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Public Law Department

CAN COMPANIES MAKE COVID-19 VACCINES AVAILABLE TO THEIR EMPLOYEES?

The mounting hopes generated by the start of the vaccination campaign - symbolically, very late in 2020, but with increased intensity since the first days of January 2021 - have led to a growing climate of unease and impatience as the foreseeable first incidents, setbacks and unforeseen events have begun to emerge.

Against this backdrop, some companies with specific characteristics due to their significant size or wide scope of action, have asked us, whether, hypothetically, they could contribute to the vaccination plan and accelerate the vaccination of employees in Spain, through their own risk prevention and friendly society systems.

The answer, which is far from final (and shall likely be susceptible to modulation over the medium term), is in truth that, today, this possibility does not seem to have been considered.

In Spain, as in the other countries of the European Union, vaccines from the European portfolio, to which those authorised so far by the European Medicines Agency belong (BioNTech and Pfizer, Moderna, and the most recent addition, AstraZeneca/Oxford), are acquired publicly through a centralised system for EU/Member States.

The Agreement between the European Commission and the 27 Member States on Covid-19 vaccines, reached in Madrid on 20 July 2020, has as its point of departure its understanding that vaccines are a "global public asset", and thus the entire production and procurement process is redirected, including contributing to funding their production, to the Advance Purchase Agreements ("APA") that the European Union has signed with some pharmaceutical companies.

Today there does not appear to be scope outside the APAs for the acquisition of vaccines by individuals, although this assessment could perhaps be nuanced if the content and the wording of these APAs were to be made public and susceptible to detailed scrutiny and review¹. The same public/state centralisation philosophy affecting the procurement of vaccines has inspired, uniformly in all EU countries, their distribution and administration², in accordance with protocolised parameters.

Commission Decision 2020/4192 of 18 June 2020, which conceives Member States as guarantors and participants in the model of implementation of the vaccine and, insofar as Spain is concerned, the "COVID-19 Vaccination Strategy" (most recent

¹ On 29 January 2021, the Commission issued a redacted version of the APA signed with Astra/Zeneca on 27 August 2020, from which, likewise, it is impossible to glean a full awareness of the underlying contractual mechanics, but from which, in principle, it would appear that this possibility cannot be inferred.

² It is unnecessary to clarify that vaccines which are not authorised as medicinal products in Europe cannot, of course, be administered in Spain: art. 9.1., of the consolidated text of the Law on Guarantees and Rational Use of Medications and Healthcare Products (Royal Legislative Decree 1/2015 of 24 July).

version, 2 December 2020, hereinafter, the "**Strategy**") are clear when they indicate that it is "*The Ministry of Health (who) will purchase the corresponding doses for Spain under the European strategy and vaccines will be administered free of charge to citizens through the National Health System*".

From the premise that the National Health System is the only body enabled to administer the vaccine, the Strategy deploys an entire model of distribution, storage, custody and, finally, administration thereof, in which, for now, there is no room for private collaboration, and, more specifically, collaboration of mutual healthcare societies. The protocolization established for the administration of doses and their access to the register specifically implemented to document that administration have not been designed, in principle, for public-private collaboration.

In fact, some friendly healthcare societies for public civil servants, such as MUFACE or MUGEJU, who have structural agreements to collaborate with the public to fulfil the vaccination schedules, have chosen to refer the vaccination of their affiliates to the National Health System, and are working in the early phases to help or speed up their access, for example, by reviewing the correct identification and updating their members' data.

It cannot, in any event, be ruled out that, where the management or implementation system advances in the near future, the mechanism could be opened up to collaboration premised or agreed beforehand with other institutions, such as friendly healthcare societies, although this should fall within the powers of the Autonomous Regions and within the so-called co-governance of the Interterritorial Council of the National Health System.

As we have said, so far, neither the acquisition nor the distribution nor, as such, the administration of vaccines outside the National Health System has been authorised.

As the groups awaiting immunisation expand, the doses of vaccines available grow and the logistics requirements multiply for their administration and distribution, everything seems to indicate that there will be spaces for collaboration. In this sense, the risk prevention and healthcare friendly services whose data are most up-to-date and which have the greatest versatility could play a role in implementing vaccinations, for example, given that they have contributed in the past in vaccination campaigns such as that for flu, will be best placed.