup>39</sup>. This last point suggests that effective lobbying requires the formation of policy networks, and the degree of influence will depend on the nature of the policy network.

Additionally, Michalowitz gives a framework to the study of the influence of interest groups and policy networks, I will use her approach to my analysis. She concludes that the influence of a group depends on different factors; on the *degree of conflict* between actors and decision-makers; and on the *type of influence* exerted<sup>40</sup>. According to her, 'the degree to which interest groups form advocacy coalitions with other organizations that share their interest or the degree to which interest groups have to fight their cause against a wide range of opposed interest is likely to influence the

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<sup>38</sup> Mazey-Richardson. 'Interest Groups and Brussels Bureaucracy', in Hayward-Menon (eds), *Governing Europe*. Oxford University Press (2003), p. 208-231.

<sup>39</sup> Coen, D. 'Business Interest and European Integration', in: Blame, R., Chabanet, D. and Wright, V. (eds): *L'action collective en Europe*, Sciences Po Press Paris (2002), p. 261-267.

<sup>40</sup> Michalowitz, I. 'Assessing Conditions for Influence of Interest Groups in the EU', *106 of Political Science Series*, Institute for Advanced Studies, Vienna (2005)

strength of an opinion voiced to alter a legislative act.<sup>41</sup> Therefore, it is beneficial if the initial opinion of the decision-makers and the interest group or the broader policy network about the policy issue is almost the same, because it will be easier to amend the process from that position.

Additionally, we can distinguish three types of influence. First, the ‘directional influence’ is expected by the highest degree of conflict, where the actors aim to alter the core content of the legislative act. Such influencing activities are mainly unsuccessful. Second, the ‘technical influence’ focuses on changing the details of a legislation act, which might be easily successful. And finally, the best strategy is to ‘influence the agenda-setting’ because if interest groups can successfully influence in the initial phase of the policy process, no further altering is necessary<sup>42</sup>.

In this paper I will analyze the different stages of the policy process of pharmaceutical parallel trade. I will focus on the failures of the lobby strategy based on the interest groups literature. I will add to the analysis Michalowitz’s factors of influence, because the contribution of the policy networks might be measured by their degree of influence on decision-makers.

## **HYPOTHESIS I.**

The manufacturers cannot impose their preferences related to parallel trade at the EU level because the conflict of interest between decision-makers’ and manufacturers’ opinion has been too high. Furthermore, the type of influence (‘directional influence’) they have used is mainly unsuccessful in influencing. Additionally, there was a problem

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<sup>41</sup> (ibid.) pp. 7.

<sup>42</sup> (ibid.) pp. 10.

of timing their activity, since the policy-process of parallel trade has begun before the interest group of manufacturers has been established. Therefore, they could not influence the agenda-setting phase, which is the most important part of the policy-process. Moreover, coalition-building has not been efficient enough since the group of parallel traders has more powerful supporters and better access to the venues that the complex EU policy process provides.

## **2. Positive and negative integration**

As stated above, the policy network approach bears certain limitation. In particular, the role played by institutions is left out. Therefore, I will use Scharpf's approach about the positive and negative integration. Within the EU, the logic of the institutional system promotes a negative type of integration. Positive integration, defines as creating common forms of administration is by contrast more difficult to implement.

According to Scharpf, negative integration refers to the reduction of barriers of trade or different national regulations in order to harmonize national legislation<sup>43</sup>. As Scharpf states, the commitment of the member states to create the Common Market has been ratified by national parliaments, and the doctrine of the supremacy of EU law has been established through the decisions of the Court of Justice<sup>44</sup>. Therefore, the Court of Justice and the Commission could expand the scope of negative integration without the

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<sup>43</sup> Scharpf, 'Negative and Positive integration in the Political Economy of European Welfare States', in: Gary Marks (ed.) *Governing in the European Union*. London: Sage (1996), p. 15-39

<sup>44</sup> Scharpf, Fritz W. 'Balancing Positive and Negative Integration: The Regulatory Options for Europe', *MPIfG Working Paper* 97/8, November 1997, pp. 2.

participation of the Council of Ministers, which might block or slow down the policy process.

Additionally, the positive type of integration means the creation of new common formal and informal institutions, which brings new binding rules for the member states. The institutional logic of the EU with the unanimity voting makes it difficult to set up new common rules. However, the system of the Qualified Majority Voting (QMV) has facilitated the process of decision-making in the Council of Ministers since the Single European Act of 1986, the veto power remains available for countries, and the unanimity rule is still present in a lot of decisions of the Council. Therefore, it is rather difficult to take decisions in the Council of Ministers.

Thus, negative integration can more easily occur within the EU than positive integration. If the Commission and the Court are in favor of the specific policy issue which requires negative integration, the process of negative integration can take place without the agreement of the Council of Ministers.

## **HYPOTHESIS II.**

The voice of the pharmaceutical manufacturers has not been heard yet because they are interested in policy outcomes that would have required positive integration. However, it is not easy to reach positive integration within the EU.

## II. Positions of different policy networks

The policy process in the field of pharmaceutical parallel trade is mainly influenced by two policy networks. The first group aims to eliminate parallel trade. The most proactive group within this network is the European Federation of Pharmaceutical Industries and Associations (EFPIA), which is the interest group of the manufacturers. The second group supports and tries to secure the process of parallel trade. The group's interests are better represented by the group of parallel traders, the European Association of Euro-Pharmaceutical Companies (EAEPC), which is the leader of the process.

### 2.1. Policy network of the manufacturers

The group of the manufacturers aims to eliminate parallel trade in order to increase the competitiveness of the pharmaceutical sector within the EU<sup>45</sup>. The manufacturers state that parallel trade reduces the profit of innovative firms, making the climate of the EU less attractive for research and development. According to statistics published by EFPIA<sup>46</sup>, the pharmaceutical industry is losing competitiveness compared to the USA and Japan<sup>47</sup>. Additionally, EFPIA explains that the reason for that is the activity of parallel trade<sup>48</sup>.

<sup>45</sup>Humer, F. B. 'A Tainted Trade', *European Pharmaceutical Executive*, Nov/Dec 2005, <http://www.efpia.org/Objects/2/Files/EPE11-LastWord-Humer-3ABC5.pdf>, 02.02.2007

<sup>46</sup> The Pharmaceutical Industry in Figures, 2006, Published by EFPIA, <http://www.efpia.org/Objects/2/Files/infigures2006.pdf>, 12. 03. 2006

<sup>47</sup>Parallel trade, from the WebSite of EFPIA, <http://www.efpia.org/content/default.asp?PageID=171>, 03.03.2007

<sup>48</sup> Kanavos, P and others. 'The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis', *Special Research Paper*, LSE Health and Social Care London School of Economics and Political Science, <http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/Workingpapers/Paper.pdf>, 11.11.2006

The European Association of Full-line Wholesalers (GRIP) shares the view of the EFPIA about the policy issue, it supports the activity of the manufactures against parallel trade. There are two reasons why GRIP agrees on this policy issue with the manufacturers. First, the wholesalers and manufactures have interdependent business relationships, the strategic partnership requires the support each other's goals, and wholesalers can help to create physical obstacles for the practice of parallel trade.

