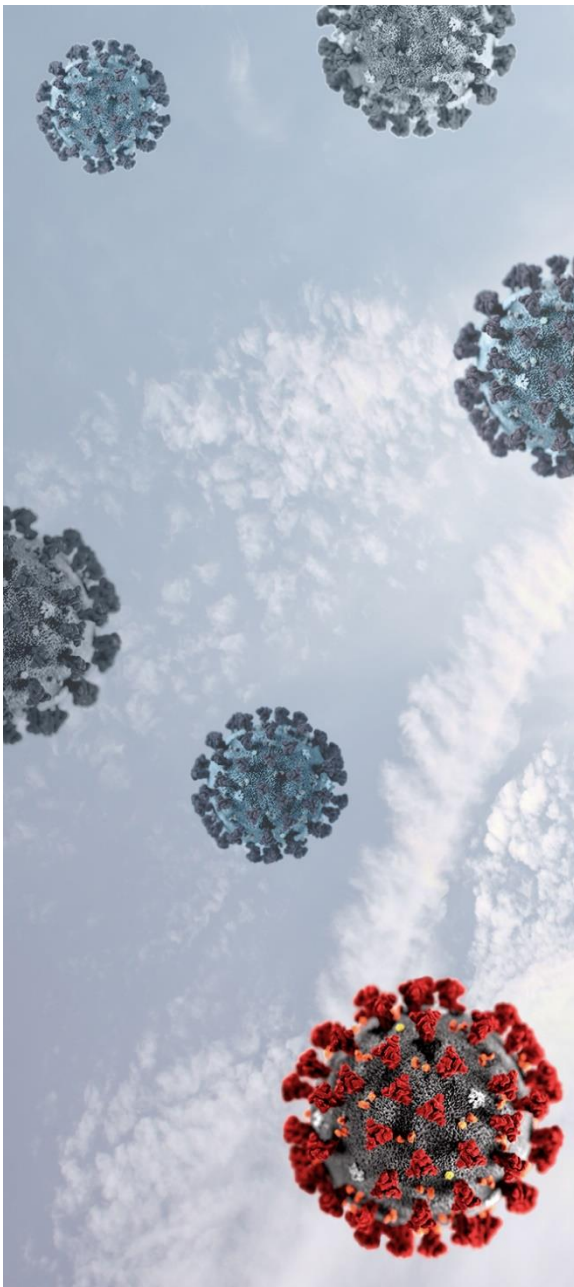


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# Impact of COVID-19 legislative changes: Pharmaceutical and healthcare technology industries

## Legal Flash

March 17, 2020



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Because of the situation generated by the COVID-19 virus, the Government of Spain has adopted a series of measures that, with regard to the pharmaceutical and healthcare technology industries, have taken the form of Spanish Royal Decree 7/2020 and especially Spanish Royal Decree 463/2020, of March 14, declaring a state of alarm [*Real Decreto 463/2020, de declaración del estado de alarma*], as well as Spanish Ministerial Orders SND/232/2020, SND/233/2020 and SND/234/2020, all of March 15.

We will take a detailed look at these measures, which may be amended or expanded over the coming days given the exceptional nature of the situation.



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## Possibility for the Government to regulate the mechanism for establishing prices

Spanish Royal Decree-Law 7/2020, of March 12, adopting urgent measures to respond to the economic impact of COVID-19 [*Real Decreto-ley 7/2020, por el que se adoptan medidas urgentes para responder al impacto económico del COVID-19*], has amended section 94.3 of the Spanish Guarantees and Rational Use of Medications and Healthcare Products Act [*Ley de garantías y uso racional de los medicamentos y productos sanitarios*] approved by Spanish Royal Legislative Decree 1/2015, of July 24, in the following way:

*“The Government may regulate the mechanism for fixing the prices of non-prescription medicinal products and healthcare products dispensed in Spain, as well as other products necessary to protect public health, following an objective and transparent system.*

*In the event of a healthcare emergency, and in order to protect public health, the Inter-Ministerial Commission on Pricing of Medicinal Products may set the maximum public sales price for the medicinal products and products referred to in the preceding paragraph for as long as the emergency persists.”*

This includes the possibility for the Government to regulate not only the mechanism for fixing the prices of over-the-counter medicinal products and medical devices, but also those of other products necessary for protecting public health (which could include personal protective equipment). Moreover, in the event of a healthcare emergency and in order to protect public health, the Inter-Ministerial Commission on Pricing of Medicinal Products may set the maximum public sales price for all those products (medicinal products and the other products mentioned) for as long as the emergency persists.

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## Measures affecting the functioning of the Spanish National Health System

Spanish Royal Decree 463/2020, of March 14, declaring a state of alarm for the management of the healthcare crisis caused by COVID-19 (the “**State of Alarm Royal Decree**”):

- The competent authority is the Ministry of Health: all civil healthcare authorities from government entities throughout Spain, as well as all officials and employees working for them, will be under the direct orders of the Ministry of Health insofar as necessary to protect people, property and places, and they may be ordered to provide services that are extraordinary in terms of their duration and nature.



