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European Medicines Agency: riddled with conflicts of interest



An audit conducted by the European Commission addressed the European Medicines Agency's (EMA) handling of the conflicts of interest of those involved in its activities (1). It took two years of procedures and the intervention of the European Ombudsman for the non-profit organisation Formindep to obtain a copy of this audit, which the EMA was refusing to release (2). And for good reason...

Ineffective management of potential conflicts of interest. In 2008, the auditors examined a sample of 36 external experts, 15 product team leaders responsible for Marketing Authorisation (MA) procedures within the EMA, and 8 MA applications (1).

Irregularities were noted for 26 of the 36 experts: missing or out-of-date information in the EMA's conflicts of interest database, unsigned declaration of interests forms, discrepancies between the details in hard copies and the database, etc. (1).

One of the 15 product team leaders declared having worked for a pharmaceutical company in 2006 and subsequently became product team leader for

3 drugs manufactured by the same company. Two persons declared having worked for 2 pharmaceutical companies for over 5 years, before becoming product team leaders for some of these companies' drugs. One person who reported owning shares in a pharmaceutical company was a product team leader for 3 drugs manufactured by that company. One product team leader's spouse worked for the pharmaceutical company that produced the drug concerned, despite the team leader having disclosed this link (1).

For 5 of the 8 audited MA applications, 6 of the experts who helped evaluate the drug were not registered in the EMA database of experts. In 11 cases in which the potential risk of conflicts of interest was rated as high, they had not been followed up, in contravention of EMA rules. For 3 drugs, the declaration of interests forms for 6 experts had not been updated (1).

Still awaiting transparency and reliability in 2012. This irresponsible management undoubtedly explains in part the inadequacy of European MAs, which is regularly shown in *Prescrire's* New Products section.

In order to find out if the EMA's leaders have put the agency back on track, the EMA or the European Commission will have to publish the results of the audit conducted in 2011, without waiting for a complaint to be lodged with the European Ombudsman.

The EMA must be transparent and reliable if healthcare disasters are to be prevented. The European Parliament made the right decision in refusing to grant discharge to the EMA's 2010 budget, notably because of the agency's appalling management of conflicts of interest (3).

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