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# NEWGOV

## New Modes of Governance

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**Summary**

The paper summarises the major findings of the SEEIRA project. The project analyses the role of independent regulatory agencies (IRAs) and networks in rendering the adoption of and adaptation to EU policies in Central Eastern European (CEE) and Southern member states smoother i.e. reducing the risks of implementation conflicts in ‘weak’ countries already during the pre-accession phase and after accession. Delegation of regulatory competencies to IRAs and networks lies at the core of current innovations in EU governance and experimentation with novel modes of governance that depart from traditional command-and-control uniformly binding regulatory approaches. While the aim of the project is to identify the conditions under which the departure from traditional modes of conducting pre-accession negotiations is a viable alternative in order to secure effective and efficient internalisation of legal and policy requirements emanating from the *acquis communautaire* in candidate member states it also raises questions related to the emergence of delegation to participatory networks in different policy areas.

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## Abbreviations

BAT	Best Available Techniques
CADREAC	Collaboration Agreement between Drug Regulatory Authorities in the European Union Associated Countries
CEE	Central and Eastern European
CEEC	Central and Eastern European Countries
COMECON	Council for Mutual Economic Assistance
CPMP	Committee for Proprietary Medicinal Products
CVMP	Committee for Veterinary Medicinal Products
EC	European Communities
EEA	European Environment Agency
ELV	Emission Limit Values
EMA	European Agency for the Evaluation of Medicinal Products
EU	European Union
IMPEL	European Network for the Implementation and Enforcement of Environmental Law
IPPC	Integrated Pollution Prevention and Control
IRA	Independent Regulatory Agency
NEWGOV	New Modes of Governance Project
NGO	Non-Governmental Organisation
NMG	new modes of governance
OGYI	Hungarian National Institute of Pharmacy
PA	Principal/Agent Framework
PERF	Pan-European Regulatory Forum
PHARE	Programme of Community aid to the countries of Central and Eastern Europe (Poland and Hungary: Aid for Restructuring of the Economies)
SEEIRA	Smoothing Eastern Enlargement: Independent Regulatory Agencies and Non-Hierarchical Steering –project no. 14
TWG	Technical Working Group

## I. Introduction

In recent years, most enlargement research focused on theorizing the process of eastern enlargement, analysing the incentives of both the EU and candidate member states to initiate a gradual process of legal and policy approximation with the prospect of eventual membership (e.g., Friis/Murphy 1999; Schimmelfennig 2001, 2003; Schimmelfennig/Sedelmeier 2002). In the context of the recent enlargement of the EU with the inclusion of ten new member states mostly from the Central Eastern European region (CEE) literature largely focuses on the candidates states' fitness to join the EU with emphasis on the extent to which they fulfil the criteria for membership specified in the 1993 Copenhagen and 1995 Madrid Councils with emphasis on democratic institutions, human rights and the rule of law, credible and functioning structures and institutions and the development of administrative and judicial capacities to effectively implement the *acquis communautaire* (Grabbe 2003; Goetz, 2000). Given their transitory phase one of the biggest challenges for CEECs regarding their EU membership is the effective implementation and compliance with EU rules. Implementing the EU *acquis* exposes their domestic institutional and regulatory structures and patterns of policy making to significant pressures for adjustment to the new regulatory regime. On the one hand, the full adoption of the *acquis* represents a unique opportunity to modernize the domestic regulatory regimes of the CEECs and expand their economic orientation to western European markets through the upgrade of their product standards to EU requirements. On the other hand, as latecomers to the EU, the CEECs face two serious problems regarding the adoption of EU legislation. First, they never had the possibility to influence European regulation according to their preferences and policy traditions. Second, they often lack adequate institutional structures and capacities to effectively implement and enforce European regulations. This double disadvantage for European latecomers has led to concerns in the new member countries about the full implementation of all EU directives. Given the depth and breadth of required adaptations the academic literature has focused on the application of novel policy instruments by the EU in order to assist candidate member states to build up their administrative capacities such as the PHARE and twinning programmes and the extent of anticipatory administrative adaptation in CEE countries as well as the effectiveness of evolving systems of domestic coordination of EU membership. However, literature on pre-accession negotiations rarely departs from traditional negotiating modes between the Commission and core executives from candidate member states (Prange and Koutalakis, 2005).

In light of the enormous economic, political and administrative challenges posed by the EU's eastern enlargement, we raise the question of the extent to which the European Commission has widened the type of actors involved into pre-accession negotiations beyond the core executive in order to enhance input and output legitimacy of the process and, in effect, improve the likelihood of effective and efficient adoption of and adaptation to the *acquis communautaire* in the new member states. Therefore, the project addresses a number of pertinent questions focusing mainly on the *effectiveness* and *efficiency* of alternative modes of pre-accession negotiations in various areas of the *acquis*. However, it is inevitable to disregard the important issue of the conditions under which novel modes of conducting pre-accession negotiations emerge in the first place since those constitute important properties that affect their post-delegation functioning. In order to assess both the effectiveness and the efficiency of alternative/complementary modes of pre-accession negotiations we raise the following questions: Under which conditions does the EU depart from traditional modes of pre-accession negotiations in order to reach domestic actors beyond the core executives? What are the emerging institutional properties of these alternative modes of pre-accession negotiations? Under which conditions do they enhance efficiency and effectiveness in the adoption of and adaptation to the *acquis communautaire*? Which actors are involved at different stages of the policy process

(e.g. national/European agencies; national/European associations; national/transnational NGOs; enterprise representatives; European Commission; national civil servants)? Which are the incentives of non-executive and private actors to commit their resources to co-regulatory networks? Which steering modes are used (e.g. arguing; learning; persuasion; economic incentives) and are they efficient in reducing conflicts with regard to the adoption of the *acquis communautaire* in new member states?

