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COVID-19
Measures for pharma and health sectors

1 April 2020

1. Introduction

The rapid escalation of the COVID-19 health crisis has created an unprecedented situation that poses numerous legal challenges both at an international and national level.

During these past weeks many countries, including Spain, have passed regulations with two objectives: to protect the health of their citizens and to mitigate, as much as possible, the economic consequences of this pandemic.

After adopting a series of urgent and extraordinary measures through Royal Decree-Law 6/2020 of 10 March on urgent measures in the economic sector and to protect public health ("**RDLaw 6/2020**") and Royal Decree-Law 7/2020 of 12 March on urgent measures to address the economic impact of COVID-19 ("**RDLaw 7/2020**"), on 14 March 2020 the Spanish Government passed Royal Decree 463/2020 declaring a state of emergency to manage the COVID-19 health crisis (the "**State of Emergency RD**") and intensify the measures already adopted to mitigate its health, social and economic impact. On 17 March, Royal Decree-Law 8/2020 on urgent and exceptional measures to address the social and economic impact of COVID-19 ("**RDLaw 8/2020**") was approved. The State of Emergency RD was modified by Royal Decree 456/2020 of 17 March and several ministerial orders and administrative resolutions have been adopted since to deal with this exceptional situation.

The impact, whether health, economic or social, of the pandemic's expansion and of the measures adopted to address the crisis will be enormous and have a particular effect on several important industries for the Spanish economy. The purpose of this newsletter is to take a practical approach to some of the legal implications that are of particular interest to operators in the PHARMACEUTICAL AND HEALTH SECTOR in view of the current circumstances.

As the situation evolves over the following weeks the Spanish Government will adopt additional measures and has already extended the state of emergency. To keep our clients promptly informed of every development, we have prepared a compendium of all the measures adopted in Spain, which will be updated daily (available in Spanish here).

2. Initial considerations on the State of Emergency Royal Decree

2.1. STATE OF EMERGENCY RD

Pursuant to the State of Emergency RD and article 4 (b) and (d) of Basic Law 4/1981 of 1 June regulating states of emergency, exception and siege (*Ley Orgánica 4/1981, de 1 de junio, de los estados de alarma, excepción y sitio*), a state of emergency was declared on 14 March 2020 to manage the COVID-19 health emergency.

During the state of emergency, the Government is the "competent authority" and, under the direction of the Prime Minister, the Ministers of Internal Affairs; Public Health; Defence; and Transport, Mobility and Urban Affairs are "delegated competent authorities". They have exceptional powers to issue orders, resolutions, rules and interpretation instructions to ensure that the necessary ordinary and extraordinary services are provided to protect people, assets and places. These measures can be implemented without following the normal administrative procedure but will be subject to judicial supervision.

The state of emergency was initially declared for 15 calendar days and was extended on 25 April until 00:00 hours on 12 April with the approval of the Spanish Congress.

2.2. EXTRAORDINARY MEASURES ADOPTED PRIOR TO THE STATE OF EMERGENCY

Over the years the Spanish authorities have been given special powers to acquire medicines and medical devices affected by "exceptional supply difficulties". Specifically:

a) Article 4 of Basic Law 3/1986 of 14 April on special public health measures ("**LO 3/1986**") provides that when a medicine or medical device is affected by exceptional supply difficulties, and in order to ensure its better distribution, the authorities may (i) centralise supply; and (ii) limit its prescription to the identification of high-risk groups, development of analytical and diagnostic tests, compliance with protocols, providing the health authorities with information on treatments and other similar measures.

b) Article 24 of Law 14/1986 of 25 April on general health measures provides that, when there is an existing (or suspicion of an) imminent and extraordinary risk to health, the health authorities may adopt the preventive measures they consider appropriate, such as seizing or immobilising products, suspending activities, closing companies or their premises, taking control of material and human resources, and any other measures that are justified on public health grounds. The duration of the measures may not exceed what is necessary in light of the situation of risk that they were adopted to deal with.

