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COVID-19
Measures for the pharma and health sectors

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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 ("**RDL 6/2020**") and Royal Decree-Law 7/2020 of 12 March on urgent measures to address the economic impact of COVID-19 ("**RDL 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 ("**RDL 8/2020**") was approved. Subsequently, successive decree-laws with different additional measures have been passed, the State of Emergency RD has been modified to extend the duration of the state of emergency, and several ministerial orders and administrative resolutions have been introduced to address the exceptional situation.

The impact, whether health related, 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.

It is also worth noting there is a vast range of measures that apply to all economic operators across the board (labour, tax, corporate, bankruptcy, consumer contracts, etc.) and this must be taken into account by companies that operate in the pharmaceutical and health sectors. Likewise, the "***Guide to key legal matters relating to the COVID-19 health crisis***" (available on our website and LinkedIn), which takes a practical and thus non-exhaustive approach, analyses certain legal issues (of a civil, commercial,

procedural, administrative, labour and fiscal nature, among others) that must be taken into account by economic operators in view of the current circumstances, including references where appropriate to the most important aspects of the new provisions issued in the framework of the current health crisis.

As the situation evolves over the following weeks the Spanish Government will continue to 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 then extended until 12 April and subsequently until 26 April, with the respective approvals of the Spanish Parliament on 25 March and 9 April 2020. Subsequently the Spanish Parliament authorised a further extension for another 15 days, until 10 May 2020.

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 ("**RD 1591/2009**"), provides in its articles 15 and 28.5, respectively, that the AEMPS may expressly authorise, on a case-by-case basis and in the interests of public health, the placing on the market and entry into service of products which have not yet completed the assessment procedures relating to the affixing of the CE marking, as well as authorise the importation, for justified reasons, of medical devices that do not meet the requirements for their commercialisation in Spain.

f) Lastly, the regulation regarding biocidal products also allows – on an exceptional basis – for the commercialisation and use of unauthorised biocidal products, or for the authorisation of products containing active substances that have not been approved by the EU. The regulation of these products is harmonised in the EU by Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (the "**Biocidal Regulation**"), article 55 of which expressly provides for this possibility.

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.

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), RDL 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*: RDL 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 adopted in relation to specific products and services

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, as well as by Order SND/352/2020 of 16 April to adapt and modify the procedure according to which the autonomous regions must send epidemiological information to the Ministry of Health.

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 protective products

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 marking to deal with the shortage of these masks 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 commercialised provided that it can be shown that a conformity assessment request had already been made for them.

In addition, the Ministry of Health has passed Order SND/326/2020 of 6 April establishing special measures for the granting of prior operating licences (*licencia previa de funcionamiento de instalaciones*) and for the entry into service of certain medical devices lacking the CE marking due to the health crisis caused by COVID-19. This Order applies only to surgical masks and surgical gowns.

In order to facilitate the manufacture and entry into service of surgical masks and gowns at an adequate rate to deal with the considerable number of patients with COVID-19, this Order establishes that the AEMPS may, at the request of the interested party, grant an exceptional prior operating licence for the production facilities or a temporary modification of the existing licence, following assessment of the general condition of the facilities in question, the quality-assurance system and the documentation of the product manufactured.

Likewise, this Order provides that in order to meet the needs generated by COVID-19 the AEMPS may authorise, following an assessment of the documentation required in each case, the use of surgical masks and gowns that have not fulfilled the conformity-assessment procedures required to affix the CE marking. Depending on the product and after evaluating the guarantees offered by the manufacturer in each case, the AEMPS may establish which of the health guarantees provided for in article 4 RD 1591/2009 are required.

In accordance with the provisions of this Order, potential liability that may arise due to the exceptional prior operating licence, the use of medical devices lacking the CE marking, or the non-requirement for health guarantees in relation to a specific product, will be assumed by the State Administration

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

(*Administración General del Estado*) provided that the medical device was delivered to the Ministry of Health without the natural or legal person authorised for its manufacture and operation, or any other persons participating in that process, obtaining any profit.

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. This list of products was updated by Order SND/353/2020 of 17 April.

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 (as amended by Commission Implementing Regulation (EU) 2020/426 of 19 March 2020) and Commission Implementing Regulation (EU) 2020/568 of 23 April 2020, making the exportation of certain products subject to the production of an export authorisation, sets out that an export authorisation (in accordance with the form established in annex II of the 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. This authorisation applies to the following PPE: protective spectacles and visors, face shields, mouth-nose-protection equipment (e.g. masks), protective garments (e.g. gowns) and gloves.

h) Making centres and COVID-19 diagnostic testing available

The Ministry of Health Order SND/344/2020 of 13 April, which establishes exceptional measures to reinforce the National Health System and contain the COVID-19 health crisis, makes any private clinical diagnostic centre – as well as its personnel – available to the autonomous regions, and provides for the possibility to regulate the prices of diagnostic tests to avoid abusive situations in terms of access to this service. In any event, the carrying out of COVID-19 diagnostic tests must be prescribed by a physician, in accordance with the instructions and criteria established by the competent health authority.

