



29.8.2014

NOTICE TO MEMBERS

Subject: Petition No 1427/2013 by Helena Nandin de Carvalho (Portuguese), on providing adequate protection, on the basis of legislation, for people working at the European institutions who should be free of conflicts of interest

1. Summary of petition

The petition is based on an incident observed at the European Medicines Agency, in which certain organised groups in certain Member States have made serious allegations, casting suspicion on the integrity of the Agency's work. It was claimed, for example, that the Agency had come under excessive influence from industry, having been dependent on the Commission's DG Enterprise until 2010 and, according to the petitioner, to unproven accusations that too little attention had been devoted to conflicts of interest affecting staff and committee members.

2. Admissibility

Declared admissible on 7 May 2014. Information requested from Commission under Rule 216(6).

3. Commission reply, received on 29 August 2014

The Commission's observations

a) Regulation on efficient protection of citizens working under Declaration of Conflict of Interest in EU institutions or serving in EU committees

The request focuses on the European Medicines Agency ('EMA'). It should be noted that the rules on declarations of interests and conflicts of interests of EMA have been significantly

strengthened over the last years. As a result, EMA has developed one of the most robust and transparent policies on the handling of conflicts of interests amongst all decentralised Agencies in the EU. However, it also has been recognised that there is a need to achieving a balance between ensuring the impartiality and independence of experts involved in the Agency's work versus the need to secure the best possible scientific expertise. This topic was discussed at the EMA public workshop "Best expertise vs. conflicts of interests: Striking the right balance" on 6 September 2013. In view of these developments and taking into account the outcome of this workshop, EMA has recently revised its policy on the handling of declarations of interests of scientific committees' members and experts, which was endorsed by the Management Board in its meeting on 20 March 2014. The revised policy does not lower the requirements on the handling of declarations of interest but aims primarily at improving the processes. For example the nature of declared interest has been organised in three categories determining different consequences in the extension of conflict over time and in the involvement in EMA activities. Key definitions and concepts have also been revised. The revised policy is expected to enter into force in January 2015.

As regards the "revolving door" policy, EMA has recently published a Best Practice Guide for Staff leaving the Agency, and updated the application form for authorisation to engage in an occupation after leaving the EMA.

b) Providing remuneration of Chairmanships positions of independent committees such as those of the EMA

At its meeting on 12 June 2014, the Management Board endorsed the concept of compensation for the work of chairpersons of the scientific committees of EMA. However, the modalities and the form for any such compensation need to be further explored in order to ensure compliance with the regulatory framework. While the Commission recognises the high workload of the committee chairpersons, this issue should be seen as part of the overall sustainability of the entire Network which is under discussion notably in the context of the forthcoming revision of the entire fee system of EMA. The preparation for the revision of the legislation on EMA fees has started through an exercise launched by the Management Board which involves the collection of data about the workload and related costs of the work carried out at EU level by EMA and by the national competent authorities respectively. The data collected will provide input to the Commission in preparing the Impact Assessment and the subsequent legislative proposal. This revision of the EMA fees is the appropriate opportunity to review the activities in the Network with the aim of trying to ensure adequate funding notably of those activities which are required under the EU pharmaceutical legislation.

Conclusion

a) The Commission welcomes the revised EMA policy on declaration of interests and conflicts of interests and will continue monitoring the developments in this area.

b) The Commission will work together with EMA in order to explore the way forward for the compensation of committee chairmanships.