In terms of empirical focus the project covers politically and economically important areas such as environment and pharmaceuticals seeking to capture the dynamics of both positive and negative integration. In these areas a wide range of institutions share regulatory competences both at the EU level (Independent regulatory agencies and regulatory networks such as the European Medicines Agency – EMEA and the European Environmental Agency - EEA) and the national level (domestic agencies for the authorisation of medical products and environmental agencies) owe different tasks (i.e., information or regulation) and varying degrees of decision-making power. Moreover, both areas of EU regulatory activity witness a wide range of institutional experimentations with novel modes of policy making that often complement (and depart) from the community method. In the area of pharmaceuticals both the centralised and the mutual recognition authorisation procedures largely depend on cognitive and administrative resources of national authorisation agencies that cooperate in non-hierarchical modes of coordination. Moreover, during the 1990s pharmaceutical industry being acknowledged as one of the most dynamic in both investment and research and development potential has gained considerable influence into regulatory policy making through institutionalised forum of dialogue with the European Commission and national regulatory agencies. The same holds with environmental policies which is an area of intense experimentation with novel regulatory approaches that attempt to systematically include non-state actors (NGOs and companies) into the policy process and the proliferation of new, less coercive, market-based policy instruments both at EU level and individual member states (Collier, 1997; Jordan et al. 2003a; 2003b; Lenschow, 2002; Knill/Lenschow, 2000).

This novel regulatory environment is expected to affect the patterns of negotiations between candidate member states offering new paradigms of effective, efficient and legitimate policy making both to EU and domestic policy actors. Moreover, these novel patterns of regulatory policy making point to a fundamental mismatch between the current modes of policy making between existing and candidate member states of the EU that are not adequately captured by traditional modes of pre-accession negotiations between the Commission and core executives. While in existing member states a wide range of non-executive and private actors have the opportunity to participate directly into various stages of policy formulation and implementation, traditional pre-accession negotiations are restricted to core executives. The extent to which domestic executives are capable and/or willing to articulate those preferences in the negotiating arena depends on the patterns of interdepartmental coordination and domestic arenas of interest intermediation. In both cases national executives have considerable discretion to define national negotiating positions that often depend on considerations regarding the overall progress of approximation and package deals between different policy areas. The limited osmosis of non-executive and non-state actors with EU requirements for the adoption of the *acquis* during the preparatory phase might increase their cognitive and material capacity limitations to effectively participate into the implementation of the *acquis* in the post-accession phase. This unequal distribution of ‘say and pay’ inherent into the multilevel system of policy formulation and implementation might exacerbate compliance problems that characterised previous enlargement rounds with the inclusion of member states with allegedly weak administrative capacities to effectively adapt and adopt to the EU requirements (see Börzel, 2003). The territorial dimension of our empirical studies focuses on old and new member

states. It compares two CEECs, Poland, Hungary, with one Southern European member state, Greece.

The following sections of the paper summarise the major findings of the project regarding the territorial and policy specific dimensions of comparisons. Section two focuses on the factors that foster the emergence of alternative modes of pre-accession negotiations between the Commission and candidate member states. Section three focuses on the factors that enhance the effectiveness and efficiency of those negotiating modes in terms of the successful adoption and adaptation to the *acquis communautaire*. Evaluating systematically the conditions under which new forms of governance foster the adoption of and adaptation to the *acquis* will help to formulate policy recommendations on how to reduce implementation-problems in different phases of accession (section four). Since the EU is awaiting further rounds of accession, this issue will remain on the political agenda.

## **II. Factors fostering the emergence of novel pre-accession negotiation modes**

Literature on the emergence of NMG focuses on the driving forces that condition the incentives of political actors to depart from command-and-control steering modes and delegate policy making competencies to participatory non-hierarchical structures, their design and the consequences of delegation for democratic accountability and control. Rational choice approaches conceptualise delegation to regulatory networks as a response to powerful functional pressures emanating from the expansion of the regulatory role of the state as a distinctive mode of social coordination (Majone, 1994; 1997a). The principal/agent framework that dominates studies of delegation to IRAs, stresses four common explanations why delegation to agencies might be beneficial for political efficiency. First, delegation is used to reduce political transaction costs emerging at the stage of negotiation between political actors (cf. Epstein/O'Halloran 2000; Héritier 2003: 203). Second, delegation to a specialized agency is expected to facilitate policy continuity given the complexity of socio-economic phenomena, the acceleration of scientific and technological developments and the growth of international interdependence. Everson et al. (1999: 21) indicate that “a reason for proposing the creation of European agencies in several areas of economic and social regulation is the perception of EU citizens and economic actors alike, that the present system – with its heavy concentration on rule-making and its weak control of the enforcement process – is no longer able to cope with the regulatory challenges of globalised markets”. The high collective stakes attached to these challenges demand continuity of public action which is not always achieved by political actors because of short-term electoral constraints (Majone 2001; 1997b). Third, the increasing technical and scientific complexity of many regulatory issues has led to the establishment of agencies which contribute expertise in these substantive matters (Héritier 2003: 203). Mobilization of all knowledge relevant to public decision-making requires a stable relational context among peers that minimizes bureaucratic or political bias during deliberations (Moe 1990; 1995). Such a framework is hard to find within public administrations. Finally, agencies may pave the way for a closer incorporation of civil society into governmental institutions. Everson et al. (1999: 32) argue that the agencies' separateness from government may make them a preferred mechanism for co-opting certain groups into the decision-making process. Thus, agencies function as intermediary institutions between state and civil society. Additionally, as depoliticized bodies eager to improve their own public reputation, agencies contribute credibility and reliability as well as public confidence in regulatory processes and outcomes (Pollock 1997).

The intensity of the functional pressures analysed above determines principals' incentives to delegate regulatory functions to regulatory networks, their preferences on their institutional design as well as the incentives of non-state actors to participate in regulatory policy making. The higher the functional pressures experienced by principals in a given policy area or country the more powers they will delegate to regulatory networks and the weaker will be the control mechanisms. Principals seeking to maximize their influence over policy outcomes, attempt to optimise the equilibrium between delegation and control in order to minimize losses from the agency's tendency to gain political and bureaucratic autonomy.

