

Journal of Contemporary European Research

Volume 9, Issue 1 (2013)

Differentiating Agency Independence: Perceptions from Inside the European Medicines Agency

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Citation

Makhashvili, L. and Stephenson, P. (2013). 'Differentiating Agency Independence: Perceptions from Inside the European Medicines Agency', *Journal of Contemporary European Research*. 9 (1), pp. 4-23.

First published at: www.jcer.net

Abstract

The regulations granting the establishment of EU agencies were meant to ensure institutional independence in order to insulate everyday decision-making from political pressure, vested interests and political short-termism. However, recent events, including managerial resignations and the introduction of new rules concerning conflicts of interest, have brought renewed attention to the autonomy/independence debate. This article goes beyond the traditional *de jure/de facto* dichotomy of approaches to approaching the question of independence to consider *perceptions* of agency staff. It seeks to gauge the opinions of members of the European Medicine Agency's Management Board with regard to agency autonomy, distinguishing between four types of independence: legal, financial, administrative, decision-making. It draws on data collected using questionnaires, and interpreted using the expert evaluation method, to rank the importance given to types of independence among sub-sets of stakeholders overseeing the EMA.

Keywords

EU agencies, European Medicines Agency, autonomy, independence, management boards, perceptions

Recent events have highlighted the sensitive issue of agency independence and questioned the checks and balances in place to ensure that agencies operate autonomously from business and political interests. In June 2010, the European Ombudsman ordered the European Medicines Agency (EMA) – the body meant to ensure that all medicines in Europe are safe and effective for citizens – to 'cough up the information', accusing it of maladministration; only in February 2011 did the EMA 'acquiesce' to the demand (EUobserver.com 2011). In December 2010, the agency's executive director resigned to go and work for a private consultancy advising the pharmaceutical industry. This incidence of a high-profile agency staff member drifting between public and private sector positions – a case of 'revolving doors' – was given the green light by the agency's Management Board (MB), which, it was reported, saw no conflict of interest (European Medicines Agency 2010a, 2010b). Then, in May 2011, the question of EU agency independence was brought under the spotlight controversially when the European Parliament refused – by a decision of 637-to-4 votes – to sign off the agency's accounts; the agency being 'further bludgeoned' when the Parliament subsequently ordered an investigation into the EMA's financing and the independence of its experts vis-à-vis the pharmaceutical industry (EUobserver.com 2011).

Over the last decade, scholars have addressed the notion of agency autonomy, analysing what position agencies hold in the hierarchy of the EU's organisational structure, i.e. whether they are independent or semi-independent from – or else completely dependent on – the EU institutions and other actors (Gardner 1996; Everson and Majone 2000; Kreher 2001; Shapiro 2001; Gilardi 2002; Geradin 2005; Vos 2000, 2005; Tarrant and Keleman 2007; Groenleer 2006, 2009; Sacchetti 2009; Busuioc 2009, 2010). More recently, scholars have focused on questions of agency autonomy: beginning by drawing on earlier studies examining the link between the institutional arrangement in which an agency's operation is embedded and the scope for quasi-independent action (Gehring and Krapohl, 2007); and later examining how accountability arrangements help to reinforce autonomy (Busuioc *et al.* 2011) and which actors are most able to act autonomously, recognising a difference between autonomy in practice versus in legal terms (Egeberg and Trondal 2011).

The regulations founding the EU agencies gave them a degree of independence in order for their everyday decision-making to be insulated from political pressure and the short-term preferences of interested parties, to ensure that objective and politically-unbiased

information could be made available to decision-makers. The Commission's own activity is frequently defined, or at least heavily influenced, by the information provided by the European agencies. As a result, the functioning of agencies attracts the attention of external actors and stakeholders, each with their own political or financial agenda. 'Objective' information becomes significant and desirable, causing the interest and involvement of other actors, eager to obtain this information and influence it. Regulatory agencies have 'some formal decision-making authority' and 'are more likely to be formally shielded against interference from the Commission, the member states and stakeholders' Christensen and Nielsen (2010: 182). However, actual independence is rarely explicit in the everyday policy-making of the agencies – does it exist, or is it a myth? As Borrás *et al.* (2007: 584) assert, the daily operation of agencies cannot be decoupled from their political and social environment; their operation depends upon socially-constructed perceptions and legitimacy-related beliefs.

Investigating how agencies themselves perceive independence means trying to glean the attitudes and opinions of those working inside. The division of roles is opaque: 'external actors' sit *inside* agencies on the Management Boards. What importance do 'external' actors such as supranational institutions attach to the independence of the agency? How do member state representatives on the Management Board perceive their role vis-à-vis the Commission? Which types of independence are at stake and which is deemed most important, by whom? In which areas of activity does agency staff believe it exerts most influence? How might we measure variation among individuals within the agency?

This article aims to investigate the importance attached to various dimensions of autonomy, by investigating the perceptions of those managing the European Medicines Agency. These dimensions of autonomy comprise four types of independence: administrative, legal, financial and decision-making. The research seeks to enhance our understanding of the work of EU agencies, and their relation with the EU institutions, in particular, the European Commission. The second part of this article explores the notion of independence versus autonomy, explores agency management boards and introduces the European Medicines Agency. The third part considers a methodology for gauging how Board members rank the importance of dimensions of independence. The fourth part analyses the data collected to draw out variations in the importance attached by sub-sets within the Management Board to types of agency independence, and considers what the findings contribute to the wider literature on EU agencies.

