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Thomas Gehring and Sebastian Krapohl

SINGLE MARKET REGULATION BETWEEN  
TECHNOCRATIC  
INDEPENDENCE AND POLITICAL CONTROL:  
THE EUROPEAN AGENCY FOR THE EVALUATION OF  
MEDICINAL PRODUCTS AND THE AUTHORISATION OF  
PHARMACEUTICALS

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## **BACES Discussion Papers**

### **Bamberg Center for European Studies (BACES)**

Otto-Friedrich Universität Bamberg

Feldkirchenstraße 21

96045 Bamberg

Phone ++49 951 863-2592

Fax ++49 951 35996

Email [secretary@baces.uni-bamberg.de](mailto:secretary@baces.uni-bamberg.de)

[www.baces.uni-bamberg.de](http://www.baces.uni-bamberg.de)

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# Single Market Regulation between Technocratic Independence and Political Control: The European Agency for the Evaluation of Medicinal Products and the Authorisation of Pharmaceuticals

Thomas Gehring/Sebastian Krapohl

**Abstract:** The paper explores the successful European scheme for the authorisation of pharmaceuticals within the Single Market. Theoretically, it argues that successful regulation requires the exclusion of parochial interests from the decision process and the strict limitation of the agency's opportunities to adopt arbitrary decisions. Empirically, it holds that these conditions are fulfilled in the European authorisation scheme. The European Agency for the Evaluation of Medicinal Products (EMA) enjoys a strong agenda-setting power, while it is locked into a control arrangement that precludes arbitrary decisions. Moreover, all actors involved in the decision-making process are bound to a coherent and detailed set of legally binding decision-making criteria as well as subject to judicial review.

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## 1. Introduction

The lack of independence of the EMEA casts doubt on the widespread theoretical assumption that regulatory agencies must be largely independent in order to perform their regulatory functions successfully. In the analysis of domestic regulatory agencies, the degree of independence from government and parliamentary majorities is emphasised (Gibaldi 2002, Thatcher and Stone Sweet 2002). Usually, it is assumed that regulatory decisions will improve if intervention of actors with parochial interests is precluded (Majone 1996). It is argued that a regulatory agency, like an independent central bank, ought to act as a fiduciary of the long-term interests of its principal with a considerable margin of discretion at its disposal (Majone 2001). The virtually undisputed success of the European authorisation scheme for pharmaceuticals suggests that agency independence is *not* a necessary ingredient in successful European regulation.

The present paper explores why the centralised European system for the authorisation of pharmaceuticals with the EMEA in its centre is comparatively successful. First, it examines the arguments for independence of regulatory agencies as well as the arguments for its close control, and concludes that needed is both as much exclusion of parochial interests from the decision process as possible *and* the strict limitation of opportunities for the agency to adopt arbitrary decisions. Actors must be forced to engage in the common search of the most appropriate solution of a decision-making problem (section 2). Subsequently, the paper examines how the centralized procedure for the authorisation of innovative medicinal products ensures that adequate solutions to the decision problems are identified. It is argued that the procedure mobilizes several mechanisms that hinder the actors involved from exploiting their status within the centralised authorisation procedure to promote their parochial interests and force them into a discourse about the application of substantive rules. While the EMEA enjoys the position of a strong agenda-setter, it is locked into a control arrangement that precludes arbitrary decisions. In addition, all actors involved are bound to a coherent and detailed set of substantive decision-making criteria, which are enshrined in European directives and regulations subject to judicial review by the European Courts (section 3).

## 2. The Question of Regulatory Independence

Principal-agent theory consists of two mutually incompatible strands of argumentation. While one of them advocates independent regulatory agencies, the other insists of the necessity to oversee and control public bureaucracies (1). However, reliable regulation will need both independence from parochial interests *and* close oversight of agencies (2).

## **2.1 Arguments for Independence and Control of Regulatory Agencies**

The reason for the widespread claim that successful regulation requires independent agencies is the problem of inconsistent preferences. In modern regulatory theory, it is widely assumed that independent regulatory agencies are better suited to regulate successfully than tightly controlled state bureaucracies (e.g. Majone 1996 and 2001, Thatcher 1998). As long as preferences are coherent, it would be unreasonable for a principal, say, a parliamentary majority or the member states of the EU, to delegate implementation decisions to highly independent agencies. However, the interests of a principal are not always coherent. In many cases, long-term interests militate against situation-specific short-term interests (Elster 1979: 67-68, Keech 1995: 38-40). For example, a state or government faced with a case of hostage-taking might tend to negotiate in order to save the lives of hostages, even though the development of a reputation of negotiating provides a strong incentives to incur future crimes. In this type of situation, an actor may pursue his short-term preferences only at the expense of his long-term interests - and vice versa.

## **2.2 Institutional Requirements of a Reliable Regulatory Arrangement**

First, the arrangement ought to protect the agency as far as possible against intervention of parochial interests in order to provide sufficient freedom to produce decisions irrespective of their distributive consequences. This does not imply that all possible stakeholders, in particular the member states, are excluded from the decision process. Typically, stakeholders possess information that is relevant for proper decision-making. What matters is that interventions are limited to the submission of convincing arguments, rather than the employment of power resources. Second, the arrangement ought to provide for sufficient oversight to create effective incentives for the agency to orient its decisions along the long-term interest of its principals, and to refrain from pursuing its own interests or being captured by powerful stakeholders. An arrangement providing for mechanisms to reject decisions that do not meet the long-term community interests will not at all be counterproductive, even if it involves stakeholders, as long as their intervention helps enhance the accountability of the agency. However, it will be necessary to firmly commit all actors involved in the decision-making process, not merely the agency, to the long-term community interests.

