NEWGOV
New Modes of Governance

Integrated Project
Priority 7 – Citizens and Governance in the Knowledge-based Society

Beyond bilateral executive negotiations –
Pharmaceutical harmonization and the eastern enlargement of the EU
reference number: 14/D07

Due date of deliverable: February 2008
Actual submission date: 15 August 2008

Start date of project: 1 September 2004
Duration: 48 months

Organisation name of lead contractor for this deliverable:
Freie Universität Berlin, Charalampos Koutalakis

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<tr>
<th>Dissemination Level</th>
<th>Project co-funded by the European Commission within the Sixth Framework Programme (2002-2006)</th>
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Summary

The paper seeks to identify the conditions under which non-hierarchical steering modes are effective alternative mechanisms of conflict resolution to hierarchical imposition in the framework of expanding the EU regulatory regime to new markets with highly heterogeneous demand and supply structures. We argue that the ‘political efficiency’ and ‘policy effectiveness’ of non-hierarchical steering modes is contingent upon the political capacity of the state to mobilise dispersed resources of private actors.

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I. Introduction

The recent enlargement of the EU with the inclusion of eight new member states from the CEE region characterised with diverse economic, political and administrative traditions has engendered significant innovations in the patterns and instruments employed by the Commission in its pre-accession negotiations with candidate countries. Given the enormous economic, political and administrative challenges posed by the eastern enlargement of the EU, the Commission, for the first time, elevated the concept of administrative capacity of the prospective member states to apply the *acquis communautaire* between the fundamental criteria for accession. Administrative capacity to effectively implement binding rules emanating from EU membership was subject, for the first time, to meticulous scrutiny and assisted the deployment of a number of financial instruments (PHAPE, ISPA, SHAPARD) towards policy areas of the *acquis* that included high costs of administrative adjustment. The pre-occupation on the part of the EU with weak administrative capacities of the candidate countries had an immediate effect on the reform of the rules applied to mainstream financial instruments (ERDF, ESF, EAGF) where strengthening administrative capacity to comply with the *acquis* is from the 2007-2013 programming period a guiding principle of the programming process.

The EU’s approach to administrative capacity had a fundamental effect on the nature of pre-accession negotiations and the scope of EU intervention in the *interna corporis* of the member states. Pre-accession negotiations were conducted on a bilateral executive basis including the Commission and central governments. Conditionality as a set of positive and negative incentives aiming at altering domestic constellation of private and public interests in favour of harmonization with EU rules has been the main focus of enlargement literature (Friis/Murphy 1999; Schimmelfennig 2001, 2003; Schimmelfennig/Sedelmeier 2002). Given the desire of applicant countries to join the EU, they had little options but compliance with the rules of the game as defined unilaterally by the EU. However, the Commission’s strategy to address domestic institutional capacities at all territorial and functional spheres of competencies and the opening up of a pre-accession dialogue with multiple non-executive actors (public, private and voluntary), reduced the ability of central governments in the candidate states to resort to hierarchical steering modes in order to cope with the challenges of domestic regulatory adjustment to the *acquis communautaire*. Although the issue of administrative capacity, namely the availability of physical and cognitive resources is well explored, at least in the numerous extensive consultancy reports, political capacity, namely the capacity of the state to mobilise commitment from diverse non-executive public and private actors affected by EU membership, is largely uncharted. Under which conditions do public and private actors commit their resources in order to strengthen domestic adjustment potential of new member states with the requirement of effective harmonization with EU law? Which steering modes are employed to stimulate private resource contribution and do they serve as effective mechanisms of conflict resolution with regard to the adoption of and adaptation to the *acquis communautaire*?

Pharmaceutical 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 (Tosics, 2003: 18). Member states with a strong innovative pharmaceutical industry had introduced product patents from the ‘40s (UK), ‘60s (Germany) and ‘70s (France) under the impetus from the European Patent Convention. Greece, Spain and Portugal aligned their regulatory approaches only in the beginning of the ‘90s when the European Patent Convention was entered into force. During the same period, supplementary protection certificates (SPCs) where introduced by council regulation 1768/92.
to account for the time that elapses between the application and the actual market authorisation of the product. CEECs, in the framework of Europe agreements, gradually introduced product patents from 1991-94. In effect, from the mid-90s onwards there were neither significant regulatory gaps nor did the level of regulatory stringency was significantly lower in the candidate member states comparing to their European counterparts. However, 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. Given the phasing out of significant policy incompatibilities between domestic regulatory approaches in the CEE region with that of the EU, it is paradoxical that pharmaceutical harmonization has generated friction between European and domestic policy makers during pre-accession negotiations.

Despite legal harmonization, alignment of diverse pharmaceutical markets with the EU regulatory approach based on product patents is largely contingent upon states’ political capacity to mobilise diverse industrial interests that provide essential resources for effective monitoring and enforcement as well as societal consensus. This is particularly apt to highly technical regulatory areas, such as pharmaceuticals characterised by information asymmetries in favour of private industrial actors. 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.

Under this novel power configuration the capacity of CEE states to transform their pre-existing centralised systems of pharmaceutical regulation largely depends on their ability to mobilise dispersed resources of pharmaceutical producers. Dependency of public regulators on private resources such as information and expertise regarding the properties of pharmaceutical products reduces the effectiveness of hierarchical imposition to secure legal harmonization with EU rules. In turn, pharmaceutical industry competitiveness relies on the efficacy of the authorisation process that guarantees rapid, safe and sound access of new products to the market. Uncertainty regarding the integrative capacity of the CEEs to the highly decentralised EU regulatory regime is therefore a central determinant of pre-accession approximation process. Under which conditions do private actors commit their resources in order to enhance the regulatory capacity of the state? Which steering modes are employed to enhance private actors’ incentives to participate in joined decision making and are they effective in reducing conflicts stemming from domestic adjustment to the *acquis communautaire*?

