



## Spanish Government declares State of Emergency. How does this affect companies in the life sciences sector?

### Legal texts adopted so far

Last Thursday 12 March, the Spanish Government adopted a first set of measures to respond to the situation created by Covid-19. These were contained in Royal Decree-Law 7/2020. On Saturday 14 March, the Government declared the State of Emergency and adopted Royal Decree 463/2020 with additional measures restricting the activities of individuals and companies. The State of Emergency is due to be in force during 15 calendar days (up to 29 March), but it may be extended with the approval of Congress. On Sunday 15 March, the Ministry of Health ("MOH") issued several orders among which we highlight Order SNS/232/2020 pursuant to which reporting obligations were imposed to manufacturers and importers of certain products. In this special CAPSULAS, we try to explain, in the easiest manner possible, those measures which may have a specific impact on companies that operate in the life sciences sector.

### More funds for the NHS and easier contracts

Under Royal Decree-Law 7/2020, the Government has agreed to open a new fund of 1.000 Mio Eur that the MOH may dedicate to expenses derived from Covid-19.

The Government has also decided that any public procurement contract to purchase goods or services needed to face Covid-19 may be awarded via an extraordinary emergency system. This means that contracting may be entered into without a formal procedure, even verbally. The contracting body (a hospital or a regional healthcare service) will not need to

have a previously approved budget for the contract, and decisions taken in these cases will not be subject to ordinary administrative appeals.

### Price of medicines and of medical devices

One of the issues that has attracted more attention these days is whether the freedom to set prices for medicines and medical devices that are not reimbursed by the NHS could be limited or not. In normal circumstances, the ex-factory and retail prices of these products is free. Under Royal Decree-Law 7/2020, the law is modified, and the MOH may now establish maximum retail prices for products sold in Spain that may be needed for the protection of public health. The only condition that the law imposes on the MOH is that its decisions must be based on objective factors and must be transparent. The prices so fixed will remain valid throughout the duration of the exceptional circumstances that motivated the administrative intervention.

### The MOH as central authority

The declaration of the state of emergency means that all public healthcare services must now abide by any rule or instruction adopted by the MOH acting as central authority.

Regional authorities will continue to be the ones providing the service, and they may also adopt implementation measures, but the MOH is now vested with these extraordinary powers while the Covid-19 crisis is not solved.

Regional and local authorities may request the MOH to take any measure they deem convenient, but the MOH will be the one having the final say.



## Restrictions on freedom to operate

Companies retain, as a general rule, their freedom to operate as they may deem convenient, but the declaration of the state of emergency implies that the MOH may issue temporary orders under which a public authority may take control of any of its assets or otherwise impose specific obligations. A company, for instance, could be required to manufacture a given amount of specific products, and the authority could also dictate restrictions on customers that may be supplied. As it has been the case in other EU Members States, the MOH could prohibit exports of some products or adopt other measures that may be considered necessary to secure supplies of essential products.

As regards these issues, the law is drafted in very open and wide terms, allowing the MOH to adopt basically any measure it deems appropriate to protect public health.

## Companies obliged to cooperate

National and foreign companies located at Spain which manufacture and/or import any of the products laid down in Order SNS/232/2020 (certain types of masks, Covid-19 diagnosis kits, swabs, safety goggles, nitrile gloves, disposable and impermeable gowns, hydroalcoholic solutions, invasive mechanical ventilation devices and related consumables, alcohol for medical use and chlorhexidine), as well as those companies capable of developing them, must inform the MOH about their stock and manufacturing/importing capacity of such products. This communication must be made through the form available in the webpage of the MOH.

For the time being, all other companies do not need to take any special action other than being

informed and making sure that they are ready in the event that they receive any specific instruction. The orders issued by the MOH or a regional authority issues are mandatory. Failure to comply with them may result in administrative and criminal liability.

## Administrative and court procedures

For as long as the State of Emergency situation remains, all administrative and court procedures are stayed. When the State of Emergency finishes, they will resume at the same situation they were on 14 March 2020. So, if when going home on Friday 13 March, you still had 4 working days to answer a request for information made by any public authority or to file any submission in Court, the remaining 4 working days will start counting again from the day on which the State of Emergency finishes.

On the other hand, if you think that staying a procedure harms your interests, you may request the administrative authority or the Court that such stay does not apply.

The same stay applies to any situation where an administrative, civil or court action could be barred by limitation.

## Private contracts

It may be relevant to add that the rule on the stay of administrative and court procedures does not apply to contractual terms between private parties. If, under a private contract, you are meant to take any action within a given period of time, the State of Emergency does not give you, per se, the right to suspend the term for taking such action. In some instances you may be able to claim force majeure, but you should not count on relying on the State of Emergency situation only.