Likewise, Order SND/344/2020 imposes on all clinical diagnostic centres, both public and private, the obligation to notify the authorities of confirmed cases of COVID-19 (i.e. those that have tested positive).

Finally, Order SND/344/2020 also establishes the obligation for all public or private entities to inform the authorities of products used to diagnose COVID-19 (swabs for sampling, virus transport media, inactivation reagents, nucleic acid extraction kits or PCR reactions, or rapid diagnostic tests) that they have acquired, by indicating the type of material, number of units acquired and their intended use. Once this information has been received, the Ministry of Health may adopt, if necessary, the appropriate measures to respond to the need for and urgency of these products, with the aim of guaranteeing the principles of equity and cohesion.

Certain autonomous regions have adopted their own regulations within the intervention framework provided by Order SND/344/2020 (e.g. Order SAN/320/2020 of 15 April of the Department of Health of the Autonomous Region of Aragon, which requires that any entity, organisation or company, whether public or private, that proposes to perform or purchase diagnostic tests outside the scope of the Public Health System of Aragon must have prior authorisation from the health authority to perform such tests, and provides for the possibility of sanctions in the event of non-compliance; Order 459/2020 of 22 April of the Ministry of Health of the Autonomous Region of Madrid).

On 15 April, European Commission Communication 2020/C 122 I/01 was published in the Official Journal of the European Union, providing Guidelines on COVID-19 *in vitro* diagnostic tests and their performance. It sets out certain considerations in relation to the performance of such tests and the validation of their results and calls for action to ensure that the performance of products is the best that can reasonably be achieved and the approaches taken to assessment and validation of their performance are consistent across the European Union.

i) Home delivery of medicines

Among the many provisions approved by the autonomous regions, the protocols for home delivery of medicines and health products by pharmacies during the COVID-19 health crisis (approved by Order of 26 March of the Ministry of Health and Families of Andalusia, and Order 442/2020 of the Ministry of Health of the Autonomous Region of Madrid) should be highlighted.

Those who cannot receive support from other people in their environment and who cannot leave their homes (i.e. people with mobility problems, acute illnesses or complex chronic processes included in the groups at greatest risk of infection by COVID-19, people who due to their age or particular fragility are more vulnerable to infection, or people under home quarantine) may benefit from this form of dispensation of medicines.

This home delivery will include medicines (both those that do and do not require a medical prescription) and medical devices, with the necessary verification of the prescription and the corresponding health card when so required. Dispensation and preparation of the order will always be carried out by a pharmacist, who must ensure that the instructions given by the prescribing physician are followed. The home-delivery service must be carried out by pharmacy staff and may not incur any additional costs as regards the economic contribution corresponding to the medicines or medical devices dispensed. This method of dispensation cannot be publicised, although the public may be informed through official portals (i.e. official associations of pharmacists).

Without prejudice to the fact that these protocols are to remain in force only as long as the state of emergency is in place, they could represent a relevant precedent for the home delivery of medicines by pharmacies.

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 RDL 7/2020 to allow the Government to regulate the NPS Products pricing system and, in exceptional health situations, to allow

the Interministerial Drug Pricing Commission (*Comisión Interministerial de Precios de los Medicamentos,* the "**CIPM**") to establish the maximum retail price of medicines, medical devices and NPS Products, with the objective of guaranteeing citizens' access to these products and to address the spread of COVID-19 in Spain, as indicated in the introduction to RDL 7/2020.

Under this legal framework, Order SND/354/2020 of 19 April was approved, establishing exceptional measures to guarantee the population's access to products recommended for use as hygienic measures to prevent the spread of COVID-19. By means of this Order, the Ministry of Health authorises the CIPM to set the maximum price for sale to the public of certain medical devices (i.e. surgical masks, nitrile gloves and any other medical devices considered essential to minimise the risk of COVID-19 spreading among the population, as determined by resolution of the head of the General Secretariat of Health) and other NPS Products (e.g. reusable or single-use hygienic masks, antiseptic gels and hydroalcoholic solutions for hands, of a cosmetic nature, authorised by the AEMPS). During its meeting on 21 April, the CIPM agreed to set a maximum retail price for surgical masks of EUR 0.96 per unit, and a maximum retail price for gels and hydroalcoholic solutions authorised by the AEMPS of EUR 0.021 per ml (up to 150 ml), EUR 0.018 per ml (between 150 ml and 300 ml) and EUR 0.015 per ml (between 300 ml and 1000 ml), VAT included, as determined by the Resolution of 22 April 2020 of the General Directorate of the Common Services Portfolio of the National Health and Pharmacy System (*Dirección General de Cartera Común de Servicios del Sistema Nacional de Salud y Farmacia*). The setting of the maximum retail price for hygienic masks (single-use and reusable) and antiseptics for healthy skin (*antisépticos de piel sana*) was postponed to the next meeting of the CIPM.

