EUROPEAN AGENCIES : AN INSIDE PERSPECTIVE

Fernand Sauer, Honorary Director General of the European Commission, presentation given at seminars of the European Institute of Public Administration, Maastricht, 2006-2007

Summary:

The first, second and third wave of European agencies have contributed to enforce European policies and restore the credit of the European Union and the confidence of its citizens. Capable of mobilizing a wealth of national expertise in new and innovative ways, in-between national agencies and European institutions, they have facilitated the implementation of European policies in complex and sensitive areas. By pooling the best expertise available in Europe, they have improved the quality and acceptance of European decision-making.

New agencies have a difficult start in trying to merge the best traditions from the European Commission, national institutes, and from the relevant sector of activities. In growing together with newly created national agencies, they have crafted new tools and found better solutions.

Heads of national agencies were sometimes hostile to the creation of their European rival, and tried to reassert their authority. The host country may also have lost interest, leaving the young agency alone with the formidable combined tasks of finding a suitable building, launching the first recruitments, establishing its expert networks and delivering its intended scientific job on time.

After some 15 years of operation, the performance European agencies, compared to their US federal counterparts, is satisfactory given their much smaller size. European agencies have real impact on the world scene and on the activities of international organizations. Their institutionalization is now well under way. The role played by the Executive director is crucial for the success or failure of an European agency.

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1. Introduction

Over the last 15 years, European Agencies have become a familiar feature of EU governance structures. Nevertheless, these European bodies, have so far not been mentioned in successive revisions of the EU treaties. They still are not fully recognised as European institutions, but only as European "bodies". Nevertheless, their institutionalization is well under way.

European agencies tend to fill a gap in terms of practical implementation of Community law, in sectors of high technical complexity. They follow a trend observed over the last twenty years in most Member States to delegate the management of major health or safety issues to skilled autonomous public organizations, in order to restore public confidence.

After the initial creation in 1975 of CEDEFOP and the European Foundation for the Improvement of Living and Working Conditions, the second wave of European agencies during the nineties was met with a great deal of scepticism and hostility from economic operators, heads of national agencies as well from officials within the Commission. I experienced this during the lengthy negotiations leading to the creation of the European Medicines Agency, which I then headed in London from 1994 to 2000.

Independent agencies are neither an initial nor an original feature of EU governance mechanisms. Their design was inspired from well functioning federal models in the United States, Germany, Switzerland and Canada. When, during the nineties, the agency concept spread across most Member States, even those without a federal or regional tradition, it also became trendy at EU level, mainly to tackle complex issues related to health, safety and security. The emergence of independent agencies during the late nineties offered a credible response to food scares and adverse drug reactions, when European citizens not longer trusted the traditional way of decision making.

At EU level, agencies were accused of infringing on national prerogatives or of the total opposite: re-nationalising Community policies. EU agencies were never set-up spontaneously, but always on the back of a deep crisis. Once in place, they would not become very visible when performing their function properly in their respective technical sectors. Controversies, scandals or errors would of course hit the media headlines. In addition, like most EU bodies, they may lack legitimacy in the eye of the European public. Hence the burden of proof for scientific excellence, openness and transparency is much greater for European than for national agencies.

Nevertheless, European agencies tend to fill an important gap in terms of concrete implementation of Community policies, tangible results benefiting European citizens and long-term integration of national expert networks. Outside the European Union, they offer interesting opportunities to integrate EFTA countries and associate other "neighbourhood" countries to EU activities. They also provide a credible scientific basis for many international initiatives of the European Union towards big trading partners or within international organizations (UN system and WTO).

2. In search of better governance for complex technical decisions

During the nineties the public and the media wanted to know more about the societal impact of decisions which so far had been left to politicians and technocrats: nuclear safety, blood transfusion, hormones in life stock production, transport and global warming, aviation security, quality and safety of health products. There was a general suspicion that political interference and conflict of interests prevailed over scientific rationale. When confronted with serious mistakes, ministers tended to accuse their scientific advisers for not having provided a clear picture of the situation. A French minister was quoted as saying that she felt "responsible, but not guilty" for having made the wrong decision. A health minister and his director general were jailed for having organised a systematic racketing of pharmaceutical firms who wanted to access the Italian market.

Thus, separating scientific experts from central government and providing them with autonomous resources and professional independence appeared necessary to restore public confidence. Politicians ceased the momentum to shift the blame for hot and difficult societal issues on these new external, scientifically based, public organisations. Depending on the constitutional environment, regulatory agencies were given the power either to decide, or to make public their scientific advice to the decision-making authority.

With the exception of the trade-mark Office in Alicante (Office for Harmonisation in the Internal market), the European Community gave preference to the advisory model, in order to limit the danger of creating scientific ivory towers and headless technical bureaucracies. The public requires full transparency but does not always accept that science should "rule the world". Indeed, in an ideal world, harmful products such as tobacco products would be totally banned. On the one hand, the public wants to know the true story behind complex adverse events. On the other hand, democratically elected governments have to respect the expectations of ordinary citizens. Pedagogical efforts and behavioural changes could minimize accidents and diseases and improve our quality of life.

Other consideration, such as ethics, public order, civil liberties may justify that, given the complex EU institutional arrangements, the Commission should remain politically responsible for final decisions before Parliament and Council. It was argued that trade marks exception took place in the field of private law, without public order consequences. The creation of the Aviation safety agency re-opened the possibility to sub-delegate to EU agencies executive decisions affecting operators.

