

Pharmaceutical Harmonization in Central Eastern Europe – New Modes of Governance in the Shadow of Conditionality

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1. Introduction

On 1 May 2004, the European Union (EU) faced its most challenging enlargement ever when ten new countries joined. One of the biggest challenges for Central and Eastern European Countries (CEECs) regarding their EU membership is the effective implementation and compliance with EU rules. 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 late-comers to the EU, the CEECs face two serious problems regarding the adoption of EU legislation. First, they never had the opportunity 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.

Pharmaceutical harmonization was one of the most contested areas in the recent enlargement process. The pharmaceutical industry is a so-called 'strategic' sector for Europe, characterized by a high degree of internationalisation and innovation-intensity. The pharmaceutical sector is one of the most standardized sectors in the internal market. EU regulations address several areas of medical product standards (marketing authorizations, testing, manufacturing, distribution, and labeling, advertising, pricing and post-authorisation surveillance). From 1 May 2004 the new member states had to up-

grade their existing market authorisations to meet EU standards. Products from CEE had to obtain market authorisation according to EU rules or be withdrawn from the markets. 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 in order to secure access to EU markets.

2. The limits of bilateral executive negotiations

The Commission initially did not develop a particular strategy for the accession countries. From the outset of pre-accession negotiations, the EU placed considerable emphasis on the free movement of goods in order to ensure that products can move freely across borders. The White Paper on the Preparation of the Associated Countries of Central and Eastern Europe for Integration into the Internal Market of the Union lays down the technical regulations and standards which candidates have to implement in their national industries. The central negotiator on behalf of the EU was the Commission. The Technical Assistance Information Exchange Office (TALEX) was supposed to provide assistance on Community legislation, its transposition into national legislation, legal terminology, translation, training, and exchanges of experts. Hence, comprehensive legal harmonization without specific derogations remained the core of the EU's method of enlargement.

However, bilateral executive negotiations failed to capture the complexity of heterogeneous demands of multiple public and private actors with contested expectations re-

garding enlargement. Given the considerable market fragmentation and divergence in member state pricing policies, leading multinational organic firms were concerned that CEECs' accession to the EU, with their lower pricing levels, will spark a huge increase in parallel trade from CEECs to the rest of the internal market. 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. As a result the innovative industry favored the adoption of 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 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. 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. Generic industry fiercely opposed such derogations. The former 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 on average at prices of 30-80% of the original price on the market. The generic industry was put on the defensive from the early stages of the pre-accession negotiations. Their fundamental aim was to avoid the abolition of Bolar provisions for all CEECs reflecting the enormous expectations for generic expansion in that region after enlargement.

Moreover, new member states' regulatory authorities faced considerable problems in aligning their modes of operation to new regulatory requirements. Pharmaceutical markets in the COMECON region were regulated on the basis of process rather than product patents. The former provide less comprehensive 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. Member states with a strong innovative pharmaceutical industry had introduced product patents from the 1940s (UK), 1960s (Germany) and 1970s (France) under the impetus from the European Patent Convention. Greece, Spain and Portugal aligned their regulatory approaches only at the beginning of the 1990s when the European Patent Convention came into force. During the same period, supplementary protection certificates (SPCs) were introduced by council regulation 1768/92 to account for the time that elapses between the application and the actual market authorisation of the product. The traditional enlargement ap-

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proach 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 weak. Although CEECs, in the framework of Europe agreements, gradually introduced product patents from 1991-94, domestic regulatory authorities lacked the experience and expertise to fully implement them. As a result, in annual reports on the progress of pre-accession negotiations the Commission emphasized that on pharmaceutical and chemical products legislative alignment was progressing at a slower pace than previously announced.

3. Designing a new strategy: delegation and institutionalisation

After years of stagnation in the transposition and implementation of pharmaceutical regulations in the CEECs, the Commission – backed by member states and the organic industry – 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 the European Agency for the Evaluation of Medicinal Products (EMeA) that undertook the role of moderator and arbitrator between national and sectoral specific interests in the framework of two regulatory networks, the Pan-European Regulatory Forum (PERF) and the Collaboration Agreement between Drug Regulatory Authorities in the European Union Associated Countries (CADREAC). PERF is a unique institutional arrangement concerning pre-accession negotiations. Following a meeting between the Commission, EMeA and the drug regulatory authorities of the CEECs in 1997, PERF was established as a 'structured partnership' "to help the associated countries fulfil the requirements of the White Paper for Technical Regulations in the pharmaceutical sector. PERF as a transnational policy network involving (national and European) regulators and industry representatives facilitated horizontal regulatory learning.

The first phase of PERF (PERF I) covered the period from September 1999 until September 2000. The programme included 31 working group meetings. PERF II, consisting

Further reading

This policy brief is based on research carried out within the NEWGOV project no. 14 on "Smoothing Eastern Enlargement: Independent Regulatory Agencies & Non-Hierarchical Steering". 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. The project is led by Charalampos Koutalakis.

Further information can be found on the NEWGOV Website in the [special section](#) of project no. 14.

of 35 meetings, a series of secondments and joint visits operated from June 2001 to August 2002. PERF III, which ran from January to December 2003, finally concluded the process. The Priority Action Areas of the Forum were: pharmacovigilance, practical arrangements for implementation of the *acquis*, dossier assessment, responsibilities and mandate of competent authorities, telematics and good manufacturing practices. During the PERF process, candidate countries did not only 'learn' to interpret those parts of EU pharmaceutical legislation which are uniformly implemented in all member states, but also those parts which allow for some flexibility and which are implemented in different ways in the member states. Thus, mutual understanding facilitated the internalisation of legal requirements for the effective implementation of EU legislation, most notably the update of product dossiers. 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 advi-

sor 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 and its core role within the European pharmaceutical network, the EMeA 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. 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'.

4. Assessing the prospects of alternative modes of pre-accession negotiations

Through delegation and institutionalisation the Commission achieved a 'smoother' enlargement process as compared to the traditional enlargement mode based on purely bilateral negotiations between the Commission and national executives. While the Commission did not deviate from the principle that future members have to accept all EU rules, it showed flexibility with regard both to the method of conducting pre-accession negotiations with candidate countries and the inclusion of non-executive and private actors to the process. As a result candidate countries' demand for derogations from the *acquis communautaire* were minimised.

The essence of this rather exceptional case, comparing to the experience from pre-accession negotiations in other chapters of the *acquis*, demonstrates the merits of deploying participatory structures that facilitate consensual decision making through deliberative decision making processes. However, some remaining problems indicate that 'regulatory learning' within networks cannot alone bring about harmonization. The most contentious issues, such as parallel trade; the right of generic industry to conduct research and development of generic medicines and to generate 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; and the duration of supplementary protection certificates for products authorised in the new member states before their entry to the EU were largely left out of the PERF process to be resolved by intergovernmental bargaining. In light of greater ambitions for future enlargement (e.g., Croatia, Turkey) and the growing need to make EU policies more effective the departure from bilateral executive negotiations appears as a challenging alternative mode of accommodating divergent preferences, interests and expectations.

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