

Management of conflicts of interest at the EMA: are drug evaluations really shielded from industry influence?

We are writing in response to your editorial 'Management of conflicts of interest at the EMA: chronic failure', which was published in the June 2025 issue of *Prescrire International*. In this editorial, you particularly take issue with a perceived inaction to change the policy and put into question the Agency's need to involve individuals who may have indirect conflicts of interest in order to ensure that the Agency continues to have the relevant information to guide our recommendations.

We strongly believe that our policy has provided a balanced and robust framework for managing possible competing interests over many years. Since it first came into effect in 2004, the policy has allowed EMA to restrict or exclude the potential involvement of an expert in any Agency activity, due to interests in the pharmaceutical industry or in the medical device industry. The policy has been updated several times to reflect experience over time and to ensure that EMA's new tasks and mandates were also covered. The latest changes demonstratively increase the restrictions for members, alternates and experts involved in the activities of the Agency's scientific committees, working parties and other bodies.

EMA's policy has always prohibited individuals currently employed by or holding financial interests in a pharmaceutical company from participating in the Agency's activities, and this has remained unchanged. However, in case of other interests (e.g. role as investigator or close family member's interests), an individual's participation in certain activities may be possible, but subject to pre-defined restrictions. As is presented in the policy text, having interests is not to be confused with having a competing interest, as we consider that some interests relate to experiences and activities that contribute to an individual's expertise in a certain field. Although we note your concerns in this matter, we want to point out that our position is shared by multiple stakeholders who expressed their views in the public consultation (e.g. *Cancer patients Europe*, p.4; *European patients' forum*, p.45). In fact, patients and national competent authorities expressed their concerns about the impact of the changes on EMA's ability to involve individuals with the required expertise.

Finally, as the editorial specifically mentions that our revised policy continues to allow expert witnesses, we want to be very clear on this subject: expert witnesses can be called upon by EMA, but this applies to exceptional situations where specific expertise is required that can only be provided by a few individuals (e.g. in niche areas) who have certain (indirect) competing interests. The revised policy allows us to seek their advice as expert witness and clearly defines the limits of their involvement: testifying and giving specialist advice on a specific issue by providing information and replying to any questions. An expert witness will not be a member

or expert of a respective Agency body and will not be allowed to participate in discussions, deliberations and conclusions of this body.

Therefore, while we note your concerns, we stand firmly by our revised policy. We hope that the explanations provided in this letter offer some further clarification of our position.

Juan Garcia Burgos

Head of Public and Stakeholders Engagement Department



We would like to thank Juan Garcia Burgos for providing clarification and further details about the European Medicines Agency's (EMA) new policy for managing conflicts of interest, which came into effect on 1 May 2025 (1).

Genuine progress, but weaknesses persist

In December 2024, in response to two judgements by a European court that raised questions about whether the EMA had acted impartially in relation to two marketing authorisation decisions, the Agency decided to tighten its policy on handling conflicts of interest (2). Experts who have served as investigators in a drug trial instigated or sponsored by a pharmaceutical company are no longer allowed to participate in EMA activities relating to this drug for a 3-year period (1).

In specific situations in which no experts without conflicts of interest are available, the EMA's new policy allows it to call on "expert witnesses". The Agency takes the view that inviting the latter to testify may be in the interest of public health (1). Even if their links with pharmaceutical companies have the potential to compromise their independence and impartiality.

Underestimation of industry influence, harmful to patients

In his letter, Juan Garcia Burgos notes that certain patient organisations, such as Cancer Patients Europe and the European Patients' Forum, supported the inclusion of these exceptions in the EMA's policy for managing conflicts of interest, without pointing out that these organisations receive industry funding (3-5).

In another example of competing interests, in 2010, a former director of the EMA joined the board of a firm that lobbies on behalf of the pharmaceutical industry (6). These links between pharmaceutical companies, regulators and lobby groups, such as patient organisations, create a favourable environment for pharmaceutical companies to influence decisions to suit their own interests and priorities, which differ from those of patients.