AUTONOMY, INDEPENDENCE AND THE EUROPEAN MEDICINES AGENCY

Definitions and perspectives

There are competing academic perspectives both on agency autonomy/independence, and the use of the terms. Are they synonymous or different? Agency independence has been said to exist when an agency can introduce its own policies, issues or solutions onto the agenda (Zito 2009: 1227). Yet, an agency's independence may be only a '[relative freedom] of control by any of the other organs of the [European] Community' (Shapiro 2001: 289), limited by the founding regulations creating the EU agencies. Independence can thus be considered a situation whereby institutional behaviour is not 'guided by personal or national interest or political pressure' (European Commission, 2000: 4). Recognising the policy world as one of goal conflicts and incomplete information, Yesilkagit (2004: 532) points out that 'in reality [...] real autonomy may not correspond with the formal autonomy of agencies. Depending on the issue, agencies may enjoy more or less [...] autonomy than formally is granted to them'. As Hanretty and Koop (2012: 199) recognised recently, agencies can be independent from a range of actors, including industry, civil society and the public, as well as from governments, parliaments, parties and politicians; 'political independence' is thus understood as day-to-day decisions being free from the interference and preferences of politicians. The

authors take this distinction further, identifying *formal independence* (de jure, legal), i.e. freedom from the 'politics inherent in those legal instruments which constitute and govern the agency', as opposed to *actual independence* (de facto, practical), i.e. acting daily without direct instructions, threats or inducements by politicians and vested interests. Moreover, the former is no guarantee of the latter (Hanretty 2010: 2). In short, one must consider not only the ability of EU agencies to act relatively independently from member state government institutions, but from all potential actors. This suggests, at least, a broad and a wide definition of independence. To be autonomous, therefore, an agency must be independent of political actors as well as stakeholders or clients (Geradin 2005: 230; Trondal & Jeppesen 2008: 421; Groenleer 2009: 36).

In short then, the literature can be divided into two camps. One purports that the level of independence is determined and fixed by the founding legislature: '[what] senior officials and staff members of EU agencies can do is often constrained, and sometimes wholly determined, by the formal rules and procedures put on paper' (Groenleer 2009: 23). This includes recent work by Wonka and Rittberger (2010), which identified functional and power-based factors accounting for variations in formal independence whereby levels of political credibility, complexity and uncertainty influence how political actors endow agencies with legal independence. Another camp assumes that, in reality, independence and power go beyond what is defined by the legal statutes but concerns the practicalities of the day-to-day, as agents engage with various stakeholders in 'providing data, information, and (mainly informal) proposals that may eventually influence the actual formulation of the content of the European public policy' (Barbiero and Ongaro 2008: 397). This includes work by Busuioc *et al.* (2011), which tries to move beyond *de jure* character to *de facto* manifestation, by investigating practice inside the European Police Office, observing how low levels of actual autonomy, even if only through an overload of formal accountability mechanisms, can stifle agency development. The authors assert that 'independent (i.e. fully autonomous) agents generally do not exist in systems of representative government since they are bound by the decisions of others (ibid. 850). For operational purposes, we perceive of autonomy as comprising *types of independence* that each set of stakeholders may rank differently in order of importance, as explored later in this section.

The role and status of management boards

As Keleman (2002: 102) recognised over a decade ago, any consideration of agency independence must recognise that the Commission itself is a 'generalist independent agency' created by the member states and by extension then, one must ask, 'of what exactly were these agencies intended to be independent'. Moreover, agency design – 'including the scope of their powers and their management structures' (Keleman 2002: 94) – was not solely determined by efficiency concerns; inter-institutional politics also played a role. Seeking to exert control over agency functions, member states designed agencies with management structures and operating procedures that would ensure oversight and control. Management Boards, comprised of nationally-appointed representatives alongside Commission, European Parliament and industry representatives, select the director and scientific committee. The EMA's own Board was originally made up of two representatives per member state, as well as two per EU institutions; with decision by two-thirds majority it was easy for the supranational bodies to be outvoted. Hence, it is questionable whether, with such strong intergovernmental management, there was any transfer in regulatory responsibility (Keleman 2002: 101). Acknowledging the limits of parliamentary oversight and representation, MEPs criticised the member state domination of MBs, on the grounds of transparency and democratic accountability (ibid. 2002: 104). In the creation of later agencies, the EP secured a greater role, such as with the European Food Safety Agency, created in the wake of the Mad Cow crisis (ibid. 2002: 108-110).

To what degree is the Management Board part of the agency? Is it the pivotal element linking external stakeholders with the agency staff (experts) as Busuioc (2009, 2010) and Groenleer (2006, 2009) assert, or is it a 'puppet', pulled by external strings? Certainly individual Board members have other institutional affiliations – i.e. identities and interests – and cannot thus be seen purely to represent the singular interests of the agency; as such there is potential for conflicts of interest. Yet, this raises the issue of loyalty and trust that is implicit in the collective membership of groups, the forging of common institutional (agency and board) identity and adherence to formalised codes of conduct (European Commission 2000, 2002, 2005, 2008). There has certainly been controversy over agency departures to industry, particularly for high-profile figures with experience, insight and networks, yet one should guard against presumptions of management boards as manipulated by third parties. That said, the EMA has recently revised its policy on the handling of conflicts of interest for scientific committee members, experts and agency staff, aimed at achieving 'a more robust system'. Its Management Board, at its meeting of 13 December 2012, agreed 'to develop initiatives for greater transparency and communication with stakeholders' and endorsed 'the continuing implementation of the conflicts of interest policies and their monitoring' (European Medicines Agency 2012).