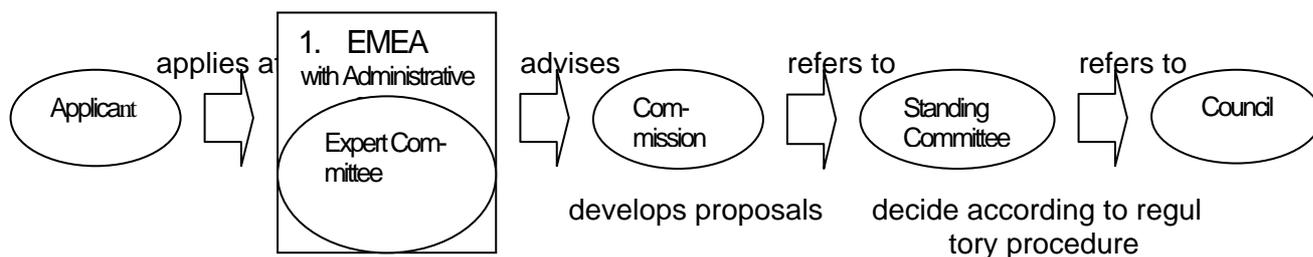
Third, the long-term community interests in regard to a particular decision ought to be readily clear. The margin for arbitrary decision-making as well as for intervention of power and parochial interests will grow, if sufficiently precise standards are absent or if multiple standards contradict each other (Shapiro 1997). To protect its own legitimacy and existence, an agency will tend to refrain from overexploiting its margin of free choice, if solutions meeting the community interest are readily distinguishable from those that do not. In principal-agent theory, it is increasingly recognised that the substantive requirements of statutes provide principals with a highly effective instrument to guide agency decision-making without having to intervene into the particular decision process (Huber et al. 2001). Moreover, substantive rules reflecting an established long-term community interest constitute externally given standards on which a discursive exchange of arguments can

rely. The 'giving-reasons requirement' (Shapiro 1992) supports this effect because it forces the actors involved to justify their decisions convincingly.

### 3. Centralised European Regulation of Pharmaceuticals: Agency, Member State Control and Substantive Standards

#### 3.1 The Agency as a Powerful Agenda-Setter

Figure 1: Centralised Authorisation Procedure for Pharmaceuticals



However, four features of the centralised authorisation procedure reinforce the agenda-setting power of the EMEA and its expert committee in the centralised authorisation procedure. They contribute to the fact that its scientific opinions cannot as easily be ignored by the other actors, as would be the case in a regular Comitology procedure. *First*, the application of a marketing authorisation is directly addressed at the EMEA and not, for instance, at the Commission. This is partly due to the fact that the regulation of pharmaceuticals includes pre-market authorisation and is not limited solely to post-market control as in most other regulatory areas (Krücken 1997). As a result, the agency and its expert committee are not only always involved in the authorisation process. They operate at the first stage of the decision-making procedure and set the agenda for the following actors by their scientific opinions. This is in sharp contrast to the traditional committee system, where the Commission is almost free to consult the expertise of scientific committees at will and enjoys the true agenda-setting power (Krapohl 2003).

*Second*, the scientific opinion on an application is elaborated within the EMEA by the Committee for Proprietary Medicinal Products. Its members act in a personal capacity, but they are not independent scientists. They shall be recruited from the regulatory agencies of the member states. As a consequence, committee members may draw upon the apparatus of their national regulatory agencies to process the overwhelming amount of information included in a average application of some 250.000 pages. Accordingly, a draft opinion elaborated by a rapporteur and a co-rapporteur are scrutinised from the perspectives of a variety of different national regulatory cultures and experiences. Decisions agreed upon within the Committee are acceptable to at least a majority of domestic regulatory agencies, and are difficult to challenge by the Commission or the member state committee. Hence, elaboration of the scientific opinion relies on an institutionalised network of member state regulatory agencies (Dehousse 1997, Majone 1997).

Due to its composition, the EMEA-Committee might seem to provide just another forum for intergovernmental negotiations (Kelemen 2002). Although its members act in a personal capacity and shall not accept orders by their member states or their domestic agency, a committee of national experts seems to be less independent from member states' interests than a committee of independent scientists might be. However, there is no indication that the committee is significantly misused by member states pursuing their parochial interests. A consensual decision-making style points to the fact that committee members tend to argue about validity claims. As indicated in Table 1, a vast majority (ca. 90%) of opinions were adopted by unanimity. Just below 10% of all decisions were taken by a majority vote. The share of majority votes increases slightly in the case of decisions addressing restrictions of an authorisation. If the committee members intended to misuse the forum to bargain over state interests or national regulatory cultures, majority voting might be expected to prevail. Rational actors can be expected stop bargaining, if a sufficiently high majority has been gathered. Likewise, decisions based upon bargaining power and parochial interests would frequently not be acceptable to all committee members, because larger packages are difficult to put together.