In the logic of the Council, delegating powers to a European agency designed as a consortium owned by national agencies was sometimes preferable to delegating such powers to the Commission alone. The Commission was accused of not being able to cope with detailed technicalities. This would constitute an alternative to "comitology" and short-circuit the Commission, provided the agency is capable of pooling the best expertise available throughout Europe. In addition, an European agency should be able to manage the interface between national regulatory authorities and to reduce, or at least contain, the growing overall expertise costs.

My own point of view is that arms length relations between a strong advisory type agency and a politically responsible Commission, supervised by the European Parliament, strikes the right democratic balance. Binding legislation should continue to be delegated to the Commission, even if agencies should provide the scientific and technical basis for updating the applicable

norms and standards. Within the existing EU legislative requirements, agencies should be able to express detailed guidance for users and economic operators. Such "guidelines" would facilitate well accepted procedures, without preventing operators from adopting innovative approaches, together with a proper validation.

When it comes to individual decisions affecting operators, the power of adjudication can be entirely delegated to an agency when it is purely a matter of technical implementation. When there is room for political judgement, the Commission should either retain the power of adjudication, or reserve the right to overrule the agency in exceptional circumstances. In both cases the Commission normally has to accept the scrutiny of Member States through one of the "comitology" procedures, with some form of parliamentary supervision. It can be argued that, in an age of "electronic government" the whole process should be drastically shortened. In emergencies (i.e. the recall of defective products), provisional decisions should be taken immediately and the scrutiny should take place after, to confirm or not the initial position.

3. Personal experience with European agencies

It is not easy to explain scientific issues to the general public or indeed the concept of benefit/risk, especially in societies that are showing themselves increasingly adverse to any risk at all. This is the challenge faced by all regulatory authorities worldwide. Putting in place a reliable and independent source of scientific opinion and information is an important means of ensuring public credibility. One aspect of this is creating a robust legislative framework, but there must also be confidence in the professionalism and competence of the regulatory body managing the system.

Public opinion surveys have shown traditionally high levels of support and confidence in the work of the FDA. One of the reasons for this is the FDA's long-standing record of scientific excellence and the perceived independence of its scientific opinion. This model of scientific agencies independent from their political authority is one that was increasingly being applied in Europe. Although US federal agencies were an inspiration for many national governments struggling with complex technical and regulatory issues, the idea of a Food and Drug Administration for Europe remained a "tabou" subject, especially in the pharmaceutical sector. The newly created national agencies feared for their independence and future development prospects. Most multinational companies preferred to survive alongside weak and sometimes corrupt national authorities rather than confront a strong European regulator as powerful as the US FDA. On the other hand, patient and consumer organizations, innovative biotech companies and the European Parliament supported the idea of an European agency.

Having been responsible for designing and implementing the pharmaceutical measures contained in the 300 measures of the Single Market White Paper[1] (1985/1992), I became convinced that national regulators working separately would not trust each other enough to recognise their respective evaluations. In addition to an extensive harmonisation of pharmaceutical legislation, the harmonisation of marketing authorization decisions could only be achieved by a strong central coordination mechanism, supported by a large network of national experts. Dismantling national authorities and replacing them with a massive European body would not automatically achieve better results. The alternative was to create a

[1] European Commission, « Completing the Internal Market », COM(85) 310, June 1985.

"virtual FDA", a hub where national regulators would have to work together and share their scarce resources on complex scientific issues related to important new products.

Inside the Commission, some were of the opinion that the so-called "new approach", combining mutual recognition and industrial standardization could also be applied to the pharmaceutical sector, without any need for central coordination. This did not take into account the strong public health traditions of all Member States. Others considered that the Commission should be entrusted with that strong co-ordination function. In fact, Member States were ready to share their sovereignty among themselves and maybe involve the Commission in the process. They were not willing to delegate their powers entirely to the European Commission.

The result of several years of scientific networking and regulatory preparatory work and 3 years of intense negotiations between Commission, Parliament and Council, was a small (but beautiful[2]) European Medicines Agency (EMEA[3]), jointly owned by national agencies, in charge of risk assessment and to a considerable extent, of risk management. The legal theory at the time was that marketing authorizations could not be delegated to an agency. Therefore, the Commission, in consultation with a regulatory committee, had to rubber stamp the final decision, except in exceptional circumstances. Over the years, the Commission has never raised an objection to the several hundred draft decisions it received from the EMEA[4].

When in 2000 I was asked to chair the working group on regulatory agencies in preparation for the White Paper on European Governance, I noted a change of attitude towards agencies in the Commission services. Agencies started to be seen as a useful tool for implementing complex EU policies. Given the "mad cow disease" food crisis, it was now easier to argue in favour of agencies when health and security issues required a high level of scientific and independent expertise. The "Meroni doctrine" about delegation of executive powers was being reconsidered. Instead of rejecting or glorifying agencies, this preparatory work analysed the objective conditions and criteria which would justify or not the creation of a new agency at EU level.