c) Likewise, article 3.3 of Royal Legislative Decree 1/2015 of 24 July approving the restated text of the Law on guarantees and rational use of medicinal products and medical devices ("**RDLeg 1/2015**") provides that the Government may adopt special measures in relation to the manufacturing, importation, supply and dispensing of medicines (even when there is not a situation of exceptional need). In fact, these provisions have been applied in previous health crises (for example, in 2006, as a consequence of the N1H1 flu pandemic).

d) Additionally, article 24.5 of RDLeg 1/2015 provides, in relation to medicines, that the Spanish Medicines and Medical Devices Agency ("**AEMPS**" according to its Spanish acronym) may temporarily authorise the supply of non-authorised medicines as a response to the suspected or confirmed spread of harmful pathogenic agents, toxins, chemical agents or nuclear radiation, such as COVID-19. In such circumstances, "*if the use of medicines for non-authorised indications or the use of non-authorised medicines is recommended or mandated by the competent authorities, authorisation holders and other professionals involved in the process would be exempted of civil and administrative liability for all the consequences derived from the use of the medicine, except for the harm caused by defective products*".

e) Similarly, Royal Decree 1591/2009 of 16 October regulating medical devices, provides in its article 28.5 that the AEMPS may authorise the importation, for justified reasons, of medical devices that do not meet the requirements for their commercialisation in Spain.

2.3. NEW MEASURES INTRODUCED BY THE STATE OF EMERGENCY RD IN RELATION TO THE PHARMACEUTICAL AND HEALTH SECTORS

The measures adopted in the context of the COVID-19 health crisis are numerous and diverse in their nature and scope. We review the measures that are specific to the pharmaceutical and health sectors

or that have a particular impact on them. It is also worth noting there is a vast range of measures that apply to all economic operators across the board and that must be taken into account by companies that operate in the pharmaceutical and health sectors (see the "***Guide to key legal matters relating to the COVID-19 health crisis***" available on our website and Linkedin).

2.3.1 Reinforcement of the NHS

Article 12 of the State of Emergency RD seeks to reinforce the National Health System ("**NHS**" according to its Spanish acronym) throughout the country with the following measures:

a) *Centralised control by the Ministry of Health.* Further to the powers assigned to the Ministry of Health as a "delegated competent authority", all health authorities in Spain (as well as the civil servants and other employees assigned to them) have been placed under the direct orders of the Ministry of Health in order to protect people, goods and places.

b) *Cohesion and equity.* The Ministry of Health may take all necessary actions to ensure cohesion and equity in the provision of health services by regional and local authorities.

c) *Redistribution of resources.* Measures may be taken to ensure the optimal distribution of technical and human resources according to need throughout Spain. For example, this would allow for the transfer of equipment and personnel from one hospital to another, even if they are located in different regions.

d) *Private resources.* Privately owned health centres, services and establishments (and their personnel) have also been placed under the orders of the Ministry of Health inasmuch as this is necessary to reinforce the NHS.

2.3.2 Ensuring the supply of goods and services necessary to safeguard public health

The major part of the package of measures adopted in relation to the pharmaceutical and health sectors is designed to guarantee the continuous availability of essential products. There are a series of general measures that give the authorities the power to act to ensure the availability of goods and services necessary to safeguard public health, and other more specific measures designed to guarantee the availability of particular products, all adopted in accordance with the aforementioned COVID-19 regulations and existing statutory provisions.

(A) General measures

Among the many measures adopted in the context of the state of emergency, of particular note is the possibility of issuing orders of any kind to ensure the availability of essential products, taking temporary control of and occupying plants and premises, ordering temporary requisitions and requiring individuals to assist with necessary activities.

