EDITORIAL

Management of conflicts of interest at the EMA: chronic failure

In late 2024, the European Medicines Agency (EMA) pushed through a public consultation on its policy for handling competing interests of the experts it calls upon to participate in various Agency activities. The EMA has long fallen short in its management of conflicts of interest (1).

Thanks in particular to the efforts of the Medicines in Europe Forum, co-founded by Prescrire, the 2004 European regulation that established the EMA requires it to make public any competing interests among its staff and experts that could be "*prejudicial to their independence*" (2). It took 2 years, and a complaint to the European Ombudsman by Formindep (a French non-profit that advocates for independent medical information), to release the findings of a 2009 audit by the European Commission, which revealed numerous examples of the EMA's failure to enforce its own rules: information omitted from declaration of interests forms, product team leaders who had recently worked with the pharmaceutical companies for whose drugs they were now responsible, etc. (3). This audit was one of the reasons why the European Parliament refused to approve the discharge of the EMA's 2009 and 2010 budgets (2-4). In 2012, in response to this pressure from the Parliament, the EMA tightened its policy on the handling of conflicts of interest. Then relaxed it in 2014, for example by reducing (and for some cases abolishing) the 3- to 5-year "cooling-off" period, during which key opinion leaders who had received payments from pharmaceutical companies were excluded from positions of responsibility, such as chairing a scientific committee (2).

In this latest development, after a decade of inaction, the EMA took just a few months to propose tougher rules on handling conflicts of interest. This time, the impetus came from the pharmaceutical industry and its use of experts' competing interests to its own ends (1,5).

The new draft policy, released in October 2024 for consultation, followed the annulment (in March and June 2024) by a European court of 2 refusals to grant marketing authorisation, as called for by the pharmaceutical companies concerned (1). The companies had argued that the experts engaged by the EMA had competing interests with a rival company (5). The EMA's new policy, adopted in December 2024, requires, among other things, that experts who have served as investigators in a drug trial cannot participate in EMA activities relating to the disease concerned for at least 3 years. They can, however, be called upon as "*expert witnesses*" (6).

In Prescrire's response to the consultation, we took issue in particular with the EMA's suggestion that high-quality scientific advice and impartial, independent experts are conflicting needs (1,7). As if the EMA had bought into the myth that competing interests are proof of a person's expertise...

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References **1-** EMA "Handling of competing interests: revised rules for committee members and experts" 10 October 2024: 5 pages. **2-** English.prescrire.org > Advancing healthcare policy > Chronological recap ("The most important changes in the new legislation" [July 2004]; "EU Parliament says no and no again to EMA: Independent groups echo decision" [May 2012], "European Medicines Agency (EMA) softens its conflict of interest policy: Does this further open the door to undue influence instead of closing it?" [November 2014]) **3-** "European Medicines Agency: riddled with conflicts of interest" *Prescrire Int* 2012; 21 (132): 278. **4-** "European Medicines Agency: transparency policy marred by too many failings" *Prescrire Int* 2022; 31 (237): 130-139. **5-** "Après les affaires Aplidin® et Hopveus®, l'EMA renforce ses règles sur les conflits d'intérêts" APMnews 11 October 2024: 3 pages. **6-** EMA "European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts" 12 December 2024: 19 pages. **7-** "Prescrire's response to public consultation on European Medicines Agency policy on handling of competing interests of scientific committees' members and experts" 30 October 2024: 5 pages.

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