**Table 1: Table 1: Decision-Making within Expert Committee<sup>1</sup>**

Decision	Opinion of the Expert Committee					Total
	Authorisation		Authorisation with Restrictions		No Authorisation <sup>2</sup>	
Unanimity	142		76		1	219 90,5%
Majority Vote	10		7			17 7,0%
Appeal Procedure <sup>3</sup>			3		3	6 2,5%
Total	152	62,8%	86	35,5%	4 1,7%	242

*Third*, it is difficult for the Commission to deviate from the EMEA opinion because it is obliged to justify this step on the basis of the rules of the authorisation procedure. In case of scientific doubt, it cannot amend the opinion but must refer the matter back to the EMEA. Further, the Standing Committee representing member state interests is envisaged to decide in written procedure, but a meeting of will be called, if the Commission proposal deviates from the scientific opinion. Altogether, the procedure provides strong incentives for the Commission to stick to the EMEA opinion rather than to deviate from it. Once again, the agenda-setting power of the agency is increased. Empirical data confirm this finding. Table 2 indicates that not a single Commission proposal submitted until May 2001 deviated from the scientific opinion of the agency committee and no such deviation is

<sup>1</sup> Figures result from a dataset that includes all authorisations adopted under the centralised authorisation procedure from the setting into force of the procedure in 1995 until the end of 2002. The data were collected by the authors on the basis of EMEA publications on the Internet ([www.emea.eu.int](http://www.emea.eu.int)).

<sup>2</sup> The small number of negative decisions is due to the fact that most companies withdraw their application to prevent that failing applications is published, if the committee indicates to take a negative decision.

<sup>3</sup> All appeal procedures were initiated after a majority vote in the expert committee. The applying companies usually do not appeal against a negative decision by unanimity because of the low probability of success.

known for the time thereafter. Consequently, the EMEA-committee throughout pre-determined the decisions of the Standing Committee.

**Table 2: Decisions by Commission and Member State Committee<sup>4</sup>**

<b>Authorisation decisions until 1<sup>st</sup> May 2001</b>	<b>262</b>
Deviation of the Commission from the opinion of the expert committee	0
Negative vote of the member states committee on a Commission's proposal	0
Meeting of the member states committee	9 (3,44%)
Qualified majority vote of the member states committee	5 (1,91%)

Fourth, the centralised authorisation procedure does not envisage that member states meet and discuss authorisation decisions within the Standing Committee. They shall decide in a written procedure unless the Commission deviates from the EMEA opinion (which it never does), if a member state indicates objections, or if the matter is highly urgent. Normally, member states merely receive the Commission proposal and must react within 30 days, if they have objections against it. If no member state indicates any objections, the decision is passed automatically. Even if the committee operates formally according to the most restrictive of all Comitology procedures (Franchino 2000, Steunenberg et al. 1996), it rarely decides anything in practice. Table 2 shows that the committee decided in 253 out of 262 authorisation decisions in the written procedure and met just for nine applications. Four of these nine decisions received unanimous support, while merely five were taken by a qualified majority. Not a single decision proposal was eventually rejected by the committee and none was referred to the Council. Consequently, all final decisions originating from the centralised authorisation procedure were identical with the respective scientific opinions elaborated by the EMEA-Committee.

### **3.2 Legally Binding Substantive Standards Limit the Room for Manoeuvre**

As the substantive standards are legally binding, the European courts join the 'authorisation game' as additional players and will have the last word on whether standards have been correctly applied or not. An applicant company is entitled to be authorised to market its medicinal product, unless the criteria of safety, efficacy and quality are not met. Hence, at least a badly reasoned *negative* authorisation decision can easily be brought before the European Court of First Instance, or in second instance to the European Court of Justice (Collatz 1996: 134). Legal standing of applicants is based upon the fact that they are the immediate addressees of the Commission decisions. Practically, they are in need of legal protection because they will usually have incurred costs of many million Euros for research and development of an innovative medicinal product. Hypothetically, a member state could also instigate court proceedings against an allegedly wrong authorisation decision.

<sup>4</sup> Figures are provided by the Commission: COM 2001 (404) final, 26.11.2001: 8-9. They include the decisions according to the centralised procedure and the arbitration procedure. Other data about the political phase of the procedure are not available. Note that the arbitration procedure operates exactly the same way as the centralised authorisation procedure.

### **3.3 The Significance of Informal Substantive Standards**

In spite of its detailed provisions, the code spelling out the substantive criteria for the assessment of the safety, efficacy and quality of pharmaceuticals does not fully abolish the discretion of the expert committee. This is especially due to the fact that an application to a medicinal product always requires a trade-off between the general principles of safety and efficacy. The more effective a product is, the more side-effects will it usually cause (Heilmann 2002). If effects have always to be weighed against side-effects, there will be no single best solution, but a range of possible ways of accommodating the contradictory principles. The task of balancing principles creates room for manoeuvre for the expert committee.

Instead of exploiting this room for manoeuvre in an ad hoc fashion, the expert committee voluntarily limits its own discretion in the single application case by a great number of rules of different type. These rules are far more detailed than the substantive decision-making criteria of the Community code for medicinal products for human use. Usually, they are elaborated by various working groups of the expert committee, partly in order to provide advise to future applicants, and some emerge from the international conference on harmonisation (ICH) founded by the United States, Japan and the EU to harmonise their national (or supranational) authorisations of medicinal products as a first step towards a global market for pharmaceuticals. The rules are published on the EMEA homepage even in draft stages in order to allow interested circles to comment and react upon them. As table 3 indicates, the expert committee developed an extensive set of rules of different type.

**Table 3: Informal Decision-Making Rules of the Expert Committee at 1<sup>st</sup> June 2003<sup>5</sup>**

Working Group	Working Group			Guidelines			Points to Consider			Position Papers and Statements		%
	Ad-adopted	Draft	Concept Paper	Adopted	Draft	Concept Paper	Adopted	Draft	Concept Paper	Adopted	Draft	
Efficacy	6	3	3	2		2	4	1	1	1		7,49
Quality	34	3	11	18	5	5	1					25,08
Pharmaco-vigilanz	22	4	6				1			1		11,07
Blood Products	4		1				2			1		2,61
Biotechno-logy	12	9										6,84
ICH	12	3	2	4		5	13			11		16,29
Herbal Medicines	50	1								4	3	18,89
General	1	1		1			1			1		1,63
Herbal Medicines	2						1					0,98
General	3						8			17		9,12
%		62,87			13,68			10,75			12,7	100%

<sup>5</sup> Figures stem from a dataset including all informal decision-making rules published by the EMEA (www.emea.eu.int) at 1.6.2003. In addition, rules for 'Good Manufacturing Practices' are published by the Commission, which specify the Directive 91/356/EEC and create binding EU law.

