European Ombudsman

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Visit to the European Medicines Agency (EMA)

Dear Mr Pott,

I am writing in order to share with you the results of the visit that I made to the European Medicines Agency (EMA) on Monday, 2 May 2011. Before explaining my findings and suggestions, I shall briefly recall: (1) the purpose of the visit; (2) the topics identified for discussion; and (3) the meeting with EMA staff, which was the key element of the visit.

1. The purpose of the Ombudsman's visit to the EMA

The entry into force of the Treaty of Lisbon in December 2009 gave to the Charter of Fundamental Rights of the European Union the same legal value as the Treaties. Among the rights of citizenship that the Charter contains is the right to good administration (Article 41). Furthermore, the Lisbon Treaty provides for enhanced transparency, for greater opportunities for public participation in the Union's policy-making and for more dialogue with civil society. In order to help the EU institutions to fulfil these promises to citizens and thereby win and maintain their trust, I have decided to devote more of the resources of my office to promoting an administrative culture of service to citizens[1].

A culture of service involves not only a firm commitment to the principles set out in the European Code of Good Administrative Behaviour, but also

- engagement with citizens as part of core business;
- willingness to do more for citizens than merely fulfil legal obligations;
- a *proactive* approach towards informing and involving citizens and reconciling different rights and interests.

[1] See the Ombudsman's *Strategy for the Mandate*, September 2010 available on-line at: http://www.ombudsman.europa.eu/resources/strategy.faces

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The past 15 years or so have seen the creation of a large number of EU agencies[2]. The current landscape of agencies results from a case-by-case approach rather than an overall vision of their place in the Union's institutional framework. Indeed, no generally agreed legal or administrative definition of the term "agency" exists, nor do the bodies that are commonly referred to as agencies have similar legal structures, or the same arrangements for accountability and governance[3]. Their diversity can make it difficult for citizens to understand how the Lisbon Treaty's promises of public participation, dialogue and greater transparency are to be fulfilled as regards the agencies. Moreover, taken together, agencies now account for approximately 10% of all the complaints that lead to the opening of an Ombudsman inquiry.

In view of the foregoing, it seems important to identify and spread best practices among the agencies in relation to a culture of service. I have decided, therefore, to organise a programme of visits to EU agencies for this purpose. A mission to London in the United Kingdom in early May 2011 provided the opportunity to launch the programme with visits to the European Banking Authority (EBA), the European Medicines Agency (EMA) and the European Police College (CEPOL).

2. The topics identified for discussion

The three agencies visited in early May 2011 (EBA, EMA and CEPOL) were informed in advance of the main questions the Ombudsman wished to address during his visit. These questions, which were the same for all three agencies, were framed on the basis of the above-mentioned general considerations. They were as follows:

- Does the agency make information and documents available to the public proactively, as well as respond correctly to requests?
- How well does the agency respond to complaints?
- Does the agency have appropriate policies and procedures for dealing with ethical issues?

As regards the first question, the Ombudsman's services carried out a preliminary analysis of the EMA's website and sent it to the EMA in advance of the visit. The analysis also covered the language policy of the website.

As regards the second question, the Ombudsman's services analysed the 46 complaints against the European Medicines Agency received since the Ombudsman's office began functioning in 1995. Nineteen of these cases were declared inadmissible. In a further seven cases, the Ombudsman concluded that an inquiry was not justified. Inquiries were opened in 23 cases, of which seven were ongoing at the time of the visit.

[2] The Europa website http://europa.eu/agencies/index_en.htm now lists 42 bodies of various types, classified as: policy agencies (23), common security and defence policy agencies (3), police and judicial co-operation agencies (3), Euratom agencies (2), executive agencies (6), financial supervisory bodies (4) and the European Institute of Innovation and Technology.

[3] Communication from the Commission to the European Parliament and the Council, *European agencies – The way forward*, COM(2008) 135 final, (SEC(2008) 323), 11 March 2008. The six Executive agencies are an exception, since they have a common legal basis (Council Regulation 58/2003 of 19 December 2002 laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes 2003 OJ L 11 p. 1).

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As regards the third question, the Ombudsman identified two aspects in particular that he wished to discuss: (a) the handling of potential conflicts of interest and (b) information to staff on whistleblowing.

3. The meeting on 2 May 2011

The meeting began at 15.00 and concluded at 16.30. The Ombudsman was accompanied by Mr Ian Harden, Secretary General and Mr Fergal Ó Regan, Head of Legal Unit D. The EMA was represented by: Pharm. Noël Wathion, Head of Patient Health Protection; Mr Martin Harvey Allchurch, Head of the office of the Executive Director; Mr David Mackay, Head of Veterinary Medicines and Product Data Management; Ms Frances Nuttall, Head of Human Resources Administration; Mr Vincenzo Salvatore, Head of Legal Service; Mr Alessandro Spina, Legal Advisor; and Ms Sarah Weatherley, Web Manager.