Specifically, article 13 of the State of Emergency RD authorises the Ministry of Health to:

a) *Procurement*: issue the necessary orders to ensure the market is supplied and manufacturing facilities are operating.

b) *Control and occupation of plants and premises*: temporarily take control of and occupy plants, factories, workshops, operations and establishments of any type, including privately owned health centres, services and establishments, as well as those that are used for pharmaceutical activities (excluding private domiciles); and

c) *Temporary requisitions and mandatory collaboration from individuals*: temporarily requisition any type of goods and require individuals to assist with activities that are necessary to safeguard public health.

The need to equip the Government with extraordinary mechanisms to ensure the supply of these products had already seen the modification of existing regulations before the state of emergency was declared. Through the modification of article 4 of LO 3/1986 (see Section 2.2.a), RDLaw 6/2020 introduced measures to ensure the supply and availability of essential products that are not considered medicines or medical devices. This encompassed biocide products and disinfectant products (for use on humans or surfaces), and some types of personal protective equipment ("**PPE**") that have proved to be essential to safeguard public health in the context of the COVID-19 health crisis. In particular:

a) *Centralised supply*: the catalogue of products that can be supplied centrally has been extended to not only include medicines and medical devices, but also "any product necessary for the protection of health that may be affected by exceptional procurement difficulties" ("**NPS Products**", according to the Spanish acronym).

b) *Prescription*: RDLaw 6/2020 allows the prescription of not only medicines and medical devices, but also NPS Products, to be restricted to the identification of high-risk-groups or compliance with protocols, among other priorities.

(B) Special measures already adopted in relation to specific products

The main measures adopted in the context of the current health crisis in relation to specific products and services for which a special need has been identified, even if there are not yet serious supply shortages, are listed below (they apply in particular to PPE, diagnostic tests, mechanical ventilation devices and intensive care, anaesthesia and reanimation equipment for hospitals).

a) Reporting to the Ministry of Health on public and private sector capacities and resources

Immediately after the state of emergency was declared on 15 March, Order SND/234/2020 on contention and reporting measures to address the COVID-19 health crisis was passed by the Ministry of Health.

In addition to reporting on the spread of the virus, the Order obliges the autonomous regions to inform the Ministry of Health:

(i) daily on their operating capacity (e.g. intensive care units, operating rooms, reanimation capabilities);

(ii) weekly, or when changes occur, on their material resources needs (e.g. PPE, diagnostic kits, biocides); and

(iii) on the number of invasive mechanical ventilation devices, medicalised ambulances and non-medicalised ambulances available in each hospital, be it public or private, in their region.

The Order was modified by Order SND/267/2020 of 20 March to include public and private hospitals handling COVID-19 cases and that have intensive care unit beds, reanimation or post-anaesthesia recovery facilities.

b) Reporting to the Ministry of Health on the availability of PPE, invasive mechanical ventilation devices, diagnostic kits and chlorhexidine

Further to the State of Emergency RD, Order SND/233/2020 on reporting obligations was also passed on 20 March. The items affected by this Order include PPE, invasive mechanical ventilation devices, diagnostic kits and chlorhexidine.

The Order obliged manufacturing and importing companies based in Spain to report to the Ministry of Health within two days on their stock of and capacity to produce (daily units) the listed items.

In response to questions raised by several parties, the same day the AEMPS issued an Informative Note clarifying that once an obliged party has fulfilled its reporting obligations under the Order, there is no obligation to cease the sale or distribution of the items, to put them into quarantine or block them, unless Order SND/233/2020 is modified or a party receives a specific order to do so from a competent authority.

c) More flexible requirements for face masks

Through the Resolution of 20 March of the Secretary General for Industry and Small and Medium Enterprises, a series of measures have been adopted relating to the acquisition of alternatives to PPE face masks with the CE mark to deal with the shortage of PPE with the required CE mark in the national market and the urgent need for these products to protect against COVID-19.