Second, as parallel traders sell, for example, Greek products for English patients, parallel traders have to repack the products and give information about the products in English. According to the groups of manufacturers, the process of repacking increases the opportunity of counterfeiting pharmaceutical products, and it can damage the quality of the products, threatening the reputation of the brands. Therefore, parallel trade is considered as an additional opportunity for counterfeiting, and the fight against counterfeiting is also important for the wholesalers.

The group of consumers (BEUC) also supports also the view of the manufacturers in this policy issue. Parallel trade helps price harmonization on the pharmaceutical market within the EU, but the group of consumers does not see price harmonization as bringing 'substantial benefits' to end-users. Besides they share the view of the wholesalers that parallel trade means an additional threat for the spread of counterfeited products<sup>49</sup>.

The EFPIA has some additional arguments why to eliminate parallel trade within the EU. Pharmaceuticals should be exempted from the free movement of goods because of the high innovation cost of the originalities, besides the safety reasons. The high

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<sup>49</sup> Parallel trade in medicines, Eurarchiv.com, Published: Tuesday 17 August 2004, Updated: Friday 8 September 2006, <http://www.euractiv.com/en/health/parallel-trade-medicines/article-117528>, 11.11.2006

quality of medicines has to be ensured by a closed system of suppliers in order to protect the health of the patients. The patent rights should secure enough time to the recovery of the innovation costs for the manufacturers, while the principle of the free movement of goods enables the existence of further distribution channels in the national markets besides the manufacturer's one, creating obstacles for the manufacturer for maximizing his benefits of patent right. Additionally, parallel trade can create shortages on the parallel export markets, which may impede the access of the patients to medicines.

In sum, 'EFPIA considers that the European Commission is taking an overly formalistic approach in applying the EC competition rules to protect parallel trade where such a rigid approach is not warranted in the case of price-controlled pharmaceuticals'<sup>50</sup> The aim of the groups of manufacturers is the artificial partitioning of the internal market of pharmaceutical products in order to eliminate parallel trade and increase the competitiveness of the sector. EFPIA seeks to attract pharmaceutical R&D within Europe and support the rewarding of pharmaceutical innovation.

The group of manufacturers has supporters among the actors of the EU institutions and member states. At the beginning of the policy process the European Parliament voted against the Commission's initiations to set up price harmonization within the EU on the pharmaceutical markets, as the member states have not been ready to cede competences to the EU level in the health sector. The European Parliament argued with the importance of the subsidiary in this question<sup>51</sup>. However, the completion of the internal market has been a more important policy issue since the 1970s, and there

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<sup>50</sup>European Federation of Pharmaceutical Association (EFPIA) (2005) Parallel trade in medicines, [www.efpia.org/content/Default.asp?PageID=171](http://www.efpia.org/content/Default.asp?PageID=171), 04.03.2007

<sup>51</sup>Permanand, G. and Mossialos, E. 'Theorising the Development of the European Union Framework for Pharmaceutical Regulation', *LSE Health and Social Care Discussion Paper Number 13* (2004), p. 1-42, pp. 29

are still lots of members of the European Parliament who oppose the practice of parallel trade considering consumer protection, safety issues or business interest of the pharmaceutical manufacturers. Within the Commission no specific DG supports the elimination of parallel trade however, DG Enterprise considers it as high priority to increase the competitiveness of the pharmaceutical sector<sup>52</sup>.

Since pharmaceutical prices are high in the UK and Germany, they are the main targets of parallel importers. These two member states oppose the legacy of parallel trade, because it reduces the profit of manufactures, shifting additional income for traders, decreasing the competitiveness of manufacturers in these countries. Therefore, the Association of the British Pharmaceutical Industry (ABPI) is also opposed to parallel trade as is the national association of German manufacturers<sup>53</sup>.

The interdependent interests of the above-mentioned policy actors create a policy network with the aim to eliminate parallel trade in the EU. The shared values and interests of the policy network help collective action and participation of these actors in the policy process of the parallel. On behalf of the common goal, the members of the policy network have to cooperate. Additionally, EFPIA is an experienced organization with numerous successful lobby projects<sup>54</sup> and with a lot of allies besides its strong arguments related to parallel trade, so it is a puzzle why the voice of the group of manufacturers has not been heard yet in the policy process of parallel trade.

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<sup>52</sup> Interview (online) with Christophe de Callatay, EFPIA Communication/PR Manager, 27.04. 2007

<sup>53</sup> Association of the British Pharmaceutical Industry (ABPI) (May 2006) Parallel trade in medicines, [http://www.abpi.org.uk/press/media\\_briefings\\_06/Green\\_parallel\\_trade06.pdf](http://www.abpi.org.uk/press/media_briefings_06/Green_parallel_trade06.pdf), 04.04.2007

<sup>54</sup> Greenwood, J. 'Pharma and Biotech: Virtues and Trends in EU Lobbying' in Pedler, R. H. and M.P.C.M. Van Schendelen (eds), *Lobbying the European Union*, Dartmouth Publishing Company (1994), p. 183-199, pp. 186



## **2.2. Policy network of the parallel traders**

The leader of the opposing policy network is the EAEPC, who bases its arguments on the principles that parallel trade causes cheaper prices, increases competition and helps to complete the internal market by its price equalization effect<sup>55</sup>. Therefore, parallel trade is beneficial for the patients and health systems because of the increased savings, while ‘it redistributes only small parts of the industry profits towards member states and consumers’<sup>56</sup>. Additionally, parallel traders have to repack products, which is an additional quality control, it brings an extra layer of safety into the supply chain.

The group of parallel traders enjoys the support of the Commission, as DG Competition, DG Enterprise and Industry, DG Internal Market and Services and DG Information Society and Media are in favor of market liberalization, the completion of internal market, and the free movement of goods and services. As Commissioner Mario Monti states, ‘leaving aside the details, we take the view that the industry is wrong first and foremost - in contending that parallel trade in medicines even harms consumers and secondly in arguing that the Commission's policy brings no benefits at all for consumers in the high price countries’<sup>57</sup>. Parallel traders only with the support of these very powerful DGs would already form an influential policy network. However, they have also other supporters.

The European Brand Association (AIM) is also in favor of parallel trade, since it is interested in the exhaustion of property rights within EU. There is a growing

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<sup>55</sup> Enemark, U. And others. ‘The economic impact of parallel import of pharmaceuticals’, CAST - Centre for Applied Health Services Research and Technology Assessment, (2006), [http://www.cast.sdu.dk/pdf/Parallel\\_import\\_rapport\\_13\\_06\\_1430\\_opdateret\\_final.pdf](http://www.cast.sdu.dk/pdf/Parallel_import_rapport_13_06_1430_opdateret_final.pdf), 10.11.2006

<sup>56</sup> Parallel trade in medicines, Eurarchiv.com, Published: Tuesday 17 August 2004 | Updated: Friday 8 September 2006, <http://www.euractiv.com/en/health/parallel-trade-medicines/article-117528>, 11.11.2006

<sup>57</sup> Speech of Mario Monti on Parallel trade, [http://www.paralleltrade.pl/cel\\_dzialania.php](http://www.paralleltrade.pl/cel_dzialania.php), 03.04.2007

international pressure on the EU to a global exhaustion of property rights, which would harm the European knowledge-based industry. As part of its strategy, in order to avoid the global exhaustion of property rights, AIM supports the

‘exhaustion of trade mark rights within the European Economic Area because it enables goods to circulate freely through the EEA as one single market, it offers consistent consumer protection within that market whilst preserving EU achievements in environmental and social protection, and it allows the returns from innovation to go to the innovators’<sup>58</sup>.

