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From: Richard Price <[REDACTED]>
Sent: 31 August 2014 21:24
To: Euro-Ombudsman
Subject: [EOWEB] EAHP response to Expert Groups consultation
Attachments: EAHP RESPONSE TO EUROPEAN OMBUDSMAN CONSULTATION ON EXPERT GROUPS.docx

Sender

Sender Richard Price [REDACTED]
Date Sunday, August 31, 2014 9:24:05 PM CEST

Your data

Part 1 - Contact information

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Language you would like to receive an answer in en - English

Part 2 - Data

Subject EAHP response to Expert Groups consultation

The European Association of Hospital Pharmacists is an association of national organisations from 34 countries representing hospital pharmacists at European and international levels.

<http://www.eahp.eu/about-us>

- 1. Which specific Commission expert groups do you consider to lack a balanced representation of relevant areas of expertise and interest in their membership? What, according to you, is the root cause of the unbalanced composition of the Commission expert groups identified by you?**

Content

EAHP considers the consultation and expert advice processes for implementation of the Falsified Medicines Directive to be imperfect. In particular, the Delegated Act for implementation of the Directive has been developed and drawn up with the support of a 'Member States' Expert Group' where EAHP consider it would have been more opportune to involve experts from a wider range of impacted stakeholders in this process^[1]. The potential costs and impacts of the Directive's medicines verification features are substantial and permitting broader input into the month-by-month development of the Delegated Act would have been beneficial. The rationale for only involving member state competent authorities, and keeping drafts of the Delegated Act under development strictly confidential, is not clear to us, and is restricts open scrutiny before finalization of the Act.

- 2. The Commission's horizontal rules on expert groups allow for the Commission to appoint individual experts in their personal capacity. In your experience, does this possibility give rise to concern in terms of the balanced composition of expert groups and/or conflicts**

of interest?

In the case of the Expert Group on implementation of the Falsified Medicines Directive, it would have been beneficial to appoint experts from beyond Member State competent authorities alone (e.g. from interest groups likely to be involved in on the ground implementation and interpretation of the Act's requirements). Therefore EAHP supports the ability of the Commission to make appointments in this way, and indeed sees a need to encourage broader use of the ability.

1. **3. Do you consider that the current level of transparency regarding the composition of Commission expert groups, in particular through the Register of Commission Expert Groups and Other Similar Entities, is sufficient? In particular, does the information made available by the Commission allow you to ascertain which interests are represented by the members of Commission expert groups? If not, where do you see room for improvement? Do you consider that the current level of transparency regarding the work of expert groups, in particular through the publication of agendas and minutes, is sufficient?**

In the case of the Expert Group on implementation of the Falsified Medicines Directive, there is room for improvement in transparency. For example, draft texts of Delegated Acts have not been made publicly available, and the rationale for suggesting sensitivity on the topic is not clear. Permitting the wider stakeholder community to openly scrutinize suggested legal texts is to the benefit of good public policy making in our opinion. EAHP is not aware that meeting dates, agendas, minutes and other documents in relation to the work of this Expert Group were published.

1. **4. Where the Commission publishes calls for application for membership in expert groups, do you consider that these calls provide for selection criteria which sufficiently take into account the need for a balanced composition of expert groups? If not, where do you see room for improvement? In your view, could the Commission do more to raise awareness about these calls, with a view to encouraging applications? If so, what concrete steps could it take in this regard?**

In a general sense, for those Expert Groups for which the Commission has openly recruited, it is EAHP's observation that the Commission efforts to publicise the call have been reasonable. E.g, promotion via its website and social media communication tools. However, there is no guarantee that the desired target groups and individuals for a call will necessarily be monitoring these websites on a regular basis so there is also a role for proactive direct communication to European and national associations likely to be in a position to reach the desired target group. The Commission should be encouraged to undertake such direct approach awareness raising of Expert Group calls.

Open recruitment of Expert Groups against selection criteria appears to EAHP as best practice and should be encouraged.

1. **5. Do you have any experience in applying for membership in a Commission expert group? If so, did you face any problems in the application process? If not, are you aware of any such problems faced by civil society organisations? Based on your experience, do the costs inherent in participation/the lack of comprehensive reimbursement schemes discourage civil society organisations from applying for membership?**

EAHP does not identify any problems in this regard.

1. **6. Please give us your views on which measures could contribute to a more balanced composition of Commission expert groups.**

The Commission should strive for high standards in transparency, not as an imposed obligation from outside agencies, but because transparency leads to better scrutiny, better decision making, wider input and improved policy. The self-interest of high standards of transparency should therefore be accepted and encouraged within the Commission.

To this end, in the development of Delegated Acts, the Commission should be encouraged to make use of Expert Groups of wider composition than only Member State competent authorities, and ensure an open approach to publication of meeting dates, agendas, minutes and documents under discussion.

Consideration should also be given to making Expert Group meetings open for members of the public to

attend and observe, respecting room size constraints etc.

7. Do you have any other comments?

The process of forming Delegated Acts is still comparatively novel. EAHP therefore understand it is a process likely to evolve with experience. However we strongly counsel that stakeholders beyond Member State competent authorities alone be involved in the ongoing procedure of scrutinizing legal text for its fitness for purpose, and that, as well as public consultation at the start of the process, a public consultation be conducted at the end of the process before final adoption of a legal text. This could prevent foreseeable implementation problems from emerging.

[1] <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2752>

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