The European Medicines Agency

The EMA is most similar to the regulatory model (Eberlein and Grande 2005: 95) and 'comes closest to being a fully-fledged regulatory body' (Majone 2001a: 263). As Gehring and Krapohl (2007: 209) assert, the EMA could be considered 'among the most important supranational regulatory authorities' and was 'a blueprint for future agencies'. The issue of authorising medicinal products is highly sensitive, heavily disputed, worth billions of Euros, and impacts upon individuals, often directly and immediately. Moreover, health and safety regulation is one of the 'arenas in which scientific and technological information battles are central to political outcomes' (Vos 2000: 1130). The issue area is a 'politically sensitive and emotionally-laden [issue] ... which not only [involves] enormous economic interests but also [concerns] the public health of millions of EU citizens' (Groenleer 2009: 141). In addition, the pharmaceuticals industry is a highly developed, organised and 'intensely regulated' field (Feick 2002: 5), hence the frequent and intense interactions between the EMA and its stakeholders. Its information is essential and potentially influential for all stakeholders (Vos 2000: 1132).

The EMA (formerly European Agency for the Evaluation of Medicinal Products) was established by regulation in 1993 (Council 1993; EP and Council 1994). Based in London, its size has grown rapidly; in July 2011 the agency signed a 25-year lease to rent half of a new 20-storey tower in Canary Wharf. It now employs over 720 staff members of whom around 300 are scientific staff, alongside administrative staff and an increasing amount of IT support to manage European databases. Initially, the EMA was functionally and institutionally separate from the Unit for Pharmaceuticals and Cosmetics of the Directorate General (DG) III (Industry). It then came under the responsibility of DG Enterprise but since March 2010 answers to DG SANCO (Health and Consumers). The agency has responsibility to '[protect] and [promote] public and animal health, through the evaluation and supervision of medicines for human and veterinary use' (European Medicines Agency 2010) and 'was designed to accelerate the slow, fragmented and costly process of assessment and authorization of pharmaceutical products and thus to facilitate the completion of the internal market in pharmaceuticals' (Tarrant and Keleman 2007: 32). The agency serves the role of a 'hub of networks of national administrative agencies, research centres, testing laboratories and other expert bodies' (Keleman 2002: 103) and 'coordinates national activities with respect to post-marketing surveillance [...] inspection and laboratory controls' (Majone 2001a: 271).

Importantly, for any discussion of independence, the EMA does not adopt binding decisions but instead prepares recommendations based on the scientific and technical expertise of its committees, which it then sends to the European Commission, which ultimately decides whether to license a certain pharmaceutical or not (Eberlein and Grande 2005: 95). Because of the co-decision procedure, the European Parliament, Council and European Commission are all effectively political principals of the EMA (Krapohl 2004: 520). As Thatcher (2011: 9) asserts, this implies a complex process involving the Commission, member state representatives and the Council, though 'in practice things may well differ'. The agency's Management Board functions as a 'steering body' in charge of overseeing the budget, appointing the executive director and monitoring performance (Vos 2000: 1126). It is composed of 35 members with a voting right – one representative from each EU member state, two each from the Commission, European Parliament and patients' organisations, and one from veterinarians' and doctors' organisations. Moreover, delegates from Iceland, Liechtenstein and Norway sit in as observers. The Commission, member states and observers usually have alternate representatives as well (European Medicines Agency 2009a, 2009b).

Busuioc (2010: 146) has identified a conflict of interest in the EMA's Management Board, particularly when it comes to payments made to national medicines agencies for work carried out on its behalf, asking whether the systems used are worthy of sound financial management. She reveals how the former executive director lamented the often 'tricky political balance' and delicate nature of securing agreements among Board members. Suffering from 'multiple accountabilities disorder' (MAD), a term put forward by Koppell (2005), the MB was seen to choose to protect the interests of national offices, rather than 'protecting the efficiency and financial health of the agency which it steers' (Busuioc 2010: 146.).

Types of independence

Legal

The EMA does not have a Treaty base because it was founded by secondary legislation (European Parliament and Council 2004; Krapohl 2004: 520). Hence, as Geradin (2005: 231) claims, 'the EU legislative institutions can ... [potentially] limit the attributions of [the EMA] and could even decide to dismantle [it]'. The Council of Ministers established the EMA by regulation but today both the Council and EP have the right to amend the founding legislation. In functional terms, delegating power without guaranteeing a degree of independence is ineffective due to the high risk of an agent failing to provide long-term credible commitments, hence Majone's (2001b: 109-110) argument that it is in the best interests of the principals to provide at least minimal support for independence. On this basis, one might claim that, although the EMA's legal status can, in principle at least, be modified, it would be costly to do so. As Groenleer (2009: 32) asserts, once an organisation's founders have endowed it with legal personality, it is difficult to alter'.

The EP has many mechanisms to control the EMA, including monitoring its website, compulsory regular reporting by the executive director in the specialised parliamentary committee, through the feedback of its representative in the administrative board, as well as EP committee delegation visits to the agency every two years (Corbett *et al.* 2007). It can give 'negative advice' on the appointment of its executive director (Andoura and Timmerman 2008: 14-16). Moreover, the EP has previously 'supported inquiries by the European Ombudsman into administrative procedures and urged it adopt and publicize administrative codes of conduct' (Keleman 2002: 110). Recently, the EMA took up the European Ombudsman's recommendation, agreeing to further broaden access to documents held by the agency (European Medicines Agency 2010). In addition, the European Court of Justice (ECJ) monitors the actions and decisions of the EMA and,

at the request of EU institutions or citizens, can further scrutinise its functioning (Keleman 2002: 99). This procedure is especially important because the applicants (e.g. citizens) may be directly affected by any newly-authorised pharmaceutical product – hence, the possibility to take a case to the ECJ against the EMA's 'decisions'.

