– Improving the quality and safety of packaging, patient leaflets and medicine "overviews" (online plain-language summaries of public assessment reports). The EMA should systematically require user testing by patients and/or health professionals. It should also provide clear information about the benefits of treatments demonstrated in clinical studies and the remaining uncertainties, as well as about the gaps and weaknesses in the evidence for the drug's efficacy.

Overall, Prescrire considers that the network's proposed priorities focus too much on new technologies and interactions between institutions and partners, and not enough on the key role of drug regulatory agencies, which is to ensure that new drugs provide documented benefits while also protecting patients from adverse effects (2).

► Translated from *Rev Prescrire* June 2025 Volume 45 N° 500 • Page 474

References 1- EMA and HMA "Seizing opportunities in a changing medicines landscape" 2025: 20 pages. www.ema.europa.eu accessed 24 March 2025: 15 pages. **2-** "Prescrire's response to Public consultation on European Medicines Agencies Network Strategy to 2028" 3 December 2024: 21 pages.

EMA: handling the competing interests of its experts

● Prescrire has contributed to a public consultation organised by the European Medicines Agency on its new policy for handling the competing interests of scientific committee members and experts.

The European Medicines Agency (EMA) recently proposed changes to its policy for handling competing interests, after two pharmaceutical companies succeeded in getting EMA decisions annulled by a European court on the grounds of competing interests that called into question the impartiality of the experts (1,2).

In November 2024, in its response to the public consultation on this policy, Prescrire emphasised the need for the EMA to follow the principles set out in Article 63 (2) of Regulation (EC) No 726/2004, which stipulates that scientific committee members and experts shall not have financial interests in the health products industry that could affect their impartiality.

Prescrire noted that it was puzzled by the fact that the EMA presents the requirements for its experts to be impartial and independent as being in conflict with its responsibility to provide the best possible scientific advice concerning the evaluation of drugs. This indicates that the EMA remains in denial about the influence of competing interests on the decision-making process. In Prescrire's view, these requirements in fact go hand in hand and complement one another: consulting independent, impartial experts is essential for robust evaluation of the safety and efficacy of drugs.

Prescrire called for the EMA policy to refrain from spreading the fallacious message that the best experts necessarily have interests in pharmaceutical companies. It recommended that the EMA build up a network of independent experts instead.

Prescrire suggested that the EMA improve its system for assessing declarations of competing interests by appointing an independent ethics expert responsible for checking the accuracy of the declarations submitted by experts.

To ensure the transparency of this work, Prescrire recommended that this ethics expert should send an annual report of their findings to the European Court of Auditors, the European Parliament and the European Ombudsman, with a particular focus on any cases of non-compliance that they identify. This report should also be made publicly available (3).

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References 1- EMA "Handling competing interests". www.ema.europa.eu accessed 24 March 2025: 15 pages. **2-** "Management of conflicts of interest at the EMA: chronic failure" *Prescrire Int* 2025; 34 (271): 143. **3-** "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.