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COVID-19
EMEA Life Sciences Survey

What measures have EMEA governments taken in the life sciences sector to fight COVID-19?

29 May 2020

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INTRODUCTION

What measures have EMEA governments taken in the life sciences sector to fight COVID-19?

As COVID-19 rapidly spreads to every corner of the globe and is officially declared a pandemic, governments across the world are adopting emergency measures to fight against this extraordinary situation. Ultimately, all these measures are aimed at protecting the health and wellbeing of citizens. However, on the healthcare and life sciences front in particular, such measures range from intervention powers to guarantee adequate supplies of treatment and medical equipment, to the relaxation of deadlines and regulatory requirements to simplify administrative procedures wherever possible, so that competent authorities, manufacturers and other actors can focus on urgent priorities related to the COVID-19 crisis.

The Baker McKenzie Healthcare and Life Sciences Industry Group is pleased to provide you with an overview of the measures that governments across the EMEA region, which includes some of the worst hit countries, have adopted in the area of healthcare and life sciences in response to the COVID-19 outbreak.

In this guide, Baker McKenzie lawyers across EMEA share their high-level views on the following areas:

Requisition powers
- Has the Government established any powers to requisition assets and premises?
- Is it converting hotels into hospitals / medical centers for quarantine and self-isolation?
- Is it controlling the distribution of medicinal products / medical devices?

Price and reimbursement
- Has the price and reimbursement procedures for medicinal products and medical devices been affected?

Public procurement
- Has the Government adopted exceptional public procurement measures?
- Have procedural requirements been relaxed for Covid-19 related medicines and devices?
- Are sanctions foreseen for unfilled orders?

Legal deadlines
- Have legal/ administrative deadlines been suspended / relaxed?
- Have these measures had an impact on MA approvals, public procurement, etc.?

Relaxation of regulatory rules
- Has the Government relaxed regulatory rules?
- Have special measures been adopted?
- What are the main changes?

This guide offers only a high-level view and does not constitute legal advice. The COVID-19 outbreak is an escalating situation, authorities are issuing advice on a daily basis and it is crucial to assess these measures on a case-by-case basis.

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Uzbekistan

Quick Glance Overview

	Belgium	Czech Rep	France	Germany	Hungary	Italy	Kazakhstan	Netherlands	Poland	Russia	South Africa	Spain	Sweden	Switzerland	Turkey	UK	Ukraine	Uzbekistan
Specific COVID-19 legislation enacted?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Has the government established any powers to requisition assets and premises?	✗	✓	✓	✓	✓	✓	✓	✗	✓	✗	✓	✓	✗	✓	✗	✗	✗	✗
Are you seeing hotels being converted into hospitals/medical centers for quarantine and self-isolation?	✗	✗	✓	✓	✗	✗	✗	✗	✗	✗	✗	✓	✗	✗	✗	✗	✗	✓
Is it controlling the distribution of medicinal products/medical devices?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Has the price and reimbursement procedures for medicinal products and medical devices been affected?	✗	✗	✓	✓	✓	✗	✗	✓	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓
Has the government adopted exceptional public procurement measures?	✗	✗	✓	✓	✓	✗	✓	✗	✗	✗	✓	✓	✗	✗	✗	✓	✓	✓
Have procedural requirements been relaxed for COVID-19 related medicines and devices?	✓	✗	✗	✓	✓	✓	✓	✗	✓	✓	✗	✓	✗	✗	✗	✓	✓	✓
Have legal/administrative deadlines been suspended/relaxed?	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓
Have these measures had an impact on MA approvals, public procurement, etc.?	✗	✓	✓	✓	✓	✓	✗	✗	✗	✓	✗	✓	✗	✗	✓	✓	✓	✓
Has the government relaxed regulatory rules?	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Have special measures for clinical trials been adopted?	✓	✓	✓	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✗

European Union

At the EU level, the Commission is making an effort to coordinate a common European response to the outbreak. This is not proving an easy task due to the dramatic times in which Member States are living; actions are being taken unilaterally at a national level.

The following measures are worth highlighting:

Guidance on the optimal and rational supply of medicines to avoid shortages

On 8 April 2020, the Commission published guidance aimed at ensuring the continued supply of medicines necessary for the treatment of COVID-19 and an equitable distribution of such medicines for patients in Europe. This guidance is addressed to EU Member States and EEA countries.