This Resolution is in line with Recommendation (EU) 2020/403 of the Commission of 13 March on conformity assessment and market surveillance procedures within the context of the COVID-19 threat, which invites all economic agents of the supply chain of PPE and medical devices, as well as notified bodies and market surveillance authorities, to set up all measures at their disposal to ensure that the supply of such products is able to face the continuous increase in demand for them. The Recommendation suggests the OMS recommendations be used as a reference to select appropriate PPE and that, in the case of medical devices, Member States may exceptionally not comply with all the requirements of the conformity assessment procedure, and in particular, authorise the commercialisation in the EU market (for a limited period of time) of products that have not have completed such conformity assessments.

In line with the Recommendation, the Resolution provides that certain NIOSH[1] and Chinese specifications, as long as they comply with technical requirements specified in the Resolution, are sufficient. The public acquisition of face masks that comply with these specifications will be possible, subject to authorisation from the health authorities, to be given exclusively to healthcare personnel. Subject to analysis by a health authority or an autonomous region, these products may also be

[1] The US National Institute for Occupational Safety and Health.

commercialised provided that it can be shown that a conformity assessment request had already been made for them.

d) Reporting, supply and manufacturing obligations regarding certain essential drugs

Health Ministry Order SND/276/2020 of 23 March requires manufacturers and holders of marketing authorisations for the medicines listed in its annex I to provide the AEMPS with the following information within 24 hours: (i) available stock; (ii) amount supplied in the last 24 hours; and (iii) batch release and receipt forecasts (dates and quantities). This information must be updated on a daily basis using the application on the AEMPS's website.

It also requires them to take the necessary measures to guarantee the supply of these drugs to health centres and services in accordance with their needs, including provision for daily supplies. Finally, it sets out that the Ministry of Health may order that priority be given to the manufacture of certain drugs, and that the AEMPS will be allowed to collect information from drug manufacturers about their manufacturing forecasts.

The products in question include multiple presentations of about one hundred active principles, such as morphine, insulin, paracetamol, glucose, heparin, chloroquine and hydroxychloroquine.

e) Controlled distribution of all hydroxychloroquine/chloroquine stock

On 23 March the AEMPS published a note on its website on the controlled distribution of all stocks of hydroxychloroquine/cloroquine, further to a measure adopted on 16 March to control the increasing demand for them related to COVID-19.

Priority is to be given to the use of these products for their authorised indications (lupus or rheumatoid arthritis) in those patients who were already being treated with them, and their distribution is to be maintained through pharmacies. In order to control demand, no more product will be made available until further notice; all the existing product in pharmacies will be used for repeat prescriptions to chronic patients for authorised indications, and the AEMPS and the regional authorities will guarantee the monthly stock for these patients.

Remaining stocks will be made available to hospitals (i) to treat chronic patients; (ii) for ongoing clinical trials; and (iii) to treat patients with pneumonia. The AEMPS stressed that there is still little evidence that these drugs are effective in the treatment of patients with COVID-19.

f) Dispensing and administration of hospital medicines within the NHS

The Ministry of Health's Order SND/293/2020 of 25 March establishes conditions for dispensing and administering hospital medicines.

Specifically, it limits the amount of hospital-dispensation medicines to be delivered to patients to two months of treatment per patient (which may be reduced to one month if ordered by the AEMPS to guarantee the availability of medicines). This limit does not apply to medicines dispensed in the framework of clinical trials. In fact, it is generally recommended that clinical trial patients are given an amount of medication that covers a longer period of treatment than usual.

This Order also exceptionally allows regional pharmaceutical authorities to establish measures that guarantee the availability of medicines to outpatients. Specifically, a) hospital-dispensation medicines do not have to be dispensed from hospital facilities, b) medication can be delivered to the homes of patients participating in clinical trials (in which case the promoter is in charge of the delivery logistics under the direction of the hospital pharmacy service and the principal investigator), and c) hospital-use medicines can be administered outside hospitals.

g) Restriction on PPE exports outside the European Union

At an EU level, Commission Implementing Regulation (EU) 2020/402 of 14 March 2020, making the exportation of certain products subject to the production of an export authorisation ("**Implementing Regulation 2020/402**"), sets out that an export authorisation (in accordance with the form established in annex II of the same Regulation) will be required to export PPE outside of the European Union, regardless of whether or not they originate from the EU. The authorisation must be granted by the competent authorities of the Member State where the exporter is established. Without this authorisation, exports are prohibited.

