2010 discharge: European Medicines Agency (EMA)

2011/2220(DEC) - 02/10/2012 - Committee report tabled for plenary, single reading

The Committee on Budgetary Control adopted the second reading report of Monica Luisa MACOVEI (PPE, RO) on the discharge of the European Medicines Agency (EMA) which calls on the European Parliament **to grant the Executive Director of the European Medicines Agency discharge in respect of the implementation of the Agency's budget for the financial year 2010**.

To recall, in May 2012, Parliament postponed the discharge decision for the Agency chiefly because there was a **problem of conflict of interest** of some staff (as reported in the summary dated 10/05/2012).

Members approved the closure of the Agency accounts for the 2010 financial year and made a series of recommendations to take into account on the granting of the discharge:

- **transparency and management of conflict of interest**: Members take note that the Agency is organising for November 2012 **a workshop gathering a broad range of interested parties in the view of developing the modalities of providing public access to clinical trial data with a view to strengthening transparency.** They also note that the Agency has improved the scope and methodology of the systematic *ex-ante* and *ex-post* controls related to the screening of declaration of interest and that it will perform a yearly evaluation of its revised policy on declaration of interest. They invite the Agency to keep the discharge authority informed on the implementation of its revised policy on a 6-month basis;
- **a "revolving door" case**: Members underline that, in June 2012, a "revolving door" case occurred in the Agency, the former Head of Legal Service joined as senior counsel a US-based law firm having a number of pharmaceutical industry companies as clients. They take note that the Executive Director of the Agency launched a review of the work performed by the former Head of Legal Service and expect the Agency to inform the discharge authority on the outcomes of this review by the end of 2012;
- **screening process of declarations of interest**: Members welcome that the Agency proceeded to a screening process of the declarations of interest of its experts and committee members who have been actively involved in the Agency's activities between 1 January and 31 May 2012 against their *curriculum vitae*. They also welcome the Agency's initiative to publish on its website the declarations of interests of its staff occupying management positions as well as other initiatives going in the direction of improved transparency. However, they agree with the Agency that a high level of reliability and honesty concerning the declaration of interests can only be achieved **if pharmaceutical companies themselves make public the list of experts and research centres with which they work**, and the sums concerned in their financial links with them;
- **for steps to be taken in cases of non-compliance**: Members consider that steps have to be taken should cases of non-compliance with existing rules occur with a view to remedying the shortcomings. Either the European Parliament or the European legislator has to address these problems by changing the existing rules and regulations to eliminate possible loopholes. In the meantime, Members call on the Agency to introduce in each of its annual activity report a special section describing the actions taken to prevent and manage conflict of interest.

In general, Members welcome the agreement on the Joint Statement and Common Approach adopted in June 2012 by the European Parliament, the Council and the Commission on decentralised agencies in which certain elements of importance to the discharge have been addressed and taken up.