In the spirit of European solidarity, Member States are called to lift export bans which are impeding the trade of medicines within the internal market and to refrain from requisition of medicines, intermediates or active pharmaceutical ingredients even when these measures are legally justifiable.

Member States are also called to ensure that companies increase production where needed and work at full capacity.

The guideline foresees significant **relaxation of regulatory measures**. In particular, Member States shall streamline and accelerate variation procedures concerning change of API suppliers, designation of new manufacturing sites or extension of expiry dates. The guideline does not address products approved through the EU centralized procedure. The argument could, however, be made that similar flexibility should be demonstrated for those products.

According to the guideline, Member States should be able to reallocate stock between hospitals, hospital protocols should be shared EU-wide and the following measures should be adopted in case of confirmed shortages:

- Extension of expiry dates where possible
- Use of magistral formulas and veterinary medicines
- Use medicines off label and in clinical trials

The need for coordination extends to pharmacy level, where Member States are called to prevent excessive purchasing and to introduce restrictions on sales.

EU export controls

The Commission has introduced temporary authorization requirements on exports of certain medical/protective equipment to destinations outside the EU. See Commission Implementing Regulation (EU) No 2020/568, which replaces Commission Implementing Regulation (EU) 2020/402, as amended by Commission Implementing Regulation (EU) 2020/426).

The overall aim of these measures is to ensure adequate supply of medical and protective equipment across the Union. Regulation (EU) No 2020/568 amends the list of products that require export authorization outside of the customs territory of the EU to masks, spectacles and protective garments and extends the geographical exception, including to the Western Balkans.

Further information on EU export controls can be found in our blog-post here.

Public procurement

On 31 March 2020, the Commission published guidance aimed at simplifying public procurements while still upholding high safety and quality standards. The guidance offers an overview of the options and flexibilities available for the purchase of supplies, services and works needed to address the crisis.

Further to the guidance, in cases of urgency public buyers can reduce the deadlines to accelerate open or restricted procedures. If the shortened deadlines are not sufficient, public buyers may opt for a negotiated procedure without prior publication. The guideline also encourages public buyers to find alternative ways of engaging with the market to supply much-needed medical products.

The magnitude of the outbreak has also led the Commission to enter into **Joint Procurement Agreements (JPA)** with Member States (and the United Kingdom and Norway) to enable the joint purchase of medical equipment and supplies. To date, the Commission has launched four different calls for tender with participation of up to 25 Member States. Further details on these JPAs can be found here.

European Union

Legal deadlines

On 25 March 2020 the Commission announced its intention to postpone for one year the application date of the Medical Devices Regulation (**MDR**), which was due to become applicable on 26 May 2020. The aim is to take pressure off national authorities, notified bodies, manufacturers and other actors so they can focus fully on urgent priorities related to the COVID-19 crisis. The legislative procedure to amend the MDR was launched on 3 April and can be found here.

Relaxation of Regulatory Rules

The Commission has made calls for relaxation of measures in relation to the authorization of medicines (see the guidance on the optimal supply of medicines to avoid shortages described above).

In addition, on 10 April 2020, the Commission, Heads of Medicines Agencies (**HMA**) and the European Medicines Agency (**EMA**) adopted a question-and-answer (Q&A) document to provide guidance to stakeholders on adaptations to the regulatory framework to address challenges arising from COVID-19.

This guidance document covers national and centralized authorization procedures. The document focuses on marketing authorizations, manufacturing and importation, quality variations and product information. It reminds of the existing tools foreseen in the legislation that allow for certain flexibility (e.g., compassionate use, sunset clause exemptions) and contemplates the possibility for companies to request postponement of renewal deadlines, speedier variations for COVID-19 medicines and lighter product information requirements. In the context of manufacturing and importation, the guidance foresees specific processes for COVID-19 related medicines (Exceptional Change Management Process, ECMP).

In relation to medical products, the following should be noted:

On 20 March 2020, the European Commission and Standardization Organization agreed that all the relevant European harmonized standards will exceptionally be made freely available for all interested companies. This was followed by the adoption of revised harmonized standards on 24 March 2020 in relation to critical devices such as medical facemasks, surgical drapes, gowns and suits, washer-disinfectors or sterilization.