Implementing Regulation 2020/402 will be applicable during six weeks from the date of its publication in the Official Journal of the European Union (15 March 2020) and applies to the PPE listed in its annex: protective spectacles and visors, face shields, mouth-nose-protection equipment (e.g. masks), protective garments (e.g. gowns) and gloves.

2.3.3 Economic reinforcement measures

Chapter I of the State of Emergency RD contains a series of measures to provide financial support to the health sector. It acknowledges the extraordinary pressure that the COVID-19 outbreak is placing on the NHS, both on public health services and healthcare assistance providers. In response, it sets out a series of measures to reinforce the financing of the regional health authorities.

Of particular note is the modification of article 94.3 RDLeg 1/2015 by article 7 RDLaw 7/2020 to allow the Government to regulate for the first time the NPS Products pricing system and, in exceptional health situations, to allow the Interministerial Drug Pricing Commission (*Comisión Interministerial de Precios de los Medicamentos*) to establish the maximum retail price of medicines, medical devices and NPS Products.

By doing so, state intervention in the retail price of medical devices and NPS Products is permitted temporarily. This is done with the objective of guaranteeing citizens' access to them, and to address the spread of COVID-19 in Spain, as indicated in the preamble to RDLaw 7/2020.

2.3.4 Other measures

a) Public procurement

Service contracts and health, pharmaceutical or other supply contracts linked to the COVID-19 health crisis are not affected by the extraordinary suspension and extension measures introduced by article 34 of RDLaw 8/2020.

b) Measures to support research into COVID-19

Among the very diverse measures introduced by RDLaw 8/2020, the financial support for research into COVID-19 (article 36 and following) is of particular interest to the pharmaceutical and health sector. It includes a €24 million credit awarded to the *Instituto de Salud Carlos III* for direct subsidy payments to be made to COVID-19 projects and research programmes.

c) Special rules on public sector agreements related to COVID-19

Given the important role that the agreements regulated in article 47 and following of Law 40/2015 regulating the public sector have in the pharmaceutical and health sector, the measures introduced in this respect by RDLaw 8/2020 must be mentioned. They provide that agreements executed under this

framework to manage the COVID-19 health crisis are exempt from fulfilling some of the standard requirements. In particular, an explanatory report (*memoria justificativa*), legal services report and other mandatory reports normally required will not have to be submitted, nor will the prior authorisation of the Ministry of Tax and Public Authorities (*Ministerio de Hacienda y Administraciones Públicas*) be required. The agreement must still be recorded in the National Electronic Registry of Cooperating Bodies and Instruments of the public sector (*Registro Electrónico estatal de Órganos e Instrumentos de Cooperación*) and it must be published in the BOE (Spanish Official Gazette), but these requirements need not be met for it to enter into force.

d) Recommendations for the pharmaceutical manufacturing and distribution sectors. Contingency plans

On 17 March, the AEMPS issued a series of recommendations addressed specifically to manufacturers and distributors of medicines, medical devices and biocide products, which supplement the general recommendations published by the Ministry of Health's Health Alerts and Emergencies Coordination Centre (*Centro de Coordinación de Alertas y Emergencias Sanitarias del Ministerio de Sanidad*). They include the need to prepare contingency plans that include the organisation of work shifts and making provision for additional resources to cover staff shortages, especially for those activities considered critical. They also recommend increasing margins in terms of stock and delivery terms, and suggest contracting additional suppliers or involving third parties in manufacturing processes.

e) Exceptional measures to safeguard ongoing clinical trials and mitigate the problems caused by COVID-19

In a Note of 16 March, the AEMPS published a series of recommendations aimed at safeguarding ongoing clinical trials to the extent possible. It acknowledges that the COVID-19 health crisis may compromise activities such as programmed follow-up visits, external personnel's access to centres and in situ trial monitoring. It may also be necessary to transfer patients from one centre to another, and there could be a drop in the personnel in charge of monitoring trials. The recommendations include (i) reviewing the need for face-to-face visits; (ii) suspending recruitment and even treatment in order to avoid unnecessary risks; (iii) measures to guarantee patients' access to the trialled medication; and (iv) reviewing monitoring plans in order to avoid overloading staff.