The paper seeks to identify the conditions under which non-hierarchical steering modes are effective alternative mechanisms of conflict resolution to hierarchical imposition in the

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1 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 (e.g., European Commission 1999a, 1999b, 1999c).
framework of expanding the EU regulatory regime to new markets with highly heterogeneous demand and supply structures. We argue that the ‘political efficiency’ and ‘policy effectiveness’ of non-hierarchical steering modes is contingent upon the political capacity of the state to mobilise dispersed resources of private actors. Although pre-existing policy traditions of interest intermediation and their deliberative effects between participants are significant determinants of the political capacity of the state, transitional countries, like the CEE, are characterised by significant path breaks in the pre-existing relations between state and non-state actors. Transition to open economy may disturb this equilibrium through changes in the actor’s power configuration. This changing configuration affects both the relative power position of the state that is yielding its primary role in the pre-existing centrally planned regulatory regime.

The following session of the paper will provide essential background information related to the nature of pre-accession negotiations between the Commission and the CEECs in the area of pharmaceutical harmonization (session two). In this area of pre-accession negotiations the European Commission in cooperation with the EMA and national regulatory authorities from member and candidate states as well as industrial representative organisations undertook a number of initiatives that opened up pre-accession negotiations to state actors beyond the core executives and private actors through the decentralisation of pre-accession approximation dialogue to a regulatory network including multiple public and private actors from the candidate countries coordinated by EMA. The combination of positive, negative and learning incentives raises a number of pertinent questions regarding the effectiveness of non-hierarchical modes of steering as an alternative to bilateral negotiations between the Commission and core executives from the candidate countries. Section three will identify the conditions under which private actors commit their resources to enhance political capacity of candidate states to embark upon effective harmonization with EU rules. We argue that private actor’s incentives to enhance the transformative capacity of the state are shaped by the structural characteristics of domestic pharmaceutical markets and their positioning into the regional and global competitive environment. These factors shape their preferences and expectations regarding legal harmonization with EU rules and, in effect, determine the outcome of pre-accession negotiations. The analysis focuses on Poland and Hungary, two member states with highly diverse pharmaceutical markets in terms of innovative potential, market orientation of domestic firms and domestic public and private demand for medical products. Section four reviews our preliminary findings regarding the harmonization process in Poland and Hungary.

II. The opening up of pre-accession negotiations to non-state actors in the pharmaceutical policy area

Pharmaceutical legislation addresses several areas of medical product standards (marketing authorizations, testing, manufacturing, distribution, and labeling, advertising, pricing and post-authorisation surveillance). From May 1st, 2004 the new member states had to upgrade their existing market authorisations according to EU standards. CEE products had to obtain market authorisation according to EU rules or withdrawn from the market. Therefore, domestic producers had to update authorisation dossiers that contain all essential regulatory information and comply with additional requirements to meet EU standards before the date of accession. Authorisations issued by EMA according to the centralised procedure (mandatory for biotechnology products and optional for other innovative medicines) were automatically valid in all new member states. Domestic institutional adjustment to EU authorisation imposes adaptation costs to domestic pharmaceutical industry to harmonise its products with EU rules in order to secure access to the EU markets. In this case compliance is a prerequisite for business
viability. Business may opt for strategies that secure their autonomy by internalising the cost of upgrading product standards to its final units, though most firms seek to build-up their transformative capacity by establishing coalitions through collaborations, mergers and acquisitions with foreign firms by offering access to their markets in return of expertise and know how. Public actors also face adaptation costs related to the establishment of novel authorisation and monitoring structures and procedures that may require new technologies and human resources. Public actors also face additional economic and political costs involved to domestic health care system reforms aiming at containing high prices with consumer pressure for accessibility to high quality medicines from the EU.

However, such general incentive schemes are misleading since they ignore significant variations/differentiation in each product market. The fundamental division in pharmaceutical markets is between organic vs. generics industry. The innovative industry, largely outside the CEE region, is research intensive. In terms of R&D-intensity (R&D-investment in relation to turn-over), the pharmaceutical sector in Europe ranks second behind aerospace. Additionally, pharmaceuticals still provide, by far, the largest positive contribution to the EU’s trade balance in high-technology sectors (cf. European Commission 2000b).

Given the considerable market fragmentation and divergence in member state pricing policies, the inclusion of new member states with considerably divergent market structures has bolstered uncertainties between leading multinational innovative pharmaceutical companies related to long-term revenue potential of their products. Despite the fact that EU’s expansion to new pharmaceutical markets presents significant market opportunities especially in those countries with prior limited access to high quality medicines, lower pricing levels in new member states would boost the growth of parallel trade from CEECs to the rest of the internal market. Moreover, cost containment policies of domestic health care systems in the new member states enhance current trends that favor generics substitution over patented products. Since new member states’ healthcare expenditure per capita is about 2.5 times lower than that of the EU 15 such economic disparities coupled with reimbursement policies that encourage generic substitution in order to contain public health care expenditure would considerably affect the consumer accessibility of new products because of the national governments’ inability to afford them. As a result, the innovative industry expected that they would lose substantial sales in the leading EU markets to parallel traders exporting branded products at cheaper prices from the new member states to higher-priced old member states. Therefore, despite the general preference of organic industry in favor of effective legal harmonization, their interest was also to achieve specific derogations from the principle of free movement of goods into the internal market in order prevent parallel trade. Such a position was reinforced by past experiences from the southern enlargement, with Greece and Spain being nowadays the largest parallel traders in Europe (Kanavos et al. 2004). As a result the innovative industry pressed the Commission to adopt a specific provision that prevents parallel trade (i.e. the establishment of free movement of goods) and a general ban of the so-called Bolar (Roche Products v. Bolar Pharmaceuticals) provisions from the domestic regulatory regimes of the CEECs. The latter allow for research and development of generic medicines and for the generation of data for regulatory purposes prior to the expiration of the patent term of the corresponding organic product. The purpose of this exception to the exclusivity conferred by a patent is to permit potential competitors of the patent owner to initiate proceedings for granting marketing authorisation during the term of the patent. This allows generic industry to sell in competition with the patent owner from the date on which the patent expires. In the largest competitors of

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2 However, in recent years generic substitution policies emerge also in countries with strong organics industry such as the UK, Germany, France and Italy.
the EU (the United States and Japan), the Bolar provisions are seen as a means of re-establishing an equivalent balancing of interests between the organic industry benefiting from the extension of the patent term and the generic manufacturers. The same holds for the “stockpiling exception” permitting storage of the patented products in the six months leading up to the expiry of a patent. In Europe the so-called Bolar provisions are not harmonized and are subject to domestic regulatory regimes.