The main points made by the EMA representatives at the meeting were that the EMA:

- was established in 1995 with a limited mandate. Its responsibilities have subsequently been increased and, in 2012, will be further expanded as regards pharmacovigilance;
- conducted a survey of users of its website in 2007, the results of which were fed into a major investment in re-design of the website that came online in July 2010. A re-survey of the 1200 respondents, carried out in January 2011, produced 500 responses and showed an increase in satisfaction levels;
- consulted stakeholders and the public before adopting its transparency policy;
- has disclosed over half a million pages of documents so far in 2011 in response to requests for access;
- systematically seeks to help applicants for documents to identify the documents they really want;
- plans to make it easier to request access to documents and information by creating a dedicated page on the website for this purpose;
- aims to move from the current passive disclosure of documents to more proactive publication of documents at key milestones in the evaluation process for medicinal products;
- is working closely with the National Competent Authorities (NCAs) in the Member States, which are closer to citizens than the EMA, with a view to agreeing a common approach as regards commercially confidential information and personal data;
- has proposed new rules on conflicts of interest and share-holdings for staff members and expects these to be approved by the Management Board in June 2011. These new rules would forbid newly-recruited members of staff to hold any shares in companies that have dealings with EMA. Existing members of staff will be required during 2011 to divest themselves of any shares they currently hold in companies that have dealings with EMA;

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- applied Article 16 of the Staff Regulations when considering the information provided by its former Executive Director concerning his post-tenure activities and put the relevant information on its website;

- intends further to strengthen, with effect from 1 September 2011, its rules for members and experts concerning conflicts of interest;

- provides guidance to its staff on whistleblowing ("rights and obligations on reporting improprieties"), on its staff intranet and reminds staff twice a year in its internal newsletter of the existence of this guidance and where to find it;

- intends to respond to the Ombudsman's public consultation on public service principles. *(A response was sent by the Head of Human Resources Administration later the same day).*

Overriding public interest

The EMA representatives asked for advice as to what might constitute an "overriding public interest" that would justify the public disclosure of documents/information, which would otherwise be exempt from disclosure. In response the Ombudsman and his team made the following points:

- For purposes of the Regulation on public access to documents[4], an overriding public interest constitutes an "exception to an exception". An overriding public interest in disclosure is possible when the relevant exception is the protection of commercial interests. However, there is no possibility of an overriding public interest if disclosure would undermine the protection of "the privacy and integrity of the individual, in particular in accordance with [Union] legislation regarding the protection of personal data".

- The EMA's core responsibilities for protection of health might lead it to consider that there was an overriding public interest in disclosure of information or documents that it would otherwise have a duty not to disclose in order to protect, in particular, commercial interests. Circumstances might also arise in which the EMA might consider that maintaining public trust in its work constituted an overriding public interest justifying disclosure.

Case 2493/2008/FOR

The Ombudsman took the opportunity of the visit to request clarification of one aspect of the EMA's reply to his further inquiries in this case (which concerns a request for public access to adverse reaction reports relating to the drug Roaccutane). In the further inquiries, the Ombudsman asked the Agency three questions, including the following:

> "Can EMA expressly confirm that, in its reply of 16 September 2010 to the complainant's request for access, the Agency provided the complainant with access to all reports of suspected serious adverse reactions to the medicinal product Roaccutane (isotretinoin) in its possession? In this respect, the Ombudsman noted that the reports provided to the complainant date from 1995. He requested the Agency

[4] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, 2001 OJ L 145 p. 43.

to inform him whether it holds, either in electronic or paper form, reports dating from before 1995."

In its reply, the EMA stated:

"The Agency confirms that the EudraVigilance database does not contain reports originated before 1995, year in which the Agency was first established."

The Ombudsman asked for clarification as to whether the answer given by the EMA implies that the EMA does not possess adverse reaction reports in paper form and that it does not possess electronic adverse reaction reports in any database other than the EudraVigilance database. In response, the EMA representatives explained that EMA requires information regarding products authorised by NCAs ("non-centrally-authorised products") to be supplied to it exclusively in electronic form. These are all stored by the EMA in the EudraVigilance database. The EMA expressly stated that it is not, therefore, in possession of any adverse reaction reports in paper form concerning Roaccutane, which is a non-centrally-authorised product. In addition, the EMA expressly stated that it does not possess adverse reaction reports in electronic form apart from the reports contained in the EudraVigilance database. The EMA then expressly confirmed that, after the Ombudsman's Draft Recommendation, it had granted the complainant partial access to all the reports in its possession concerning Roaccutane.