Both policy areas generate high costs of adaptation both to the Commission that faces uncertainties regarding the compliance capacity of candidate member states and national regulators that face financial, cognitive and administrative limitations to adapt to the requirements attached to EU legislation and private actors affected by the new regulatory environment. In the pharmaceutical area harmonization was a highly contested area of the *acquis communautaire*. Pharmaceutical markets in the COMECON region were regulated on the basis of process rather than product patents. The former provide insufficient protection of intellectual property than product patents since exclusivity of rights conferred to the patents holder can be evaded by producers using a different product process. Therefore, from the outset of pre-accession negotiations the Commission emphasized that on pharmaceutical and chemical products legislative alignment was progressing at a slower pace than expected due to significant diversity of CEEC's regulatory traditions with EU law. In its 1999 progress report, the Commission still recorded that most of the candidate countries had achieved only a poor level of compliance with the *acquis* with regard to the free movement of goods, especially referring to the pharmaceutical sector.

Moreover, the EU regulatory system for medicines is structured around the principles of decentralisation and integration based on a plurality of collaborative arrangements between national authorisations agencies that undertake market authorisation and post-authorisation surveillance. The central node of the network governance in pharmaceuticals is the European Medicines Agency (EMA) that undertakes the role of coordinator of collaborative arrangements between independent national agencies in the framework of centralised and decentralised authorisation procedures. The emerging system of shared allocation of competencies between multiple national regulatory agencies reflects the imperatives of highly heterogeneous national health systems. Market fragmentation due to different pricing systems restricts EMA's potential to resort to hierarchical binding regulatory instruments. Instead the agency increasingly employs soft law such as good manufacturing, laboratory and clinical practices addressed to national regulatory authorities and pharmaceutical firms and consumers. Divergent traditions and capacities of domestic regulators would seriously undermine those principles.

High functional pressures for adaptation also characterise the environmental policy area. One of the biggest challenges facing the Central Eastern European accession countries (CEECs) regarding their EU membership is the implementation of EU legislation and compliance with those laws concerning, in particular, the environment. Implementing the environmental *acquis* will not only be an expensive attempt taking into account that the bulk of these legal acts impose considerable costs in infrastructure. It will also expose domestic institutional and administrative structures and patterns of policy making to significant pressures for adjustment to the requirements attached to the implementation of EU environmental policies. A number of scholars and policy reports converge on the conclusion that CEECs' institutional and administrative deficiencies are likely to undermine effective implementation (Baker et al., 1998; Carius et al., 1998; Jehlicka, 2002). The European Commission in a preliminary evaluation of

implementing capacities of accession countries undertaken in Agenda 2000 predicts that no accession country will be able to meet in total the obligations laid down by the environmental *acquis* (European Commission, *Agenda 2000*, vol. I, COM (97) 2000, 1997: p. 67). Despite recent experimentation with new flexible policy instruments such as voluntary agreements, tradable permits, deposit refund systems and tax incentives, environmental harmonization does not significantly depart from the traditional Community method of regulation, namely transnational cooperation at the stage of policy formulation and decentralization in favor of the national level of implementation (application, monitoring and enforcement). Already from the beginning of the 1990s, this system has reached its limits. The accession of southern European member states (Greece 1981, Spain and Portugal 1986) with weak institutional and administrative capacities and limited or even no prior experience in pro-active environmental policies, coupled with an acceleration of legislative output that followed the launch of the internal market programme have fostered the emergence of a persistent deficit in member states' compliance with environmental legislation (Börzel 2003).

The relative little experience and administrative capacities of domestic regulators in applying the *acquis* and uncertainties over the outcome of pre-accession negotiations generate powerful incentives to the Commission, national regulators and private actors affected by the process of legal and policy harmonization in both areas to engage in wider participatory patterns of pre-accession negotiations in order to generate trust, enhance learning capacities of domestic actors and reduce the risk of conflicts at the post-accession phase. However, empirical analysis revealed considerable variations in the strategies followed by the European Commission in order to achieve effective legal and policy harmonization at the pre-accession stage of negotiations with candidate countries. In the pharmaceutical area after years of stagnation in the transposition and implementation of pharmaceutical regulations in the CEECs, the Commission – backed by member states and industry – launched a new harmonization approach placing the EMEA at the core of a more institutionalized structure, the Pan-European Regulatory Forum (PERF), in order to assist CEEC institution-building and adjustment to the *acquis communautaire* in pharmaceuticals.<sup>1</sup> This new 'decentralized' approach altered the enlargement mode from pure bilateral negotiations between the Commission and the delegations of the candidate countries into a regulatory arena consisting of representatives from drug regulatory agencies, industry as well as consumer and health organizations.

PERF was a unique institutional arrangement. Following a meeting between the Commission, EMEA and the drug regulatory authorities of the CEECs in November 1997, PERF was established as a 'structured partnership' "to help the associated countries fulfil the requirements of the White Paper for Technical Regulations in respect of the pharmaceutical sector" (EMEA 2001: 7). The first phase of PERF (PERF I) ran from September 1999 until September 2000. The programme included 31 working group meetings. PERF II, consisting of 35 meetings, a

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<sup>1</sup> EMEA was established in 1993 as part of a new regulatory system that came into operation in 1995 (Lewis/Abraham 2001). EMEA's task is to evaluate and authorize medicinal products for human and veterinary use so as to protect public health and facilitate the free circulation of pharmaceuticals in the EU. EMEA is *de facto*, if not *de jure*, a 'quasi'-decision-making agency as the Commission normally decides upon the recommendations of the agency. However, before reaching its decision, the Commission must consult either the committee responsible for medicinal products for human use (Committee for Proprietary Medicinal Products, CPMP) or the Committee for Veterinary Medicinal Products (CVMP). Member states also have the right to send written observations on the draft decisions of the Commission. However, in order to be effective, the adverse opinions of the two committees, or the member states, must demonstrate that an important scientific issue has escaped the notice of the applicant, the relevant scientific committee of the agency, the agency itself, and the Commission. This is considered to be rather unlikely (Everson et al. 1999: 11).

series of secondments and joint visits, was scheduled to run from June 2001 to August 2002. PERF III, which ran from January to December 2003, finally concluded the process.