In addition, Order SND/354/2020 establishes certain obligations in relation to consumer information and compliance with technical specifications for the hygienic masks covered by this regulation, determining that sales of single surgical masks that are not individually packaged can only be made in pharmacies. Likewise, antiseptics, gels and hydroalcoholic solutions for hands, of a cosmetic nature, that have not been authorised by the AEMPS cannot on their labelling claim to have characteristics that may cause consumers to interpret that the product possesses certain properties which have not been verified, such as "protection/disinfection against viruses" or the like.

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 RDL8/2020.

b) Measures to support research into COVID-19

Among the very diverse measures introduced by RDL8/2020, 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 RDL 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) No fees charged

The sixth additional provision of Royal Decree Law 13/2020 of 7 April implementing urgent measures regarding agricultural employment provides that, during the public health emergency caused by COVID-19, no fees will be charged in relation to the following: (i) authorisation procedures for clinical trials researching COVID-19-related medicines, provided that the trial is carried out for non-commercial purposes or the sponsor is a public body; (ii) procedures for the granting of exceptional prior operating licences to manufacture medical devices necessary for the protection of public health and in order to ensure supply during the COVID-19 health crisis (see section 2. (B)(c) above); and (iii) authorisation

procedures for clinical research with medical devices carried out in connection with the COVID-19 health crisis.

g) Guidelines for optimal and rational supply of medicines

On 8 April 2020, European Commission Communication 2020/C 116 I/01 was published in the Official Journal of the European Union. The Guidelines focus on the rational supply, allocation and use of medicines to treat patients with COVID-19. They also cover any medicines at risk of shortage due to the COVID-19 outbreak.

The Commission urges Member States to act in accordance with the following guidelines:

- Showing solidarity:
  - (i) Lifting export bans and restrictions on medicines within the internal market. In particular, measures leading to the requisitioning of medicines, intermediates or active pharmaceutical ingredients or preventing their production should not be considered as options
  - (ii) Stockpiling (in moderate quantities and on the basis of epidemiological recommendations) of medicinal products at the EU level (e.g. through rescEU) is the best solution for all Member States. Preventive stockpiling by individual Member States puts supply at risk for all countries
  - (iii) Ensuring that actors in the supply chain have access to reliable information on the use of medicines in the context of COVID-19, so as to avoid misuse and unnecessary stockpiling due to misinformation
- Ensuring the supply of medicines:
  - (i) Increasing and reorganising production by requiring supply-chain actors to monitor their stock and production capacity and share information with authorities, and by implementing demand-support and procurement initiatives
  - (ii) Ensuring the industry operates at full capacity by designating the manufacture of pharmaceuticals as an essential activity, by supporting the industry in the increase of its manufacturing capacity for essential medicines, and by ensuring that actors in the

pharmaceuticals supply chain have access to PPE and that their employees working at manufacturing sites are able to continue to travel to their workplace

(iii) Implementing regulatory flexibility in contexts such as changes to marketing authorisations or procedures relating to the change of suppliers or the extension of expiry dates of medicinal products

(iv) Monitoring available stock at the national level

(v) Ensuring necessary support for the wholesale sector, which must continue to operate at full capacity and supply medicines to hospitals and pharmacies, and ensuring that the sector's workers have access to the necessary PPE

(vi) Fully enforcing the "green lanes" system that has been established at border controls

(vii) Facilitating air freight and other forms of transport

(viii) Ensuring fair distribution of supply

- Ensuring optimal use of medicines in hospitals:

  (i) Equitable distribution of available medicines (reallocation of stock between hospitals)

  (ii) Exchanging hospital protocols to treat patients

  (iii) Considering alternative medicines, magistral preparations or veterinary medicines

  (iv) Extending the expiry dates of medicines, subject to certain guarantees

  (v) Using medicines "off label" and in clinical trials

- Optimising sales in pharmacies to avoid hoarding:

  (i) Introducing restrictions on sales in community pharmacies: limiting dispensing and sales of certain prescription and non-prescription medicines

  (ii) Limiting online sales of products at risk of shortage

  (iii) Reassuring patients

h) Foreign investments in the health sector

RDL 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, modifies the legal framework governing foreign investment (Law 19/2003). As a result, prior administrative authorisation is required to carry out direct foreign investments.

A control mechanism has been introduced for certain investments made by non-residents of the European Union and the European Free Trade Association, including investments made in companies in certain sectors listed in RDL 8/2020 on the basis that they affect public order, public security and public health (the "**Control Mechanism**"). In particular, as far as this memorandum is concerned, this includes critical industries (including ones relating to health, to the extent that they have been so identified), the biotechnology sector, the supply of raw materials (e.g. active ingredients) and sectors with access to sensitive information (e.g. health data).

Section 13 (restrictions on foreign investment) of the "***Guide to key legal matters relating to the COVID-19 health crisis***" (available on our website and LinkedIn) describes the new Control Mechanism.

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