EFPIA response to consultation European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts, Policy 0044

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EFPIA supports the EMA's aim to balance the requirement of impartiality and independence of its experts with the public interest in obtaining the best possible scientific advice on matters concerning the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use. As EFPIA, we strongly believe in the importance of expertise-driven scientific assessment. Therefore, we welcome an approach grounded in proportionality, balancing impartiality with the need to secure the best (specialist) scientific expertise for involvement in the Agency's activities.

EFPIA appreciates that the revised policy clarifies the management of potential conflicts of interest, particularly those arising from activities within research organizations. However, we emphasize that Europe faces significant workforce challenges across the board. Strict interpretations of "conflict of interest" could worsen this issue, especially as research grows increasingly specialized. Additionally, recent data—such as the recently published IQVIA report[1] on clinical trial (CT) analysis—indicates a concerning decline in EU clinical research, with non-commercial CTs dropping from 1,250 in 2018 to 966 in 2023. Clinical research often serves as a surrogate marker of scientific expertise and capability development; the investigators running the trials are the forefront of medical innovation and are often used as experts of the particular therapeutic area in other contexts as well. Unless this negative trend reverses, the availability of qualified medical/scientific experts may be further constrained in the coming years.

We suspect that some of the proposed changes to EMA's Policy 0044 could impact innovation by potentially limiting access to suitable experts. It is crucial that the policy's implementation does not restrict the participation of individuals with the required expertise. Please find below some specific comments and improvement proposals to mitigate the risks of unintended consequences and to increase clarity.

Interests of Research Organisations (RO)

The revised policy provides clarity on the handling of interests in research organizations (ROs), including a specific definition of ROs, a new list and definition of relevant interests, and an additional Annex (Annex 3) detailing restrictions related to these interests.

We consider the following aspects of the proposed inclusion and/or restrictions on experts with RO interests to be appropriate:

- Research organisations that undertake roles such as manufacturing of medicinal products or medical devices or are acting as marketing authorisation applicant/holder should indeed be treated similarly as pharmaceutical and medical device company experts.
- The proposed restrictions on members or experts who have declared to be "engaged in occupational activities" are appropriate.

[1] IQVIA, *Assessing the clinical trial ecosystem in Europe*, October 2024, https://efpia.eu/media/3edpooqp/assessing-the-clinical-trial-ecosystem-in-europe.pdf

- We support maintaining restrictions on individuals involved in a research organization unit that manufactures ATMPs under the hospital exemption.
- Interests relating to manufacturing and marketing authorization holding are accurately captured.
- To maintain sufficient expertise for the Agency's work, involving "individuals with other interests in research organizations" with "appropriate restrictions based on declared interests and the Agency's activity to be involved in".

We offer the following suggestions to further refine the criteria:

- There is room to better define restrictions related to an RO's independent R&D of medicinal products, particularly in repurposing contexts (e.g., when not conducted with a company, outside regulatory engagement, or prior to market authorization). This could be further clarified in Section 3.2.2.1 on Direct Interests and Section 4.2.1 on Achieving a Robust Process.
- We suggest including "collaboration" activities (which we understand as broader than "affiliation") as part of "affiliation to a research organization," in line with the reference to "interests in research organizations" on p. 10. Contractual arrangements or remuneration should not solely determine a person's involvement or affiliation with an RO unit.
- Based on the tables in Annex 1 and 2, persons with interests in ROs could not be involved in decision-taking roles, but their opinion will serve as input to the functions who take the decision. This could be clarified further in the policy's main text.
- The management of situations in which persons intend to be engaged in "occupational activities" is already covered by the Policy**.** As "occupational activities" are not defined, the scope of the Policy rules in section 4.2.1. addressing these situations is, however, not clear. These activities should be defined, or at a minimum cover consultancy as well as employment.
- In addition, it would make sense that, under section 4.2.1., the EMA has an opportunity to restrict a person's further involvement in its activities if they notify their intent to undertake *any* activity that is subject to restrictions under the Policy. Considering the revision of the restrictions on ROs, this section should therefore refer also to ROs.

Rival Products vs Products "in declared condition"

EFPIA supports the removal of the "rival products" definition and references to "rival products" throughout the policy. However, if the term "any product in the declared condition" is used in its place, this may lead to divergences in interpretation and practical application of the related restrictions. This term could potentially cover a wider range of products than "rival products," which is based on similarity in target patient population and capacity to constitute commercial competition, in addition to similarity of clinical objective (i.e., treating, preventing or diagnosing a particular condition). The introduction of this new concept may therefore further limit experts' involvement in EMA activities in areas where expertise is already limited (e.g., gene therapy). The introduction of a caveat to the restrictions that apply also to "any product in the declared condition" to the effect that they do not apply when there are very few products in the declared condition, or the treatment approach is novel, may be difficult to operate in practice. It is therefore particularly important to leverage the rules on expert witnesses in such cases. Considering the above, we ask for confirmation in the Policy that expert witnesses can be brought in even when they are otherwise barred (not just limited, as the current text suggests) from involvement in the activity in question.

Conflict of Interest Declaration

Acknowledging the inherent challenges in achieving complete neutrality, we propose a flexible, transparent approach for conflict of interest declarations, aligned with frameworks used by other regulatory agencies, such as by the Health Technology Assessment (HTA) bodies. This may include establishing clear thresholds for allowable earnings or other forms of engagement with pharmaceutical companies, which would enable experts to remain eligible without compromising integrity. Such measures would promote transparency, minimize bias, and ensure European investigators and evaluative bodies operate on a comparable playing field with other global regulatory entities.

EU Regulatory Network's Resource Constrains

We call on the European Commission and the European Medicines Agency (EMA) to undertake a comprehensive review of regulatory system resourcing. This review should incorporate an in-depth assessment of how current conflict of interest policies contribute to resourcing limitations and examine strategies for mitigating them. We recommend the exploration of targeted programs or pilot initiatives that proactively identify and engage highly qualified experts. Furthermore, we appreciate that both public and private sector compete for the same experts when it comes to pharmaceutical innovation. Evaluating the potential for enhanced incentives to retain expert participation in public regulatory processes/expert tasks could mitigate the risk of losing key contributors to industry roles. We further urge the EMA to prioritize the active involvement of experts from EU member states, recognizing their indispensable role in supporting the robust, diverse expertise necessary for thorough scientific assessments.

Review Cycle of Revised Policy

Finally, the EMA's previous commitment to review the policy after three years (or sooner if necessary) has been removed in the current revision. We propose reinstating this commitment and that EMA confirms their intention to review the policy based on the experiences gained about the impact of the proposed changes.