



European Ombudsman

Emily O'Reilly
European Ombudsman

Mr Andreas Pott
Acting Executive Director
European Medicines Agency (EMA)
30 Churchill Place
Canary Wharf
LONDON E14 5EU
ROYAUME-UNI

Strasbourg, 12 -03- 2015

Re: Correspondence with the regulatory agencies in relation to the adoption of a Transparency Policy

Dear Mr Pott,

You may be aware that I wrote to EFSA, ECHA and EASA in September 2014 to obtain information in relation to their plans to adopt transparency policies. As I already had the opportunity to comment on EMA's proactive transparency policy, my letter of 3 September 2014 was not addressed to you. Having received all the relevant information, however, I thought it would be useful to now include EMA in this correspondence.¹

The work of the regulatory agencies

My correspondence on this issue has heightened my awareness of the challenges faced by regulatory agencies and the need for you to strike the right balance along a number of key dimensions: you must ensure that the products you evaluate are safe, and yet be careful not to stymie the commercial potential of the sector you are responsible for. You need to obtain top-class scientific advice, which is independent of vested interests: if you fail on either count, you risk making mistakes. You need to work independently, while being held accountable. You need to operate transparently, while reassuring commercial entities that their legitimate interests will be protected.

Part of my role is to ensure that you have the mechanisms and procedures, the checks and balances in place to allow you to strike the right balance in each of these areas of your work.

¹ My letter of 3 September 2014 should be seen as a specific follow-up action to the Ombudsman's series of visits, whose aim was to identify and spread best practices used by EU agencies in their relations with citizens. The final report containing an overview of the results of the visits and ideas for the Ombudsman's future policy towards the agencies is now available on my website. See <http://www.ombudsman.europa.eu/en/activities/visitsreport.faces/en/59248/html.bookmark>



Relevant Ombudsman case-work

Against this background, I would like to draw your attention to three initiatives recently conducted by my office that could be of relevance to you.

(i) On 22 September 2014, I issued recommendations and guidelines to the European Commission to make its review processes on "**revolving doors**" cases more robust to avoid conflicts of interest. I called on the Commission to regularly publish online all relevant information as regards senior EU officials, including their names, who leave to work outside the EU administration. The sixteen measures I proposed are available on my website, along with the Commission's response.²

(ii) On 6 January 2015, I made ten suggestions to the Commission on how to enhance **transparency and public participation** in relation to the ongoing Transatlantic Trade and Investment Partnership negotiations (TTIP)³. In particular, suggestions 6, 7 and 8 sought to promote transparency in relation to meetings with professional organisations and self-employed individuals.

(iii) On 27 January 2015, I informed the Commission of my preliminary analysis in relation to achieving a balanced composition and greater transparency of **expert groups**⁴. Some of the considerations could be relevant to you. I would, for example, draw EMA's attention to my suggestion that in order to be eligible to be appointed as a member of a Commission expert group, an organisation must be registered in the Transparency Register⁵.

Next steps

While the aforementioned suggestions and recommendations are addressed to the Commission, I am convinced that they could prove useful for your work. I note, for instance, that the main categories of complaints to the Ombudsman in relation to the regulatory agencies over the past three years have included: (i) access to documents; (ii) conflicts of interest issues, including revolving doors and membership of advisory groups/working groups/scientific panels; (iii) public participation (use of languages in consultation, for example).

I will continue to deal with these issues through the complaints procedure and will further consider the need for own-initiative inquiries⁶. I also intend to produce guidance papers in a range of areas of relevance to your work in the coming years. As I embark upon this body of work, please let me emphasise that the following considerations are foremost in my mind: I want to make the best use of resources; to build on, but not duplicate, the work of others⁷; and to ensure that the EU public administration can profit from the expertise of my office to help build capacity internally.

² <http://www.ombudsman.europa.eu/en/cases/draftrecommendation.faces/en/56216/html.bookmark>

³ <http://www.ombudsman.europa.eu/en/cases/decision.faces/en/58668/html.bookmark>

⁴ <http://www.ombudsman.europa.eu/en/cases/correspondence.faces/en/58861/html.bookmark>

⁵ I note a parallel with ECHA's criterion that, to obtain accreditation with ECHA, organisations need to be registered in the Transparency Register.

⁶ The Ombudsman undertakes inquiries on her own initiative where she finds grounds to do so. As well as inquiring into any possible maladministration, these inquiries are intended to be helpful to the particular institution and to promote good administrative practice.

⁷ I understand that the agencies have an online communication tool that serves as a platform for exchange of information, knowledge and best practices. In addition, I know that the relevant European Parliament committees, the Commission, the European Court of Auditors, and the European Data Protection Supervisor produce material to help guide and direct the agencies in their work.



I hope to have the opportunity to discuss these matters with you. In the meantime, I am pleased to mention that my Office will, once again, address the annual meeting of the Inter-Agency Legal Network (IALN) to take place in Parma (Italy) on 16-17 April 2015.

Yours sincerely,

Emily O'Reilly