The generics industry is less R&D intensive. In general, generic products are equivalent to the original brand products: they contain the same active substance, comply with the same rules of production and pharmacovigilance and show the same quality, safety and efficacy as the original brand product – with the exception that they are sold in average at prices of 30-80% of the original price on the market. The generic industry was put in the defensive from the early stages of the pre-accession negotiations. Their fundamental aim was to avoid the abolition (i.e. harmonization beyond the acquis) of Bolar provisions for all CEEs reflecting the enormous expectations for generic expansion in that region after enlargement.

Contested expectations regarding enlargement on the part of western European industry intensified given the diverse regulatory traditions of the CEECs in the pharmaceutical sector. The central negotiator on behalf of the EU was the Commission employing the White Paper as a ‘route-map’ for the implementation of EU pharmaceutical legislation. The Technical Assistance Information Exchange Office (TAIEX) was supposed to provide assistance on Community legislation, its transposition into national legislation, legal terminology, translation, training, and exchanges of experts.

This ‘old’ enlargement approach raised serious problems in the candidate countries as their regulatory structures and drug authorization processes differed significantly from the EU’s, and their institutional capacities to implement the acquis were indeed very weak. Given the dominance of generic industry in the region and the immense pressure exerted to domestic regulatory authorities to update product authorisations in a relatively short period of time it is not surprising that in several opinions on the candidate countries’ application for membership, the Commission emphasized that on pharmaceutical and chemical products legislative alignment was progressing at a slower pace than previously announced.

The Commission initially in cooperation with the innovative industry which in general has close relations both with DG Enterprise and the EMA, being acknowledged as an important sector for the overall competitiveness of the EU vis-à-vis the US, undertook a number of initiatives that opened up pre-accession negotiations to state actors beyond the core executives and the industry. These initiatives were facilitated by EMA that undertook the role of moderator and arbitrator between national and sectoral specific interests in the framework of two regulatory networks, the PERF and the Collaboration Agreement between Drug Regulatory Authorities in the European Union Associated Countries (CADREAC) (Prange and Koutalakis, 2005). PERF is a unique institutional arrangement. Following a meeting between the Commission, EMA 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” (EMA 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 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 (Koutalakis 2004). PERF facilitated cooperation, discourse and learning especially in the most pressing areas of the acquis, most notably the update of product dossiers. The candidate countries were encouraged to ‘examine’, ‘identify’, ‘facilitate’ or ‘advance’ certain needs.
for accession. EMA 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. The Priority Action Areas of the Forum were:

- Pharmacovigilance
- Practical arrangements for implementation of the Acquis Communitaire
- Dossier Assessment
- Responsibilities and mandate of competent authorities
- Telematics and GMP

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, the EMA 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” especially in the area of upgrading authorisation processes for domestic products already circulating before entry to the EU (EMA 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 were effectively insulated from the process; second, PERF seems to have reduced the mutual uncertainty among actors, while enhancing efficiency through ‘transnational network building’.

Perhaps the essence of this rather exceptional case, comparing to the experience from pre-accession negotiations in other chapter of the acquis, demonstrates the merits of deploying participatory structures that facilitate consensual decision making through deliberative decision making process. However, remaining problems indicate that ‘regulatory learning’ within networks cannot alone bring about harmonization. Most contentious issues such as parallel trade, the right of generic industry to conduct research and development of generic medicines and generation data for regulatory purposes prior to the expiration of the patent term of the organic/innovative product, the market authorisation for products circulating in domestic markets before accession, the duration of supplementary protection certificates for products authorised in the new member states before their entry to the EU where largely left out of the PERF process to be resolved by intergovernmental bargaining.

III. NMGs effective and efficient?

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 accountably 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 po-
itical 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 (Pollack 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. Despite common functional pressures experienced by national regulatory systems there are persistent variations in their regulatory philosophy across the EU. These variations are attributed to different state traditions and domestic constellation of interests that condition the constitutive actors’ preferences regarding delegation of regulatory functions to participatory networks. State relations with industrial actors, compatibility with the wider domestic reform agenda are institutional and political properties that enable or hinder the emergence of regulatory networks as effective organizational responses to powerful functional pressures (Thatcher and Stone Sweet, 2002: 13). Beyond functional pressures that may be identical or vary across different member states, the ability of non-state actors to provide essential resources and engineer consensual policy making is a factor that determines constitutive actors’ preferences in favour of delegation to participatory institutions (Eberlein and Kerwer, 2002: 5; Grande 2000: 20). Pre-existing convergence of preferences between resourceful actors and the likelihood of consensual regulatory outcomes reduce the risk of ‘agency losses’ i.e. the gradual emergence of divergent preferences and agendas from the ones initially delegated by the principals in the policy area. This is not to dismiss the fundamental claims of constructivist approaches regarding the effects of delegation to regulatory networks on the gradual evolution of consensual negotiating modes of interactions between participating actors. However, given the challenges imposed by the quantitative (large number of accession countries) and qualitative (weak admin-
istructive capacities of accession countries to ensure effective legal harmonization) dimension of eastern enlargement, accommodating constellation of interests between key actors and their ability to engineer consensus by insulating from politicization pressures are key properties that affect actors’ preferences regarding the institutional design of accession negotiations.

In regulatory areas characterised by unequal distribution of cognitive resources in favour of private actors, agency design and functionality is conditioned upon private actors incentives to commit their resources into regulatory policy making. Private actors may gain influence into the regulatory policy outcomes, reduce compliance costs comparing to command-and-control regulations and increase their control over other actors’ compliance behaviour and competitive advantages. However, they have to commit considerable resources into the policy making that have assess vis-à-vis other opportunities for influence for example through direct lobbying (Broscheid and Coen, 2002). The unequal distribution of resources such as expertise over product qualities in favour of private actors may create disincentives to share regulatory information that wouldn’t be otherwise accessible to competitors. Moreover, public firms may find difficulties to justify the commitment of these resources to their investors unless they demonstrate tangible effects on their overall corporate performance.