AIM is satisfied with the current level of protection of innovative products within the EU. Therefore, as parallel trade contributes to the exhaustion of property rights within the EU, AIM supports the practice of parallel trade.

The Netherlands and Denmark are the strongest supporters of parallel trade among the member states, because they regard parallel trade as the reducer of health costs. Additionally, both countries are in favor of liberal economic policies, which promotes the elimination of the national barriers of trade. Therefore, on behalf of these two reasons they are strongly interested in the free movement of goods and parallel trade.

In sum, parallel traders and its allies also form also a strong policy network, and the activity of this policy network seems to be more successful regarding the present situation of the policy process of parallel trade, as pharmaceutical parallel trade is a legal activity in the EU. Additionally, the most important difference between the two policy network is that more powerful DGs are the supporters of the parallel traders. However, the group of manufacturers does not enjoy the support of any DGs.

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<sup>58</sup> AIM Web, Overview, [http://www.aim.be/polandpub/polandpub\\_main.html](http://www.aim.be/polandpub/polandpub_main.html), 03.03. 2007

### III. Policy outcomes

The following review of the policy outcomes related to parallel trade is chronologically organized. The practice of parallel trade began with the De Peijper case in 1974, when the ECJ delivered a judgment that states that parallel trade is a legal form of trade within the EU<sup>59</sup>. This judgment defined the later decisions of the ECJ and strongly influenced the opinion of the actors of the EU. Therefore, the Commission published a Communication related to parallel trade in 1982<sup>60</sup>, where it provides a practical guideline for parallel traders based on the De Peijper judgment of the ECJ and the Directive of the Council about the free movement of goods<sup>61</sup>. In the following years, a broad discussion began about the free movement of medicines and pricing within the EU, with the active participation of the stakeholders.

As a next step, the Commission has further pursued the harmonization of the pharmaceutical markets within the EU and planned to issue a Directive in 1986. As a rule, harmonization might happen with a focus on the reimbursement systems of the member states, or through price harmonization. Hence, the EU competence is limited in the field of health; the Commission can only promote the creation of the European pharmaceutical market by price harmonization<sup>62</sup>. Additionally, the issue of price harmonization has not been supported by the stakeholders because companies feared that

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<sup>59</sup> Case 104/75 De Peijper (1976) ECR 613

<sup>60</sup> OJ No C 115 of 6. 5. 1982, p. 5

<sup>61</sup> Directive 65/65/EEC (OJ No 22 of 9. 2. 1965); Directive 75/318/EEC (OJ No L 147 of 9. 6. 1975); Directive 75/319/EEC (OJ No L 147 of 9. 6. 1975); and Directive 78/25/EEC, (OJ No L 11 of 14. 1. 1978.)

<sup>62</sup> Cucic, S. 'European Union health policy and its implication for national convergence', *International Journal for Quality of Health Care*, (2000), Volume 12, Number 3: 217-225

the 'harmonization forces prices down to the lowest level in any member states'<sup>63</sup>, hitting their profits and risking innovation and employment. Moreover, member states were afraid of price harmonization because prices might be harmonized upwards, which might create problems for the limited health care budgets.

Therefore, the Council approved a Directive in 1989 that was less ambitious than the draft directive issued by the Commission<sup>64</sup>, it does not contain the explicit prospect of price harmonization. However, the Directive refers to 'further progress towards convergence'. The 'Transparency Directive'<sup>65</sup> came into force in 1990, and its importance lies in that it is designed to assure open and verifiable criteria in pricing and reimbursement decisions within member states. This means that member states cannot restrict the import and export of pharmaceutical products through national policies.

After the Transparency Directive, the next step of the policy process was the Commission's Communication of 1993<sup>66</sup>, by which the Commission aimed to identify the common interest of stakeholders. The global competitiveness of the pharmaceutical sector is a common interest of all stakeholders; therefore, since this communication, the argumentation of the Commission about promoting the free movement of goods has been based on the idea that a single market for medicines would increase the competitiveness of the sector.

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<sup>63</sup> Mossialos, Elias, Brian Abel-Smith. 'The regulation of the European Pharmaceutical Industry'. In *New Challenges to the European Union: Policies and Policy-Making*, Ed. Stavridis, Stelios, England: Dartmouth (1997), p. 357-401, pp. 389.

<sup>64</sup> Permanand, G. 'Theorizing the Development of the European Union. Framework for Pharmaceutical Regulation'. *LSE Health & Social Care Discussion paper Number 13*, (2004), [http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DPI13\\_2004.pdf](http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DPI13_2004.pdf), 03.03.2007 p. 29.

<sup>65</sup> 89/105/EEC

<sup>66</sup> COM(93)718, 'Communication on the Outlines of an Industrial Policy for the Pharmaceutical Sector in the European Community'

Additionally, the Bangemann Roundtable, organized by the Commission<sup>67</sup> between 1996 and 1998, was an informal consultation which was intended to offer all stakeholders a platform to express their opinion about the liberalization of the pharmaceutical market. The Commission, industry representatives (EFPIA, and individual companies) and national regulatory authorities, as well as professional organizations took part in the discussion. The discussion covered the topic of liberalization, which would require the abolition of barriers on trade. Therefore, the liberalization of the pharmaceutical market would secure the legal practice of parallel trade. However, on this key topic the interests were too sensitive to concede on. Therefore, the Bangemann Roundtable could not achieve any results related to price harmonization.

In contrast, this discussion of stakeholders about price harmonization and parallel trade had an impact on the Commission: it noted the inefficiencies created by parallel trade<sup>68</sup> in the *Communication on the single market on pharmaceuticals*<sup>69</sup> of 1998. Besides the fact that in this document the Commission emphasizes the integrative force of parallel trade, it mentions the possible negative impacts of the practice. However, the Commission further emphasizes the importance of the completion of the single market, and it published another communication on the practice of parallel trade. According to

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<sup>67</sup> Pharmaceutical policy has been the issue area of Directorate-General Industry until the reform of the European Commission in 1999. Later on it has been shared with the EMEA. DG Social Policy had no competence over pharmaceuticals per se, and currently DG Enterprise is responsible for pharmaceutical policy. (Based on Permanand, G. (2004) 'Theorizing the Development of the European Union. Framework for Pharmaceutical Regulation'. LSE Health & Social Care Discussion paper Number 13)

<sup>68</sup> Permanand, G. 'Theorizing the Development of the European Union. Framework for Pharmaceutical Regulation'. *LSE Health & Social Care Discussion paper Number 13*, (2004) [http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DPI13\\_2004.pdf](http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DPI13_2004.pdf), 03.03.2007

<sup>69</sup> COM (1998) 588 final, Communication of the Commission, Communication on the Single Market in Pharmaceuticals

this Communication of the Commission of 2003 on parallel trade, the parallel trade of pharmaceutical products is a

lawful form of trade within the internal market based on article 28 of the EC Treaty and subject to the derogations regarding the protection of human health and life and the protection of industrial and commercial property, provided by article 30 of the EC Treaty<sup>70</sup>.