Despite their informality, these rules create a binding force on the expert committee and cannot be ignored or changed at will. The rules are not legally binding and do not change the legal position of any other actor involved, be it the member states, the Commission, or the applicant. They are not reinforced by judicial review, because the task of rule-making is not formally assigned to the agency. The creation of their de facto binding force on the committee is based upon at least three interrelated mechanisms. *First*, the rules constitute the principal instrument of the EMEA to inform possible applicants of additional criteria upon which its scientific opinion will be based. It will simply smoothen the authorization process if applicants become aware of data to be submitted and tests to be passed as well as of products without a prospect of being approved. Moreover, it reinforces the attractiveness of the new European authorisation procedure which is partly competing with domestic authorisations. And vice versa: Applying firms will voluntarily attempt to fulfil the requirements of these rules, if the committee credibly promises to apply them in its decisions. Otherwise, they would have to persuade the committee of the adequacy of their own way of proving the safety, efficacy and quality of their products. However, there would be no incentive of the applying companies to follow the rules, if the committee were expected to change them from case to case, or if it adopted decisions in contradiction to its own rules. Hence, the committee develops a strong interest in committing itself to the sincere application of its own rules.

*Second*, the decision situation within the expert committee militates for the development of, and adherence to, rules because interests are difficult to accommodate within the single case-specific decisions. If the committee is interested in developing the reputation as a scientifically oriented expert committee rather than an intergovernmental bargaining forum, it must strive for consensual decisions. Accordingly, contradictory national preferences or domestic authorisation cultures must be reconciled in almost every single case. If every single decision threatens to leave some actors aggrieved because the room for 'deals' is narrow, consensus formation cannot predominantly be based upon balancing interests in an ad hoc fashion. An emerging minority will tend to accept even an unwelcome decision, if it is compatible with accepted rules and principles.

*Third*, while position papers and statements can be adopted ad hoc by the expert committee, the most important sets of rules enshrined in guidelines and points to consider documents are developed in a formal administrative procedure, which includes the consultation of stakeholders, such as pharmaceutical companies or the authorisation bodies of the member states.<sup>6</sup> This procedure takes a longer period of time than a centralised authorisation procedure. Accordingly, these rules reflect a high degree of commitment and cannot be changed for every single new decision.

### **3.4 Further Improvement through a More Independent Agency ?**

One of the most important institutional innovations in the European Union during the last decade is the emergence of supranational regulatory agencies. Currently, six agencies

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<sup>6</sup> CPMP/2024/98: Standing Operating Procedure for Developing CPMP Guidelines and Points to Consider Documents.

with regulatory competencies exist within the Single Market, including the European Agency for the Evaluation of Medicinal Products. Other agencies, like the European Environment Agency and the European Agency for Health and Safety at Work fulfil different functions such as information gathering and promotion of the social dialogue (Kreher 1997, Everson et al. 1999). In its White Paper on Governance (European Commission 2001), the Commission announced to propose further agencies to enhance the efficacy and transparency of regulatory policy-making. At its summit in December 2003 in Rome, the European Council commissioned no less than nine locations for new regulatory agencies. Hence, agencies constitute an increasingly widespread institutional arrangement for regulation in the Single Market.

The European Agency for the Evaluation of Medicinal Products (EMA) is a prominent example of supranational regulatory agencies (Gardner 1996, Feick 2000a). Founded in 1993, it may be conceived of as the blueprint of future agencies. It constitutes the cornerstone of the European authorisation system for pharmaceuticals and has significantly contributed to the emergence of a single market for these products, which had been blocked for many years by divergent domestic regulations. Moreover, stakeholders related to the sector, including competent authorities of the member states as well as producers and patient associations, generally appreciate the new authorisation system (Cameron McKenna and Anderson Consulting 2001). However, the status of the EMA vis-à-vis the political actors is a far cry from the independence of the European System of Central Banks and independent agencies within the United States (Shapiro 1997). While it enjoys remarkably far-reaching competencies (Everson 1996, Majone 1997), it is by far not as independent as it may seem at first glance. The Member states refrained from giving up their control of the decision process (see Keleman 2002). Consequently, the EMA is part of two multi-tier decision-making processes in which both the member states and the Commission are involved.

The paper concludes that the system at large, not merely the EMA, ensures the production of reasonable outcomes irrespective of their distributive consequences. The combination of a skilfully constructed control chain involving different actors and detailed substantive decision-making criteria leads to results that are at least as reliable as decisions produced by a fully independent agency because parochial interests are excluded while a powerful accountability system is established.

Authorization of pharmaceuticals raises the problem of inconsistent interests. As demonstrated by the Thalomid (or Contergan) scandal of the 1960s, pharmaceuticals can be extremely harmful (e.g. Kirk 1999). Not only are biologically or chemically highly active substances deliberately incorporated, but consumers will usually be unable to judge the quality of medicinal products themselves, so that information asymmetries between producers and consumers exist (Feick 2000b). The regulation of these products according to reliable and comparatively strict standards should be in the long-term interests of the community. However, clinical testing of pharmaceuticals is extremely expensive and producers may depend economically on the authorization of a particular product. Patients might eagerly await authorization of a pharmaceutical promising to cure a dangerous disease. Hence, decision-makers may be under considerable pressure from interest groups

to decide according to the particularities of the specific situation. If this is done repeatedly, authorizations become unreliable and do not promise to ensure the safety of pharmaceuticals.