Although the capacity of the state to mobilise private resources can be determined with reference to pre-existing policy traditions of interest intermediation and their deliberative effects between participants, transitional economies, like the CEE, are characterised by significant path breaks in the pre-existing equilibrium between state and non-state actors. Transition to open economy may disturb this equilibrium through changes in the actor’s power configuration. This changing configuration affects both the relative power position of the state that is yielding its primary role in the pre-existing centrally planned regulatory regime. From central planning the state assumes more the role of mediator and/or facilitator of global/European capital requirements. Private actors may gain or lose autonomy depending on their expectations from the opening up of markets. Under this novel power configuration the transformative capacity of the state largely depends on its ability to mobilise dispersed resources of private actors which manifest low degree of loyalty and commitment to a given domestic market. Under which conditions do private actors commit their resources into participatory regulatory network in order to strengthen the political transformative capacity of the state?

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’). Conceptualising state capacity, namely the capacity of the state to cast a credible shadow of hierarchy 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 both in southern and central eastern European member states (also, Börzel 2007).

Domestic regulators play a crucial role in private actors’ preference formation. First through their administrative capacities such qualified personnel, effective enforcement mechanisms and financial incentives to mitigate compliance cost to industry can guarantee effective enforcement. 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 and product standards. The shadow of hierarchy therefore affects the incentives of private actors to participate into transnational regulatory networks. In both cases the ability of domestic regulators to mobilise private cognitive resources necessary to secure effective harmonization with EU standards as a crucial factor that affects post-delegation functionality of those regulatory networks is affected by their capacity to cast a credible shadow of hierarchy through positive and negative incentives.

The following part will examine these propositions in the light of empirical evidence from pre-accession negotiations and the effectiveness of regulatory interaction in the framework of PERF in Hungary and Poland.

**IV. Pharmaceutical harmonization in Hungary and Poland**

Empirical evidence from pharmaceutical pre-accession negotiations hardly confirms the predictions of the principal/agent framework. Given the profound similarities in regulatory traditions between the CEECs, domestic actors both from the existing member states and the accession countries experience common functional pressures emanating from the requirements for the adaptation to the EU pharmaceutical acquis. To a large extent these functional pressures are reflected to the diverse outcomes of pre-accession negotiations. These can be classified into two broad categories. The first category comprises special provisions adopted for all accession countries aiming at alleviating potential competitiveness distortions emanating from the relative recent introduction of product patents in the region. According to a 'specific mechanism' incorporated to the Accession Treaty, parallel trade from the CEECs is not permitted for pharmaceutical products whose patents or supplementary protection certificates were filed in a member state at a time when such protection could not be obtained in one of the new member states (except from Malta and Cyprus). In these cases the patent holder can rely on the exclusivity rights derived from the patent in order to import the product into a member state where it enjoys patent protection. The second category of outcomes comprises country specific derogations negotiated between the Commission and individual member states. Negotiations focused on the terms of application of Council Regulation 1768/1992 into national regulatory systems of the new member states, regarding the upgrade of market authorisations of products and the implementation of supplementary protection certificates. In both cases the Commission stressed that in accession countries the application of Council Regulation should have certain retroactive effects extending patent protection even before the date of accession in order to prevent market distortions emanating from the recent introduction of patent protection in the CEECs. In both areas bilateral pre-accession negotiations were accompanied by systematic preparations in the framework of PERF with the aim at transferring experience and expertise and resolving conflicts between national regulatory authorities and private industry in the process of upgrading domestic products’ authorisation requirements and property rights. The outcome of pre-accession negotiations and the effectiveness of regulatory interactions in the framework of PERF vary considerably between accession countries reflecting the capacity of central governments to mobilise public and private resources in favour of harmonization with EU law.

**IV.1 Hungary**

Under COMECON, market differentiation and specialisation of CEE economies was centrally planned. Hungary was the leading pharmaceutical producing country (specialising also in electronics and motors). The five largest nationalised firms (Chinoin, Richter, Wander, Alkaloida and Phylaxia, Egis, Biogal) dominated the CEE region and the USSR markets. As a re-
sult the then National Institute of Pharmacy (OGYI) had a leading role in collaborative regulatory arrangements evolved around the Coordinating Centre of the so-called Drug Affair Cooperation of the COMECON countries. Regulatory cooperation between COMECON authorisation institutes was optional based on indicative guidelines regarding drug authorisation and evaluation procedures. Within this collaborative framework, OGYI had the leading role in drafting non-binding recommendations based on western standards given the export orientation of Hungarian pharmaceutical industry. The most prominent example is pharmacopoeia that was drafted on European therapeutic evaluations of active substances. Our interviewees stress the positive effects of intense international scientific exchanges that allowed the transferring of pharmaceutical knowledge and development in the US and leading European pharmaceutical countries in Hungary (Interview, Director General, OGYI).

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.

Reforms followed two steps. In the aftermath of 1968, the so-called New Economic Mechanism introduced some degree of decentralisation in economic planning by replacing direct physical planning by indirect price-based instruments and an emphasis on a minimum formal independence of enterprises but intact state ownership. In 1982, the state, as a response to increasing competitiveness problems in COMECON stemming from the 1970s oil crisis, promoted enterprise autonomy and some large industries obtained foreign trading rights. Large pharmaceutical enterprises were the first to benefit from these rights and soon manifested considerable export-led growth potential trading mainly with Germany and Austria. The significant diversion of trade from the former COMECON partners to west European markets insulated domestic industry from the downturn from the collapse of the Soviet Union.