Juan Garcia Burgos stresses that the use of "expert witnesses" will be restricted to "exceptional situations", and that they will not be allowed to take part

in any deliberations or decisions. Their exclusion from the decision-making process constitutes progress. It may be that a specialist in a particular field or disease can provide insights and comments that are useful for the analysis of evaluation data. But links with pharmaceutical companies can create a conflict of interests, with a risk of the specialist overestimating the benefits of a drug or underestimating its adverse effects. These links are an obstacle to the independence and impartiality that patients need from a drug regulator. Without exception.

Improve transparency, in the interest of patients

In November 2024, Prescrire called on the EMA to be more transparent about its use of “expert witnesses”, by publishing their testimony alongside the minutes of the meetings they attend, and by stating the reasons for calling on these witnesses, as well as defining the scope of their testimony. More broadly, Prescrire encouraged the EMA to make its procedures for managing conflicts of interest more transparent, to introduce independent checks on the declarations submitted by its experts, and to submit an annual report to the European Court of Auditors, the European Parliament and the European Ombudsman (7).

IN PRACTICE The EMA’s recent decision to tighten up its policy for managing conflicts of interest constitutes progress. However, it still allows certain exceptions that have the potential to influence the

Agency’s decisions, and ultimately the prescribing behaviour of healthcare professionals, who are already highly exposed to industry influence (8-10).

Prescrire continues to encourage the EMA to further strengthen its rules in order to create a culture of transparency, and to develop a network of independent experts, so as to prioritise the interests of patients and the safety and quality of health care.

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 2- Prescrire Editorial Staff “Management of conflicts of interest at the EMA: chronic failure” *Prescrire Int* 2025; **34** (271): 143.
 3- EMA - “Overview of comments received on the draft revision of EMA’s Policy on handling competing interests of scientific committee members and experts (‘Policy 0044’, EMA/54457/2024)” 14 April 2024: 84 pages.
 4- European Patients’ Forum “EPF acknowledgement of financial support in 2024” 2024. www.eu-patient.eu accessed 7 August 2025: 5 pages.
 5- Cancer Patients Europe “Annual report 2023” 2024: 17 pages.
 6- Prescrire Editorial Staff “Revolving door between the public and private sectors: conflict of interest” *Prescrire Int* 2023; **32** (244): 3.
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 8- Prescrire Editorial Staff “Meals: a particularly influential gift” *Prescrire Int* 2018; **27** (197): 246-251.
 9- Prescrire Editorial Staff “Gifts to doctors wield undue influence in France” *Prescrire Int* 2020; **29** (215): 135.
 10- Prescrire Rédaction “Les étudiants en médecine très exposés à la promotion pharmaceutique et peu formés pour s’en prémunir” *Rev Prescrire* 2023; **43** (474): 298-299.

Paediatric drugs: WHO consultation

● Prescrire has given its backing to the World Health Organization’s proposed guideline for better addressing the needs of children when developing drugs for this population.

In March 2025, as part of the World Health Organization’s (WHO) public consultation on its draft working document on the development of paediatric medicines, Prescrire supported the main points of the WHO’s proposals. In its response, Prescrire underscored the need for the following, among other requirements:

- Thorough assessment of packaging by drug regulatory agencies;
- Improved information for the public on packaging items;
- Unambiguous labelling of dose strengths and concentrations;

- Inclusion of the international nonproprietary name (INN), in clearly legible lettering, on labelling and on the leaflet intended for patients and their caregivers;
- Improved dosing devices and mandatory user testing by patients and caregivers;
- Use of child-proof caps for all bottles of oral liquid medicines.

Prescrire also recommended:

- Encouraging pharmaceutical companies to conduct readability and comprehensibility tests with patients and their caregivers;

- Making assessment reports on the development of paediatric forms and packaging freely accessible online;
- Requiring information about the use of excipients and preservatives;
- Requiring all patient leaflets to provide clear information about the doses to be prepared and measured (1).

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References 1- Prescrire Editorial Staff “Draft working document for comments - Development of paediatric medicines: points to consider in formulation” January 2025: 51 pages.
