



Joint Open Letter to Members of the European Parliament

Brussels, 9 May 2011

Concern: Support for audit of European Medicines Agency by the European Court of Auditors

Dear Member of the European Parliament,

We are writing to you on behalf of Corporate Europe Observatory and Health Action International (HAI) Europe, regarding the findings of the Committee for Budgetary Control in the *Report on discharge in respect of the implementation of the budget of the European Medicines Agency (EMA) for the financial year 2009*. You will be discussing this report in Plenary on Tuesday 10 May 2011.

We echo the concerns raised in the report regarding the Agency's handling of potential conflicts of interest of its experts and staff. Recognising that conflicts of interest could jeopardize the independence of the Agency's decisions and its processes, we urge Parliamentarians to call for the European Court of Auditors to perform an audit of the EMA.

Independence in the provision of scientific and expert advice is crucial to balanced decision-making. Conflicts of interest can bias regulatory affairs, while compromised decisions could result in the market approval of medicines of questionable efficacy or unproven safety, ultimately putting European citizens' health at risk.

Our main concerns relate to the application of the EMA's Staff Regulation to former employees and the evaluation of potential conflicts of interest at the Management Board level.

Evaluation of the Staff Regulation concerning former employees

Recently, we have questioned the rigour of the application of the Staff Regulation in the case of former EMA Executive Director, Mr. Thomas Lonngren. It came to our attention that Mr. Lonngren took positions in the private pharmaceutical sector within weeks of leaving his public post at the Agency. The EMA's Management Board was quick to approve these appointments, basing their decision on very limited information provided by Mr. Lonngren. Restrictions on Mr. Lonngren's new positions were announced by the Management Board only after conflicts of interest concerns were raised by multiple health and transparency advocates, including HAI Europe.

We question the Management Board's conclusion that Mr. Lonngren's paid and unpaid roles as a strategic advisor to the pharmaceutical industry did not represent a conflict of interest with his former responsibilities as the EMA's Executive Director, which included overseeing the evaluation and authorization of new medicines.

The EMA's new *Policy on the handling of conflicts of interest* defines experts who play strategic advisory roles to pharmaceutical companies as having direct interests with industry. This warrants a higher risk level and certain restrictions on their involvement at the Agency. Clearly the EMA recognises the potential for undue influence posed by strategic advisory roles.

Yet, the Management Board has granted an exception for the former Executive Director, judging that his activities with consultancies - that advise pharmaceutical companies on developing new products and reducing barriers to market access - do not conflict with the Agency's mandate.

We therefore welcome a review of how all comparable cases were handled by the EMA's Management Board, and we urge the Parliament to publish the findings of such a report.

Code of Conduct applied to the Management Board

The Code of Conduct requires each committee member, expert, and staff member, to declare his or her interests. In addition, the Code of Conduct reinforces Article 63 (2) of Council Regulation (EC) No 726/2004, which lays down that:

"Members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality."

Past research from the Corporate Europe Observatory demonstrated that the two patient delegates on the Management Board represented organisations heavily funded by the pharmaceutical industry. Yet, neither of their declarations of interest statements disclosed this information, indicating that the Agency clearly did not verify the accuracy or completeness of the details presented.

The Management Board holds administrative powers on matters concerning the Agency's budget and workplans, as well as in the selection of the Executive Director. Consequently, members of the Management Board are in a direct position to influence the course of the Agency.

Given the breadth of the Management Board's competence, it is inappropriate for its members to have links with the pharmaceutical industry that cause conflicts of interest— whether through paid employment, unpaid advisory roles, or as a representative of a company-funded organisation.

The Agency has adopted a revised *Policy on the handling of conflicts of interest of scientific committee members and experts*, which will be implemented in the second quarter of 2011. Curiously, the Management Board is exempt from being evaluated against these stringent criteria.

We stress that the new *Policy on handling conflicts of interest* should be applied to all experts and representatives at the EMA without exception, including the Management Board. These steps are essential to guard the EMA's highest governing body from undue influence and to ensure public trust in their decisions.

Transparency and accountability are essential elements of sound decision-making. As public representatives, we urge you to call for an audit of the EMA's handling of Conflicts of interest. Any unwarranted influence affecting the independence of experts or staff members who evaluate

medicines could have serious consequences for public health. This medicines regulatory agency needs to be held accountable to its central stakeholder: European citizens.

Sincerely,

Corporate Europe Observatory

Health Action International Europe



Corporate Europe Observatory (CEO) is a research and campaign group working to expose and challenge the privileged access and influence enjoyed by corporations and their lobby groups in EU policy making. This corporate capture of EU decision-making leads to policies that exacerbate social injustice and accelerate environmental destruction across the world.

More information: <http://www.corporateeurope.org>

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Health Action International (HAI) Europe is an independent European network of health, consumer and development organisations working to increase access to essential medicines and improve their rational use.

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