After 1989 Hungarian foreign direct investment of innovative industry was catalytic to the competitiveness of Hungarian pharmaceutical industry. All formerly state-owned firms were privatised between 1991-1996 and were acquired by foreign multinationals. The new companies that emerged are: Biogal (Israel), Chinoïn (France), EGIS (France), Human (Canada-Israel), ICN Hungary (USA), Pharmavit (USA), Richter, nowadays the only firm controlled by Hungarian investors (State Property Holding (APV Rt.).
Table 1: Overview of the main Hungarian Pharmaceutical Firms

<table>
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<th>Companies</th>
<th>Main owners</th>
<th>Main owners (%)</th>
<th>Other owners (%)</th>
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<tr>
<td>Biogal</td>
<td>ORVET GmbH/ TEVA (Israel)</td>
<td>99,1</td>
<td>0,9</td>
</tr>
<tr>
<td>Chinoin</td>
<td>Sanofi (France)</td>
<td>est.99,1</td>
<td>0,9</td>
</tr>
<tr>
<td>Egis</td>
<td>Servire (France)</td>
<td>51,0</td>
<td>49,0</td>
</tr>
<tr>
<td>Human</td>
<td>Novopharma (Canada)</td>
<td>65,69</td>
<td>2,02</td>
</tr>
<tr>
<td>ICN Hungary (former Alkaloida)</td>
<td>ICN Pharmaceuticals (USA)</td>
<td>90,97</td>
<td>9,03</td>
</tr>
<tr>
<td>Pharmavit</td>
<td>Bristol Meyers Squibb (USA)</td>
<td>99,9</td>
<td>0,1</td>
</tr>
<tr>
<td>Richter</td>
<td>Foreign financial investors</td>
<td>59,92</td>
<td>12,97</td>
</tr>
<tr>
<td></td>
<td>State Property Holding (APV Rt.)</td>
<td>27,11</td>
<td></td>
</tr>
</tbody>
</table>

Source: [www.magyosz.org](http://www.magyosz.org)

As a result Hungary is the only CEE country that demonstrates research and development potential, listed between the countries with the highest number of innovative projects initiated by firms, universities and research institutes and between the countries with the highest concentration of multinational companies in the region (CEC 2001: 45 and 25). These developments had a profound effect on the market orientation of Hungarian pharmaceutical companies. The following table demonstrates that in recent years the export orientation of Hungarian pharmaceutical firms has been reversed from the traditional trading partners, the former soviet republics and Russia to the EU:

Table 2: Hungarian Exports of Pharmaceuticals (1998-2003) in million USD

![Graph of Hungarian Exports of Pharmaceuticals (1998-2003)](image)

Source: Own elaboration based on data from the Hungarian Statistical Office.
The sectors’ growth is mainly export driven with approximately 67.7 percent of overall profits corresponding to almost half of the production volume. Among the top-10 targeted countries, four (4) are members of the EU (Germany, Austria, UK and France). Active ingredients are mainly shipped to the EU and the U.S. while finished products are exported to more than 80 countries. From the former soviet republics the main trade partners are Russia, Ukraine, Lithuania and the CEE counterparts to the EU (Poland, Czech Republic, Slovakia and Romania) due to traditional commercial ties prior to the 1990s.

As a result, the actual drug evaluation and registration system reflects international standards and national traditions. Hungary introduced compulsory registration of pharmaceuticals already in 1933, laboratory controls in 1927, clinical trials (since 1951) and human clinical pharmaceutical experiments (in 1967) as prerequisites for new-drug approval and Good Manufacturing Practice (in 1974). Hungary was also the first CEE country to grant independent regulatory competences to OGYI already in 1991. Prior to 1987 applications for drug authorisations were approved by the Ministry of Health after a recommendation and assessment by the OGYI. During 1987-1991, the institute became an independent decision making regarding only the registration of products with the Ministry of Health retaining control over marketing licenses. In 1991 OGYI was granted full autonomy as an independent regulatory agency responsible for assessment, authorisation, post-marketing surveillance and inspections of medicinal products. Applications are assessed on the basis of the drug's quality, safety, and efficacy. Although the Ministry of Health appoints OGYI’s general director, approves its budget plan and controls its financial management, OGYI is independent from public budget, financed by fees paid by pharmaceutical industry for the authorisation of products, licence maintenance as well as the amendment and upgrading of existing authorisations.

The internal organisation of OGYI has been modelled on the EMA. Authorisations for medical products for human use are assessed by the OGYI’s National Drug Evaluation Committee (OGYEB, Országos Gyógyszerértékelő Bizottság), which has similar functions with EMA’s Committee for Proprietary Medicinal Products (CPMP). OGYEB is comprises the head of departments of OGYI, senior and fellow workers and the director general. The committee meets every second week in order to handle incoming applications and approve registration and authorization applications, after different departments of OGYI complete their evaluations. The proceedings of the committee meetings are open to the public and available in the OGYI website. 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. Appeals against the decisions of OGYI can be made to the Ministry of Health.

In the post-1989 period and before accession to the EU, the dominant position of Hungarian pharmaceutical industry and the legacy of the COMECON collaborative framework, OGYI undertook a number of initiatives with the aim at structuring the emerging regional market according to western regulatory standards. Hungary was the first to become a member of World Health Organization (WHO) and the Pharmaceutical Inspection Convention of the European Free Trade Association (EFTA PIC). According to the AIPM’s (Association of Innovative Pharmaceutical Manufacturers, Hungary) director, the real transition of the domestic regulatory regime took place not with the country’s accession to the EU but in the beginning of the 1990s. ‘From that time, with the appearance of the multinational companies, a new mentality began to spread in the country. Hence, later the accession and the preparations for it brought about a much more limited effect.