PERF was based on cooperation, discourse and learning. The candidate countries were encouraged to ‘examine’, ‘identify’, ‘facilitate’ or ‘advance’ certain needs for accession. EMEA played a specific role within this framework: it served as an agenda-setter by presenting programme proposals and tender documents to the relevant committees, it acted as a mediator by contributing to the finding of compromises in difficult issue areas, and as an advisor to the Commission by monitoring and evaluating the CEECs’ implementation progress. Even more important, through its political independence, its status as a ‘quasi-independent’ agency (Dehousse 2002) and its core role within the European pharmaceutical network, it was able to keep political struggles largely out of PERF, strengthening continuity, stability and accountability in the interaction between participants. Additionally, PERF sought to assist the candidate countries’ regulatory authorities to achieve a ‘smooth’ transition to EU membership by participating in the decision-making process (i.e., the comitology committees) already during the phasing-in period.

At a very early stage, all participants underlined that “considerable achievements in terms of an improved understanding of the pharmaceutical ‘*acquis*’ had been made” (EMEA 2001: 7). This development was supported by two characteristics of the process: first, the discussions were dominated by the technical problems of the candidate countries’ regulatory drug agencies, while national interests seemed to play no role; second, PERF seems to have reduced the mutual uncertainty among actors, while enhancing efficiency through ‘transnational network building’. As a result, the programme has been implemented almost in its entirety within one year. However, remaining problems indicate that ‘regulatory learning’ within networks cannot alone bring about the adoption of the *acquis* in total, but has still to be accompanied by administrative capacity building in the accession countries. In this context, the environmental sector seems to be the best example for implementation shortcomings due to the lack of administrative capacities (cf. Homeyer et al. 2000).

Through delegation and institutionalization the Commission supported a ‘smoother’ enlargement process as compared to the ‘old’ enlargement model of purely bilateral negotiations between the Commission and national executives. The candidate countries ‘learned’ how to interpret regulations within the PERF network whose negotiation mode was based on ‘talking’ and ‘discussing’ in order to ‘explain’ EU legislation. While the Commission did not deviate from the principle that future members have to accept all EU rules (see Avery/Cameron 1998), it showed flexibility with regard to the method of conducting pre-accession negotiations with candidate countries. In the end, the Commission was able to keep the candidate countries’ demand for derogations from the *acquis communautaire* low.

Contrary to the case of pharmaceutical regulation, environmental legal harmonization in the framework of pre-accession negotiations was a domain reserved for CEE state executives and the Commission (Lippert et al. 2001). In the environmental area the lack of a truly regulatory agency to serve as the central node of interaction between potential participants significantly reduced the Commission’s available options. The EEA has only recently gained momentum in monitoring the application of EU law in the member states, whereas it has no role in its enforcement.

The EEA was created in 1990 as an independent agency, but became operational only in 1994.<sup>2</sup> Its main tasks are to provide ‘objective, reliable and comparable information’ enabling the member states to take the requisite measures to protect the environment, assess the results of these measures and to ensure that the public is properly informed about the state of environment’.<sup>3</sup> In fact, the EEA is an independent agency but with limited decision-making competencies, especially regarding monitoring and enforcement of environmental law.<sup>4</sup> A high quality of information supplied by the EEA is indispensable for all stages of the policy cycle due to the complex, technical nature of environmental problems. However, the agency’s direct involvement at the stages of actual implementation, monitoring and enforcement of environmental legislation at the national level is limited. At best, the agency’s role is confined to technical assistance in relation to practical application by the Commission and the member states of certain legislative measures of a technical nature such as identifying environmental indicators, designing and monitoring reporting systems and methodologies for the application of Greenhouse Gas Monitoring mechanisms, the Habitats, the Water Framework Directive and the Waste Directives. The same holds for the evaluation of the effectiveness of legislative measures, the review of regulatory approaches adopted by EU institutions and direct support to the legislative process through developing amendments and undertaking cost-benefit appraisals of different policy options.

Given the limitations regarding the EEA’s standing in European environmental governance, the agency’s role in pre-accession negotiations is narrower compared to the experience with the EMEA. The agency was the first EU institution to accommodate the CEECs prior to their accession to the EU.<sup>5</sup> Cooperation between the EEA and CEECs started already in 1996 through a number of PHARE programmes with the aim of improving quality of environmental information. The same holds for IMPEL. the European Council decided in 1991 to create an informal network of national enforcement authorities, the so-called Chester Network, renamed IMPEL in 1993. Similarly to PERF, the network seeks to establish horizontal contacts between national enforcement authorities in order to enhance the preparation of measures, consultation and better practical follow-up of legislation and improve consistency in implementation. IMPEL’s main objectives are to share information and experiences, discuss problems and offer practical advice, to contribute to a greater consistency of approach between fragmented legislative measures, to promote mutual understanding of the common characteristics and differences of national regulatory systems and to develop best practices and standards of permitting, inspection, monitoring and enforcement of EU environmental

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<sup>2</sup> Council Regulation No 1210/90 of 7 May 1990 on the establishment of the European Environmental Agency and the European Environmental Information and Observation Network.

<sup>3</sup> Legal autonomy *vis-à-vis* Community institutions and the member states was viewed as an antidote to the failure of traditional legislative instruments establishing mandatory reporting obligations to member states in policy areas such as air pollution, forest damage and quality of waters to facilitate high quality coherent data. According to a 1993 IEEP report both state of environment data and information on national policy measures were either poorly drafted or not submitted at all by member states concerned with the use of such information to initiate infringement proceedings under Art. 226 TEU.

<sup>4</sup> The EEA is a separate body with independent Management Board comprising a representative from each member state normally senior environmental policy officials, two representatives from the Commission’s Directorates for Environment and Science, Research and Development and two scientific experts designated by the European Parliament.