The Ombudsman informed the EMA that he would communicate the above information to the complainant in the context of his on-going inquiry in Case 2493/2008/FOR, with a view to obtaining the complainant's observations in relation thereto.

4. The Ombudsman's findings and suggestions

A. Making information and documents available to the public proactively, as well as responding correctly to requests

(i) The Ombudsman welcomes the EMA's proactive approach to transparency and, in particular, its intention to publish proactively on its website, key milestone documents relating to the evaluation of medicinal products.

(ii) The Ombudsman also welcomes the EMA's commitment to make it easier to request access to documents and information that it has not published proactively by creating a dedicated page on its website for this purpose.

(iii) The Ombudsman congratulates the EMA on the investment it has made in improving its website http://www.ema.europa.eu and on seeking and taking into account stakeholder views in doing so.

The Ombudsman's suggestions:

(a) The EMA should make clear, in its co-operation with the National Competent Authorities (NCAs) on issues of transparency, that there can be no question of accepting the lowest common denominator. As an EU agency, the EMA must respect the fundamental right of citizens to have access to documents (Article 42 of the Charter of Fundamental Rights, Article 15(3) of the Treaty on the Functioning of the European Union). It should also aim to

encourage each NCA to be as transparent as the law in its Member State *allows* it to be and not merely to comply with legal *obligations* in this regard.

(b) While recognising the role of the NCAs, the EMA should regard visible engagement with citizens as an essential part of its own core business, in order to secure and maintain citizens' trust in the EMA as a Union agency.

(c) The EMA should aim to make the homepage of its website, as well as information on the EMA's functions and language policy, available in all 23 Treaty languages. By greeting citizens who visit the website in their own language and explaining its functions to them, the EMA would demonstrate clearly that it recognises that all citizens of the European Union have a legitimate interest in its work.

(d) The EMA should regard the possibility of an overriding public interest in disclosure not merely as an argument to which it might have to react, if put forward by an applicant, but also as a basis for disclosing information and documents proactively.

B. Responding to complaints

The Ombudsman is pleased to note that the EMA has shown a positive attitude towards all Ombudsman inquiries; that it has replied in due time and responded positively to the Ombudsman's suggestions for resolving complaints; and that EMA staff have been co-operative and helpful during the inspections of documents that have taken place.

The Ombudsman encourages the EMA to make the right to complain to the Ombudsman more visible on its website.

C. Policies and procedures for dealing with ethical issues

(i) The Ombudsman welcomes both the EMA's decision to prevent its staff from having any shareholdings in companies that have dealings with the EMA and its declared intention to strengthen its rules for members and experts concerning conflicts of interest.

(ii) The Ombudsman also welcomes the EMA's guidance to its staff on whistleblowing, as well as its twice-yearly reminder to staff of the existence of this guidance and where to find it.

The Ombudsman's suggestions:

(a) In revising its rules on conflicts of interest, the EMA should have regard to the views of the OECD on the importance of avoiding "apparent" as well as "real" conflicts of interest[5]. This will help ensure public confidence and trust in its work.

(b) The EMA could consider putting a draft of its revised rules on conflicts of interest on its website and inviting public comment before the rules are finalised. This would demonstrate engagement with citizens as stakeholders in the EMA.

[5] See the OECD's Recommendation on Guidelines for Managing Conflict of Interest in the Public Service, June 2003 http://www.oecd.org/dataoecd/13/22/2957360.pdf

(c) As well as giving its staff guidance on whistleblowing, the EMA should put in place and give adequate publicity to a mechanism by which stakeholders and the public can raise concerns about ethical issues and receive an answer.

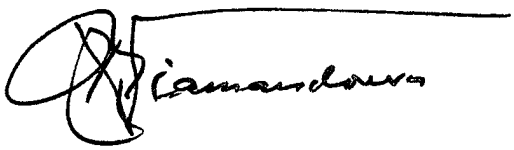
5. Concluding remarks

The European Ombudsman aims to be not only a form of external control, but also a resource to help those with management responsibilities in the EU institutions, bodies, offices and agencies to improve the quality of their administration and to build and maintain a culture of service to citizens. In addition to the suggestions made above, which I hope the EMA will find useful, I and my staff are ready to give advice on request, within the limits of my competence and resources.

I would be grateful if you could inform me, by 30 September 2011 of the follow up you have given to the above suggestions.

Finally, I would like to thank the staff of the EMA whom I met during my visit for their excellent co-operation.

Yours sincerely,



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cc. Pharm. Noël Wathion

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