EPF's feedback to the EMA's revised rules on conflict of interest

November 2024

The European Patients' Forum (EPF) welcomes the **revamping of the European Medicines Agency (EMA)'s rules on conflict of interest** as a crucial step to enhance the integrity and credibility of regulatory assessments. Maintaining high standards for the assessment of medical products is **key to ensuring trust and acceptance** of the Agency's regulatory decisions by patients and the public more broadly. Integrity implies accountability of those involved and transparency and reliability of the sources that inform the decision-making process.

We fully support the inclusion of **rules on competing interests for medical devices**, aligning them with established standards for pharmaceutical companies. The introduction of a unified three-year cooling-off period strengthens the consistent application of restrictions, further safeguarding the integrity of assessments.

We further welcome the document's emphasis on **transparency** and on the need for accurate, comprehensive, up-to-date, and publicly available declarations of interests for all experts involved in EMA activities.

Patient involvement in EMA processes and committees improves the outcomes of regulatory decisions, which ultimately contributes to the quality of medicines' evaluations and to products that better address patients' needs. We emphasise the need for a balanced approach to addressing conflicts of interest of patient representatives to ensure proportionate restrictions are applied while maintaining continued access to expertise.

EPF recognises that restrictions on research organisation participation may limit the pool of patients able to participate in EMA processes and committees, particularly in rare diseases where patient populations are very small or conditions with low survival rates. Patients engage actively and collaboratively with researchers at various stages of the research process, contributing to the enhancement of studies and ensuring that research is more relevant to patients' needs.

In addition, we call on EMA to ensure a balanced approach to handling of current and past interests in pharmaceutical companies **in the case of grants/other funding to the expert's organisation/institution.** Patient organisations channel the voice of the communities they represent in a united way and therefore provide collective and representative input. Many patient organisations have long-standing collaborations with EMA and have acquired extensive expertise in regulatory processes. However, patient organisations have increasing difficulties in securing sustainable funding to support their daily operations and are often forced to look to private funding in the absence of public support. We call on EMA to adopt a proportionate and transparent approach to restrictions on participation of experts affiliated with patient organisations that receive funding from pharmaceutical/medical devices companies or research organisations. Importantly, we call on EMA to consider the existence of appropriate governance structures and strict safeguards when assessing the potential conflicts of interest of these experts.

We welcome the **"expert witness" status**, which enables experts including patient representatives with potential conflicts of interest to contribute under defined conditions, such as when only few individuals

have the necessary expertise to provide input. This flexibility allows diverse patient insights to enhance the scientific evaluation without compromising assessment integrity. However, clearer criteria for expert witness involvement are essential to ensure the systematic inclusion of the patient voice and to draw on the valuable lived experience of patients. We urge clarification of the circumstances in which the involvement of expert witnesses can be aligned with public health interests. This clarity will facilitate more effective and meaningful patient input into the evaluation of medicines.

Maintaining a broad pool of patients for participation in regulatory processes is essential. Relying on the same patient representatives can lead to tokenism and reduce the overall representativeness of the community, thereby limiting the robustness of the evidence provided.

Patient organisations play a crucial role in managing conflicts of interest by educating their communities on these policies and promoting transparency in funding and activities. It is critical to Invest in the capacity-building of these organisations as key partners in maintaining transparency and credibility throughout the regulatory process.

EPF will continue to work with EMA to ensure that its policies effectively address the needs of patients and ensure meaningful participation in EMA's processes. We will also continue advocating for sustainable and reliable funding for patient organisations and for appropriate remuneration of patient representatives involved in EMA activities.

ABOUT EPF

The European Patients' Forum (EPF) is an independent non-profit, non-governmental umbrella organisation of patient organisations across Europe and across disease areas. Our 80 members include disease-specific patient groups active at EU level and national coalitions of patients. To read about our vision, mission, and strategy, visit: www.eu-patient.eu

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