Decision

of the European Ombudsman closing the file on the Ombudsman's visit to the European Medicines Agency (EMA) - OI/9/2011/IJH

The background to the visit

1. On 3 May 2011, the European Ombudsman made a visit to the European Medicines Agency (EMA).

2. Following that visit, correspondence was exchanged about his findings and suggestions with the then Acting Executive Director. All the relevant correspondence and documents are available on the Ombudsman's website.

3. The visit to EMA was one of three pilot visits. On the basis of the experience gained from the three pilots, a programme of visits was subsequently developed and implemented in the framework of the own-initiative inquiry power entrusted to the Ombudsman by Article 228 of the Treaty on the Functioning of the European Union. Although the visit to EMA was not originally announced as an own-initiative inquiry, it was subsequently classified as such for administrative purposes.

4. The Ombudsman's suggestions following the visit to EMA and the latter's responses are summarised below, together with the Ombudsman's assessment and conclusions.

The Ombudsman's suggestions

5. The Ombudsman made the following suggestions:

(i) 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, 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. The Ombudsman also encouraged EMA to 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.

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(ii) While recognising the role of the NCAs, 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 EMA as a Union agency.

(iii) EMA should aim to make the homepage of its website, as well as information on 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, EMA would demonstrate clearly that it recognises that all citizens of the European Union have a legitimate interest in its work. The Ombudsman also encourages EMA to make the right to complain to the Ombudsman more visible on its website.

(iv) In revising its rules on conflicts of interest, EMA should have regard to the views of the OECD on the importance of avoiding "apparent" as well as "real" conflicts of interest[1]. This will help ensure public confidence and trust in its work. EMA could also 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 EMA.

5. As well as giving its staff guidance on whistleblowing, 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.

EMA's responses and the Ombudsman's assessment

6. EMA responded to the above suggestions on 30 September 2011.

Transparency, access to documents and overriding public interest

7. As regards cooperation with the National Competent Authorities (NCAs) on issues of transparency, EMA stated that it is conscious of its leading role in promoting the adoption of 'gold standards' in the disclosure of relevant information throughout Europe and that it will work with NCAs to promote a consistent, transparent and reliable framework. Particular efforts have been made in this regard to agree on a common definition of commercial confidential information in the specific context of pharmaceutical research and development.

8. EMA also agreed that overriding public interest should be the paramount criterion driving the Agency when taking a decision on disclosure of a document or a piece of information, not only on request, but also proactively.

9. The Ombudsman welcomes EMA's commitment to transparency. The Ombudsman also notes that this commitment has been demonstrated in practice during the Ombudsman's inquiries into a number of complaints

[1] 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

against EMA concerning access to documents and information[2]. The Ombudsman notes that a decision by EMA granting access to documents from the marketing authorisation dossier of a medicinal product is currently the subject of an action for annulment[3].

Engagement with citizens as part of core business

10. EMA informed the Ombudsman that it has developed a framework of interaction with patients and consumers organisations and that work is underway to further strengthen interaction with these organisations.

11. The Ombudsman welcomes EMA's acknowledgment of the importance of engagement with citizens and civil society organisations.

EMA's website

12. EMA stated that it shared the Ombudsman's view that it should aim at expanding the amount of information available in all Treaty languages on its website. EMA also informed the Ombudsman of the results of a web-user survey which suggested that 10% of respondents use the website for personal reasons and, of these, over half would prefer to read in a language other than English.

13. EMA also indicated that it had made the right to complain to the Ombudsman more visible on its website.

14. The Ombudsman's services visited EMA's website on 25 September 2013 and found that it appears to contain no information in any language other than English. The Ombudsman regrets that EMA has not followed the good practice of, for example, the European Banking Authority, whose homepage includes a dropdown menu from which information about its role and main tasks is easily accessible in 23 languages.

Rules on conflicts of interest

15. In its response to this suggestion, EMA informed the Ombudsman that its revised policy on handling conflicts of interest came into force on 30 September 2011. Furthermore, EMA adopted a policy of putting online all the declarations of interests of experts contained in its database and providing more information on all conflicts of interest declared during a scientific review process. EMA acknowledged that it had not yet consulted the public on its policies on conflicts of interest and promised to take the Ombudsman's suggestion into account for any future revision of its policy.

16. The Ombudsman notes that important developments occurred after his visit and EMA's above-mentioned response. In particular, a special report by the Court of Auditors examined the management of conflicts of interest in four EU Agencies, of which EMA was one, and made detailed recommendations[4].

[2] In particular, cases 2560/2007/BEH, 3106/2007/FOR and 2493/2008/FOR.
[3] Case T44/13, *AbbVie Inc. and AbbVie Ltd v European Medicines Agency*, 2013 OJ C 79 p. 31
[4] Special Report no. 15 2012, Management of conflict of Interest in Selected EU Agencies. http://eca.europa.eu/portal/pls/portal/docs/1/18686746.PDF

Whistleblowing and ethical issues

17. EMA pointed out that it had already shared with the Ombudsman its policy on reporting improprieties and recalled the measures it takes to train, inform and remind staff in this regard. As regards whistleblowing by stakeholders and the public, EMA's practice is to treat all information from third parties seriously, often including it in the information presented to scientific committees. EMA expressed support for the Ombudsman's suggestion and undertook to draft a policy and consult with stakeholders on the publication of information on how to report improprieties or other issues that may raise ethical concerns.

18. The Ombudsman welcomes EMA's positive response.

Conclusions

Following his visit to EMA, the Ombudsman closes the file with the following conclusions:

The Ombudsman welcomes the constructive responses of EMA to most of his suggestions.

The visit to EMA was not originally announced as an own-initiative inquiry. The Ombudsman therefore considers that it would be inappropriate to envisage taking any further steps at present as regards making information about EMA's role and main tasks available in all languages on its website. The Ombudsman may, however, re-visit the matter in the future, through an own-initiative inquiry.

EMA will be informed of this decision.

P. Nikiforos Diamandouros

Done in Strasbourg on 27 -09- 2013