Regarding articles 28-30 of the EC Treaty, the activity of parallel trade is based on the principle of the free movement of goods within the internal market<sup>71</sup>. The European Court of Justice has repeatedly stated that 'medicinal products are not exempted from the rules of the Internal Market and has condemned State measures which restrict, without appropriate justification, parallel imports of medicines'<sup>72</sup>. Hence, the parallel trade of medicines helps the creation of a common pharmaceutical market within the EU through its price harmonization effect, which is beneficial according to several decisions of the ECJ<sup>73</sup> and communications of the Commission<sup>74</sup>.

Therefore, the Commission sought to establish a common pharmaceutical market within the EU, which required further steps to reach price harmonization. However, the benefits of parallel trade were still the subject of dispute among the stakeholders. Thus, the Commission established the European High Level Pharmaceutical Forum in 2005 in order to 'improve the performance of the pharmaceutical industry in terms of its competitiveness and contribution to social and public health objectives'<sup>75</sup>. In addition,

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<sup>70</sup> COM(2003) 839 final, Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, 03.11. 2006 pp 2.

<sup>71</sup> (ibid) pp. 6.

<sup>72</sup> (ibid.) pp. 6.

<sup>73</sup> Cases of the ECJ: Case C-143/00, Case C-113/01, Case C-201/94.

<sup>74</sup> COM(1982), COM(1993) 718 final, COM (1998) 588 final, COM (2003) 0839 final

<sup>75</sup> Pharmaceutical Forum, [http://ec.europa.eu/enterprise/phabiocom/comp\\_pf\\_en.htm](http://ec.europa.eu/enterprise/phabiocom/comp_pf_en.htm), 03.03.2007

the objective of the Forum was to reach consensus about highly disputed issues related to health care.

In the activity of the Forum, Ministers from all European member states, representatives of the European Parliament, the pharmaceutical industry, health care professionals, patients and insurance funds are involved. Additionally, three working groups of experts support the work of the Forum, of which one has the specific topic of pricing, which is strongly related to parallel trade. The Pharmaceutical Forum discusses pricing issues ‘that a member state’s authority to regulate pharmaceutical prices should extend only to those medicines purchased by the state’<sup>76</sup>, which is a step toward price harmonization within the EU.

However, the Forum concluded in 2006 that

in order to ensure access of patients and citizens to all medicines there are specific public service obligations for the supply chain. Parallel imports are not part of organized systems of distribution but they can increase price competition and can offer an opportunity for cost-containment in several EU Member States. In other EU Member States, export of these medicines leads to pressure to accept higher prices and possible stock-ruptures. Such parallel trade might shift reward for innovation from industry towards trading parties.<sup>77</sup>

The Forum emphasizes the negative effects of parallel trade on innovation, but it states that the main problem is the partitioning of the European Pharmaceutical market. Without price differences on national markets there would be no parallel trade; however, parallel trade cannot be eliminated because of the principle of the free movement of goods. The Forum will meet two more times in June 2007 and in 2008, the final decision about pharmaceutical prices can be expected by the end of the Forum meetings.

<sup>76</sup> Parallel trade in medicines, Eurarchiv.com, Published: Tuesday 17 August 2004 | Updated: Friday 8 September 2006, <http://www.euractiv.com/en/health/parallel-trade-medicines/article-117528>, 11.11.2006

<sup>77</sup> Pharmaceutical Forum Conclusions, europa.eu/.../06/358&format=PDF&aged=1&language=EN&guiLanguage=en, 03.03.2007

Additionally, there have been more cases of the ECJ in the last three years where manufactueres are obliged to restrict parallel trade because they have appropriate justifications<sup>78</sup>, and the Court has agreed on restrictive practices in these single cases<sup>79</sup>. Although, there are side-payments, the success of single cases cannot satisfy manufacturers, and they are frustrated by the lack on ruling on parallel trade<sup>80</sup>.

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<sup>78</sup> Adalat case (2004), GSK case (2006), <http://www.euractiv.com/en/health/court-demands-details-parallel-trade-pharma-innovation/article-158278>, 03. 03.2007.

<sup>79</sup> Progress Against Parallel Trade *Pharmaceutical Executive*, March 2004, <http://www.users.globalnet.co.uk/~sarahx/articles/mar04.htm>, 03.03.2007

<sup>80</sup> Drug firms frustrated by lack of ruling on parallel trade, Published: Thursday 2 June 2005, Updated: Friday 8 September 2006, <http://www.euractiv.com/en/health/drug-firms-frustrated-lack-ruling-parallel-trade/article-140335>, 03.03.2007.



## IV. Explaining Policy Outcomes

The decision-making process of pharmaceutical parallel trade was analyzed by using Richardson's approach, which divides the policy process into four stages. As there is still discussion among different actors of parallel trade within the EU, the final stage of the policy process has not occurred so far. The policy formation and policy decision phases in the policy process of parallel trade happen simultaneously because there are already several regulations and directives of the European Parliament and the Council besides the communications of the Commission and the rulings of the Court of Justice about parallel trade. However, the issue of parallel trade is still a topic of hot discussions in the EU. Therefore, I analyzed the agenda setting, policy formation and policy decision stages of the policy process of parallel trade, and I did not cover the policy implementation stage of the Richardson's approach. This chapter will argue that four factors can explain current policy outcomes. First, there was a problem with the timing of the lobby strategy. Second, the degree of conflict between the Commission and the group of manufacturers has been too high, and the type of influence they have used has not been the appropriate one. Third, the policy network of manufacturers has not been successful enough in coalition-building. Fourth, the policy network of the manufacturers has been interested in a process which requires positive integration, which is difficult to reach within the EU.

## ***4.1 The Policy Network Approach in the policy process of parallel trade***

### **4.1.1 Timing of lobby strategies**

In the analysis of the policy process of parallel trade with the Policy Network Approach, I first highlight the problem of timing. The practice of parallel trade began with the case of De Peijper in 1974. In the De Peijper case<sup>81</sup>, a Dutch importer sold products from the UK without the approval of the Dutch authority and without product marketing approval documents. The judgment delivered by the ECJ stated that “the authorities are not entitled to require from the importer to provide them with documents which are only available to the manufacturer, especially when these documents were already given to the authorities by the manufacturer”<sup>82</sup>. The ECJ explained that if the manufacturers have a monopoly to sell their products on the markets, the level of social welfare decreases. The level of prices in different member states is dependent on the decision of the manufacturers, and the government decides the final price. However, the parallel traders have an impact on prices in the higher priced countries; the parallel importer sells medicines cheaper than the manufacturer, which pushes the manufacturer, too, to decrease prices. Therefore, the Court concluded that parallel trade is favorable for the consumers, as it increases the consumer surplus.