Within the supranational context of the EU, the problem is further complicated by a classical cooperation dilemma. Experience with the largely unsuccessful mutual recognition of national authorisations (Gardener 1996, Vos 1999a: 210) demonstrates that the member states do not trust each other's authorisation decisions and might even have had an interest to protect their own industry. If every member state protects its own market, none can benefit from market integration and the pursuit of short-term interests threatens to jeopardise the emergence of an integrated market for innovative pharmaceuticals.

Both the dilemma of inconsistent preferences over time and the cooperation problem will diminish, if decisions are delegated to an agent that is largely independent from its principals. To resist the temptation of the concrete situation, the principals must sacrifice their discretion in the concrete situation (Elster 1979: 38) and bind themselves to a suitable 'mast' like Ulysses did in light of the Sirens. The 'mast' available in modern societies is an appropriate institutional restraint that creates a 'credible commitment' (Moravcsik 1999 and Shepsle 1991) and assigns implementing decisions to an actor that is unsusceptible to the temptations of specific situations. By this step, two complementary functions are separated. The legislator will determine the long-term interests of society, while the general rules will be elsewhere applied to numerous specific situations in a way that excludes, as far as possible, situation-specific and opportunistic considerations.

Entrusting an independent agency with far-reaching competencies unfortunately creates the danger of 'shirking'. It is not at all clear that a fully independent agency ensures 'good' decisions, because it is well known that bureaucracies may well develop and pursue their own interests, rather than those of their principals (Moe 1990: 121). They struggle to expand their spheres of influence and to increase their resources (e.g. budgets, employees) (e.g. Dunleavy 1991). Specialized agencies will also create the risk of 'agency capture', if they become subject to pressure from organised groups with an interest in certain regulatory policies (for the case of pharmaceuticals, see Abraham and Lewis 2000). As small groups of actors (e.g. the producers of pharmaceuticals) are much better organised than diffuse interests of large groups (e.g. the consumers of pharmaceuticals), an agency might tend to prefer the perspectives of some stakeholders to those of others.

The need to control the activities of an agency appears to militate against the desirability of its independence. Principals seem to be in a new dilemma: If they choose to employ a strong oversight mechanism (Franchino 2000, Pollack 1997) and closely supervise every single decision, agency independence will diminish. And if they establish an independent agency, they must soften the grip on the agency's decision-making.

The dilemma of control and independence may be overcome if we focus in the first place on the desirable outcome of a decision-making process, and only in the second place on the design of an institution capable of producing these decisions. A regulatory system will produce 'good' decisions (Joerges 1999), if they are efficient, solve the underlying problem, and do not jeopardise the long-term interests of the principals. This necessarily very general definition suggests that a good regulatory decision should not be determined ac-

ording to its distributive effects and to the constellation of power and parochial interests among the member states or other interested actors. A good decision will meet the conditions of a Habermasian discourse. According to the 'general principle of discourse', valid "are exactly those norms of behaviour which could be agreed upon by all those possibly affected, if they were participants in rational discourses" (Habermas 1992: 138, translation provided). Decisions will be more likely to be acceptable even to the member states and other stakeholders, if they are 'reasonable' and can be convincingly justified.

If the primary concern of regulatory decision-making is not balancing of stakeholder interests, but elaboration of reasonable decisions irrespective of their distributive effects, an appropriate regulatory system will provide incentives for decision-makers to refrain from power-based bargaining and engage in deliberation (discursive arguing). Bargaining is commonly defined as an exchange of credible threats and promises based on external power resources (Elster 1989). In contrast, deliberation (Joerges/Neyer 1997) is directed at influencing the decision process by convincing arguments (Risse 2000, Gehring 2003). An institutional arrangement will reduce the opportunities for successful bargaining, if it reinforces the relevance of reasonable arguments compared to threats and promises, and if it narrows the margin for discrete choice.

The authorisation of pharmaceuticals with the EMEA in its centre may be considered as a success story of European regulatory policy-making. There are at least two indicators for the success of the scheme. First, scandals and major problems of the established decision-making system did not occur so far. An extensive evaluation on behalf of the Commission revealed satisfaction among an overwhelming majority of all groups of stakeholders, such as national authorisation bodies, pharmaceutical companies and consumer groups, with the current authorisation system (Cameron McKenna/Anderson Consulting 2001). Second, the authorisation scheme is not at all challenged or even significantly revised during the current reform process which will lead to the adoption of an amended core regulation.<sup>7</sup> Instead, the applicability of the centralised procedure will be extended to further categories of pharmaceuticals.

In this section, we evaluate the impact of the existing institutional arrangement on the performance of the system. We argue that its successful operation is based upon three pillars. The Agency enjoys a strong agenda-setting power in respect to the scientific evaluation of applications (1). An extensive set of legally binding rules that is supervised by an active European Court of Justice limits the room for manoeuvre for all public actors involved in the authorisation procedure (2). And an even more detailed set of informal rules provides substantive criteria for the making of acceptable decisions (3). Finally, we briefly discuss some reform proposals designed to enhance the independence of EMEA (4.).

