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From: @ema.europa.eu on behalf of @ema.europa.eu
Sent: 28 February 2017 16:43
To: EO-GuidelinesComment
Cc: HICKEY Rosita; ROOVERS Koen
Subject: EMA comments_Draft practical guidelines for EU officials interacting with interest representatives

Dear Ms O'Reilly

The European Medicines Agency welcomes the European Ombudsman's initiative to draft high level practical guidance for public officials to take into account when engaging with interested parties, so-called interest representatives.

In this context we wish to highlight that EMA's Founding Regulation (namely Article 78 of Regulation 726/2004) governs explicitly the format of interactions between the Agency and the interested representatives. In line with the legal provisions, the EMA's Management Board in consultation with the European Commission has adopted policy documents to manage conflicts of interests and a code of conduct which sets out the practice for members of the Agency's Management Board, Scientific Committees, rapporteurs, experts and staff on direct and indirect interests, and the necessity to declare them in order to avoid and manage potential conflicts of interests.

Frameworks for stakeholder interaction:

In June 2016, EMA's Management Board adopted an overarching Framework for Stakeholder Relation Management which captures the principles for the management of EMA's key stakeholder interactions. The framework documents have been developed in consultation with the European Commission (DG SANTE) and highlights transparency as an essential principle in stakeholders' relation management.

To create and increase transparency, the following principles of methodology have been identified and are being applied by the Agency:

- Publication of the criteria for stakeholders eligibility for participation in EMA activities and a register of eligible organisations;
- Publication of agenda and reports of stakeholder events hosted by EMA;
- Publication of annual reports on the interaction with each stakeholder group.

With regard to its industry stakeholders in particular, a formalised framework for interactions was adopted by EMA's Management Board in October 2015. An annual report of EMA's engagement with industry stakeholders in 2015 has been published. Eligibility criteria for industry stakeholders have been finalised in June 2016 for implementation in 2017. These criteria take into account the general principles for stakeholder consultation outlined in the European Commission's Better Regulation package and require entry in the European Commission's EU Transparency registry. A list of eligible industry stakeholder organisations according to these criteria will be published on the EMA website in January 2017.

Similarly, a framework of interaction with patients and consumers as well as a framework of interaction with healthcare professionals were developed in 2005 and 2011 respectively. They refer to relevant eligibility criteria and identify the modalities of interaction. Regular meetings take place with patients consumers and healthcare professionals organisations. The related agendas, minutes, and presentations are published on EMA website.

All stakeholder framework documentation is available on the Agency's website.

Taking into consideration the above-mentioned information, the Agency would respectfully submit the following comments on the draft guidance document for your consideration.

Comments on EO draft practical guidelines:

As a general comment, in developing further these guidelines it is important to take into account the legal framework applicable to each EU Agency as well as the level of interaction defined in accordance with EC's Better Regulation package i.e

1. Inform (to enable feedback e.g. news items, Q&As, information Day);

2. Consult (via written consultation e.g. guidelines development, public consultations on deliverables);

3. Consult & Involve (based on direct interactions e.g. focus groups) and,

4. Co-operate (jointly engaging towards a common technical goal e.g. technical expert groups).

As far as the substance is concerned, the first 2 levels of stakeholder involvement referred to above are open to all external parties/stakeholders and do not require specific eligibility criteria to be applied. The eligibility criteria apply where an organisation seeks more direct interaction at the latter 2 levels.

- For point 3, it is not always possible to avoid the sensitive debates or predict their outcomes, so this could perhaps be re-worded or deleted.
- With regard to point 5 in the "Do" column, the reference to "private interests" is not completely clear here; perhaps refer to the interests of the institution.
- Point 6 in the "Do" Column sounds ambiguous and could give rise to confusion. We would suggest rephrasing this sentence, in particular "Err on the side of caution". We would kindly propose to modify it with a more neutral sentence "Act impartially"
- Points 6-10 in the "Don't" Column are fine with us as they mirror some provisions of the EMA Code of Good Administrative Behaviour

We look forward to receiving the final version of these guidelines in due course.

Kind regards

Head of Corporate Stakeholders Department
Head of Stakeholders and Communication Division ad interim

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