Financial

Due to the fact that the agency's EU financing is made up of non-compulsory expenditure, the EP has the power to grant (or not) the discharge of EU funds: it refused to do so in May 2011. Under the procedure, the executive director of the EMA is 'heard by the European Parliament (Budget Control Committee) on the budgetary exercise in question' (Sacchetti 2009: 17). The EP can also ask for reports and attendance at parliamentary committees, to overcome accountability concerns (Barbieri and Ongaro 2008: 411-412). Unlike many other agencies, the EMA's budget is not totally reliant on the Community funds; around 70 per cent is revenues generated from fees charged to pharmaceutical companies (Groenleer 2009: 157; Barbieri and Ongaro 2008: 416; Permanand and Vos 2008: 31). Such budgetary distribution is supposed to increase agency independence vis-à-vis the EU institutions, though this also raises questions about the dependence upon private firms, and the transactional nature of the relationship. When taking into account internal financial rules, the mechanisms regulating the fixing of fees and the influence of political actors over them, claims of agency budgetary independence are less convincing. The adoption and control of the EMA's internal financial rules are highly controlled by the Management Board and the Court of Auditors, as Kreher (2001: 236) observes; their control is the duty of a financial controller appointed by the MB or its budgetary committee.

Administrative

The EP's power to appoint the EMA's director is limited. Although the EP can refuse a candidate for the post of executive director, the agency's Management Board can override their advice and appoint the candidate, usually selected on the basis of professionalism. Thus the EP is denied the opportunity to refuse the candidate for political reasons alone (Andoura and Timmerman 2008). By contrast, the EP has been influential in introducing 'formalized, open, transparent administrative procedures that create opportunity for its interest group allies to engage in indirect, 'fire-alarm' oversight and control' (Keleman 2002: 104-105). The director is selected by the MB from the nominees' list introduced by the European Commission (European Medicines Agency 2009a). Usually one representative, appointed by the MB, participates in the selection process of potential candidates, alongside the European Commission. Given that any final recommendation is based on scientific and technical evidence, the credibility and independence of experts producing this evidence needs to be ensured. In the case of the EMA, the agency itself nominates the experts but it is a mandatory procedure to consult the MB, without whose approval their choice is not legal.

Decision-making

The ultimate right of decision is another mechanism to control the agency's decision-making capacity in cases of conflict of interest. If the European Commission, with the consultation of the standing committees, cannot make a decision on a specific issue then it is referred to the Council, enabling this institution to further restrict the decision-making autonomy of the EMA. In addition to their ability to control the agency through the Council, the member states are strongly represented on its Management Board. The MB generally monopolises decision-making and ultimately controls many aspects of the

agency's functioning. As a result, the member states are arguably the actors most influential on the EMA itself in terms of determining its degree of independence.

The Commission's influence on agency decision-making and finances is apparent, given that it has the final say on the policies of the agency. If the Commission overturns an agency recommendation, it must 'justify the deviation, and provide a good argument for the decision' (Krapohl 2004: 532). Busuioc (2009: 612) highlights the informal power of the Commission in influencing decision-making, which originates in its role as financial provider. However, since the EMA is partially self-financed and partially-dependent on EU funds, the Commission's influence on the agency's financial and decision-making independence is expected to be neither high nor low. Groenleer (2009: 166) emphasises various methods that the competent national bodies employ to force their interests upon the agency. The first, and arguably most important, is a system of pharmaceutical self-assessment – national authorities can broker their preferences through a network of Heads of the Medicines Agencies (HMA), which currently presents 'a mechanism for communicating the views of [the] member states' competent authorities with the Commission and the EMEA' (ibid. 166).

All decisions are ultimately adopted by the European Commission, but the EMA 'nonetheless plays a highly autonomous role in industrial and social regulation' (Everson and Majone 2000: 65). The reasons for this are two-fold: firstly, although the decision-making of the agency is controlled, in Majone's (2001a) words, 'with information, knowledge and persuasion as the principal means of influence', the EMA uses the opportunity to assert influence and (to some degree) play an independent role in the process; secondly, it is in the interests of the EMA's committees to be as objective as possible, in order to maintain trust and credibility with decision-makers at higher levels. The importance placed on independence has grown significantly over time (Everson and Majone 2000: 59), but the accounts scandal of May 2011 has damaged political trust and external perceptions of objectivity.

THEORY AND RESEARCH METHODOLOGY

Theory

Theorists of sociological institutionalism (SI) believe that an institution is not purely a rational tool in the hands of its creators emphasising the role of argumentation and persuasion in a process of negotiation between and *inside* institutions. They argue that this process of 'interaction and the exchange of views can lead to the creation of new identities, attitudes, or roles' (Lewis 2003: 107-108). Borrás *et al.* (2007: 584) assert that 'socially-constructed perceptions and legitimacy beliefs, institutional path dependency and actor-related arguments (constellations, resources, knowledge)' are crucial to the setting up, but thereafter, also the running of agencies. We can discern from this that perceptions of effectiveness and legitimacy inside the agency are shaped by, and contingent upon, the social and political environment both within the various internal agency fora used for decision-making and control, and externally. Eventually, a '[thick] institutional environment' (Lewis 2003: 106) might (re)shape the belief systems of the actors involved in its functioning. Thus, investigating how actors inside the agency perceive themselves (to be and to behave) is necessary, in order to obtain a more comprehensive picture of independence. Groenleer (2009: 42) claims that 'the process of institutionalization differentiates the organization from its environment, makes it robust in the face of changing (and adverse) conditions, and gives it an autonomous status beyond the assigned legal mandates and formal tasks'. In short, agencies may develop a distinctive set of values and a strong organisational culture, evolving from 'rational tools into social institutions' (ibid.). Recognising this has obvious implications for research methods and design, hence the use of questionnaires and interviews in this article to investigate attitudes towards autonomy.