The design the authorisation procedure reflects the intention of the member states and the Commission to solve a cooperation problem as well as their unwillingness to delegate full decision-making competencies to the EMEA. Until the 1990s, marketing was envisaged to

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<sup>7</sup> Proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products; Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use; Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products' in: COM (2001) 404 final, 26.11.2001.

rely on the mutual recognition of national authorisations, but the member states did not trust each other in this respect (Collatz 1996: 48, Vos 1999a: 210). A centralised authorisation procedure was needed to achieve a Single Market for pharmaceuticals. Unwilling to delegate this matter to an ever growing Commission or to a newly established regulatory agency, the member states chose a complex authorisation procedure involving several actors including their domestic authorisation bodies (Kelemen 2002). With its Meroni doctrine, the European Court of Justice had already in the 1950s closed the door for the extensive delegation of formal decision-making competencies to entities not empowered by the European Treaties (Türk 1996, Vos 1999a: 200). The Commission was also reluctant to create an independent agency, because this might have undermined the 'institutional balance' between the established EU-institutions (Majone 2002).

The centralised authorisation procedure for pharmaceuticals establishes a system of differentiated decision-making which allocates particular functions to the different stages and actors involved (Gehring 2002: 254-257). It is enshrined in Council Regulation (EEC) No 2309/93 (OJ No L 214 of 24.8.1993) and illustrated in Figure 1. A producer submits its application to the EMEA which develops a scientific opinion. The scientific work is done by an expert committee supported by the administration of the agency. Next is the Commission which transfers the opinion into the a decision proposal. The formal decision is eventually taken by the Standing Committee for Human Medicinal Products, i.e. a Comitology committee operating according to the procedure IIIb (Vos 1999b), in which the member states are represented. If the member states endorse the proposal by qualified majority, it is adopted. Otherwise it is referred to the Council. Apparently, strong control is designed to prevent that the agency deviates from the community interest and follows its own agenda.

The formal status of the EMEA within this multi-tiered procedure appears to be quite weak. It is obvious that the agency can be strongly controlled by the other actors of the procedure. It evaluates applications for the authorisation of pharmaceuticals, but final decisions are taken elsewhere. Hence, regulatory decisions cannot be adopted independently from the Commission and the member states. They carry the form of Commission decisions, and if a European institution will be held legally accountable, it will be the Commission. At first glance, the EMEA might appear as a somewhat over-sized scientific advisory committee of the Commission which might fulfil the function of a conditional agenda setter, depending on agreement with the Commission (Tsebelis 1994).

To conclude, the EMEA is an unusually strong agenda-setter in the centralised authorisation procedure. It is always involved in the decision-making process as the first player and it is difficult for the other players, namely the Commission and the member states gathered in the Standing Committee, to overrule its scientific opinions. As a result, the substantive content of the final policy outcome of the procedure over the last eight years was entirely determined by the EMEA.

All actors involved in the authorisation process are obliged to decide according to the substantive criteria codified in Council Regulation No 2309/93. Apart from narrowly defined exceptions to meet moral concerns in some countries (e.g. Irish concerns against pharmaceuticals for abortion), authorisation decisions shall exclusively rely on the evaluation

of the safety, efficacy and quality of a medicinal product. They shall ignore factors like the economic well-being of the pharmaceutical industry or financial constraints of domestic health care systems. The broad criteria are specified by a detailed 'Community code relating to medicinal products for human use' now enshrined in Directive 2001/83/EC (OJ No L 311 of 28.11.2001, 67). Apart from fundamental definitions and some procedural rules, this code provides detailed standards for the medical tests, which every pharmaceutical must pass through and which are subject to examination during the authorisation procedure.

Judicial litigation over authorisation decisions is not merely a hypothetical possibility. A number of cases have already been decided upon, while others are still pending. Hence, courts are becoming important actors in the European authorisation procedure, and producers are, occasionally, prepared to challenge negative authorisation decisions. The relevance of European law and European courts for the authorisation system for pharmaceuticals became evident in a judicial struggle about the authorisation of anorectics, i.e. medicinal products against obesity. In 2000, the Commission withdrew market authorisations for an old group of these pharmaceuticals.<sup>8</sup> The initial authorisations had been granted long before the establishment of the centralised authorisation system by national authorisation agencies. It was not only disputed whether the Commission was competent to decide upon their withdrawal, the decision was also scientifically badly reasoned. The expert committee had based its opinion only on a changing scientific consensus about the authorisation of anorectics. The pharmaceutical companies brought the matter in front of the European Court of First instance, which rejected the joint positions of the Commission and the expert committee in both controversial issues.<sup>9</sup> Remarkably, the court did not only address the formalities of the cases. It examined the merits of the scientific opinion elaborated by the expert committee in great detail and delved into the substance of the authorisation decision. In another decision,<sup>10</sup> the European Court of First Instance interpreted the requirement of direct concern extensively and widened the scope of potential plaintiffs. In this case, an employee instigated proceedings against a positive authorisation decision for a pharmaceutical of her own company. The Court of First Instance accepted this action, because it judged the involvement of the employee in the medical test of the respective product as sufficient to establish a direct concern. With this decision, the asymmetry of judicial review in favour of the pharmaceutical industry was partly reduced.

The shadow of the substantive decision-making criteria and the threat of supervision by the European courts create fundamental consequences for the interaction of the actors involved in the centralised authorisation procedure. The chain of sub-decisions adopted first by the EMEA expert committee, then by the Commission and finally by the Standing Committee are not integrated by political power any more, which would reinforce the role of the Standing Committee representing interests of the member states, but by European law (see Joerges and Neyer 1997). And apart from the procedural requirements, European law enforces the substantive standards enacted by the European legislator. Conse-

<sup>8</sup> See Commission Decisions: C(2000)452, C(2000)453 and C(2000)608, 9.3.2000.

<sup>9</sup> See judgement of the Court of First Instance in joined cases T-74/00, T-76/00, T-83/00 to T-85/00, T-132/00, T-137/00 and T-141/00, 26.11.2002.