<sup>5</sup> Negotiations on enlargement of the EEA were opened in March 2000, and the CEECs became full members in 2002.

law by member states.<sup>6</sup> Given the positive experience from IMPEL, AC IMPEL was created in 1997. AC IMPEL operated as an informal parallel network of enforcement authorities from the ten accession countries. In 2003, AC IMPEL merged with the main IMPEL network. During the five years of its activity, the network has served as a forum for transferring experience and expertise to the new member states through several PHARE projects targeted at training inspectors, the identification of specific problems of each associated country and developing administrative capacities in order to ‘smoothen’ the legal approximation process as well as a better understanding of the obligations emanating from the environmental *acquis*. The effectiveness of IMPEL in ‘smoothing’ eastern enlargements by filling the gap between the adoption of legislation and the actual application has to be assessed in view of other available institutional alternatives. Informality of interactions between participants has facilitated the development of mutual trust and has tapered national tendencies to inhibit information regarding the actual state of domestic compliance capacities. The extent to which this perspective offers a viable institutional alternative to the creation of a truly independent decentralized enforcement agency, such as the US Environmental Protection Agency, still remains an open issue to be re-assessed in light of the first annual reports on monitoring the application of EU environmental law in the new member states.

Empirical evidence hardly confirms the predictions of PA framework regarding the emergence of new modes of governance in the first place. Despite common functional pressures experienced by EU and domestic regulators as well as private actors affected by legal harmonization there considerable variations in pre-accession strategies followed by the Commission in the area of pharmaceutical and environmental regulations. Constitutive actors’ preferences in favour of the institutionalisation of participatory modes of pre-accession negotiations are conditioned upon considerations regarding their capacity to generate a gradual evolution of consensual negotiating modes of interactions between participating actors (Eberlein and Kerwer, 2002: 5; Grande 2000: 20). Delegation to participatory regulatory networks is more likely to emerge in policy areas characterised identifiable closed policy communities of actors that have the potential to insulate pressures for politicization and generate consensual policy outcomes. In the pharmaceutical area in spite of outstanding cleavages between organic and generic industry from both regions of the EU large corporations and domestic regulators have initiated long before the official opening up of pre-accession negotiations regulatory networks of cooperation with domestic regulators seeking to align authorization procedures. Collaboration Agreements between Drug Regulatory Authorities in the European Union Associated

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<sup>6</sup> IMPEL operates as an informal network with only a small secretariat established in 1997 under the auspices of DG Environment. Its main platform of strategic decisions related to the adoption of working programmes and budgets are the plenary meetings, normally taking place twice a year. These meetings are co-chaired by the Council’s ‘troika’ and the European Commission. In fact, its structure has been the subject of continuous experimentation. Its initial format was dominated by experts dealing with industrial installations and air pollution. It is not surprising that given the evolution of IMPEL along this thematic path, the network was dominated by more experienced enforcement specialists from northern EU member states. IMPEL was initially divided into four working groups coordinating cooperation on technical, procedural and legal aspects of permitting, compliance monitoring and inspection and managing enforcement processes. In 1997, these working groups were replaced by two standing committees specializing in legal policy and legal implementation and in practical issues of managing enforcement respectively. Currently the working group and standing committee systems have been fused into a more flexible project-based structure. Informality has facilitated the development of mutual trust between national representatives and has served as a necessary precondition for enhancing the network’s influence in the legislative process, especially regarding the development of joint views on the coherence, practicality and enforceability of EU environmental legislation, which are often used by the Commission and the Parliament as feedback information in the drafting of new legislative proposals.

Countries (CADREAC), a formal cooperation between CEE drug regulatory authorities established in 1997 was the most prominent example of those activities.

On the contrary, the heterogeneity of regulatory arenas with multiple often contradictory sectoral and national preferences and interests generated powerful disincentives both to the Commission and national executives to open up the negotiating arena to both non-state actors and lower ranks of their administration. The absence of a central institution with the potential to act as the central node of interactions between potential participants, such as the EMEA, made it comparatively difficult to apply a similar approach to that used in pharmaceuticals.

The prevalence of traditional modes of pre-accession negotiations in the area of environmental policies led to us to rethink our initial case selection. Instead of abandoning the environmental case we decided to redirect our empirical analysis to a case where delegation of regulatory competencies to a participatory network emerges not as an ad hoc practice in the framework of pre-accession negotiations but as a novel institutional arrangement where candidate member states have to internalise as a part of the environmental *acquis communautaire*. The case of the IPPC technical working groups is the most prominent case of such practices in EU environmental policies. The IPPC directive provides for the institutionalisation of several technical working groups that undertake significant regulatory competencies regarding the definition of best available technology based emission limit values (BAT-Based ELVs) for a wide variety of sectoral industrial activities. Although BAT-based ELVs have no binding character per se, they have a strong normative influence on national permitting systems since they serve as reference documents for domestic permitting systems. In order to comply with the IPPC directive the latter have to demonstrate that industrial permits for emissions into air, soil, water and energy consumption are equivalent to BAT-based ELVs adjusted to local environmental, technological and economic conditions. The inclusion of the IPPC case in our project operates as a control case that seeks to capture the conditions under which regulatory networks enjoy input legitimacy as a *signe qua non* condition for effectiveness and efficiency of policy outcomes in a highly divergent regulatory environment that of product standards.

### **III. Factors fostering effectiveness and efficiency at the post delegation phase**

Most studies about the role of independent agencies and regulatory networks focus on the conditions for the establishment of delegation. However interesting, these studies tend to disregard the question of input legitimacy as a necessary condition for political effectiveness and policy efficiency of regulatory networks in the post delegation phase. In our project we define political effectiveness and policy efficiency as the ability of domestic actors to adopt and adapt to the requirements emanating from the *acquis communautaire*. We therefore account for the number of transition periods negotiated and granted to candidate member states at the pre-accession stage.

The main objective of the project is therefore to assess the extent to which delegation of regulatory competences to participatory regulatory networks is a sufficient condition for the emergence of highly inclusive modes of policy making that are capable of facilitating a smooth enlargement process reducing the risks of conflicts at the pre- and post-accession phases. It analyses the ways in which public and private actors articulate their interests into these novel regulatory networks and the emerging modes of coordination between them and generate input legitimacy to regulatory policy making. Mobilization of all existing knowledge relevant to public decision making requires a stable relational context among peers that minimizes bureaucratic or political bias during deliberations and guarantees legitimacy at the input phase of

regulatory policy making. Procedural credibility is therefore an essential institutional property that contributes to policy effectiveness and political efficiency in terms of the ability of emerging participatory structures to accommodate diversity of highly heterogeneous preferences at the input phase of the decision making process and generate consensual policy outcomes.