Research design and methodology

In order to rank the importance given to types of independence inside the EMA, and to see how this relates to the role played by different sets of political and non-political stakeholders on the Management Board, our research goes beyond the formal language and official rhetoric of the documents. It seeks to gauge the opinions and experiences of Board members to try to ascertain where they may be similarities and differences in attitudes towards agency (and Board) independence. Given their scope for oversight, Board members can provide valuable and comprehensive information about the agency's influence on decision-making processes and, to a limited degree, about the influence of external stakeholders present on the Board on agency activity, including priorities, work plans and regulatory recommendations. However, their views may be more general and less specialised than committee members. Admittedly, however, other agency staff may have very different and varying degrees of concern over issues of autonomy, one might assume technical experts to be less concerned or more distant from political dilemmas of independence (see Wonka and Rittberger's (2011) examination of agency staff attitudes towards EU integration, policy issues and their role in policy-making).

Questionnaires (see appendix) were circulated and then interviews conducted to gauge the opinions of agency stakeholders distinguishing between four different MB groups: 1) EU member states; 2) alternate members; 3) doctors', patients' and veterinarians' organisations; and 4) the EP and European Commission. In order to identify the most important aspects of the independence from the data obtained, the Expert Evaluation Method was used; thereafter, answers given by the members of the EMA's Management Board were calculated using the formula given below.

Questionnaire design

Participants were asked to respond to a series of statements (technically-speaking not questions but rather affirmative statements), some of which had to be ranked in order of importance. Results were aggregated to generate quantitative data. The questionnaire also gleaned qualitative data since participants could provide further comments in an open-ended section, which significantly increased the quality of information obtained (Goldstein, 2002). The questionnaire was divided into four blocks. Part A (question 1) investigated which type of independence was perceived to be most or least significant. The various members of the MB were asked to rank legal, financial, administrative and decision-making independence from 1 (most important) to 4 (least important). Part B (questions 2-13) studied administrative independence. Part C (questions 14-15) examined the role of national and common European interests in the decision-making process of the Board. Part D (questions 16-20) explored the financial independence of the EMA. Respondents were required to mark only one answer from five options. The scaling of answers was close to the standard 'five-level Likert item'.

The analysis of the questionnaire was divided into two parts. Firstly, the importance of different aspects of EMA independence (question Q1) was examined using the Expert Evaluation Method. Secondly, the degree of influence of various interested parties on various aspects of agency activity was calculated (questions 2-20). The questionnaire was sent to the members of the Management Board of the EMA (i.e. 'insiders'), including to alternate members and observers. Due to missing candidates or contacts, a total number of 30 questionnaires were sent out. The same indicator was 25 for the alternate members, observers and alternate observers together. The maximum number of respondents depended on the size of the MB; in this case, 35 permanent members. To maximise the response rate and glean as much information as possible, we added alternate members and observers.

The Expert Evaluation Method (EEM)

The main goal of the EEM is to assess the positions, opinions and attitudes of people. They may include academics, key decision-makers, heads of political as well as civic organisations, executives, parliamentarians, etc. (Matviyenko 2000). The method uses the so called 'coefficient of concordance (W)' (I-Kuei Lin 1989: 2000), which is calculated by a simple mathematical model known as Kendall's formula (Kendall and Gibbons 1990; Legendre 2005; Siegel and Castellan 1988: 266; Zhilyakova and Larin 2009), as illustrated in Figure 1. The final result of the EEM is reflected in the coefficient of concordance, with a mathematical number that ranges from 0 to 1. Complete agreement among experts is expressed as 1, while total disagreement equates to 0. The W has been applied to the first question of the survey to ascertain the opinion of the whole of the EMA's Management Board, as well as sub-sets within it.

Figure 1: The coefficient of concordance.

$$W = \frac{12 * S}{m^2(n^3 - n)}$$

where W = the coefficient of concordance

n = number of experts

m = number of factors

S = sum of squared deviations (differences)

$$S = \sum_{i=1}^n \left[\sum_{j=1}^m x_{ij} - \bar{x}_{ij} \right]^2$$

where S = sum of squared deviations

Σ = simple sum of points, calculated by means of summation of all responses by EMA Board members, each aspect of independence treated separately