Several aspects of this reflection process were taken up by the Commission in its 2002 Communication[5] and in the 2005 draft inter-institutional agreement[6]. The temporary suspension of the inter-institutional dialogue on agencies shows how difficult it is to apply ex-post a doctrine to so many different agencies, some of which have been in place for more than ten years. Indeed, this reminds me of the past difficulty of defining a doctrine ex-ante. The Commission, having finalised its proposal for a regulation establishing the EMEA in June 1990, made an attempt to define its general policy on agencies before submitting its proposal to Council and Parliament. These internal discussions were not conclusive and the proposal was transmitted to the other institutions in December 1990, without an accompanying broader doctrine. On the positive side, Commission services and the Members States have been able

[2] Fernand Sauer: "Small is beautiful" in E-SHARP, March/April 2006, London.
[3] Name later changed to « EMA » ; more information on: www.emea.europa.eu
[4] Fernand Sauer: « Agence européenne d'évaluation des médicaments: bilan de cinq ans d'expérience » in Bulletin et Mémoires de l'Académie royale de médecine de Belgique, Volume 155, Année 2000, N° 5-6, pp. 254-262, séance publique du 24 juin 2000.
[5] The operating framework for the EU Regulatory agencies, COM (2002)718 of 11.12.2002
[6] COM (2005)59 of 25.02.2005

in the meantime to learn from that diversity and select successful experiences to serve as models.

I have benefited greatly from my experience as an executive director of the EMEA. I had to put in practise the theories which I had preached during tough negotiations. The practical exercise is sometimes even tougher, but always challenging. Executive directors have created an informal club to exchange knowledge and tips. This experience was particularly useful and handy when launching, from 2003 to 2005 the new Centre for Disease Prevention and Control in Stockholm (ECDC, www.ecdc.europa.eu). I participated in the early phase of creation of the Executive Agency for the Public Health Programme (PHEA, www.ec.europa.eu/phea), which started its operations in Luxembourg in 2006. In fact, the launch of an executive agency is more like creating a new Commission service than a decentralised agency. This does not mean that is easier.

I came across very similar governance issues with two new bodies prefiguring another wave of agencies in the context of European research Area, respectively based on Article 169 and 171 of the Treaty. I acted as rapporteur for the external review of The European and Developing Countries Clinical Partnership (EDCTP) established in 2003 by 15 European countries to develop new clinical interventions and adapt existing treatments to address the needs of sub-Saharan Africa in the field of poverty related diseases (www.edctp.org). I also participated in the impact assessment of a new public/private partnership: the Innovative Medicines Initiative Joint Undertaking to strengthen Europe's position in pharmaceutical research (http://imi.europa.eu). The rest of this chapter will be based on my personal experience of dealing with European agencies, mainly the EMEA and also the ECDC.

4. New EU agencies and their "older" US counterparts

Historically, most of the prestigious federal models, which still survive today, can be traced back to the United States of America. Starting in 1889 with the Interstate Commerce Commission, some 57 US federal agencies were progressively set up. Over several decades the US federal agencies have generally established a good reputation at home and abroad, in terms of scientific excellence and public confidence. They differ in size and longevity from their EU counterparts but provide a model for future expansion.

The US Food and Drug Administration (FDA) based in Rockville, Maryland It was created in 1906 to deal with vaccines. It presently monitors a significant share of the US consumer market, especially food, medicinal products, medical devices and cosmetics (www.fda.gov). The FDA employs more than 9 000 permanent staff members, assisted by numerous expert panels and laboratories, with an annual budget of 2 billion$. The European Medicines Agency, established in London in 1995, focuses on the evaluation of new medicines, whilst conventional medicines continue to be evaluated by national agencies. The EMEA employs some 500 staff members and relies on a network of 4000 national experts, with a budget of 170 million €. The European Food Safety Authority (EFSA) started in Brussels in 2002 and is now based in Parma, with a budget of 50 million € and 160 staff (www.efsa.europa.eu).

The US Centre for Disease Control, established in Atlanta, provides another example of progressive growth of a federal agency. It started with malaria in 1946 and covers now all infectious and chronic diseases, with 15 000 staff and a budget of 8 billion $ (www.cdc.gov). The European Centre for Disease Prevention and Control (ECDC) was set up in 2005 in

Stockholm, focusing on pan-European threats from communicable diseases. It currently employs some 200 staff with a budget of € 40 million. Its remit may be extended to other major diseases following an evaluation which is underway.

Major differences between US and EU agencies can be attributed to the necessary maturation process, as well as to the different institutional background, as shown in the table below.

Despite the historical and institutional differences, there are many similarities between EU decentralised agencies and their US federal counterparts, in terms of objectives, missions and requirements. They share similar scientific criteria and principles at the heart of their core business. There is often a convergence between their basic processes and practices. They all seek international recognition of their performances and results.

In addition, they are dealing with, and sharing, similar reflections on common themes such as: independence/autonomy, conflicts of interests, confidentiality, scientific methodologies and risk assessment, regulatory guidance, involvement of consumer groups.

Differences (in 2007)	**US federal agencies**	**EU independent agencies**
First agency	1889 : Interstate Commerce Commission	1975 : CEDEFOP & EUROFOUND
Number of agencies:	57 independent agencies	30 « decentralized» EU agencies
Type of organization:	heavily centralised, with external scientific panels	decentralized, always linked to national networks
Staff (in-house):	Thousands per agency Total: well over 100.000	Hundred per agency Total : around 4.000
Budgets	Average : 1 to 7 billion $ Total: well over $100 billion	From 15 to 150 million € €1 billion, half from EU subsidy
Typical powers:	Delegated regulatory powers	Advisory rather than regulatory
Links to executive branch	President Office of Managment and Budget	Commission Secretariat Generlal + operational directorates
Parliament scrutiny	Nomination by Congress, frequent hearings, budget allocation	Episodic hearings + subsidy
Normative powers	Frequent (1946 Administrative Proceedings Act)	De facto influence, not formal
Adjudication powers	Frequent (1966 Regulatory impact analysis/Freedom of Info Act)	Exceptional (Meroni)
Judicial control	Internal administrative and Federal courts	First Instance and ECJ, Court of Audit
Enforcement	Federal & States	Member States
Public visibility	Well known and well respected	Exceptional

5. The foundation of a new agency: the EMEA

During the 80's, I don't remember any general debate within the Commission services on the concept of European agencies. I guess therefore, that the history of most "second generation" European agencies started within an operational service of the Commission, confronted with an impossible new job. In some cases, the project was initiated after a high level discussion of Heads of states and Government with the President of the European Commission, for example on environmental protection.

