



Procurement of COVID-19 medicinal products outside public procurement rules

Royal Decree-Law 3/2022, of 1 March, published in the Official State Gazette of 2 March 2022

Background

On 2 March 2022, Royal Decree-Law 3/2022 on measures to enhance sustainability in road freight transport and on the functioning of the logistics chain was published in the Official Journal. This legal instrument includes an interesting Additional Provision on medicinal products against COVID-19.

According to this Additional Provision, certain medicinal products may be supplied outside the Public Procurement Law, merely by executing a contract without a public call for tender.

Which products can be purchased without tendering?

This special regime applies to authorized medicinal products (whether by Spanish or EU authorities), which meet a particular medical need in the fight against COVID-19 that is not yet covered. As explained in the preamble, this includes products that may reduce the risk of serious illness and death due to COVID-19, or those aimed at preventing this disease. This special regime does not apply to products that have not received a marketing authorization (i.e., medicines for compassionate use), but may apply to products that are subject to a conditional authorization.

Who and when?

According to this Royal Decree-Law, these special contracts that do not require a public

call for tender may be entered into with any public body integrated in the Spanish central administration. Regional authorities (are not authorized to operate under this special regime.

These contracts may be concluded until 31 December 2022.

Characteristics of supply agreements

The wording of this Royal Decree-Law suggests that this special regime will only apply to supply agreements that are governed by a law different from Spanish one..

In addition, these agreements may include liability clauses other than those set out in the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices. Special liability regimes may be provided for, as was the case with vaccines.

Lastly, these contracts may include advance payment clauses without the need to comply with the conditions set out in the General Budget Law.