However, 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. The then director of OGYI suggested that Hungary and other CEECs would accept the automatic validity of authorizations granted under the centralized procedure in their domestic markets only if they would be allowed to participate in the EMA’s committees where the technical decisions are made. The Commission was reluctant to grant such a status to every accession country. As a result CADREAC emerged as a regulatory network of representing the interests of CEE industry and national regulatory authorities. Participation of in CADREAC was voluntary. CADREAC was particularly successful in two areas of pharmaceutical approximation. First, it elaborated a simplified procedure to be followed by domestic regulatory authorities for medicines already circulating in the EU through the centralized or the mutual recognition procedure and accelerated regulatory requirements for market entry such as the translation of prescription texts in domestic languages, labeling of products and partition of active substances. Second, the preparatory work undertaken by CADREAC in cooperation with CEE pharmaceutical industry provided for the opportunity to file authorization applications according to mutual recognition procedure. Apart from its apparent success in regulatory approximation of its members with EU standards, CADREAC served as a focal point for CEE generics industry that viewed regional cooperation as an attempt to counterbalance the dominance of organic industry concerns in pre-accession negotiations. Generic industry representation through MAGYOSZ (Magyarországi Gyógyszergyártók Országos Szövetsége, Hungarian Pharmaceutical Manufacturers Association) is diverse reflecting different interests and expectations of Hungarian generic and internationally-owned organic firms. When interviewed, presidents of both Hungarian Associations (MAGYOSZ and AIPM) were fully aware of their European level counterparts. AIPM is an associate member in EFPIA while both AIPM and MAGYOSZ are full members in the International Federation of Pharmaceutical Industries and Associations (IFPIA, a worldwide organisation in which EFPIA is also a member) and MAGYOSZ is also a full member of the AESGP (Association of European Self-Medication Industry) and EGA. However, at the aftermath of accession negotiations, the domestic generic industry (mainly Richter Ltd) was in a disadvantageous position compared to the multi-national innovative firms based in Hungary. Richter and other generic firms are full members in EGA. Still, they had no formal interest representation in the EU before the accession. Part of the problem is that EGA represents not only national generic associations but also individual firms in contrast to EPFIA that operates as a “super federation” of national federations of organics industry associations. EGA’s broader scope of membership often impedes the articulation of diverse interests into a common position. Therefore, generic firms, identified with CADREAC as a potential counterbalancing power to the dominance of foreign multinationals and organic industry in issues related to the introduction of supplementary protection certificates, and the abolition of Bolar provisions proposed by EPFIA (Interview, Director Richter LtD).

These initiatives enhanced OGYI’s capacity to mobilise private industrial actors in favour of effective harmonization with EU standards. The initiation of PERF by the Commission was perceived by domestic actors as the natural continuation of CADREAC in order to resolve outstanding problems remaining from CADREAC. As it has already been mentioned, at the initial stage of pre-accession negotiations, the most pressing problem was the upgrade of au-
thorisations for domestic products circulating the Hungarian market prior to EU accession. PERF attracted the interest of the bulk of Hungarian firms. However, their assessment of the effectiveness of regulatory interactions is diverse. Ex post evaluations are quite critical given the outcomes of pre-accession negotiations regarding parallel trade and the supplementary protection certificates despite the fact that these issues were not resolved in the framework of PERF but through bilateral executive negotiations. As, the development director of Richter Ltd, who took part in all three PERF conferences, argues “it was about that how can the western institutional system and requirements press down in the throat of the accession countries”.

An additional critique was that although PERF coincided with the revision of pharmaceutical regulations that became in force only a month before the CEECs accession to the EU (April 2004) there was no influence of the new member states. Therefore, PERF was criticised for its failure to serve as an effective conflict resolution mechanism in issues that were eventually left outside of its scope. When asked about the effectiveness of regulatory work undertaken in the framework of PERF, industrial representatives stress its contribution to the development of the mutual understanding capabilities of the two parties (EU and non EU members) as well as its effectiveness in fostering compliance with EU law prior to accession. Through the PERF, Hungarian industry and the OGYI became familiar with their novel regulatory environment and adjusted their political, legal, technical and administrative tasks and in order to comply with the acquis without legal enforcements. Among several actions undertaken in the framework of PERF, industrial actors stress the positive effects of a “twinning project”. According to this project the national authorization offices and pharmaceutical companies could exchange employees in order to familiarise with novel regulatory requirements. The OGYI did not participate in this project, but more Hungarian firms (like Pfizer) used the possibility. Pairs were created out of the different company workers and these pairs worked then together. The exchange of experience and expertise at company level was so successful that was replicated recently in Romania and Bulgaria. Most importantly, interactions between public and private actors in the auspices of PERF served as a basis for the elaboration of common positions between industrial actors seeking to influence the national position represented by the Ministry of Foreign Affairs.

The outcome of OGYI’s capacity to secure consensus between affected actors was a smooth harmonization process. At the beginning of pre-accession negotiations, Hungary requested several derogations including a 5 year transition period to introduce the SPC and data exclusivity. However, according to the opinion of pharmaceutical experts, it was more tactic than real aim connected with demands for derogations in environmental policy (Interview, Director MAGYOSZ). The final agreement provided for a retrospective effect of SPC for products patented after 1st January 2000. The case of data exclusivity is more delicate. The accession treaty provided for a 6 year term, (starting from January 1st: 2003), for products marketed after this date. However, before Hungary’s accession, the EU amended the relevant legislation to prolong this period from six to 11 year. Hungary, together with other CEECs (Poland, Slovenia and Malta) protested against this development arguing that it was a unilateral decision not negotiated in the Accession Treaty. As a result, Hungary submitted a proposal for a derogation of 5 to 10 years for the introduction of the new directive. An independent consultant confirmed that the new regulation would cost to Hungarian generic industry approximately €40 million per annum. Despite this rather exceptional case Hungary managed to effectively harmonize its domestic regulatory requirements with the EU prior to its accession with no specific derogations already from 2003 with the adoption of a new pharmaceutical law.
IV.2 Poland

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%). 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 generic consumption country with approximately 63% of total value and 86% of total quantity of products circulating the domestic market.

Privatisation of the former state-owned pharmaceutical consortium Polfa, a generic firm covering mainly the domestic demand with limited export orientation to small COMECON markets, was the second most significant development. Polfa attracted the investments mainly from East European generic firms, apart from Glaxo Wellcome and ICN pharmaceuticals, due to the lower production costs, approximately 4 times below the EU average and 30% below the Vishegrad group. The table below provides an overview of investors to different branches of the Polfa group.

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3 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%).


5 The average price of domestic medicines is €1.57 while the corresponding price of foreign medicines is €8.03 (Source: Instytut Leków – Centrum Monitorowania Konsumpcji Leków, cited in: MinisterstwoGospodarki i Pracy / Ministerstwo Skarbu Państwa: Strategia dla przemysłu farmaceutycznego do roku 2008, Warszawa 2005, p.16f).