In the absence of a general doctrine or internal guidelines, individual initiatives appeared to have been opportunistic and left to a large extent to local improvisation. This was long before the Commission had imposed the use of green papers, white papers, impact assessments, open access to documents and the like. It is difficult to reconstruct the genesis of these agencies, in the absence of published documentation. Naturally, operational services of the Commission tended to focus on action, rather than on reporting and on historical archives. Horizontal services of the Commission, such as the Legal service or the Secretariat General, were, at the time, more concerned with general legislative work, such as the completion of the Single Internal Market.

The pharmaceutical unit which I managed was able to inspire 13 pharmaceutical measures in the 1992 Single Market catalogue, including testing requirements for all categories of human and veterinary medicines, special incentives for biotech products, control of advertising, rules for prescription drugs, transparency of pricing and social security and wholesale distribution[7]. One item on the list was carefully labelled as follows in the 1985 catalogue:

"Completion of the work for the elimination of barriers to free circulation of pharmaceuticals: choice of the most appropriate system in the light of the experience acquired from the different Community registration procedures (1989-1990)."

The above mentioned Community registration procedures were consultative, leaving full discretion to national competent authorities. The "decentralised" procedure aiming at the mutual recognition of national authorisations did not succeed and was largely boycotted by industry, for fear of parallel imports. The "concertation" procedure introduced a joint initial evaluation for biotech products, with some interesting outcomes but without binding effects.

The concept of the European Medicines Agency (EMEA) can be traced back to one simple triangular slide we produced in public conferences around 1987:

- at the top, 50 biotech/high tech products, accessing a worldwide market through a "centralized procedure",
- several hundred products in the middle, destined to an European market through mutual recognition and,
- on the base line, thousands of products which would continue to follow national procedures, unless a European referral would be requested by a competent authority.

In the beginning, industry was somewhat divided. The new system represented a competitive challenge for many national companies, comfortably established in their local markets. Big

[7] Fernand Sauer : « Evolution de la réglementation des médicaments dans la Communauté européenne », Revue du Marché Commun n°320, septembre/octobre 1988.

multinationals were at best neutral, having shown their ability to take advantage of split markets. Nevertheless, the EMEA represented a magnificent opportunity for small innovative European companies who could directly acquire their "passport to Europe" without help from bigger firms

There were no major difficulties on the scientific side, since the best experts in Europe had already been working together within the European scientific committees in charge of human and veterinary medicinal products (CPMP[8], CVMP) and their working parties, flanked by hundreds of governmental experts from national agencies, public research and university hospitals. In particular, We were able to enrol some of the best experts to conduct a major effort of harmonisation of testing requirements in the framework of the International Conference of Harmonisation (ICH), together with the US Food and Drug Administration and the Japanese Ministry of Health.

Soon, this expert network became a joint venture for the protection and promotion of public health, owned by national agencies as well as European Institutions and fully supported by patients and innovative companies. In March 1988, the Commission produced a detailed and critical report on the shortcomings of the existing voluntary registration procedures [9], which was followed one year later by a public "Memorandum on the future system for the authorization of medicinal products in the EEC" in order to trigger a wider consultation.

A complex package of 4 proposals[10] based on Article 110A of the Single European Act was submitted to Council and Parliament via the co-operation procedure under the qualified majority rule. Apart from other controversies, Germany objected strongly against the principle of an agency being assimilated to a legislative harmonisation measure. After lengthy discussions, the legal basis in the Treaty was changed to Article 235, also called "mini-revision of the treaty", requiring unanimity. The Commission made a concession, in exchange for unanimous adoption[11].

On the occasion of the revision of the pharmaceutical legislation[12], the Council finally accepted that the EMEA Regulation should be based on the harmonisation legal basis as well as on the public health article of the Treaty (Articles 95 and 152 of the Amsterdam Treaty).

[8] Pr J-M Alexandre, chairman of the efficacy working party and then of the main EMEA Committee (CPMP) played a major role in rallying the scientific community, until 2001.
[9] Report from the Commission to the Council on the activities of the Committee for Proprietary Medicinal Products/CPMP, COM(88) 143 of 22.03.1988.
[10] Commission proposals modifying the existing pharmaceutical legislation and establishing the European central authorization system and the EMEA, OJ N°C330 of 31.12.1990.
[11] Council Directives 93/39/EEC, 93/40/EEC and 93/41/EEC, were adopted on 14 June 1993 and a Council Regulation (EEC) n°2309/93 on 22 July 1993 (O.J. n° L 214 of 24.08.93).
[12] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Official Journal L 136, 30/4/2004 p. 1 - 33).

