Biomedical Alliance in Europe

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Medical societies call on EMA to maintain balanced approach to managing conflicts of interest

Medical experts play a key role and contribute to the regulatory system for medicines and medical devices, and it is important that any conflicts of interest are managed in a balanced manner taking into account the different roles and responsibilities that many clinical experts have. The BioMed Alliance, representing 35 European medical and research societies, therefore shares its views on the EMA Draft Revision of Conflict of Interest Policy, highlighting key concerns that may prevent the involvement of experts in regulatory processes at EU level.

Background

Following recent court cases[1], the European Medicines Agency (EMA) and other EU institutions have revised their conflict of interest policies for involving scientific experts, and BioMed Alliance has argued that the application has become overly restrictive[2]. Regulatory authorities must align and collaborate to ensure that COI policies are implemented in a way that enhances transparency whilst ensuring that the necessary expertise can be brought in, in the interest of patients and public health systems. It is therefore essential to avoid an unnecessarily rigid interpretation of COI policies. This is particularly the case in fields where there the pool of experts is already small, such as in rare diseases or for certain paediatric indications, where experts are much sought after.

Many scientists and clinicians with the necessary expertise to provide an authoritative review of a new medicine or medical device, and particularly the leading experts, are likely to be involved in a variety of research, academic and regulatory roles. Transparency on these activities is key, and a balanced and sufficiently flexible approach to managing conflicts is necessary to prevent the exclusion of high-quality clinical expertise, while taking into account the specificities of different medical fields.

The BioMed Alliance recognises the importance of having clear rules on managing conflict of interest, and which most biomedical societies have also established within their own organisations. However, the BioMed Alliance would like to express several concerns with the recent proposed changes in the EMA's Conflict of Interest Policy, which we believe may unduly affect availability of highly qualified experts and, ultimately, the quality of scientific advice provided.

Specific consideration for the EMA's revised draft COI policy

Proportionality

[1] Court of Justice in Joined Cases C-6/21 and C-16/21 P and Case C-291/22 P)

[2] See BioMed Alliance feedback to the consultation on the initiative 'Health technology assessment – procedural rules for assessing and managing conflicts of interest' here https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13751-Health-technology-assessment-procedural-rules-for-assessing-and-managing-conflicts-of-interest/F3470374_en

We welcome the EMA's mentioning of the need to have its approach '*..guided by the principle of proportionality and has to be balanced with the need to secure the best (specialist) scientific expertise for involvement in the Agency's activities related to medicinal products for human and veterinary use or medical devices*'. While blatant conflicts of interest need to be prevented, a balanced approach should be taken, and the priority must be to ensure that the best scientific expertise can be involved.

Managing conflicts of interest in research organisations

The revised guidance now details how to manage the involvement of experts in research organisations[3], which are defined as *'…any entity, including but not limited to universities, hospitals or learned societies, whose primary goal is to pursue scientific research or to do so alongside the provision of educational and/or healthcare services'*. We believe that this definition is quite broad, and may need additional clarification, considering that, for instance, not all hospitals or learned societies carry out research. It therefore needs to be specified when research is seen as the primary goal of these organisations.

However, the guidance also mentions that some departments of research organisations may be considered at the same level as a manufacturer: '*any unit within a research organisation that develops or manufactures medicinal products (including ATMPs under the hospital exemption) or medical devices or acts as a marketing authorisation applicant or holder for a medicinal product may be considered in the same way as a pharmaceutical company or a medical device company for the purpose of this policy*'.

In-house preparations of medicinal products, in-house devices and diagnostic tests are widely used in the health sector. In certain fields such as rare diseases, the top experts may be involved in the development of ATMPs or in-house devices. A sufficiently flexible approach is necessary, along with a clear definition and information on the practical application, for instance within healthcare institutions and academia. Experts develop ATMPs or in-house devices as healthcare services to meet their patients' needs, and often because there is no viable alternative available. Clear conflicts of interest must be avoided, but these special circumstances must be taken into account to make a careful assessment of the potential conflicting interest, to prevent a large number of experts from being excluded.

Role of learned societies

Learned societies bring together large numbers of healthcare professionals in their fields and can be good partners in identifying experts with specific knowledge, while their established, generally strong conflict of interest policies enable them to also consider such aspects when identifying experts.

[3] See page 5 of the guidance, Definition of a Research Organisation