<sup>10</sup> See decision of the president of the European Court of First Instance in case T-326/99 R, 7.4.2000.

quently, all actors involved in the authorisation procedure are motivated to engaged in some sort of collective search for decisions that sincerely apply the binding substantive criteria provided for by the legislator. Apparently, the EMEA expert committee is best equipped to engage in a deliberation about an appropriate scientific opinion or, as one may coin it, in a serious application discourse. Its members are not free to bargain over domestic preferences, because scientific opinions have to be justified with convincing reasons. They will struggle to reach consensus at least on the core of their decisions because an outvoted minority, or a disappointed applicant, can otherwise be expected to bring the matter before the Commission or the Standing Committee. The room for manoeuvre of the non-scientific actors within the procedure, namely the Commission and the Standing Committee, for non-scientific (i.e. 'political') intervention is almost absent. If either the Commission or the Standing Committee raise scientific objections against a scientific opinion of the expert committee, they are not entitled to disregard or amend the opinion, but must refer the matter back to the EMEA. If they attempted to raise political objections, the decision can be cancelled by the courts.

Hence, all actors are effectively, not merely formally, bound by the existing substantive criteria. The agenda-setting power of the expert committee is further strengthened, but only as long as it adheres to these criteria. The non-scientific actors exclusively fulfil a tacit oversight of whether the criteria are seriously applied, and provide an additional incentive for the expert committee to deliberate sincerely. It is hardly imaginable that they deviate from a scientifically sound opinion of the expert committee without eventually being called back by the European courts.

In spite of its detailed provisions, the code spelling out the substantive criteria for the assessment of the safety, efficacy and quality of pharmaceuticals does not fully abolish the discretion of the expert committee. This is especially due to the fact that an application to a medicinal product always requires a trade-off between the general principles of safety and efficacy. The more effective a product is, the more side-effects will it usually cause (Heilmann 2002). If effects have always to be weighed against side-effects, there will be no single best solution, but a range of possible ways of accommodating the contradictory principles. The task of balancing principles creates room for manoeuvre for the expert committee.

Instead of exploiting this room for manoeuvre in an ad hoc fashion, the expert committee voluntarily limits its own discretion in the single application case by a great number of rules of different type. These rules are far more detailed than the substantive decision-making criteria of the Community code for medicinal products for human use. Usually, they are elaborated by various working groups of the expert committee, partly in order to provide advise to future applicants, and some emerge from the international conference on harmonisation (ICH) founded by the United States, Japan and the EU to harmonise their national (or supranational) authorisations of medicinal products as a first step towards a global market for pharmaceuticals. The rules are published on the EMEA homepage even in draft stages in order to allow interested circles to comment and react upon them. As table 3 indicates, the expert committee developed an extensive set of rules of different type.

The significance of the informal rules is demonstrated by a quite successful guideline in the pharmaceuticals sector concerning the risk caused by BSE. Unlike in the foodstuffs sector, the risk of BSE in pharmaceuticals was not subject of wide political debates, although many vaccines are produced with bovine sera. Five years before the infectiousness of BSE for human beings was proven, and ten years before similarly strict rules for foodstuffs were established (Krapohl 2003), the expert committee for pharmaceuticals adopted in 1991 its first and already very strict guideline that was slightly revised in 2001.<sup>11</sup> It contained provisions about the origin of bovine material, about the nature of the material itself and about the processing of this material. After the guideline received the status of EU law in 1999 (because it was taken over into the Community code for human medicinal products), all centralised and national authorisations of pharmaceuticals in the EU were checked as to their compatibility with these criteria.<sup>12</sup> As a result, one national authorisation from the United Kingdom for a vaccine against polio was withdrawn, because it was produced with bovine sera from British cows. Apart from the fact that the EMEA acquired some de facto rule-making competence in this case, it turned out that authorisations of pharmaceuticals were successfully protected against the risk of BSE with this guideline.

The extensive reliance on self-created and formally non-binding rules modifies the making of decisions. Within. By committing itself to adopting decisions that do not contradict its own rules, the committee reduces the number of options that could be chosen. It voluntarily cuts the room of manoeuvre for bargaining about member state interests and domestic regulatory cultures once again. If bargaining becomes virtually impossible on most aspects of a decision, a strong incentive for deliberation is created. And deliberation will become easier, if reasonable and widely accepted criteria exist that provide reliable points of reference. The output of a rule-based decision-making system will be more coherent and less arbitrary than one based upon ad hoc decisions.

While there is wide agreement on the success of the existing centralized authorisation procedure (Cameron McKenna/Anderson Consulting 2001), proposals to further improve the system have been submitted in the current political debate on the reform of the system. Most important are the proposals to change the composition of the EMEA-expert committee and to weaken, or completely abolish, the supervisory stages of the decision-making procedure. We argue that there are good reasons to assume that these proposals would not result in a better decision-making procedure capable of producing improved output.

Originally, in 1991, the European Parliament had struggled for an expert committee composed of totally independent scientists rather than officials from the national authorisation bodies.<sup>13</sup> In the current reform process, it proposes a selection of the committee members

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<sup>11</sup> Committee for Proprietary Medicinal Products and Committee for Veterinary Medicinal Products (31.5.2001): Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMEA/410/01 rev 1).

<sup>12</sup> Committee for Proprietary Medicinal Products (28.2.2001): Public Statement on the Evaluation of Bovine Spongiform Encephalopathies (BSE)-risk via the use of materials of bovine origin in or during the manufacture of vaccines (EMEA/CPMP/BWP/476/01).