6. Setting-up a new agency: site and preparatory measures

The designation of the seat of European Institutions and bodies remains the privilege of inter-governmental negotiations. During the nineties this principle was strictly applied. Any questions related to the seat could not be raised by the Commission or even the Council, but was to be left for the European Council. The Commission was prevented from taking any concrete preparatory measure before the seat question had been settled. The launch of the European Environment Agency (EEA) was therefore considerably delayed.

Having formalised the designation of the seat of the European Institutions at its previous meeting, the European Council fixed the location of several European agencies, including the EEA and EMEA, on 29 October 1993. Many countries had offered a full range of offices and services to host their favourite agency. Other countries relied on public relations campaigns and luxurious brochures. The results came as a surprise. Barcelona lost the EMEA to London at the very last minute. The Portuguese prime minister who had asked for the medicines agency ("drugs" in American English), got in fact the European Centre for Drugs and Drug Addictions.

The preparatory work for setting up the European Medicines Agency started immediately, with the first meeting of the management board in December 1993, at the initiative of the Commission services who provided an interim support. A small task-force was set up by the Commission department in charge of pharmaceuticals in order to launch the first recruitment and training of staff, to establish a telematic network and archiving facilities, in line with an external study conducted by Touche Ross. A new budget line had to be requested from Parliament with the necessary appropriations (ECU 4 million for 1994). Detailed arrangements for the complementary financing of the system through user fees took the form of a Council Regulation in 1995.

Since the host country did not provide any building or financial support, the first task was to select an appropriate site in London and adapt the building to the needs of the agency, After my nomination as executive director in April 1994 and with the help of the Chairman, Strachan Heppell, and members of the management board, I was able to focus on finding a suitable location at a reasonable price. Canary Wharf in London Docklands offered good quality premises, but the area was at the time not well connected to the public transport system. We obtained a free boat service from Westminster Pier on the Thames until completion of the Jubilee Underground Line and excellent conditions for a long term lease. Over the last ten years, Canary Wharf has become a vibrant, modern, busy and expensive extension of the City, with excellent connections to Eurostar and the City Airport.

When I thought I could concentrate on scientific work, I found I had only 6 months to get the empty building ready for the inauguration in January 1995. In parallel to the first recruitments, with the informal help of colleagues in the Commission research department, I was busy choosing carpets and chairs, designing meeting rooms and interpretation facilities. Most important for a Frenchman's reputation, I had to help designing the kitchen and to obtain a license for decent wines to be served at the canteen, instead of tea, in order to prevent delegates from disappearing into nearby pubs. The decisive step was to arrange a fully equipped office space for each delegation and a small travel agency so that delegates would feel welcome and at home when working at the EMEA.

With the complicity of a friend, art teacher at the European School in Brussels, hundreds of children were convinced to produce some 300 paintings to illustrate medicines for the opening of the EMEA. These extraordinary pictures of witchcraft, complex brain machines and romantic hallucinations, still decorate the building today.

7. From concept to reality: the decisive start-up phase

Whilst the fitting out was taking place at 7, Westferry Circus (Canary Wharf), a handful of courageous collaborators performed miracles in inventing from scratch and improvising the new European authorization procedures. They were later joined by young and equally enthusiastic colleagues who had to undergo a massive training exercise.

The new scientific committees were immediately convened in January 1995 to start the evaluation work. The first opinion (Gonal-F) was delivered in May 1995 to a then small biotech company which became a leading European company afterwards: Serono. This was followed in July by the first opinion on a veterinary vaccine and the adoption in a record time of a great number of maximum residue levels of veterinary medicines in food products.

While the combination of national evaluations took up to 6 years before a new product could be placed on the market of all Member States, the EMEA always managed to keep the whole process under one year, including the granting of a single European authorization by the Commission. Patients have a much faster access to new therapies. Innovative companies gain a couple of years of patent term.

The rationale behind the European marketing authorization system is resource optimization and quality improvements. This had to be put in practice. Each scientific evaluation had to be carried out by two independent teams (rapporteurs/co-rapporteurs) and subjected to peer review in the scientific committees, instead of repetition of the same activity in each Member State. The scientific competence of committee members and experts had to be guaranteed by the nominating Member State and is reinforced by peer review. When acting for the EMEA, members and experts had to do so independently of their nominating authority.

All members of the Management Board, scientific committees and expert groups, as well as staff members were required to make public declarations of interests, available for inspection at the EMEA premises in London. The declarations of interests and curriculum vitae of the 4000 experts working with the EMEA was also made available on request.

This inaugurated a solid tradition of transparency and openness at the EMEA with the full publication of all assessment reports. These critical evaluation reports (EPARs) were put on the Internet before the final authorization, so that any “state of the art” objection from the worldwide scientific community could be taken into account. No other authority in the world, including the US FDA was in a position to do the same. As an independent drug regulatory authority, the EMEA had to be open to public and political scrutiny to ensure that procedures are correctly followed, that resources are correctly spent and that independence is ensured. At the end of the start-up period, all documents produced by the EMEA were made available through an Internet public register[13].

[13] Fernand Sauer : "The European Medicines Evaluation Agency and European Pharmaceutical Approvals: Efficiency, Transparency and Accountability" in "The EC

8. Consolidation and extension of the agency's activities

One of the key challenges was the multi-cultural aspects of the work of the EMEA, in particular the quality of information given to users of medicinal products in all official languages (for doctors and patients). A special network was set up with all national agencies to revise the quality of technical translations of pack leaflets and professional data sheets. The agencies' Translation Centre in Luxembourg was not equipped for such specialised tasks.