CASE ANALYSIS: RANKING DIMENSIONS OF AUTONOMY IN THE EUROPEAN MEDICINES AGENCY

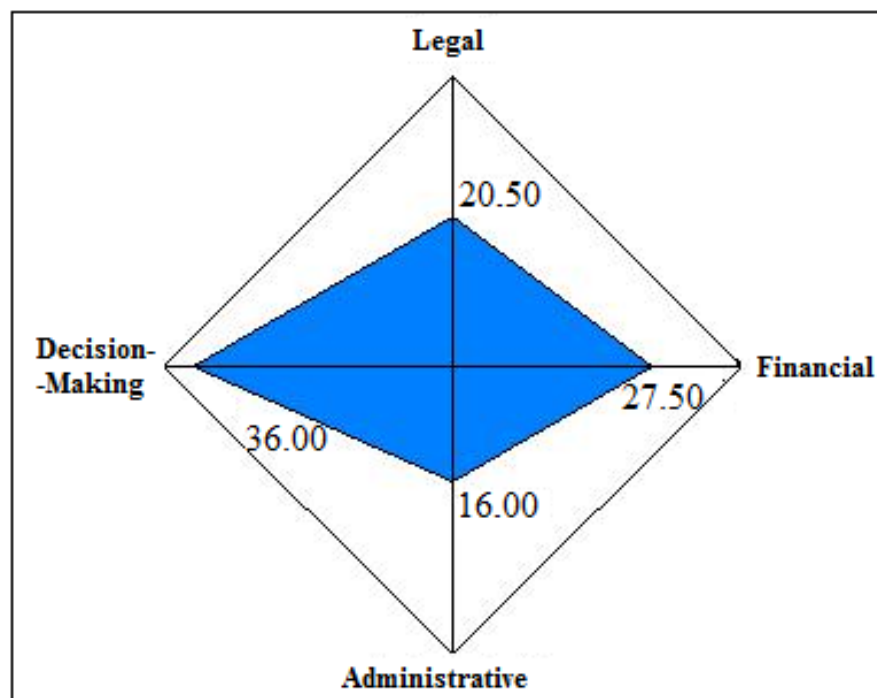
Perceptions of independence types

The response rate for the two groups was 53.3 per cent (16 replies) and 16 per cent (4 replies), respectively. For reasons of confidentiality they are identified as E1 through to E20. Analysis of the questionnaires clearly shows that decision-making independence is perceived to be the most important aspect, followed by the financial dimension. The rationale is simple – these aspects have immediate and direct effect on the EMA. A coefficient of concordance (W) of 0.46 indicates that, although there is no complete consensus among the members of the MB, there is enough consent on certain issues to consider the results reliable, as given in Table 1.

Table 1: Ranking the importance of different independence types.

Factors of independence (n = 4)	Total score across E20 respondents (n = 20)	Deviation from Mean	Square Deviation	Weight (W) = % responses ranking importance
Legal	41	-9.00	81.00	20.50
Financial	55	5.00	25.00	27.50
Administrative	32	-18.00	324.00	16.00
Decision-making	72	22.00	484.00	36.00
Total	200		914.00 (Total = S)	100
Total scores = 80; average score per factor = 2.5; coefficient of concordance = 0.46				

These results are represented in graphical form in Figure 2 below. They demonstrate that the members of the Management Board consider decision-making independence to be the most important aspect of the overall EMA independence, followed by financial, legal and administrative independence.

Figure 2: The overall perceived importance of the four independence types.

Distinguishing between group perceptions

It is possible to take this analysis further by distinguishing between the four groups of stakeholders to identify variations in the importance they place upon agency

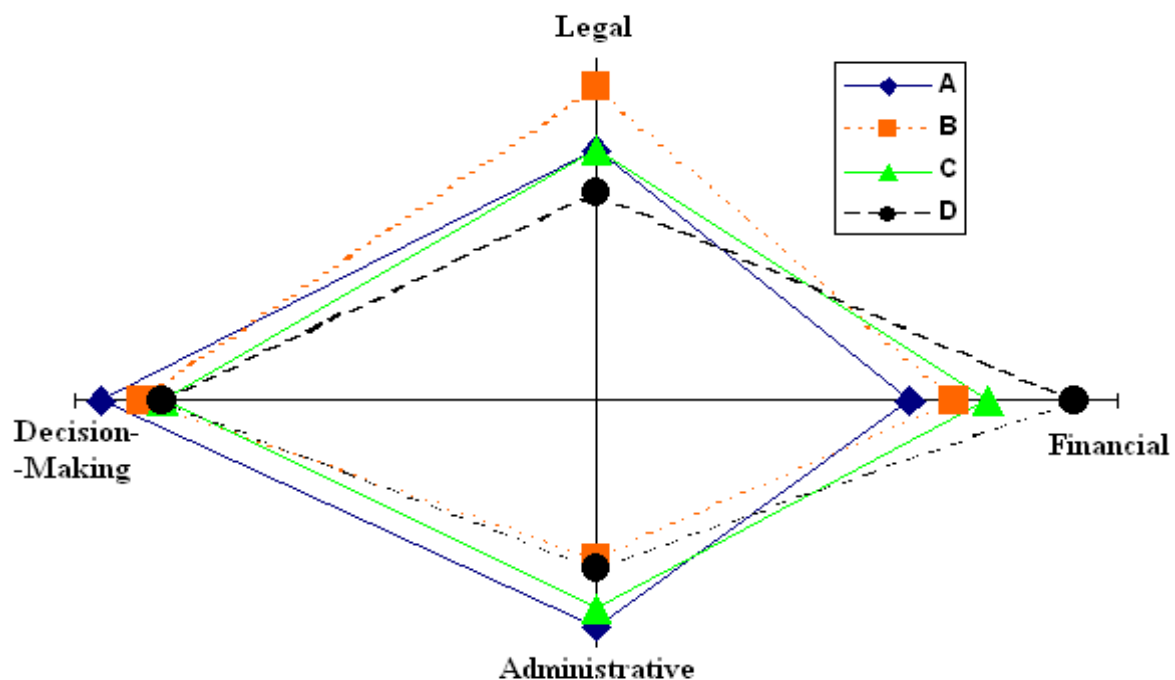
independence. Each group (i.e. group A – EU member states ($W=0.49$), group B – the alternate members ($W=0.53$), group C – doctors', patients' and veterinarians' organisations ($W=0.38$), group D – the EP and the European Commission ($W=0.82$)) has basically verified the results of the Management Board overall. In other words, financial and decision-making independence are perceived to be the most essential dimensions. At the same time, they highlight the perceived lesser importance of legal and administrative independence, as shown in Table 2.

Table 2: The importance of each independence type according to Board group.

Type of independence	Weight of each type per group				
	Group A EU member states	Group B Alternate members	Group C Doctors, patients, vets	Group D Commission and EP	Average Weight
Legal	20.00	25.00	20.00	16.67	20.50
Financial	24.00	27.50	30.00	36.67	27.50
Administrative	18.00	12.50	16.67	13.33	16.00
Decision-making	38.00	35.00	33.33	33.33	36.00

See Figure 3 below for a graphical demonstration of these results.

Figure 3: The importance of each independence type according to MB group: A) EU member states; B) alternate members; C) doctors, patients, vets; D) Commission and EP. Of the four groups, decision-making independence was perceived as the most important type by EU member states, while financial independence was most important for the Commission and EP.