<sup>13</sup> Opinion of the European Parliament to the Commission's proposal for a Council Regulation (EEC) laying down Community provisions for the authorization and supervision of medical products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ No C 183 of 15.7.1991, p. 178).

by the EMEA executive director from a list provided by the member states.<sup>14</sup> It is indeed somewhat startling that the scientific opinion on the merits of an application is elaborated by member states' regulators rather than by eminent scientists. However, a single person cannot handle an application of some 250.000 pages of documents. Currently, the members of the committee draw heavily on the support of their domestic agencies. The few non-regulators in the committee must rely on the resources of their private institutes which are presumably financed predominantly by the pharmaceutical industry. If the committee would be changed to a membership of predominantly independent scientists, the EMEA, now basically an administrative support unit for the expert committee, would have to expand its own regulatory competences dramatically. Hence, a reorganised composition of the committee would necessarily entail a radical centralisation, and completely abolish the existing network character (Dehousse 1997 and Majone 1997), of the regulatory system. Moreover, a scientific opinion currently emerges from the confrontation of domestic regulatory cultures. Its acceptance within the member states is supported by the fact that domestic authorisation bodies fulfil an important watchdog function already at an early stage of the decision-process. A regulatory system that is completely centralised at the European level cannot draw on this kind of inherent checks and balances, nor tap the related source of legitimacy.

The Commission advocates to cut back the supervisory stage of the procedure (COM [2001] 404 final). The main argument is that the formally powerful Standing Committee does not fulfil any important function in practice, while delaying the final decision. From a principal-agent perspective, formal independence of the EMEA would reinforce both the responsibility of the agency for its decisions and the accountability of its decision-makers. Currently, the system might appear as one of collective irresponsibility. The Commission is to be formally blamed for the adoption of false decisions (Collatz 1996: 134), while it does not really scrutinize the latter's content. The EMEA actually elaborates the decision, but merely acts as a scientific advisory organ in formal terms. And the member states might intervene without assuming responsibility. However, the success of the centralized authorisation procedure relies on a deliberately established system of checks and balances of the sub-systems involved. The fact that the Commission and the Standing Committee did not significantly intervene into the decision process so far does not imply that these stages are altogether futile. They establish a permanent threat of intervention in the case that unconvincing scientific opinions emerge from the EMEA. If the supervisory stages of the procedure were weakened or abolished, the courts remained as the only instance able to control the EMEA. It is questionable whether they could fulfil this function on their own. Judicial review is still largely asymmetrical, because it is easier for companies to challenge a negative authorisation decision, than it is for consumers to challenge a positive decision.

In combination, the two proposals would create a completely different system. If membership of the EMEA expert committee would be changed to consist of independent scientists, one might expect increased activity of the Standing Committee dominated by the

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<sup>14</sup> Amended proposal for a Regulation of the European Parliament and the Council (EEC) laying down Community provisions for the authorization and supervision of medical products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (COM(2002)735 final of 10.12.2002).

member states, because this would become the principal inlet for their doubts and questions. If the supervisory stages would be abolished, member state activity within the expert committee would gain even more importance. Increased autonomy of the authorization system from the member states at both sides of the current procedure would almost inevitably generate less legitimate decisions and might eventually lead to a re-politicisation of the whole system.

During the past decade, a European authorisation system for pharmaceuticals has been established that is successful in its regulatory activity and highly accepted by the different groups of stakeholders. The system is characterised by an enhanced role for the agency, as well as by the participation of a number of other actors, including the member states and the European courts. For every single decision, the system drags all actors involved into a discourse about the best possible application of generalized substantive criteria. The existing procedure establishes a regulatory system, which is at least as likely to produce 'good' policy outcomes as an independent regulatory agency would be.

#### **4. Conclusion**

The existing decision-making procedure fulfils almost ideally all three conditions for successful regulation theoretically derived from section 2. *First*, the EMEA with its incorporated expert committee is sufficiently well protected against undesirable intervention of parochial interests in order to elaborate decisions irrespective of their distributive consequences. In spite of its lacking independence, it is in fact a very powerful agenda-setter that dominates the process as long as it sincerely implements the substantive criteria provided for by relevant European law. With its extensive set of guidelines and other informal rules, it developed a powerful supplementary instrument to keep itself on track and avoid less convincing ad hoc decisions. *Second*, the agency is not free to pursue its own interests at the expense of community orientation. Far from being able to adopt formal decisions independently, it is subject to two different supervisory mechanisms. The principals tacitly supervise its day-to-day decisions. The stages of the Commission and the Standing Committee can at any time be activated to serve as an emergency break should powerful action be required. Moreover, the whole system comprising the stages dominated by the EMEA, the Commission and the member states is subject to supervision by the European courts. As a result, the member states are hindered from introducing parochial interests into the process either through the expert committee or through the Standing Committee. *Third*, all actors involved are well aware of, and legally bound to, the overall community interest which is enshrined in a number of instruments of European law. These substantive standards constitute focal points for the decision-makers and reduce the number of options that can be convincingly justified.

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#### **The Author:**

##### **Prof. Dr. Thomas Gehring**

Chair of Political Sciences (Focal Area: International Politics)  
Faculty of Social and Economic Science  
Otto-Friedrich Universität Bamberg  
Feldkirchenstraße 21  
96045 Bamberg  
Tel.: 0951-863-2720  
E-mail: thomas.gehring@sowi.uni-bamberg.de

##### **Sebastian Krapohl**

Faculty of Social and Economic Science  
Otto-Friedrich Universität Bamberg  
Feldkirchenstraße 21  
96045 Bamberg  
Tel.: 0951-863-2724  
E-mail: sebastian.krapohl@sowi.uni-bamberg.de