In line with literature on new modes of governance we account for two institutional properties of regulatory networks that generate procedural credibility at the post delegation phase and generate efficient and effective policy outcomes (Héritier 2001; 2003; Jachtenfuchs 2001; Kohler-Koch/Eising 1999). First, the actor dimension and the extent to which participation of several public and private actors is balanced along territorial and functional characteristics. Second, the steering modes of interactions between participants with emphasis on the extent to which they facilitate non-hierarchical modes of interactions based on learning and persuasion rather than hierarchically imposing certain regulatory options.

In our empirical findings we identified considerable variations in the patterns of participation and involvement of domestic actors into the post-delegation operation of those regulatory networks. Although Poland and Hungary face similar challenges emanating from incompatibilities of their domestic regulatory systems with the EU pharmaceutical *acquis*, they manifested considerable variations in the extent to which domestic regulators and the industry commit resources to the functioning of transnational regulatory networks. In both cases major stakeholders face contradictory incentives to commit their resources into the functioning of regulatory networks. In the pharmaceutical area, corporations from the CEE region have a high incentive to harmonize their product standards with EU requirements. However, their incentive is largely conditioned by trade patterns prevailing in the region. Hungarian industry is traditionally more integrated to the EU markets since from the 1970s large firms obtained foreign trading rights with the EC. On the contrary Polish actors face less incentive to update their product patents according to EU requirements since they major trade partners are non-EU countries, mainly former Soviet Republics (for detailed figures see 14/D04).

The same holds for the IPPC case. Technologically advanced firms might lose competitive advantages by revealing regulatory information to their competitors. However, the opportunity to influence BAT-based ELV definitions in high levels might be beneficial to such firms that gain competitive advantages over higher emitting competitors. The latter will have to commit significant financial resources to the modernization of their production base in order to comply with higher ELV standards. Firms specialised in green technologies see the opportunity to diffuse their innovations to potential consumer firms through the influence of BAT-based ELVs. Firms with weak investment capacity in new technologies and high emission records also face both positive and negative incentives to participate in regulatory policy making. Through their participation have the opportunity to influence BAT-based ELVs into lower standards. At the same time, by revealing regulatory information they increase their vulnerability to both competitors and domestic regulators.

In both cases, functionally-driven and/or market incentive-based explanations cannot alone lead to sufficient account of private actors' choices to commit their resources to regulatory policy making. Apart from a rather limited group of firms, those producing green technologies, industrial actors face not only incentives but also powerful disincentives to commit their resources to participatory regulatory networks. The inconclusiveness functional pressures and market incentives as a driving force of transnational cooperation between stakeholders in both product and process standards point to the central role of the state as an important explanatory factor upon which input legitimacy of regulatory networks is based. Since the Commission has no means to reach directly industrial firms companies, stakeholder participation largely

depends on the capacity of the state as the locus of regulatory power that affects private actors' preference formation by generating positive or negative incentives to stakeholder participation.

In complex high technical regulatory environments such as emissions control and pharmaceuticals characterised by highly divergent interests and preferences over the desirable level of regulatory stringency, delegation is a necessary but not sufficient condition for the emergence of novel participatory forms of regulatory policy making. Although the institutionalisation of regulatory forums such as the IPPC Seville process and the PERF is a powerful signal to private stakeholders, their willingness to contribute their resources in terms of knowledge and expertise into transnational policy making largely depends upon their incentives and anticipated material and cognitive benefits. We argue that although functional pressures facing principals may well-explain the emergence of those participatory networks, their post-delegation functionality in a multi-level regulatory environment such as the EU is largely contingent upon domestic institutional conditions that affect private actors' preference formation in favour or against participation to regulatory networks. The capacity of the state to mobilise private actors' resources towards effective harmonization with EU requirements is a crucial explanatory factor of post-delegation functionality of regulatory networks.

Domestic regulators play a crucial role in private actors' preference formation. First through their administrative capacities such as qualified personnel, effective enforcement mechanisms and financial incentives to mitigate compliance cost to industry can guarantee effective enforcement regulatory outcomes of network interactions. High levels of administrative capacity to effectively enforce the *acquis* stimulate additional incentives for private actors to participate into transnational regulatory networks since they can influence the precise requirements upon which domestic regulators exercise their enforcement mandate. Low levels of administrative capacity might generate disincentives for private actor participation since they recognize the inability of domestic regulators to effectively enforce the regulatory requirements of the directive. Given the low possibilities to face negative sanctions from domestic regulators in case of non-compliance private actors are unwilling to bear the costs of participation in transnational attempts to loosely coordinate their production processes. Both cases under investigation point to a second important property of the state that also affects the incentives of private actor participation into transnational regulatory networks. In both cases the capacity of domestic regulators to mobilise private cognitive resources necessary to secure effective harmonization with EU standards is a crucial factor that affects post-delegation functionality of those regulatory networks. In the IPPC case since decisions in those network interactions are not binding, public regulators have considerable leverage in specifying BAT-based ELVs according to national, regional and local environmental, economic and technological conditions. Therefore the directive leaves considerable space for bargaining between public regulators and private firms at the domestic level for the specification of precise requirements for industrial plants affected by the directive. Even if domestic regulators possess significant administrative resources they are dependent on private actors for essential regulatory information related to production processes that is often protected by intellectual property rules. Therefore, the capacity of the state to mobilise private resources in terms of knowledge and expertise related to the interpretation of BAT-based ELVs in light of the specific conditions of affected industry is crucial for the effective application of the directive. The same holds for the pharmaceutical sector, where domestic regulators largely depend on resources from producers regarding the quality of regulatory information included into the authorisation dossiers. Therefore, the capacity of the state to uphold property rights and generate trust in its interactions with industrial actors is a crucial determinant of the incentives of private actors to commit their resources into regulatory policy making. Factors such as state traditions, constellation of