The measures adopted do not require prior approval from the AEMPS or the Clinical Research Ethical Committees (*Comités Éticos de Investigación*) and will not be considered protocol infringements, but they must be properly documented and reported once the health crisis is over.

Finally, the AEMPS states priority will be given to evaluation of clinical trials aimed at treating or preventing diseases associated with COVID-19. From a practical point of view, the AEMPS has opened a channel dedicated to receiving proposals from promoters and researchers and has offered its scientific and regulatory support for the configuration of clinical trials.

f) Foreign investments in the health sector

RDLaw 8/2020 (fourth final provision), as amended by Royal Decree Law 11/2020 of 31 March adopting additional urgent social and economic measures to address the COVID-19 health crisis ("**RDLaw 11/2020**"), modifies the foreign investment regulations legal framework (Law 19/2003), and suspends the liberalisation of certain foreign direct investments in Spain. As a result, prior administrative authorisation is required to carry out direct foreign investments.

"Direct foreign investments", are defined as those investments that lead to the foreign investor holding more than 10% of a Spanish entity's capital or participating "in an effective way in the management or control" of a Spanish entity, provided that (a) the investors are residents outside the EU or the European Free Trade Association ("**EFTA**"); or (b) the investors are residents within the EU or the EFTA, but their ultimate beneficial owners (*titularidad real*) are resident outside the EU or the EFTA. It will be considered that such ultimate beneficial owners are resident outside the EU or the EFTA if non-EU or non-EFTA residents hold or ultimately control, directly or indirectly, 25% or more of the investor's capital or of the investor's voting rights, or when by other means they may exercise direct or indirect control over the investor.

In particular, prior administrative authorisation will be required to carry out the following direct foreign investments:

- Investments in companies operating in sectors listed in RDLaw 8/2020, which are considered to affect public order, public security and public health. They include the health and biotechnology sector, and sectors with access to sensitive information (e.g. personal data).
- Regardless of the sector in which the Spanish entity receiving foreign investment operates, investments carried out by specific types of investors, i.e. those controlled by foreign

governments, those already participating in sectors affecting other Member States' public security, order or health, and those that may have committed criminal or illegal activities in other countries, regardless of whether or not they are Member States.

A minimum amount threshold below which a foreign investment would be exempt from the prior authorisation requirement could be set in future regulations.

As regards the authorisation procedure, the second transitional provision of RDLaw 11/2020 establishes a simplified authorisation procedure for foreign investments where: (i) evidence is provided of the existence of an agreement between the parties or a binding offer in which the price was fixed or determined prior to 18 March 2020; or (ii) the amount to be invested is between €1 million and €5 million. As a temporary measure and until a minimum threshold (for the prior authorisation to be required) is set, foreign investments below €1 million will not require an authorisation

Foreign investments performed without the required authorisation will not be valid, will have no legal effect and will be considered an infringement that could be sanctioned with fines of up to the amount invested.

The new rules pose a number of questions, such as whether the restrictions apply to investments where several non-EU or non-EFTA investors (when considered together but not acting in concert) hold or ultimately control, directly or indirectly, 25% or more of the share capital or the voting rights of the investor; the definition of what it means to participate in an effective way in the management or control of an entity; the situation of foreign investors which already have a shareholding of more than 10% and intend to increase it (or maintain it, for example, in a rights issue); and many others.

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