Capsulas

Facing the challenge of regulating conflicts of interest at national and European levels

Summary of Jordi Faus' speech at the 24th SEDISA National Congress

Jordi Faus participated in the 24th National Congress of SEDISA with a presentation on one of the most current topics in healthcare administration: conflicts of interest in administrative procedures within the pharmaceutical sector.

Why this issue matters

Both European and national regulatory agencies rely on external experts for the evaluation of medicinal products and medical devices. This is essential to ensure that decisions are taken with the necessary rigorousness, protecting public health and fostering innovation in the pharmaceutical sector. However, the involvement of non-public sector experts generates an important debate on independence and the management of conflicts of interest.

Article 41 of the Charter of Fundamental Rights of the European Union recognises the right of every person to have their affairs handled impartially and fairly by the EU institutions. This principle imposes the obligation to avoid any circumstance that could compromise the objectivity of administrative action. On the other hand, Article 52 of the Charter states that this right may be limited if necessary to meet objectives of general interest or to protect the rights and freedoms of others.

Therefore, although there is a right to impartial and fair conduct on the part of the administration, this right may be limited when required by reasons of the general interest.

The Hopveus case®

A landmark case on the matter is the judgment of the Court of Justice of the European Union (CJEU) in the Hopevus® case. Hopveus® is a medicinal product to treat alcohol dependence. The CJEU annulled the EMA's decision to refuse marketing authorisation for Hopveus® due to the involvement, in the evaluation process, of an expert who had served as principal investigator in the pivotal clinical trials of a competing product.

The EMA's conflict of interest policy in place at the time (Policy 0044) allowed a principal investigator of a competing product to participate in an expert panel, provided that the investigator refrained from intervening in the final deliberations and voting on the opinion. Before the CJEU, the EMA argued that, in order to properly fulfil its role in the evaluation of medicinal products, it had to balance impartiality with the need for the best possible scientific advice. In doing so, the EMA argued that the public interest could justify the involvement of certain experts, even if there was a conflict of interest.

Despite the above, the CJEU adopted a stricter interpretation: the mere exclusion of the expert from the final deliberations was not sufficient to ensure the impartiality of the procedure. The EMA's reaction was to change its policy by excluding experts with direct interests in similar medicinal products from the assessment committees.

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The challenge of conflicts of interest in the EU

This strict interpretation gives rise to a crucial question: how can quality evaluations be guaranteed in fields where expert knowledge is limited, as in the case of rare or ultra-rare diseases? In this regard, the EMA's own Policy 0044 on conflicts of interest recognises that there may be situations that require a special regime. For this reason, the figure of the "expert witness" has been strengthened, who will be able to provide expertise when requested by the EMA, but without participating in the discussions and final deliberations of its committees. It remains to be seen whether these changes will be sufficient to balance the need for the best scientific advice with the interpretation made by the CJEU.

It is precisely at this crossroads that we must consider the participation of experts in the joint clinical assessments and joint scientific consultations provided for in the Health Technology Assessment Regulation. These experts should be selected for their expertise in their therapeutic area, act in their individual capacity and have no interests, financial or otherwise, that could compromise their independence or impartiality.

The European Commission, aware of the CJEU precedents on conflicts of interest, has included specific provisions in the Implementing Regulation for the application of the Health Technology Assessment Regulation. In particular, article 7.3 allows, in exceptional cases such as rare diseases, to rely on experts with conflicts of interest, provided that there are no alternatives and their appropriate participation is ensured. Recital 15 of the Regulation clarifies that this exception seeks to balance the requirement of independence with the need to ensure the best scientific knowledge for the benefit of the public interest.

The challenge of conflicts of interest in Spain

The legal landscape is complex and a strict insistence on expert impartiality may constrain the administration's ability to act.

In September 2024, the Ministry of Health presented a Draft Royal Decree on Health Technology Assessment, which will regulate this issue in Spain. The draft of the new Law on Medicinal products and Medical Devices, recently submitted to the public hearing process, also proposes a stricter regulation of the participation of experts, establishing incompatibilities for those with links to the industry.

Our proposal on this matter is mitigating the blanket exclusion of experts with potential conflicts of interest to avoid unintended consequences that may limit access to qualified knowledge. In this regard, the concept of the "expert witness" is a useful starting point. It will be necessary to clearly define the situations in which a conflict of interest may be deemed to exist and to ensure that the legitimate pursuit of impartiality does not result in excessive negative side effects.