In this first phase of the policy process, the Court of Justice took a decision where the voice of manufacturers was not heard because the Court did not provide any forum

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<sup>81</sup> Case 104/75 De Peijper (1976) ECR 613

<sup>82</sup> Mossialos, Elias, Brian Abel-Smith. ‘The regulation of the European Pharmaceutical Industry’. In *New Challenges to the European Union: Policies and Policy-Making*, Ed. Stavridis, Stelios, England: Dartmouth (1997), p. 357-401 pp. 381

for interest groups. Additionally, this first ruling of the Court has defined the later phases of the policy process<sup>83</sup>. Therefore, it was disadvantageous for the manufacturers that they could not organize themselves against parallel trade before the decision of the Court was taken. However, the judgment of the Court did not reflect the influence of the policy network of parallel traders, since the group of parallel traders has not been organized at this time, either.

If the network of manufacturers had formed their arguments before the discussion began about parallel trade, they could have influenced the policy process in the agenda-setting phase.<sup>84</sup> The timing of lobby activity is very important because after the initiation phase it is not easy to make relevant changes to the policy. As a group of experts of the pharmaceutical market, they could have had some influence on the first phase of the policy process, but the group of manufacturers organized themselves only later in the EU. However, a successful lobby strategy requires the active participation of the interest group in all of the policy phases<sup>85</sup>.

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<sup>83</sup> (ibid.)

<sup>84</sup> The manufacturers' interest group has been established in 1978, four years later than the decision of the Court came out.

<sup>85</sup> Lehmann, W. 'Lobbying in the European Union: Current rules and practices', *Working Paper, Constitutional Affairs Series, AFCO 104 EN*, (2003), Directorate-General for Research

#### 4.1.2 Degree of conflict between the Commission and the manufacturers

The Policy Network Approach identifies a considerable problem in the later phase of the policy process. According to the approach of Michalowitz<sup>86</sup>, the degree of conflict is high between the actors of the EU institutions and the group of manufacturers. The high degree of conflict makes it difficult for the manufacturers to prevail with their arguments. They have to voice a very strong opinion to alter legislative acts because of the wide range of opposed interests within the EU actors, especially in the Commission. Thus, the high degree of conflict is the reason why the group of manufacturers uses the directional type of influence. According to Michalowitz, 'with type of interest, the degree to which the political core interest of the decision-making institutions in a draft legislative act is touched'<sup>87</sup>. Directional influence aims to alter the core content of the legislative act, this type of influence is used by the 'strongest conflictual potential'<sup>88</sup>. Therefore, it takes enormous efforts to reach success with directional influence, since the well-organized policy network of parallel traders represents opposed interests, and the Commission supports the view of the parallel traders. Thus, directional influence can mainly reach side-payments. In this section, the analysis of the policy process highlights these problems of the manufacturers' lobby strategy.

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<sup>86</sup> Michalowitz, I. 'Assessing Conditions for Influence of Interest Groups in the EU', *106 of Political Science Series*, Institute for Advanced Studies, Vienna (2005)

<sup>87</sup> (ibid.) pp. 9

<sup>88</sup> Michalowitz, I. 'Assessing Conditions for Influence of Interest Groups in the EU', *106 of Political Science Series*, Institute for Advanced Studies, Vienna (2005), pp. 9

The lobby strategy of the manufacturers focuses on the Commission, the aim of the manufacturers being to alter the opinion of the DGs about the practice of parallel trade. The network of manufacturers uses the opportunity to convince the EU actors and to influence the policy process through consultations (for example the Bangemann Roundtable and the Pharmaceutical Forum). Additionally, they voice their strong opinion on formal and informal channels via speeches<sup>89</sup>, public presentations, articles<sup>90</sup>, publications<sup>91</sup> and conferences. According to their lobby strategy, manufacturers try to influence the policy process before the publication of an official document, and they give reflections and feedbacks<sup>92</sup> on formal statements of EU institutions. The policy network of the manufacturers has lobby activity also in the Parliament, but focuses its resources on lobbying the Commission.

The Commission's position was not favorable for the manufacturers in the policy process, which is of key importance because the Commission as the initiator in the policy process is the most powerful actor. Additionally, the creation of a harmonized market for pharmaceuticals has been a longstanding objective of the Commission<sup>93</sup>. It argues that the creation of the single market can increase competitiveness in all the sectors. According to the Commission, parallel trade of medicines facilitates the creation of the single market.

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<sup>89</sup> Speakeasy Interview published in Pharmaceutical Marketing Europe where Brian Ager covers such topics as information to patient, parallel trade, industry's reputation and IMI - September 2006. <http://www.efpia.org/Content/Default.asp?PageID=191>

<sup>90</sup> Pharmaceutical Marketing - Marketing & NHS - EFPIA identifies weaknesses in EU's competitiveness report, <http://www.efpia.org/Content/Default.asp?PageID=191>, 05.05.2007; Ager, B. (2006) 'The right medicine', <http://www.efpia.org/Content/Default.asp?PageID=191>, 05.05.2007

<sup>91</sup> The Research Base Pharmaceutical Industry - A Key Actor for a Healthy Europe by Brian Ager - Article published in Hospital Healthcare Europe - July 2006. <http://www.efpia.org/Content/Default.asp?PageID=191>, 05.05.2007

<sup>92</sup> European Pharmaceutical Industry Determined to Address Parallel Trade of Medicines After Today's European Court of Justice Ruling, [www.euractiv.com/en/health/drug-firms-frustrated-lack-ruling-parallel-trade/article-140335](http://www.euractiv.com/en/health/drug-firms-frustrated-lack-ruling-parallel-trade/article-140335), 04.04.2007

<sup>93</sup> Mossialos, Elias, Brian Abel-Smith. 'The regulation of the European Pharmaceutical Industry'. In *New Challenges to the European Union: Policies and Policy-Making*, Ed. Stavridis, Stelios, England: Dartmouth (1997), p. 357-401, pp. 388.

Furthermore, the Commission has been successful in the policy process in furthering its preferences. However, there are still considerable differences between member states both in the reimbursement and pricing of medicines<sup>94</sup>, and there are plenty of groups which do not aim at price harmonization per se. Analyzing the policy process of parallel trade, it is clear that the Commission uses a step-by-step approach in extending its preferences, which is reflected in its communications and initiatives: it will be shown in four steps. The policy network of the manufacturers has been able to reach only side-payments.

First, the Commission as the guardian of the Treaty states in the Communication of 1982<sup>95</sup> that following the Directives of the Council related to the free movement of goods<sup>96</sup> and considering the De Peijper judgment delivered by the Court, this legal background 'gives the Commission interpretative rulings, enabling it to exercise more stringent checks on the application of the rules of the Treaty on free movement of goods, in particular the provision of Articles 30 to 36 of the EEC Treaty'<sup>97</sup>. Therefore, the Communication provides a guideline to the practice of parallel trade, which is the first announced opinion of the Commission about parallel trade.