A, B, C and D correspond to Group A, Group B, Group C and Group 4 respectively.

Discussion of the findings

The analysis highlights that the decision-making independence and financial independence of the EMA are perceived to be most important by the MB, while the legal and administrative dimensions are of lesser concern to its members. Groups C and D (Commission and EP) and Group C (doctors, patients, vets) place particular attention only on financial and decision-making independence, while Groups A and B (alternate members) also focus on legal independence at some point. All groups give less significance to the administrative aspect of the EMA's independence.

Legal independence

The results show the lesser perceived importance of legal independence. Hence, it is supposed that stakeholders are less interested in seeking to influence agency-related legislation. As previously explained, it is not in the interests of the EU institutions to curb agency independence too severely. The EP is interested mostly 'in the founding regulation of the agency and tries to influence it as much as it can in order to ensure that the tasks and the autonomy of the agency are described in the most acceptable way to the EP' (interviewee 2 23.05.2010). Indeed, during the 'founding phase', the EP had strong power over the legal independence of the agency 'by influencing its institutional arrangement in the founding act, yet there is relatively little interest in the day-to-day work of the agency' (ibid.). Moreover, enjoying a widely recognised legal personality, the EMA perceives itself to be a *de facto* independent legal actor vis-à-vis third parties. Like other EU institutions with a legal personality, it is accountable to the EU Courts. In this sense, actors on the EMA Management Board believe the agency's legal independence to be 'safe', despite considerable stakeholder influence.

Financial independence

As the analysis of the questionnaire results shows, financial independence is felt to be one of the most essential types for the EMA, hence the high number of stakeholders interested in agency finances. In particular, the findings emphasise a strong role for the European Commission in the financial management of the Board due to its role as budgetary provider to the EMA (Q16). By contrast, although the EP has the power of budgetary discharge, more than half of the Board members disagree with its actual weight in the decision-making process (Q17) – though this is likely to have changed since the events of May 2011. Another significant actor is the Court of Auditors. To the statement: '*The European Court of Auditors auditing of budgetary spending strengthens its control of the agency*' (Q18), a majority (60 per cent) of the MB members were positive as opposed to 25 per cent negative. Indeed, although Court of Auditors' reports are usually delivered quite late, there have been cases where it has exerted considerable influence over the EMA (interviewee 1 22.05.2010). However, E6 felt rather sceptical about the Court's role in the EMA's finances, stating that, theoretically at least, the Court of Auditors is the most influential controller of the agency, 'but in practice the only strong action recognized is directed towards reducing the Member States' competent authorities' proportion of the fee income that pharmaceutical companies pay to the EMA for the scientific assessment of their applications'; nonetheless such assessment is the core business of the EMA, even if it is organised by EMA staff but carried out exclusively by member states' experts. Some 65 per cent of the Board members did not identify any other noteworthy influence on the agency's financial independence (Q20). Nevertheless, some members (e.g. E17, E19) pointed at national competent authorities acting as a *rapporteurship*. Others highlight conditions such as exchange rates having a 'limiting effect' on financial independence (E1, E11).

Special attention should be paid to the issue of fees paid to the agency by third parties. To the statement: '*A significant part of the agency's budget is generated through fees paid by third parties in the medicines sector, which, as a result, increases the EMA's independence and freedom of manoeuvre*', 65 per cent of the MB members responded positively. However, one of the Board members (E6) disagreed, suggesting that:

if the [fee income] is increased, the surplus should be used to reduce the public (EU) contribution to the budget. 'Freedom of manoeuvre' will be used for hiring additional staff. Administrative staff will always find some activity to perform, but the question to be (externally) checked is to what extent additional staff is really necessary for the fulfillment of the institution's legal tasks. Financial pressure on public budgets in Europe is high, and in general this results in a cutback of public staff without reducing tasks. European Agencies such as EMA have largely been spared from that development, but should not expect this will be possible in the long term.

Administrative independence

The questionnaires show that the European Commission (65 per cent positive) and the MB (90 per cent positive) can significantly influence the appointment of the executive director (Q2 and Q4). By contrast, 55 per cent of the Board members consider that the EP does not exert the same amount of power (Q6). Interestingly, more members feel positive (45 per cent) than negative (40 per cent) about the ability of the representatives from the doctors', patients' and veterinarians' organisations to influence the appointment (Q8). The results highlight the relative influence of the MB (55 per cent positive) on the everyday work of the agency (Q5). According to the same data, other actors were felt to be less influential: while 50 per cent believe the European Commission exerts an influence, only 35 per cent felt the EP did (Q3 and Q7). The results also indicate the perception that stakeholders such as the representatives from other countries (E8), industry, academia (E10), physicians (E11) and national consumer agencies (E13) can at some point influence the appointment and everyday work of the executive director (Q12 and Q13). For example, E10 commented that, 'through its [i.e. the EMA's] wide range of consultations, industry or academia, by participating in setting the agenda of the agency, they can thereby influence the everyday work of the executive director'.

Decision-making independence

The results emphasise the great importance and the powerful role of the Management Board and European Commission in the decision-making process. However, as the Board members underline, national and common European interests are usually balanced (Q14 and Q15), thus minimising the possibility of subjectivity among decision-makers. Contrary to the majority of questionnaire answers, interviewee 1 argued that in the case of the Commission, the agency is 'firmly consolidated by practice', well operated and powerful enough to do whatever it wants and not to agree with the Commission, implying that the Commission cannot actually influence it very much.

Other than the Board, another way in which the EU member states might influence the EMA is via the Committee for Medicinal Products for Human Use (CHMP), most members of which are not independent scientists, but representatives of the competent national authorities. Often members are risk managers in the national agencies deciding on the authorisation of new medicines. In this regard, the member states, and national competent authorities in particular, play a strong role in the decision-making process (interviewee 1).