A second challenge was the consolidation of the early achievements. Members of staff participated in a quality management system project from 1997 on. This programme established specific goals for each unit, performance indicators and steps to improve transparency and optimisation of human and logistical resources. This included :

- the introduction of a novel financial accounting system for financial reporting (SI2);
- the identification and monitoring of cost centres through analytical accounting methods; and
- the implementation of a home made electronic time management sheet (ActiTrak) to allow an accurate identification of the time taken by each staff member for different tasks.

A third challenge was the interface with all partners by a high-speed Intranet link to allow for exchange of information (e.g. of safety alerts) – the European Union drug regulatory authorities' network (EudraNet), operated through a special office of the Commission Joint Research Centre.

It is an approach based on partnership with some 42 different national agencies, European Commission and all other interested parties (institutional and public). The structure of national authorities is different in each Member State; some are independent self-financing agencies, others are departments of ministries of health, some deal only with human or veterinary medicines and some with both. However, full participation of national competent authorities and consultation with other interested parties is important for the acceptability of the system. Scientific evaluation and inspection work is contracted out by the EMEA to the national competent authorities on the basis of contracts for services. These contracts set out quality requirements, performance indicators and other conditions, in return for which the EMEA pays part of the fee it receives from applicants or marketing authorization holders. The fee income of the EMEA represents three-quarters of its revenue, whereas the payments out-sourced to national agencies represents more than one-third of total EMEA expenditure.

Iceland and Norway directly participate in the work of the EMEA since 1998. Co-operation with candidate countries led to the launch of the Pan-European Regulatory Forum in 1999, which considerably facilitated the subsequent accessions and integrated the experts from the new members States at a very early stage.

The evaluation of medicines, post-marketing surveillance and scientific advice are core parts of the Agency's work. However, the EMEA also invests considerable resources in international harmonization activities, particularly the development of testing guidelines. These guidelines are adopted following 6 months consultations with all interested parties both within the EU and internationally (especially with Japan and USA in the context of the

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Agencies between Community Institutions and Constituents" Second Conference Report, European University Institute, Florence, Robert Schuman Center, March 1997.

international harmonization initiatives, ICH and VICH). The EMEA also plays a major role in support of the pharmaceutical aspects of mutual recognition agreements negotiated between the European Union and third countries.

In 1999, the EMEA established a Committee on Orphan medicinal products (for rare diseases), where patient organizations were invited to sit alongside Member States' representatives. This major institutional innovation paved the way for the acceptance of patient and doctors' representatives as permanent members of the management board.

The performances of the EMEA and of the European authorization system were the subject of a major external study published in November 2000, on the "Evaluation of the operation of Community procedures for the authorisation of medicinal products", carried out on behalf of the European Commission by Cameron McKenna and Andersen Consulting[14], followed by several proposals from the Commission to adjust the European system. The EMEA successfully responded to the huge challenge of a major overhaul of European pharmaceutical legislation in 2005, which gave wider responsibilities to the agency and strengthens post marketing surveillance as well as patient information. New tasks include pediatric medicines, advanced cellular therapies, monitoring clinical trials and setting-up special assistance to small businesses.

EMEA : MAIN RESULTS

Medicines for central EU approval (human use): ***(1995/2007)***	- Total applications - CHMP opinions - EU marketing authorisations - Variations to authorisations - Scientific advice	607 463 388 7168 835
Medicines for rare diseases 'orphan medicines': ***(since April 2000)***	- Total applications - COMP positive opinions Orphan designations by EC	630 500 450
Veterinary Medicines for central EU approval: ***(1995-2007)***	- Total applications - CVMP opinions - EU marketing authorisations - Variations to authorisations - New maxim. residues limits - Scientific advice	93 82 71 411 162 58

With considerable support from the European expertise provided by the national regulatory agencies, the new European drug approval system is working well. The EMEA, in particular its scientific committees, have established a worldwide reputation for the quality of their evaluations and opinions, without any major problem so far (see table above). Whilst the

[14] http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2000

agency's international role continues to grow, its present Executive Director, Thomas Lönngren has spelt out the "EMEA Road Map to 2010".

9. Recent experience with the ECDC in Stockholm

Communicable disease outbreaks pose a significant threat to the health and well being of the European Union's citizens, as shown during the spread of the SARS virus (Severe Acute Respiratory Syndrome) in 2003 and in the anthrax alerts of 2001, which were attributed to bio-terrorism. A major outbreak of an influenza pandemic would have catastrophic consequences. In a European Union where millions of people cross internal and external borders each day, tackling health threats requires a much closer co-operation between Member States, the European Commission, the World Health Organisation and affected countries around the world.

Since 1999, the Commission has managed a Communicable Diseases Network, based on ad hoc co-operation between Member States. In 2000 and 2001, two external evaluations of the Network highlighted weaknesses in the functioning of existing structures and reviewed options for a more effective response capacity at the EU level. In 2002, the European Parliament asked the Commission to propose appropriate structural arrangements to reinforce the EU capacity to fight diseases and to manage the first major EU public health programme.

The Health Council, at an extraordinary meeting held in May 2003 to discuss SARS, recognised the need to strengthen the EU preparedness to deal with disease outbreaks. Soon after, in July, the Commission proposed the creation of a European Centre for disease prevention and control, which was widely supported. The Regulation was quickly adopted in co-decision in first reading, within 10 months[15], which sets a record. At the EU Summit in December 2003 Sweden had been identified as the host country. The operations of the ECDCt started in May 2005.