The group of manufacturers expressed their opinion about the Communication against the legal practice of parallel trade; however their arguments were not heard. One of the reasons why their voice was not heard is that their arguments were critical towards the fundamentals of the Communication. The Commission favors the idea of the free

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<sup>94</sup> Cucic, S. 'European Union health policy and its implication for national convergence', *International Journal for Quality of Health Care*, (2000), Volume 12, Number 3, pp. 217-225

<sup>95</sup> OJ No C 115 of 6. 5. 1982, p. 5

<sup>96</sup> Directive 65/65/EEC (OJ No 22 of 9. 2. 1965); Directive 75/318/EEC (OJ No L 147 of 9. 6. 1975); Directive 75/319/EEC (OJ No L 147 of 9. 6. 1975); and Directive 78/25/EEC, (OJ No L 11 of 14. 1. 1978.)

<sup>97</sup> OJ No C 115 of 6. 5. 1982, p. 278.

movement of medicines; however, the research-based industry opposes it. Therefore, the degree of conflict was too high for a compromise to be found.

Second, the Commission has taken further measures to pursue the harmonization of the pharmaceutical markets within the EU and issued a Directive in 1986. However, the stakeholders strongly opposed the idea of price harmonization. Therefore, since discussion about parallel trade limited the Commission's initiative in price harmonization, the Commission was forced to accept that 'national differences, such as in per capita income and healthcare systems meant that price harmonization was at this stage not realistic'.<sup>98</sup> The policy network of manufacturers has been successful in lobbying at the national level, since the 'Commission could not establish sufficient consensus among the member states to move towards a stricter Community level regime'.<sup>99</sup>

The example of the Transparency Directive shows that policy networks can influence decision-making, and they can reach amendments on policy issues. However, manufacturers could only prevent price harmonization but not the restriction of the practice of parallel trade. The Transparency Directive is not a success for the manufacturers because they could reach only side-payments, as the conflict of interest between the Commission and the manufacturers is still high.

The high degree of conflict between the Commission and the manufacturers is based on the fact that price harmonization would mean the end of parallel trade, but the

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<sup>98</sup> Permanand, G. 'Theorizing the Development of the European Union. Framework for Pharmaceutical Regulation'. *LSE Health & Social Care Discussion paper Number 13*, (2004), [http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DPI13\\_2004.pdf](http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DPI13_2004.pdf), 03.03.2007

<sup>99</sup> Mossalios, E. *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality*, Open University Press: (2004), pp. 60

most important aim of the manufacturers is the partitioning of the European pharmaceutical market as long as the national systems of health care remain different. However, the competence of the Commission in health issues is limited by Community law: and the harmonization of the national health care systems is not the competence of the Commission. Since the roots of the conflict cannot be touched by the Commission, the conflict of interest between the Commission and manufacturers makes it impossible to reach major changes in the policy process. Thus, the network of the manufacturers could influence the process towards the elimination of parallel trade; however, it is not likely that manufacturers can ever reach their final goal. However, the policy network of the manufacturers has been strong enough to prevent a second Transparency Directive, which would have promoted single market in an advanced way<sup>100</sup>.

Additionally, the Transparency Directive also extended the Commission's preferences because it requires transparent and verifiable criteria of the pricing and reimbursement decisions of the member states. Hence, the Directive assures that the import and export of medicines cannot be restricted by national policies. Therefore, the Transparency Directive promotes the single market, although it is not a harmonization directive. It has not created the European pharmaceutical market, but it promotes the free movement of goods, which is the preference of the Commission.

Third, the Commission organized meetings for the stakeholders of pharmaceutical market to pursue the issue of price harmonization and to identify common objectives related to parallel trade. The Bangemann Roundtables were characterized by 'defensive

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<sup>100</sup> Permanand, G. 'Theorizing the Development of the European Union. Framework for Pharmaceutical Regulation'. *LSE Health & Social Care Discussion paper Number 13*, (2004), [http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DP13\\_2004.pdf](http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DP13_2004.pdf), 03.03.2007 p. 29.



position-taking, where the invitees spent more time countering each others' statements than they did explaining their own concerns'<sup>101</sup>. Therefore, on the issue of price harmonization the Bangemann Roundtable could not achieve any results<sup>102</sup>. The EFPIA and its allies could manage to block the Commission's intention of price harmonization due to the strong opinion they voiced. Additionally, the policy network of the manufacturers emphasized the negative impacts of parallel trade on the research based industry. Therefore, the policy network of the manufacturers achieved that the Roundtable could not end in consensus and the Commission could not issue a new directive on price harmonization.

The consequence of the Bangemann Roundtable is that the Commission also noted the inefficiencies created by parallel trade<sup>103</sup> in the *Communication on the single market on pharmaceuticals*<sup>104</sup> of 1998, which is a success for the manufacturers' lobby. Besides the fact that the Commission emphasizes the integrative force of parallel trade, it mentions the possible negative impacts of this practice. The objective of the Commission is still the completion of the single market; however, it is clear that a top-down approach cannot be implemented.

Fourth, the Communication of 2003 further promotes the completion of the single market, and it provides a comprehensive reference to recent judgments of the Court. Additionally, the Communication gives

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<sup>101</sup> Kanavos, P. and Mossialos, E. 'Outstanding Regulatory Aspects in the European Pharmaceutical Market. *Pharmacoeconomics*' (1999), 15(6), p. 519-33.

<sup>102</sup> M. Bangemann, 'Conclusions of Roundtable', Directorate-General III, internal European Commission document, December 1997

<sup>103</sup> Permanand, G. 'Theorizing the Development of the European Union. Framework for Pharmaceutical Regulation'. LSE Health & Social Care Discussion paper Number 13, (2004), [http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DPI13\\_2004.pdf](http://www.lse.ac.uk/collections/LSEHealthAndSocialCare/pdf/DiscussionPaperSeries/DPI13_2004.pdf), 03.03.2007

<sup>104</sup> COM (1998) 588 final, Communication of the Commission, Communication on the Single Market in Pharmaceuticals

guidance on practical applications of the principle of the free movement of goods to national measures relating to parallel imports, from one member state to another, of proprietary medicinal products for which marketing authorizations have already been granted in the member state of destination<sup>105</sup>.

However, the president of the EFPIA still argues that

despite finalization of the important review of the EU pharmaceutical legislation, the core problems faced by the R&D based industry remain. A key demonstration of what is undermining European pharmaceutical competitiveness is parallel trade in medicines<sup>106</sup>.

This example shows that the view of the manufacturers and the Commission did not really get closer; the degree of conflict is still high between the Commission and the manufacturers. However, the Commission is successful in furthering its policy preferences by a step-by-step approach, and the impact of the lobby of manufacturers on Commission is not important.

In sum, the policy network of the manufacturers could slow down the liberalization of the pharmaceutical market due to the strong opinion it has voiced through formal and informal channels within the EU. The lobby strategy of the manufacturers has focused on the Commission, the primary aim of the manufacturers being to convince the Commission about the harmfulness of parallel trade. However, the lobby strategy of the manufacturers has not been successful; the group of manufacturers was not able to convince the Commission and eliminate parallel trade because of at least two reasons.