6 Comparisons with western European member states and the US are striking. In countries with similar cost containment and generic replacement practices such as Germany and the UK, generics represent only 28% and 18% of the total value and 40% - 50% of total quantity of medicines circulating those markets respectively (Source: MinisterstwoGospodarki i Pracy / Ministerstwo Skarbu Państwa: Strategia dla przemysłu farmaceutycznego do roku 2008, Warszawa 2005, p.16f).

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Polish pharmaceutical industry is traditionally inward oriented. After 1989 both the total value of pharmaceutical exports and the share of exports in GDP decline steadily from 171.3 mln USD in 1994 to 151 mln USD in 2003 and 58.2% in 1994 to 14.1% in 2003, despite the inclusion of foreign investors and the opening up of European markets. The drastic fall in the significance of exports for the domestic pharmaceutical firms is the outcome of the gradual distortion of traditional trade links to Russia and Former Soviet Republics, especially during 1998-2002, the period of pre-accession negotiations with the EU. However, as the following table demonstrates the traditional directions for pharmaceutical exports remain the CEECs, Russia and the former Soviet Republics, despite the relatively late emergence of the EU as significant export destination for Polish medicines produced by the two largest EU and US investors in the Polfa group.
Our interviewees indicate that the lack of product patents for the bulk of domestic products is the biggest impediment for exports to the EU (Interview, expert, AWAFARM). Despite the introduction of product patents in 1993, products circulating the domestic market or exported in Russia and the former Soviet Republics are still not patented while registration dossiers do not exist. Therefore, Poland was between the member states that actively opposed EU demands for full harmonization in the area of pharmaceutical legislation prior and after its accession to the EU. Polish negotiators described the Commission’s requirements for the update of authorisation dossiers for all products circulating the domestic market as a ‘great shock’ given the fact that in older EU countries (for example Spain or Portugal as well as in Germany for GDR products registration books are still not updated to the requirements of the 1965 pharmaceutical directive while in some new formed states such as Slovenia and the Baltic-countries, medicines have no registration dossiers (Interview, Legal expert and chief negotiator for Poland, Ministry of European Affairs).

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 (Interview, negotiator, Polish Ministry of European Affairs). This concern is largely reflected in the nature of domestic regulatory regime. In 1991

7 The Groupings: 1. Western Europe: Austria; Belgium; Denmark; Finland; France; Germany; Great Britain; Greece; Ireland; Israel; Italy; Liechtenstein; Luxembourg; Monaco. 2. Central and Eastern European Countries (+ Baltic States): Albania; Bosnia and Herzegovina; Bulgaria; Croatia; Cyprus; Czech Republic; Estonia; Hungary; Jugoslavia; Latvia; Lithuania; Macedonia; Malta; Romania; Serbia and Montenegro; Slovakia; Slovenia. 3. Former Soviet Republics: Azerbaijan; Belarus; Georgia; Kazakhstan; Kyrgyzstan; Moldova; Russia; Tajikistan; Turkmenistan; Ukraine. 4. East Asia: China; Hongkong; India; Indonesia; Malejsia; Japan; Singapore; Sri Lanka; South Korea; Vietnam. 5. Middle East: Irak; Iran; Yemen; United Arab Emirates. 7. North America: United States of America; Canada; Mexico
Poland assigned considerable autonomy to the two scientific institutions dealing with authorisation of medicines, namely the Office for Registration of Pharmaceutical Products and Medical 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 (Urzęd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych). The new office is an internal administrative division of the Ministry of Health which since 2002 decided upon authorisations, inspections, pharmacovigilance and marketing authorisations. According to our interviews the main rational behind this rather unusual reform, given the international trend towards the establishment of independent regulatory bodies for the authorisation of medicines, was to maintain political control over public health care expenditure in drugs (Interview, Policy expert, AWAFARM and legal expert, Polish Ministry of European Affairs). 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 it regulatory practices with EU requirements. As a former scientific expert to the Polish Drug Institute put it ‘since about 2001 the country was simply unable to defend Polish interests because it lacked the expertise and grounded its policy on false presumptions, political miscalculations and ignorance of the political elite’ (Interview AWAFARM). Poland was between the countries that negotiated transition periods for the upgrade of market authorisations 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.

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8 Biuro Rejestracji Środków Farmaceutycznych i Materiałów Medycznych Instytutu Leków (my translation) and Centralny Ośrodek Techniki Medycznej (my translation).
9 Law on the Office for Medicinal Products, Medicinal Devices and Biocides from 27 July 2001 (Dz. U. Nr. 126 poz. 1379 ze zm.).
10 Poland has also negotiated transition periods for marketing authorizations for medical devices.
The poor compliance of Polish pharmaceutical products with EU requirements is largely the outcome of the weak articulation of the novel system of drug authorisation to the international scientific community. The new Ministerial authorisation office lacked the qualified scientific personnel with international affiliations to effectively participate in all initiatives seeking to build up capacities for effectively harmonising authorisations of domestic products to EU requirements. Despite the mounting problems, the Ministry of Health did not participate in CADREAC, while participation to PERF was largely symbolic only in the first phase of the programme. Comparisons with Hungary regarding participant assessments of the effectiveness of PERF are striking. The dominant view in Poland is that ‘PERF was a conference with no visible effects despite interesting contacts. No concrete problem-solving. Perf was not able to elaborate regulation models for the candidate countries. In the end the results didn’t seem to be proportional to the money and the organisational efforts put in the project (Interview Legal Expert, Polish Ministry of European Affairs). PERF I is seen more critically. ‘The Commission assumed the position of a hard negotiator leaving the candidate countries no choice despite full adaptation of the acquis. The Commission’s stance on patent protection periods was perceived particularly harsh, posing a major challenge to polish interests. PERF was a forum where the candidates could present their positions. But it was ineffective’ (Interview legal advisor, Polish Ministry of European Affairs). PERF II was more successful since it discussed the idea of introducing a European reference product for CEE generic medicines’ authorisations. Before the proposal, the Commission did not allow the authorisation of a generic product on a certain market if there wasn’t the original reference product on the market. Especially Poland was against this principle and promoted a more liberal model. The European reference product is such a model. Today, for the authorisation of a generic product the applicant doesn’t have to prove that the original reference product is present at the targeted market but it is sufficient to indicate the reference product on one of the EU markets.