interests in different regulatory domains, political leadership and compatibility with wider reform agendas and learning capacities of organizational actors have been identified as institutional and political properties that enable or hinder the emergence of IRAs as effective organizational responses to functional needs. These domestic institutional properties resonate with current discussions within the principal-agent approach that doubt about the objectivity of functional pressures driving the creation of agencies arguing that the establishment of agencies is contingent on socially constructed perceptions and legitimacy beliefs, institutional path dependency and actor-related arguments (Thatcher and Stone Sweet, 2002: 13). This leads to the assumption that the daily operation of agencies, and their effectiveness and legitimacy, can therefore hardly be decoupled from their social and political environment. This observation opens the way for the argument both about the relevance of studies about the post-delegation phase and the issue of credibility when examining input and output legitimacy. High levels of engaging capacity of the state stimulate private incentives to commit their resources since the latter are accustomed to stable repetitive interactions at the domestic level that enable mutual understanding and consensual policy decisions. Low engaging capacities of the state isolate private actors that are unwilling to commit resources and reveal important regulatory information to public regulators since they face uncertainties on their use at the domestic level. The following table seeks to map the ways in which state capacities affect private actors incentives and willingness to commit their resources into transnational regulatory policy making.

**Table 1: Mapping state capacities**

	<b>High administrative capacity</b>	<b>Low administrative capacity</b>
<b>High engaging capacity</b>	PP+	PP-
<b>Low engaging capacity</b>	PP+	PP-

Conceptualising state capacity as an independent variable challenges conventional geographically bound generalisations regarding the absence of specific scope conditions such as a minimum of political and administrative resources or pre-existing systems of interest intermediation (civil society, corporatist business-government relations both in southern and central eastern European member states (also, Börzel 2007). In order to assess the ‘political efficiency’ and ‘policy effectiveness’ of new modes of governance it is imperative to assess whether the effectiveness of regulatory networks requires specific scope conditions, such as a minimum of political and administrative resources (‘shadow of hierarchy’) or pre-existing systems of interest intermediation (civil society, corporatist business-government relations), in the candidate countries.

In our analysis we identified two core dimensions of the capacity of the state to mobilise private actors’ resources towards effective legal and policy harmonization with EU rules. The degree of institutionalisation of arenas of interest intermediation between the state and private actors and the ability of the state to provide incentives in order to alter private actors’ preferences and interests in favour of harmonization with EU rules are crucial domestic scope conditions that facilitate effective and efficient adoption of and adaptation to the *acquis communautaire*. Our three countries manifest considerable variations along both dimensions identified above. In pharmaceutical policies Poland and Hungary have followed highly divergent patterns of institutional development. Under COMECON, market differentiation and specialisation of CEE economies was centrally planned. Hungary was the leading pharmaceutical pro-

ducing country. As a result Hungary emerged from the communist period as one of the technologically most advanced countries of that region. Although the country was the first to initiate economic reforms, already from the 1960s, referred in the literature as ‘gradualist’, transition to a market economy was not straightforward. However, for the pharmaceutical sector the transition was much smoother compared to other economic sectors such as electronics. The pharmaceutical sector is by far the strongest industrial sector with high levels of interaction with Western markets. Hungary was therefore, the first CEE country to grant independent regulatory competences to an independent authorisation agency (OGYI) already in 1991. Applications are assessed on the basis of the drug's quality, safety, and efficacy. The internal organisation of OGYI has been modelled on the EMEA. The proceedings of the committees responsible for granting authorisation open to the public and applicant companies. The evaluation and authorization procedure is undertaken by a network of external collaborating institutions, usually universities and research institutes that undertake specific assignments related to the evaluation of drugs authorisations. The most significant initiative of OGYI was the initiation of CADREAC in 1995. CADREAC was a collaborative network of regulatory agencies in the CEE region with the aim at establishing an equal partnership with EU agencies, upgrade registration requirements according to EU standards and represent the interests of regional industry in their approximation dialogue with the EU. During that time, the Hungarian pharmaceutical industry was dominated by generics with only 8-10% of domestic products classified as organics, most of them not protected with product patents according to EU standards. The initiative was undertaken in the framework of approximation dialogue between the Commission and CEECs in the light of the introduction of centralized authorization procedure for biotechnology products by the EMA. This was a powerful signal to domestic pharmaceutical industry that harmonization with EU rules would follow a highly technocratic logic, insulated from politicisation and concerns over the effects of harmonization on health care costs. Therefore, domestic industry, from the early stages of pre-accession negotiations committed considerable resources to the functioning of PERF. It took an active role in all stages of the forum and facilitated training and transfer of experience and expertise through twinning projects with other regulatory agencies and companies in other candidate countries. Through the PERF, Hungarian industry and the OGYI became familiar with their novel regulatory environmental and adjusted their political, legal, technical and administrative tasks and in order to comply with the *acquis* without legal enforcements and no transition periods.

In Poland, institutional development followed highly divergent patterns that reduced the capacity of the state to mobilise private actors' resources in favour of harmonization. Under the centralised system of foreign trade assigned by COMECON, Poland was a rather peripheral power in pharmaceuticals. Domestic industrial base was dominated mainly by inward oriented firms. In the post-1989 period the outlook of Polish pharmaceutical market radically changed. The most fundamental development was the entrance to the market of foreign innovative products providing access to local population to high quality medicines. Nowadays foreign products dominate the Polish market (the share of imports to the total market value is beyond 60%).<sup>7</sup> In total there are about 66 producers on the Polish market, but only 31, mainly foreign companies, have a more than 1% share of the market (foreign companies account for 73% of the market's total value). The cataclysmic entry of foreign products of higher value has pushed the public health care reimbursement system to its limits. Cost containment policies and generic substitution is at the top of health policy priorities of Polish government. These policies coupled with low purchasing power of consumers have elevated Poland as the highest