First, the *degree of conflict* has been high between the Commission and the manufacturers. Since the Commission is in favor of the free movement of goods, the

<sup>105</sup> Parallel trade in medicines, Eurarchive, <http://www.euractiv.com/en//parallel-trade-medicines/article-117528>

<sup>106</sup> PE, European Report, February 2004, Tom McKillop, CEO of AstraZeneca and ex-president of EFPIA, [www.astrazeneca.com/archivist/2004.aspx](http://www.astrazeneca.com/archivist/2004.aspx), 03.04.2007

completion of a single market would increase the competitiveness of the pharmaceutical sector, and the free movement of medicines would facilitate the access of patients to medicines. On the other hand, manufacturers oppose the completion of the single market because of the different per capita income of the member states and different health care systems. Furthermore, parallel trade reduces the profit of the research based-industry; therefore, manufacturers' clear interest is the elimination of the process. Thus, the conflict of interest could not be reduced by the manufacturers, their arguments were not convincing enough for the Commission.

Second, the analysis of the communications and statements of the manufacturers highlights the problem that the *type of influence* which has been used by the manufacturers could not be successful. The 'directional influence' aims to alter the core content of the legislative act, like the strong opinion which has been voiced by the manufacturers. This type of influence is mostly unsuccessful because it is very difficult to achieve major changes in the beliefs of the decision-makers<sup>107</sup>.

#### 4.1.3 Lack of allies in the Commission

Coen emphasizes the importance for interest groups of finding allies<sup>108</sup> within the EU institutions because the institutional actors open new access points to the complex system of the EU policy making. Additionally, as Greenwood states, 'there is little doubt

<sup>107</sup> Michalowitz, I. 'Assessing Conditions for Influence of Interest Groups in the EU', *106 of Political Science Series*, Institute for Advanced Studies, Vienna (2005)

<sup>108</sup> Coen, D. 'Business Interest and European Integration', in: Blame, R., Chabanet, D. and Wright, V. (eds): *L'action collective en Europe*, Sciences Po Press Paris (2002), p. 261-267.

that interest groups are natural constituency of the European Commission<sup>109</sup>, since lobby groups provide information, ideas and support for the Commission. However, the importance of finding allies in the Commission or in the Parliament lies in the fact that the institutional actors can act as interlocutors of the interest of their policy network within the EU institutions. Additionally, it is easier to gain influence on the policy process, if the policy network has members within the EU institutions.

Mazey describes the multi-track strategy of lobbying<sup>110</sup>. It means that the lobby activity has more focus, it targets different institutions within the EU, and also in the member states. The group of manufacturers considers multi-track strategy as important success criteria of lobbying. Therefore, manufacturers have recognized that the policy network can be more powerful if it contains more actors from the EU institutions. Thus, they have lobby activities also in the European Parliament, and they could already convince more MEPs. The role of MEPs in the policy network of the manufacturers is very important; it provides new access points to the venues of the complex EU policy process.

However, the lobby strategy of the manufacturers has been based on finding allies within the Commission. The manufacturers have been aware of the fact that the Commission as the initiator of the policy process has enormous power, and the opinion of the Commission determines the entire policy process. DG Enterprise is involved in the issue of competitiveness of the pharmaceutical industry; thus, they have the most contact

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<sup>109</sup> Greenwood, J. 'Interest Representation in the EU: Demos rules OK?', Arena Research Seminar of 2003, <http://66.102.9.104/search?q=cache:AlUMaEqoa-AJ:www.arena.uio.no/events/papers/Greenwoodpaper.pdf, 05.05.2007>

<sup>110</sup> Mazey, Sonia and Jeremy Richardson. 'Interest groups and the EU policy making: organizational logic and venue shopping European Union', *Power and Policy-Making*, ed. Richardson, Routledge (2001), p. 208-227

with the manufacturers. DG Enterprise shares the view of the manufacturers that it is essential to increase the competitiveness of the industry. However, DG Enterprise agrees with DG Competition, that the completion of single market will raise the competitiveness of the sector<sup>111</sup>. Additionally, more powerful DGs were in favor of the policy network of parallel traders. Thus, none of the DGs supports the view of the manufacturers related to parallel trade<sup>112</sup>.

Consequently, the group of manufacturers does not have enough powerful allies in the institutions of the EU, since the group failed to find interlocutors within the Commission. If they had had more *allies* in the Commission, it would have been easier to achieve changes in the policy process of parallel trade.

## 4. 2 *Negative integration*

The Policy Network Approach bears certain limitations, for example, the role of institutions is left out. Therefore, I use the approach of Scharpf about positive and negative integration to complement the answer provided by the Policy Network Approach. According to Scharpf, the negative type of integration consists of eliminating barriers of trade, while positive integration aims to harmonize national legislation and create common forms of administration<sup>113</sup>.

<sup>111</sup> DG Enterprise: Parallel Trade of Pharmaceuticals; <http://www.euractiv.com/en/parallel-trade-medicines/article-117528>, 05.05.2007;

Consultation of the DG Enterprise with stakeholders, [http://www.eaepc.org/admin/files/eaepc\\_submission\\_to\\_dg\\_enterprise\\_-\\_final.pdf](http://www.eaepc.org/admin/files/eaepc_submission_to_dg_enterprise_-_final.pdf), 05.05.2007

<sup>112</sup> Interview (online) with Christophe de Callataÿ, Communications/Public Relations Manager, EFPIA, 27.04.2007

<sup>113</sup> Scharpf, 'Negative and Positive integration in the Political Economy of European Welfare States', in. Gary Marks (ed.) *Governing in the European Union*. London: Sage (1996), p. 15-39

As Scharpf states, EU decision rules favor liberal policy solutions<sup>114</sup>. First, national parliaments have ratified the commitment of the member states to create single market. Second, the doctrine of the supremacy of EU law has been established through the decisions of the ECJ<sup>115</sup>. Thus, competences related to economic integration have been centralized at the EU level, and exercised by the ECJ and the Commission without the involvement of the member states. Therefore, the ECJ and the Commission could expand the scope of negative integration without the participation of the Council of Ministers in the policy process.

By contrast, positive integration is by contrast more difficult to implement because it requires the consensual agreement of the member states within the Council of Ministers. Voting rules of the Council make it difficult to set up new common forms of administration. However, the qualified majority voting has facilitated the process of decision-making compared to the unanimity voting rule. But the unanimity rule is still present in a lot of decisions of the Council.

Therefore, the logic of the institutional system promotes a negative type of integration. 'Whereas market liberalization strategies can be implemented hierarchically by the ECJ and the Commission, market-correcting mechanism requires consensual agreement among member states'<sup>116</sup>. Thus, the voice of the manufacturers has not been heard, because their objective is to set up new common forms of administration, which requires positive integration.

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<sup>114</sup> Scharpf, 'Negative and Positive integration in the Political Economy of European Welfare States', in. Gary Marks (ed.) *Governing in the European Union*. London: Sage (1996), p. 15-39

<sup>115</sup> Scharpf, Fritz W. 'Balancing Positive and Negative Integration: The Regulatory Options for Europe', *MPIfG Working Paper* 97/8, November 1997, pp. 2.