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- The governments of the autonomous regions and local governments will, in principle, remain in charge of their areas of competence, although the Ministry of Health reserves the right to exercise any powers that may be necessary to guarantee consistency and equality in the provision of their services.
- The full availability of the civil authorities responsible for public health will be ensured, along with availability of the employees providing services in the public health sector.
- The possibility of determining how to best distribute all the technical and human resources throughout the country is guaranteed, in accordance with the impact that COVID-19 is having.
- Military personnel, bases and establishments will collaborate to strengthen the National Health System.
- The Minister of Health may exercise any powers that may be necessary for this purpose in relation to private healthcare centers, services and establishments. Yesterday, at 8:30 p.m., the Minister of Health confirmed in a public appearance that she has ordered an intervention into private healthcare, whereby all private healthcare facilities and resources are now at the disposal of the Healthcare Directors of the autonomous regions in their respective territories.

To implement these provisions, the Ministerial Orders of March 15 referred to above adopted the following measures:

- Human resources: authorization for exceptional hiring of medical and non-medical staff without specialist degrees to perform duties within a specialized area under certain conditions; the possibility of rehiring retired healthcare professionals; rehiring of personnel with dispensations to perform union functions; and the possibility of hiring medical and nursing students.
- Intervention in private healthcare: private healthcare centers and establishments, their personnel, and mutual workplace accident insurance companies are now at the disposal of the autonomous regions (which may also use spaces on public and private premises for healthcare uses).
- Information: the autonomous regions now have an obligation to send the Ministry of Health information on the containment measures they have adopted, epidemiological information, information on their healthcare capacity, information on their material resource needs, and information on their human resources.



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### Measures affecting the pharmaceutical and healthcare technology industries

The State of Alarm Royal Decree:

- Stipulates that the necessary orders may be given to ensure that the market remains supplied and that any production centers affected by a lack of supply of products necessary to protect public health continue to function.
- Allows for temporary intervention in and occupation of industries, factories, workshops, operations and premises of any nature, including private healthcare centers, services and establishments and those carrying out their activities in the pharmaceutical sector.
- Allows for temporary requisitions of all types of property and for the imposition of mandatory provision of personnel where necessary to protect public health in the context of this healthcare crisis.

To implement these provisions, the Ministerial Orders of March 15 referred to above (specifically Ministerial Order SND/233/2020) adopted the following measures:

- Obligation to inform: Spanish legal entities and foreign ones located in Spain that produce or import certain specific products (Type II and IIR surgical masks; FFP2 protection masks; FFP3 protection masks; COVID-19 PCR diagnostic kits and their consumables; rapid antigen detection test kits; cotton swabs; protective goggles; nitrile gloves with and without powder; disposable and impermeable gowns; hydro-alcoholic biocide and cosmetic solutions and their raw materials; invasive mechanical ventilation devices (IMV); IMV equipment consumables and disposable supplies; sanitary alcohols; chlorhexidine), or that have the capability to carry out these activities, must send the Ministry of Health (via its website and by March 17 at the latest; i.e., two days after the Order was published), information on the supply capacity referred to in the declaration form attached to the Ministerial Order.

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### Measures affecting public procurement procedures

- The measures call for centralized procurement (by the central Government) of the goods and services necessary to confront COVID-19.
- The goods and services necessary for battling COVID-19 may be procured in an emergency procedure that entails the possibility of signing contracts without having to follow a public tender or contracting procedure (and they may even be established verbally). There will also be no need to have a budget allocation for these contracts.
- However, it must also be emphasized that public tendering not related to COVID-19 will be affected by the suspension of the administrative deadlines referred to below.



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## Measures affecting administrative and judicial proceedings:

- **Procedural deadlines (court proceedings):** The time periods and deadlines imposed under procedural laws have been suspended and interrupted at all jurisdictional levels. Once the state of alarm and any extensions to it have expired, calculation of these periods will resume in the exact situation where they were when they were suspended (in other words, if there were five days left in a procedural period before it was suspended, there will still be five days remaining when the state of alarm has ended). However, judges and courts may agree to any actions that may be necessary to prevent irreparable harm to the parties' legitimate rights and interests.
- **Administrative deadlines:** The time periods and deadlines for procedures carried out by public sector entities have been suspended, except for procedures and resolutions involving situations closely related to the events justifying the state of alarm. The calculation of deadlines will resume once the state of alarm and any extensions to it have expired. Nevertheless, the competent body may agree, by means of a resolution explaining the reasoning, to carry out measures on procedures and instructions that are strictly necessary to prevent serious harm to the rights and interests of an interested party, provided the party provides consent for allowing the time period not to be suspended.

Any failure to comply with the measures adopted by the competent authorities during the State of Alarm may result in the imposition of penalties.

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