The ECDC's mission is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases, in partnership with national health protection bodies across Europe and to strengthen disease surveillance and early warning systems. By working with experts throughout Europe, ECDC aims to develop authoritative scientific opinions about the risks posed by current and emerging infectious diseases.

The first meeting of ECDC management board was held in September 2004 and it soon included representatives from civil society alongside Member States, Commission and Parliament. The preparatory work was conducted from within the health directorate of the Commission until the newly appointed Executive Director, Zsuzsanna Jakab took up her position in early 2005. Having personally been responsible for the financial and administrative activities, I handed over to ECDC all scientific, administrative and financial files in September 2005. Given the wide support within the Commission services and the national epidemiology institutes, the start-up phase went much smoother than what I had experienced ten years before with the EMEA. This shows the high degree of acceptance EU agencies have acquired by now.

[15] Regulation (EC) N° 851/2004 of Parliament and Council, OJ L 142, 30.4.2004

Although the Swedish government did not offer any building, a provisional location was freely provided by the municipality of Solna. The ECDC is now strategically located in the Tomteboda building on the Karolinska Institute Campus, close to the Nobel Prize Auditorium. With a budget of € 40 million in 2008, the Centre is set to have 200 staff. An independent evaluation has been initiated, to assess the need for the extension of the mandate to other areas in public health (such as health monitoring). The study will analyse the tasks of the Centre, its working practices, and the impact of the Centre on prevention and control of human diseases and its potential for future development.

10. Profile of the Executive Director

Within the European Institutions, the media attention is concentrated on Ministers and Commissioners. The reputation of most high-ranking Commission officials is generally limited to their own sphere of influence. This is quite different in a European agency where the Executive Director, (rather than the Chairman of the board) tends to convey the image of the organization. The initial impression given and the style of management introduced at the start-up phase may determine the reputation of the agency for many years to come.

The qualities of the ideal person to head an agency may vary in time, according to the degree of maturity of the organization. A visionary and charismatic leader is certainly needed at the start. Once the new agency is well established, the top manager has to be an enforcer and a reformist. An ideal combination of leadership and management skills is not easy to find in bureaucracies as well as in multi-national companies.

In all circumstances, the Executive Director must behave like an entrepreneur, capable of inspiring the agency's staff and scientific experts, with a good talent for internal and external communication and for networking. Financial and recruitment issues can become a nightmare in an agency of limited size and undergoing rapid growth. A good knowledge of EU financial rules and staff regulations, which are quite complex and specific, is imperative. Personal accountability is key to the continued success of the agency in dealing with the Budgetary Authority and the Court of Auditors.

In order to secure the core business of the agency, he or she must be prepared for a permanent negotiation, with the board, Commission and Parliament, with national agencies, stakeholders (industry and consumers) and international partners. Since European agencies are designed as a hub in the middle of a decentralised network, rather than a heavy hierarchical structure, the director can only convince and influence, but not instruct or command. Many important actors, for example experts and committee members, are not on the pay-role of the agency and their career does not depend on the goodwill of the Executive Director.

Some technical knowledge of the field may be useful, but the Executive Director is not expected to be the Chief Scientist of the agency. A good experience of dealing with scientists and scientific issues in a related field is probably better than belonging to a closed scientific circle or chapel in the concerned sector. It is important to have a good grasp and some practice of the EU legislation and the regulatory environment of the agency.

Finally, being attracted to multi-culturalism is an absolute must, especially in a new European agency. When joining an existing European institution or agency this is quite obvious for any candidate: either you enjoy it, or you hate it. If you are not interested in how other people

think or express their views and emotions in other cultures, you are not going to survive. This is even more crucial in a new agency where a new common culture has to be re-invented jointly by all involved parties. The Executive Director must refrain from imposing his own cultural attitudes and prejudices and act as an active listener, even if this may be difficult given the stress and tension of the pioneering years.

11. Nomination and first steps of the Executive Director

Therefore the recruitment of the Executive Director is of crucial importance. The Commission, who initiates the process, has harmonised and refined the recruitment procedure over the years. Publication in the Official Journal is the rule, but more targeted publications are made in the general press, scientific journals, on the Internet and through the administrative channels of national agencies. The Commission uses a pre-selection procedure similar to that of high-ranking EC officials: interviews of eligible candidates by an internal panel and a management consultant, and by the Commissioner in charge. The College adopts then a short list of 2 to 4 candidates, which is transmitted to the management board who elects the best candidate after having heard the short-listed candidates. The Executive Director is then confirmed by the board (or its Chair, by delegation), after a successful hearing in the competent parliamentary committee. The whole process might seem long and complicated, but it can be finalised within 6 months following publication, as was the case for the ECDC.

For a new agency, the first tasks of the Executive Director are considerable:

- Initiate staff recruitments in line with EU rules
- Search, select and adapt suitable building
- Set-up administrative and financial procedures
- Design an annual programme and a sliding plan for 3 to 5 years
- Suggest annual budgets and long term financial perspectives,
- Set up scientific committees and networks,
- Organise good contacts with the Commission, Parliament and the host country
- Visit as many national agencies and main partners as possible.

The Executive Director has to establish his or her authority and autonomy vis à vis the Commission and other members of the management board, such as the Chair. The term “management board” may be confusing since, with 3 to 4 meetings a year, the board cannot manage routine activities of a n agency. According to the agencies’ regulations, it is a supervisory board, involved in general oversight and key annual programming and financial decisions. The role of the Chair is essential to prepare and conduct board meetings and advise or warn the executive director accordingly. The Chair may also play a representation role at home or abroad. Only the Executive Director can be held accountable for the way the agency is run and should therefore keep full powers and responsibilities. The director should speak at main events and conferences and should act as the main spokesperson of the agency.