The overall negative assessments were largely influenced by PERF’s failure to elaborate on the new pharmaceutical directive that was introduced in April 2004 with no CEE involvement in its negotiation. As has already been mentioned above the new directive extends the validity of supplementary protection certificates from 6 to 8 or 10 years. This new provision is detrimental to generic industry that dominates the Polish market. Data exclusivity was the field of negotiations in the pre-accession negotiations between the ministry of European Affairs and the Commission. Poland feared negative consequences for its pharmaceutical industry, the patients and the public budget. The longer the data exclusivity period the worse off are the generic producers and the later the patients get new medicines. This would shift the balance to innovative industry that produces much more expensive products. Although Poland and the other accession countries were granted observant status to the Council they had no right to vote and influence the directive. The timing for such an important reform was seen by Polish negotiators with suspicion and its outcome has generated a negative climate that prevented Polish representatives from actively participating into the following two phases of PERF.

As a legal expert from the Ministry of Foreign Affairs puts it:

‘The Commission’s approach to the candidates was seen as unfair and lacking good political culture. The candidates where completely taken aback by the new directive and the way their positions were not considered. The new EU directive changed the conditions of membership exactly one day before the enlargement round of 2004. The new conditions stood in contrast to Poland’s accession treaty which was based upon the 2001 pharmaceutical directive. The new directive dates from 2004 and went into force on 30 April 2004, one day before the enlargement. Poland felt that this contradicted the
Commission’s proclaimed policy of dialogue, exchange of opinions and mutual learning and instead gave an example of ruthless power politics and manipulation. From 2011 the new directive will cause high financial pressure on the public budget. To maintain the same level of health care, Poland will have to increase its spending for pharmaceutical refunding. The reason is that those generics which under the former system would be expected in the market in 2011 will enter the market 4 years later in 2015. This leads either to a degradation of health care or to higher public spending. The rise in costs also affects the patients who will have to pay significantly more for their pharmaceutical products (about 60% of the rise in prizes). (Interview, Legal expert, Polish Ministry of European Affairs).

Poland asked for a transition period of 15 years regarding the extension of patents. This was denied. Poland was upset about the decision procedure. The impression was that the Commission tried to delay the decision. The final decision was based on a report ordered by the Commission regarding the assessment of the impact of the directive on Polish pharmaceutical industry. The report found that there are no significant negative effects on competitiveness of the Polish generic industry. This report was bitterly criticised by pharmaceuticals experts as unprofessional, based on false data and false presumptions. As a result the Ministry of European Affairs suggested the referral of the Council to the ECJ for ignoring Poland’s request for a transition period. As it was foreseen by the Accession Treaty, the Council was bound to react on such a demand. Such a case has not referred to the ECJ. However, the government still negotiates with the Commission for the transition period and has not yet transposed the directive.

V. Concluding remarks

The paper suggests that domestic scope conditions affect both the emergence and the effectiveness of participatory regulatory networks as alternative mechanisms of conflict resolution to bilateral executive pre-accession negotiations. 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 their compliance performance. These variations are attributed to the capacity of state actors to mobilise diverse domestic interests towards effective policy harmonization with EU standards. Beyond functional pressures, in technical areas of EU regulation, the transformative capacity of the state depends on the constellation of private actors’ preferences that condition their incentives to commit essential resources to a given policy outcome. As the case of Hungary demonstrates the capacity of the state to mobilise the necessary resources for effective problem solving in a given area is an essential condition for the effectiveness of alternative modes of conflict resolution based on participatory non-hierarchical networks of stakeholders. However, in this case the transformative capacity of the state largely depends on the degree of congruence of private actors’ preferences and expectations that enable or hinder effective policy harmonization with European standards. Preferences, interests and expectations of private actors are shaped by their positioning in domestic and international competitive environment for pharmaceuticals. The degree of integration to EU market and attractiveness to foreign investors has significant repercussions for the distribution of power between public and private actors. On the contrary in Poland, the state fails to mobilise private interest in favour of harmonization with EU rules. The state resorts to a top-down mobilisation of private resources by establishing networks of cooperation with private actors under the expectation that once institutionalised these networks may provide a stable framework that facilitates conflict resolution and the diffusion of
best regulatory practices. However, since private actors face limited incentives to participate beyond formal requirements, the effectiveness and efficiency of regulatory network is rather limited. The case of pre-accession negotiations for the harmonization of pharmaceutical regulations in the CEECs highlights the significance of market considerations in shaping policy outcomes in unpredictable ways. The abolition of free movement of CEE medicines introduced by the Commission as well as the continuation of circulation unpatented products in Poland signify the significance of the ‘shadow of the market’ over the ‘shadow of hierarchy’ as the ultimate force that induces the course of public policies.
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VII. List of interviewees

VII.1 Hungary

- Director, MAGYOSZ (Hungarian Pharmaceutical Manufacturers Association)
- President, AIPM (Association of Innovative Pharmaceutical Manufacturers)
- Director of Governmental Relations, Pfizer Kft
- Director general of the National Institute of Pharmacy (OGYI)
- Director, Development, Gedevon Richter LTD
- Chemist expert, biotechnologist and pharmaceutical registration manager, Pfizer Kft
- Senior Regulatory Affairs Manager, AstraZeneca Kft.
- Former fellow-worker of the OGYI (National Institute of Pharmacy), pharmaceutical registration expert
- Legal advisor, Administrative and Co-ordination Department, Ministry of Health
- Jurist, former member of the Hungarian Mission to the European Communities; presently member of the Permanent Representation of Hungary to the EU, Director of the Legal Service

VII.2 Poland
- Ledal Advisor to the Minister in the Ministry for European Affairs
- Chief Negotiator Ministry for European Affairs
- Former legal officer Ministry of European Affairs current employee of AWAFARM