Incompatibility between practising a healthcare profession and having a pecuniary interest in the manufacture or sale of medicinal products or medical devices

Judgment no. 483/2025, of 5 November, of the High Court of Justice of the Basque Country, Judicial Review Division, Second Chamber (ECLI:ES:TSJPV:2025:3706) on guaranteeing the independence of healthcare professionals within the framework of the provisions contained in the delegated act Royal Legislative Decree 1/2015.

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1. Incompatibility established by a delegated act

1.1. Article 4 of Royal Legislative Decree 1/2015, of 24 July, approving the recast version of the Medicinal Products and Medical Devices (Guarantees and Rational Use) Act, contains several provisions aimed at safeguarding the independence of healthcare professionals. Specifically, Article 4(1) of said legislative decree stipulates as follows:

> Without prejudice to the incompatibilities established for the carrying out of public activities, the practice of medicine, dentistry, veterinary medicine, as well as other healthcare professions

> with the power to prescribe or direct the dispensing of medicines, shall be incompatible with any kind of direct pecuniary interest deriving from the manufacture, preparation, distribution, intermediation and marketing of medicinal products and medical devices. The provisions of the Science, Technology and Innovation Act 14/2011, of 1 June, regarding the participation of personnel from research centres, controlled by the general government, in entities such centres have created or have a stake in, are exempt from the above for the purposes set out therein.

This provision reproduces the text contained in Article 3(1) of the previous Medicinal Products and Medical Devices (Guarantees and Rational Use) Act 29/2006 of 26 July [following the amendments introduced by the Seventh Final Provision of Act 14/2011 of 1 June, and by the sole article, first paragraph, of Act 28/2009 of 30 December]. This same prohibition was also included in Article 4(1) of the Medicine Act 25/1990 of 20 December.

It should be noted, however, that Article 4(1) of Royal Legislative Decree 1/2015 refers to "any kind of direct pecuniary interest deriving" from such activities, meaning that indirect pecuniary interests are not covered by the prohibition. This is confirmed by the fact that other paragraphs of Article 4 refer to "any kind of interest" deriving from the manufacture and sale of medicinal products and medical devices, without distinguishing between direct or indirect interests (see Article 4(4)), or to "whoever has a direct or indirect interest in the production, manufacture and marketing" of medicinal products or medical devices (Article 4(6)).

1.2. Recently, Judgment no. 483/2025 of 5 November of the High Court of Justice of the Basque Country, Judicial Review Division, Second Chamber, has addressed the possible application of this legal prohibition in a case involving a group of companies.

2. Judgment no. 483/2025, of 5 November, of the High Court of Justice of the Basque Country, Judicial Review Division, Second Chamber

2.1. In this specific case, two companies had applied for administrative authorisation to act as retail establishment for the dispensing of veterinary medicines, to which the competent authority responded that, as these companies had veterinary practices, they could not authorise the dispensing of veterinary medicines in the establishment where veterinary medicine was practised, and therefore required them to choose between continuing with veterinary practice or dispensing veterinary medicines.

In response to this requirement, the companies applying for authorisation replied that they no longer had the aforementioned veterinary practices and that, consequently, there would be no grounds for incompatibility.

Notwithstanding, the competent authority refused the requested authorisations, taking into account that both companies formed part of a corporate group that also included two other companies engaged in providing veterinary services. And there being a group of companies, Article 42 of the Code of Commerce is applied,

Incompatibility rules constitute a restriction on freedom of enterprise and must be interpreted restrictively

concluding that there is a centralised decision-making and business management unit with an economic gain that impacts the different member companies, which would be tantamount to the presence of the direct pecuniary interest referred to in the prohibition in Article 4(1) of Royal Legislative Decree 1/2015.

2.2. However, the High Court of Justice of the Basque Country considers that there is no incompatibility and that the aforementioned prohibition in Article 4(1) of Royal Legislative Decree 1/2015 is not infringed.

Firstly, the court notes that this is a restriction on the freedom of enterprise, recognised in Article 38 of the Constitution, and that it must therefore be interpreted restrictively. On that basis, it considers that incompatibility cannot be understood to exist simply because the companies engaged in the distribution and prescription of medicines are part of the same group of companies. In the words of the High Court of Justice of the Basque Country, "the rule is not satisfied with the mere existence of a pecuniary interest as such, but refers to it being direct, and the fact is that it cannot be disregarded that these are different companies, each with a distinct legal personality where, beyond the fact that they belong to the same group of companies through the parent company, the *de facto* existence as an economic unit without an organisation or structure and without any autonomy when taking commercial and financial decisions, so that they are in reality one and the same company, has not been analysed. Thus, it cannot be understood [that] the requirement of direct pecuniary interest is met, since at most, the fact that entities engaged in the marketing of medicines obtain an economic gain derived from another entity providing veterinary services (and vice versa) would never be a direct interest but at most indirect, insofar as such profit is assigned, at a higher level, to the parent company.

Likewise, the ruling also considers that the prohibition in Article 4(1) of Royal Legislative Decree 1/2015 is aimed at professionals engaged in the practice of medicine, dentistry, veterinary medicine, and other healthcare professions with the power to prescribe or direct the dispensing of medicines, so that these specific professionals cannot have a direct pecuniary interest in the marketing of medicines. And, in the

case analysed, "there is no evidence that the decision taken was based on the fact that the veterinary professionals providing services to the applicant entities (if any) have any direct pecuniary interest deriving from the marketing of medicinal products".

2.3. In any event, although in the specific case decided by the judgment now under discussion it has been considered that there is no incompatibility due to the mere fact that the companies involved belong to the same corporate group, it is important to note that, in reality, the possibility of incurring the prohibition is not being denied when companies are involved or when, in one of them, the specific activities are carried out by third parties under contract. Not surprisingly, it follows from the statements made in the ruling that the relevant issue is to analyse whether or not the group entails that the companies lack autonomy in the taking of their commercial and economic decisions. Because, if the companies lack such autonomy, the prohibition could be incurred. Consider, for example, a professional who sets up a corporate structure in such a way that a company of which he is the sole shareholder becomes the holding company for the majority shares of a company marketing medicinal products and another company providing professional services with the power to prescribe them, so that the professional, using his power in the aforementioned structure, instructs the company providing medical services to use or prescribe the products manufactured by the other company in the group.

The fact that the professionals who have the power to prescribe medicines are contracted persons is not necessarily an obstacle to the application of the prohibition. In fact, in practice, there are other court rulings that have applied the prohibition to companies during court-appointed receivership and even to the carrying out of their business activities through contracted third parties. This is the case, for example, in Judgment no. 275/2014, of 28 November, of the High Court of Justice of Castile and León, Judicial Review Division, First Chamber (ECLI:ES:TSJCL:2014:6052).

In the above case, a practising dental technician formed a company with another shareholder (each with a 50% stake) engaged in the professional activity of dentistry and stomatology, and was also the sole director of that company. However, according to the judgment, the establishment of the company does not eliminate the direct nature of an interest, so that the prohibition applies, and the fact that the professional activity is carried out through third parties does not exclude the existence of a direct pecuniary interest or entail the disappearance of the risk that the prohibition seeks to avoid because, in the foregoing case, the professionals working for the company were subject to the director's instructions.