Most important in terms of independence, the Executive Director must protect the agency from private interests, especially from economic operators and be perceived as a model of integrity. The relations with business can remain open and friendly but they should be fully transparent and preferably codified in consultation with all collaborators within the agency. As a matter of fact, frequent external contacts are crucial and the director often has to act as a

lobbyist, in the corridors of the Commission on the benches of Parliament, or on tour around national capital cities. There should not be a hint of preferential treatment for the director's country of origin. Sometimes, useful tips can be sought from directors of other agencies and experiences and projects should regularly be shared between the European agencies.

The question of renewal of a director after the first mandate has become controversial, as they were different versions in the regulations of various agencies. At any point in time, a director can be dismissed by the board in case of serious problems. Given the 5 years rotation principle currently applied inside the Commission for similar jobs, it was argued that the mandate of Executive Directors should be limited to one term, unless the full procedure was applied again for the second term. From my point of view, the full process of recruitment should only be applied at the end of the second mandate, given the difficulty learning the job in the first place and the instability of such a career, usually in the age bracket of 40 to 55 years. The first 5 year renewal should not be automatic, but based on a proposal from the Commission to the board, after an external and internal (so-called 360 °) appraisal.

12. Management tips and good practices

Joint ownership is essential for the success of a European network agency that should not be seen as the 28th rival organization, competing with 27 national agencies. Strong partnership links must be created with national agencies. National experts and representatives should feel at home in the new agency. At the EMEA for example, each national delegation, the Commission and Parliament received from the start a fully equipped office connected to the EMEA Intranet and to national agencies IT systems.

More generally, it is important to create a welcoming atmosphere for visitors and experts, and facilitate contacts between staff and experts during meetings and at the canteen or cafetaria. Security measures and access formalities at the reception desk should be strict and effective but also friendly.

Starting from the founding regulation, it is useful to restate, in simple terms and in consultation with staff, the mission and tasks of the agency and to identify precisely the clients, the stakeholders and the real and recognizable services and deliverables of the agency. Definition of objectives, performance indicators and good practices should be subject to wide and regular consultation within the agency but also with committee members. European agencies rely on the power of information more than on their regulatory powers. Communication through Internet, regular open conferences ("info-days") and press releases must target a wider audience than just the concerned business circles.

Given the multiple interfaces, staff members must be trusted and well trained. They should feel empowered to conduct their tasks and liaise with networks in full autonomy. International peer recognition provides a major incentive. Given the innovative nature of many activities, search of excellence must prevail over blame culture in order to maintain a constant cycle of improvements rather than to hide the difficulties. On the contrary, the organization should learn from audits and mistakes to be able to take quick corrective action and anticipate future challenges. Results should be objectively analysed and openly evaluated at annual meetings with stakeholders. The European agency should take the lead in establishing international benchmarks involving national agencies and international counterparts

Long-term planning, up to 5 years ahead is needed, especially at start-up and during transition periods. It helps to share a vision with the main partners well beyond the formal yearly plans. In particular, the management board should be involved in informal brainstorming sessions, well ahead of formal decisions. In order to maintain its credibility with the Budget Authority and the Court of Auditors, the agency must strictly respect the timing constraints of the budget cycle and also develop internal audits to anticipate external control.

13. Institutional contribution of EU agencies

European agencies have been able to build a strong bridge between European institutions, national agencies and their networks of scientific expertise, contributing to a progressive and concrete integration of policies in sensitive areas. By pooling the best expertise available in Europe, they are generally able to provide better scientific advice, not only to European decision makers, but also to each national government separately.

On the world scene, European agencies have made an impact on specialised international organizations, and on their counterparts in key countries such as the US-FDA or the US CDC when it comes to public health and food safety.

The creation of a European agency has often been triggered by a severe crisis in terms of public or media scares, by conflicting decisions between powerful national agencies and by a certain degree of frustration in the concerned sector. Once the laborious compromise on the founding regulation and the city of location has been achieved, the success of the new agency is taken for granted. That's where the real difficulties tend to begin: during the start-up period. Commission and Parliament have sometimes lost interest in their new "secular arm".

European agencies have created a new brand of working culture, from the European Commission, from national institutes, from the private sector and from the international scientific world. New have been found to conduct permanent scientific negotiations and face at the same time alerts and crisis with deep political repercussions. Confronted with dull "financial perspectives", imaginative solutions were deployed to finance the fast growth of activities as well as information and communication technology infrastructures.

Given their limited size as compared to national agencies or to US federal agencies, the performance and the success of European agencies tend to become a personal affair for the Executive Director. This is accountability at it best: no way to hide behind another body, a board or a committee. When something goes wrong, the press knows exactly where to find him or her! When the agency is working well, it is of little interest to the outside world, but there is a great deal of recognition from the interested circles in Europe: professionals, consumers and industry.

The recent budgetary freeze of subsidies by Parliament may have come as a shock to many EU agencies. It is also a sign that they have are now an important part of the European institutional game. The temporary suspension of new agency proposals may be necessary to digest the European agencies "acquis", to evaluate their current strengths and weaknesses, in order to re-launch the inter-institutional agreement discussions on a more realistic basis in future.