The role of the EP in the decision-making is marginal due to its limited involvement in the Board. For example, interviewee 1 presented one example of the EP representative, an Italian professor, who had not given any feedback to the EP: 'he was sitting more or less on his own capacity and not really providing any personal feedback'. Recently, this has been changing. Closer links with the EP have been established, including an organised feedback system. Furthermore, certain people are assigned to monitor particular agencies (nowadays a Dutch MEP for the EMA); in short, these and other instruments provide the EP with the sources of information needed if it is to be able to understand properly and control the agency. Interviewee 1 observed that essentially it possesses information rather than influence, however, as interviewee 2 argued, 'if the EP wants to turn this information into influence, it can do so'.

Finally, the Court of Justice and the Court of First Instance also play a role in controlling the EMA's functioning. Despite no legal basis for judicial review, they have always performed such a task (e.g. Court of First Instance – Case T-133/03) (interviewee 1). Although Article 263 of the Lisbon Treaty gives a constitutional right to the Courts to review the agencies, in cases where the latter's decisions are binding for third parties, their role in shaping the agency remains limited.

CONCLUSION

Finding a practical method for measuring perceptions is no easy task. This article used questionnaires in order to capture systematically Board members' opinions. It has demonstrated how agency autonomy might be analysed by conceiving of *dimensions of autonomy*, and thereafter, *differentiating independence*. Four types of independence were identified, in order to examine the beliefs of various actors within the management board, which cannot be treated as a single unit, since it comprises various sub-sets of political and non-political stakeholders, each with its own agendas, loyalties and vested interests. The method enabled results to be isolated for individual sub-sets of MB actors. Using questionnaires was useful but it was essential to complement this with interviews where possible. Face-to-face interviews with MB members are becoming more difficult as agencies increasingly employ Communications Officers to provide a single voice on agency issues. In short, sociological institutionalism's focus on perceptions, attitudes and role behaviour is useful when seeking to understand how independence is actually articulated, or played out – not on the premise of the founding legislation, but through a process of internalising and institutionalising norms and rules, as well as social learning, both *inside* the EMA in the almost 20 years since the agency was created in its original guise, and *between* the agency and its stakeholders.

This article found that the EMA possesses a higher perceived degree of independence in some areas than others. Differentiated dimensions of autonomy are acknowledged by members of the Management Board. On the basis of the results, members do not consider the agency to be either fully independent or fully dependent. Consequently, the EMA can be considered a semi-autonomous and/or semi-controlled agency. What are the implications of distinguishing different forms of agency independence, to find that decision-making independence is regarded as the most important? This finding is in some senses paradoxical since the MB is not directly concerned with regulatory questions, and does not regulate. Instead, it is the agency secretariat and various issue-specific committees which make recommendations, with the Commission taking final and binding decisions. Yet, the MB does make decisions in regarding the direction and internal functioning of the agency, an area where the Commission and other external actors would arguably not seek to exert as much direct control. The analysis showed up the contrasting perceptions of those in the MB of its strength vis-à-vis the Commission, even if managerial power was (unsurprisingly) an important factor for all respondents exerting it, collectively.

The findings presented in this paper are supported by recent research, particularly on the power of the Commission vis-à-vis EU agencies and the 'intimate' relationships that seem to develop between EU agencies and relevant DGs in the Commission – here, DG Enterprise, then DG Sanco. Thus, EU agencies seem to strengthen and legitimise (though member state engagement) the executive capacity of the Commission. Since the Lisbon Treaty introduced new changes to the roles of other agency stakeholders not identified in this research, it would be fruitful to examine whether they impose challenges to EU agencies by introducing more control mechanisms, thus potentially limiting their independence, or if the modifications provide opportunities for agencies to play a greater – and more independent – role in EU policy-making. Concerning financial and decision-making independence at least, the European Parliament looks set to play a stronger role in scrutinising how the EMA generates its revenues and recruits its 'independent' experts.

* * *

APPENDIX

No.	Question / Statement
1	In your opinion, which aspect of independence is most important?
2	The European Commission can influence the appointment of the executive director of the EMA by suggesting a candidate.
3	The European Commission can influence the everyday work of the executive director of the EMA.
4	Members of the management board of the EMA can influence the appointment of the executive director of the agency.
5	Members of the management board of the EMA can influence the everyday work of the executive director.
6	The European Parliament can influence the appointment of the executive director of the EMA.
7	The European Parliament can influence the everyday work of the executive director of the EMA.
8	Representatives of patients', doctors' and veterinarians' organisations can influence the appointment of the executive director of the EMA.
9	Representatives of patients', doctors' and veterinarians' organisations can influence the everyday work of the executive director of the EMA.
10	Other stakeholders can influence the appointment of the executive director of the EMA.
11	If you answer 'a' [strongly agree] or 'b' [agree] in question 10, please specify those stakeholders.
12	Other stakeholders can influence the everyday work of the executive director of the EMA.
13	If you answer 'a' [strongly agree] or 'b' [agree] to question 12, please specify those stakeholders.
14	National interests can influence your position during negotiations in the management board of the EMA.
15	Common European interests can influence your position during negotiations in the management board of the EMA.
16	The European Commission's role as a budgetary provider to the EMA in turn strengthens its position during the decision-making in the management board.
17	The European Parliament's power of budgetary discharge in turn strengthens its position during the decision-making in the management board.
18	The European Court of Auditors auditing of budgetary spending strengthens its control of the agency.
19	A significant part of the agency's budget is generated through fees paid by third parties in the medicines sector, which, as a result, increases the EMA's independence and freedom of manoeuvre.
20	As far as you know, is there any other actor that has an influence on the finances of the EMA?

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