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<sup>7</sup> Imports are dominated by finished products that correspond to approx. 87% of total imports of pharmaceutical goods. The largest exporters to Poland are France (18%) and Germany (15%).

generic consumption country with approximately 63% of total value and 86% of total quantity of products circulating the domestic market. This main consideration determined the course of institutional developments in Poland. From the launch of pre-accession negotiations pharmaceuticals were seen as a sensitive policy field connected mainly to public health care expenditure and rather than as a part of internal market legislation according to the EU conceptualisation of the area. Therefore, the main aim of Polish negotiators was to minimise damages to domestic generic industry in order to maintain control over social policy objectives. This concern is largely reflected in the nature of domestic regulatory regime. In 1991 Poland assigned considerable autonomy to the two scientific institutions dealing with authorisation of medicines, namely the Office for Registration of Pharmaceutical Products and Medicinal Devices and the Central Medical Technique Centre both operating as departments of the Polish Drug Institute. However, in 2002 a new law for pharmaceutical authorisations fused the two departments into a new Office for Medicinal Products, Medicinal Devices and Biocides. The new office is an internal administrative division of the Ministry of Health which since 2002 decided upon authorisations, inspections, pharmacovigilance and marketing authorisations. The reorganisation of the Polish system of pharmaceutical authorisations has disturbed both the scientific and the business community. Political control causes considerable delays in authorisations that are artificially prolonged, since the Ministry of Health is overburdened with control over the authorisation office and more vulnerable to political pressure. Therefore, Polish pharmaceutical firms are pressuring for the introduction of an independent agency. However, the most negative effect of the reform was on personnel turnover, since the authorisation office lost a significant part of its experienced staff. Approximately 70 out of 200 experts left the institute agency after the reform in 2002 to work in the private sector. Former staff of the drug institute perceived their work as purely scientific and not as administrative work attached to a Ministry. The latter failed to attract experienced scientific personnel. Political control over the authorisation process had also a negative effect on the office's financial autonomy. Since its reorganisation, the fees collected from the industry are transferred to the public budget and cannot be used flexibly for personnel training and participation in international conferences.

These developments had a detrimental effect on the state's capacity to mobilise essential resources from the pharmaceutical industry and the scientific community in order to effectively harmonize its regulatory practices with EU requirements. Both domestic regulators and industrial actors did not participate in the PERF. As a result, Poland was between the countries that negotiated transition periods for the upgrade of market authorizations granted under national law prior to their accession to the EU. Until 2008, these products can only circulate the Polish market since their registration dossiers are not updated to the EU standards. The list of these products attached to the Accession Treaty was prepared by the Ministry of Health and was heavily criticized by the industry facing barriers to trade with the EU. These medicines have obtained authorisations only for the Polish market bases on the 1991 law. These authorisations were automatically validated by the 2001 law but they don't meet the EU criteria. In some cases they correspond to medicines that are not tested (even though the 2001 law demands this) or they cannot be classified to any EU category since they consist of a mix of herbs and chemicals with no proven effect. After the end of the transition period their future is uncertain. Poland asked for a transition period of 15 years regarding the extension of patents. This was denied.

In the IPPC case the smooth adaptation of member states with no regulatory tradition in BAT based permit systems depends on their capacity to mobilise private actors' cognitive resources in terms of information regarding the production techniques used in different industrial sectors. Participation of these actors into the IPPC TWGs is therefore crucial for the legitimacy

of regulatory outcomes. Hungary, Poland and Greece, manifested considerable capacities to mobilise private actors resources in favour of harmonization with the directive. Our findings indicate that domestic institutional conditions shape the patterns of private participation into the so-called Seville process and condition their ability to benefit from their participation into transnational regulatory networks. In effect, these conditions affect the political efficiency and policy effectiveness of delegation into transnational regulatory networks in policy areas entailing high compliance costs to domestic public and private stakeholders. Pre-existing patterns of state/industry relations in environmental policies affect the capacity of the three member states to mobilize private resources that strengthen their compliance capacity with the directive. Hungary, Poland and Greece followed different paths and strategies in their attempt to mitigate compliance costs facing domestic industrial actors and the public administration itself in organizing the domestic permitting system. Hungary and Greece have strengthened their compliance capacity by mitigating compliance costs through the use of external assistance directed to industrial actor mobilization. In Hungary pre-existing patterns of cooperation between the Ministry of Environment and Water and large representative organizations of industry and commerce has enabled a rapid response to the requirement of the directive. In Greece, the IPPC directive served as the pre-condition for the emergence of novel forms of cooperation with large representative organizations that actively participated in domestic working groups and the TWGs in Seville. Poland seems to have followed a different path. The weak capacity of the Polish Ministry to mobilize industrial actors by employing cost mitigation incentives has led to limited and largely fragmented modes of participation into the IPPC regulatory networks.

#### **IV. Concluding remarks**

Our study attempted to identify the conditions under which the departure from intergovernmental bargaining as the dominant mode of pre-accession negotiations is a viable alternative to secure effective and efficient legal and policy harmonization of candidate countries. We argued that while the institutionalisation of participatory negotiating modes beyond core executives and less hierarchical modes of interactions is a powerful but not sufficient incentive for the mobilisation of all affected interests towards harmonization with EU rules. Much of the input legitimacy of multilateral regulatory networks especially designed to facilitate pre-accession preparations depends on the capacity of domestic regulators to stimulate the commitment of private resources especially from those actors that bear high costs of compliance with EU rules. The degree of institutionalisation of domestic arenas of interest intermediation and the capacity of the state to generate incentives and cost mitigation strategies are crucial determinants of the post delegation effectiveness and efficiency of those novel modes of pre-accession negotiations. Our empirical analysis has demonstrated that institutionalisation and delegation of some elements of pre-accession negotiations to non-executive, participatory regulatory networks fosters a smooth adaptation to the requirements of the *acquis communautaire* especially of those candidate member states that have the capacity to mobilise dispersed private resources that are essential for legal and policy harmonization. In these cases the institutionalisation of regulatory networks has operated a powerful incentive for domestic regulators to deploy strategies that facilitate cooperation with private actors.

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