<sup>116</sup> Littoz-Monnet, A. *The European Union and Culture between economic regulation and European cultural policy*, Manchester University Press (2007)

The policy network of manufacturers aims to eliminate parallel trade, which might happen through several ways, but all of the ways represent forms of positive integration. For example, parallel trade could be eliminated by common rules of trade restriction. By contrast, the policy network of the parallel traders is interested in economic integration, which can be implemented hierarchically by the ECJ and the Commission. Therefore, according to the approach of Scharpf, the network of the manufacturers is in a worse initial position than the policy network of parallel traders.

The Transparency Directive and the directives about marketing authorization represent the types of positive integration in the policy process of parallel trade. However, the numerous rulings of the ECJ (especially the early judgments)<sup>117</sup> promote the free movement of goods principle related to parallel trade which requires negative integration in the member states. Negative integration has happened in the case of the enforcement of the Treaty's rules on competition, and the communication of the Commission also promoted the importance of the completion of a single market through negative integration. Therefore, the policy process of parallel trade also shows that negative integration can more easily happen within the EU.

Additionally, the competence of the Commission in health issues is limited by the Community law. Therefore, the Commission can affect health matters only through indirect channels. First, by the promotion of the single market, the completion of which can lead to increasing competitiveness<sup>118</sup>. Second, the Commission aims to promote a high level of health provision in the EU. Enhancing consumer protection is viewed as an important instrument to reach this objective. The Organon case shows that the

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<sup>117</sup> Case C-143/00, Case C-113/01, Case C-201/94.

<sup>118</sup> COM (2003) 0839 final

Commission reflects a considerable degree of preoccupation<sup>119</sup> with negative integration in these issues.

In the Organon case<sup>120</sup> the Commission initiated a proceeding against the Organon Laboratories because the company tried to restrict parallel trade in the UK. The company's new pricing system on Organon contraceptive pills discards the usual 15% discount for the wholesalers. According to the new system, the discount has been available only for those who sell products only in the UK in order to eliminate parallel trade. The Commission initiated the proceeding under Article 81 EC<sup>121</sup> because the regular business relationship of Organon and the wholesalers leads to an agreement which restricts the function of the market and leads to national divisions of the pharmaceutical market. Therefore, Organon decided to change the new pricing system, and the Commission was no more in the need to take an official decision about the case. However, the case shows that the Commission as the guardian of the Treaties emphasizes the importance of competition rules and pushes negative integration in order to avoid obstacles to parallel trade.

In sum, an additional reason why the voice of the manufacturers has not been heard in the policy process of parallel trade is that manufacturers are interested in a process which requires positive integration. However, as Scharpf states, negative integration can more easily happen than positive integration within the EU because it is only dependent on the intention of the Commission and the ECJ. And as the Commission

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<sup>119</sup> Hooghe, L. and Marks, G. 'The Struggle over European Integration', *Theories of European Integration*, (2000), p. 119-141, pp. 126

<sup>120</sup> Commission decision in Organon. IP/95/1345 'Contraceptive pills: Commission puts an end to discriminatory pricing practices between the UK and the Netherlands', [ec.europa.eu/comm/competition/publications/ra9502en\\_en.pdf](http://ec.europa.eu/comm/competition/publications/ra9502en_en.pdf), 05.05.2007

<sup>121</sup> Article 81 of the EC Treaty, [http://ec.europa.eu/comm/competition/legislation/treaties/ec/art81\\_en.html](http://ec.europa.eu/comm/competition/legislation/treaties/ec/art81_en.html), 03.03.2007



has competences in the field of single market, it has acted in that direction in order to promote negative integration. Consequently, the group of manufacturers faces difficulties when they push the restriction of parallel trade.

## Conclusion

My thesis asked the question why the voice of the pharmaceutical manufacturers has not been heard yet in the policy process of pharmaceutical parallel trade. The thesis has argued that the policy network of the manufacturers has not been successful in imposing its preferences for four reasons.

First, a successful lobby strategy requires the active involvement of the policy network in the whole policy process. However, the group of manufacturers could not organize itself early enough. Therefore, they could not influence the most important phase of the policy process, the agenda-setting phase.

Second, the degree of conflict between the manufacturers and the Commission has been high throughout the entire policy process. The policy network of the manufacturers aimed to alter the opinion of the Commission; however, the degree of conflict was too high for a compromise to be found.

Third, the policy network of the manufacturers used very strong statements. They used the directional influence method, which aims to alter the core content of the legislative act. More benefits could have been reached by a less ambitious but more compromise-friendly positions, since it is very difficult to achieve major changes in the core belief of the decision-makers.

Fourth, the policy network of the manufacturers could not find supporters within the Commission. Without interlocutors in the Commission it is more difficult to influence the policy-making process.

Additionally, another main factor behind the lack of success of the manufacturer's lobby lies in the so called EU's institutional bias. The voice of the manufacturers has not been heard because manufacturers have been interested in a policy outcomes that would have required positive integration. According to Scharpf, negative integration can more easily happen within the EU because it is only dependent on the intention of the Commission and the ECJ, due to the Treaty competences. Furthermore, it does not require the involvement of the member states in the process. By contrast, positive integration requires the consensual decision of the member states within the Council of Ministers. Moreover, as the Commission has competences in the field of single market, it has acted in that direction in order to promote negative integration. The Commission aims at the elimination of barriers of trade in the pharmaceutical market. Therefore, the group of manufacturers faces difficulties when it pushes the restriction of parallel trade, which requires the partitioning of the single market.

I have found that it is useful to look at the function of the EU decision-making process through the lenses of the Policy Network Approach because the latter gives an insight into the day-to-day politics, and it shows the role and contribution of the interest groups in the policy process. The emergence of policy network approaches has been essential in order to grasp a better understanding of EU policy-making process, since they can focus on singular moments of changes, and they can describe the dynamics of integration, unlike grand theories of International Relations, which neglect the day-to-day patterns of politics. The role of subsystems was therefore brought to the fore. For example, informal consultation organized by the Commission can have an important role

in the policy process because it can serve as a platform of stakeholders where interest groups can discuss major issues related to parallel trade.

More specifically, the Policy Network Approach highlights the importance of policy networks, which are highly involved in the policy process providing information, opposition or support and legitimacy for the decisions. As a result, the Policy Network Approach enables us to get a more detailed view of the policy process than about the policy outcomes. Furthermore, it highlights the failures of the lobby strategy of the manufacturers, which can be edifying for the interest groups. In our case, we can observe that although the network of the manufacturers could not achieve its final goal so far, the network has already obtained side-payments and managed to avoid initiatives which were less advantageous for them. The Policy Network Approach also shows that interest groups can shape the policy-making process; however, it is not easy to change the position of the Commission. As a result, the power of the interest groups is not negligible in the policy process of parallel trade.

Additionally, the policy-making process of parallel trade shows that there is a tendency in the EU to liberalize markets, rather than implement market-correcting mechanisms.

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