



Exclusion of the purchase of medicinal products from the Public Sector Contracts Law

Appeal of unconstitutionality against Foral Law no. 17/2021, of 21 October, which amends Foral Law no. 2/2018, of 13 April, on Public Contracts of Navarra

Background

The Spanish Government lodged an appeal of unconstitutionality against Foral Law no. 17/2021, of 21 October, which regulates certain aspects of public contracts in Navarra, as per the Official State Gazette of 21 September 2022. This Law modifies the traditional system for the purchase of medicinal products for hospital use with the aim of making it more flexible.

In particular, this law excludes from the scope of application of public procurement rules the purchase of all medicinal products financed by the NHS and which price is set by the Ministry of Health.

Exclusion is expected to be implemented in the following way:

- (i) In the first stage, the conditions to be met by potential suppliers (payment system, penalties, volume and quality of the product, etc.) would be determined and the existing credit would be justified. At this stage, no units of product would be purchased and companies could join the system on a voluntary basis.
- (ii) (In subsequent stages, hospitals would purchase the necessary quantities of medicinal products from one of the companies that had adhered to the conditions set out in the first stage. These contracts would be subject to the provisions of Private Law.

The Spanish Government contends that this Foral Law infringes the State's exclusive law-making powers in "basic legislation on administrative contracts and concessions" and "legislation on pharmaceutical products". On the contrary, Navarra believes that the law complies with the applicable legal framework, as it governs a matter included within regional law-making powers in "administrative contracts and concessions", which can be fully exercised while "respecting the essential principles of the basic State legislation on the matter".

Recall that Navarra's law-making powers differ from that of ordinary Autonomous Communities. Hence, it is able to enact its own rules on public procurement on the sole condition that it respects "the essential principles" of the basic State regulations. The Constitutional Court defines these "essential principles" as the ideas that characterise and constitute the basis of State regulation, but does not refer to any specific provisions. Therefore, we must wait for the Constitutional Court to define what are the essential principles of the Public Sector Contracts Law, and assess whether the Foral Law respects these principles by providing for this special system for the purchase of certain medicinal products.

This issue may have further implications at EU level. The Constitutional Court must assess whether the Foral Law's special regime is compatible with Directive 2014/24/EU on public procurement. As regards this matter, the Law of Navarra has relied on the ECJ judgment of 2 June 2016 (Case C-410/14) and on the purposive



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Pg. 2/2

approach of the public procurement rules that prevails at European level.

European case law holds that the purpose of public procurement rules is to safeguard competition, and that the existence of a decision to select one economic operator amongst various is a basic element of the concept of public contract. Therefore, according to this judgment, public procurement law shall no longer apply if no such selection exists.

Regardless of the outcome of this appeal to the Constitutional Court, it is interesting to discuss the application of the Public Sector Contracts Law to the procurement of innovative medicines (which are exclusive to a single company, and have a funding resolution from the NHS and a price set by the Ministry of Health). Considering that selection does not take place (there is only one possible supplier) and that the main economic condition (price) has already been set by the administration, it could be argued that it is pointless to apply the Public Sector Contracts Law in order to safeguard competition. This perspective was presented in our contribution to the public consultation process of the draft bill amending the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices.

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