On 30 March, the Commission issued a Question and Answers document to help increase the production of medical devices by providing guidance on the following three fronts:

- Legal and technical standards for PPE manufacturing and reconverting existing facilities
- Helping economic operators, including SMEs, on the legal framework for the placing on the EU market of hydro-alcoholic gel
- Clarifying conformity assessment procedures for 3D printing and 3D printed products for medical use in the context of the outbreak

These measures complement Commission Recommendation 2020/403 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat. The Recommendation recognizes the importance to ensure that appropriate protective equipment and medical devices are swiftly made available to those who need it most, and that the efforts of manufacturers and distributors lead to increased supply without delay. The Recommendation therefore proposes:

- Opening the EU market to protective equipment manufactured in accordance with WHO recommendations rather than in strict adherence to EU harmonized standards, provided that they give a level of protection corresponding to EU requirements
- For medical devices, that Member States use their discretion to authorize derogations from EU conformity assessment procedures, as is currently permitted by EU law in exceptional circumstances
- That for a limited period of time, market surveillance authorities allow the circulation of protective equipment or medical devices for which conformity assessment procedures, including the affixing of CE marks, have not been fully finalised, provided that the products are otherwise safe in accordance with EU law
- That Member States take appropriate measures to ensure that protective equipment or medical devices not bearing the CE mark are only made available to healthcare workers

Clinical trials

On 9 March 2020, EMA urged the EU research community to prioritize large randomized controlled clinical studies as these are most likely to generate the conclusive evidence needed to enable rapid development and approval of potential COVID-19 treatments.

On 20 March 2020, the European Commission, EMA and the national Heads of Medicines Agencies published guidance on how to manage the conduct of clinical trials in the context of COVID-19. The guidance serves as an EU-level harmonized set of recommendations but warns that sponsors and investigators must also take into account specific national legislation and guidance, which may complement or take priority over the recommendations in the EU guidance.

The guidance provides information on changes and protocol deviations in ongoing trials that may be needed and includes a harmonized set of recommendations to ensure the safety of trial participants and the quality of the data generated by the trials. There is also specific advice on the initiation of new clinical trials for treatments of COVID-19, and in particular on the need for large, multinational trial protocols. The guidance was amended on 27 March 2020 to cover safety reporting, the distribution of in-vitro diagnostics, medical devices and auditing. Changes were also introduced to sections on the communication with authorities, informed consent and the distribution of investigational medicines.

On 1 April 2020, EMA issued a guidance notice against non-COVID-19 related off-label use of chloroquine and hydroxychloroquine medicines. EMA advised patients and healthcare professionals to only use chloroquine and hydroxychloroquine medicines for their authorized indications or as part of clinical trials or national emergency use programs for the treatment of COVID-19.

On 3 April 2020, EMA provided recommendations on compassionate use of remdesivir for COVID-19

Belgium

Matters	Summary
Specific COVID-19 legislation	**Legislation**: ▪ Royal Decree of 24 March 2020 on special measures to address shortages of medicines in the framework of the SARS-CoV-2 pandemic ▪ Ministerial Decree of 23 March 2020 on special measures in the context of the SARS-CoV-2 pandemic on the basis of on Book XVIII of the Code of Economic Law ▪ Ministerial Decree of 27 March 2020 amending the Ministerial Decree of 23 March 2020 on special measures in the context of the SARS-CoV-2 pandemic on the basis of on Book XVIII of the Code of Economic Law ▪ Ministerial Decree of 7 April 2020 amending the Ministerial Decree of 23 March 2020 on special measures in the context of the SARS-CoV-2 pandemic on the basis of on Book XVIII of the Code of Economic Law ▪ Ministerial Order of 23 March 2020 on urgent measures to limit the spread of the coronavirus COVID-19 ▪ Royal Decree of 18 March on the preparation and marketing of hand alcohol gels for human hygiene as part of the fight against the spread of COVID-19 ▪ Royal Decree of 17 March 2020 prohibiting the provision, commissioning and use of rapid tests for the measurement or detection of antibodies relating to the SARS-COV-2-VIRUS ▪ Decision of the Chief Executive Officer of the FAMHP, dated 27 April 2020, on the extension of various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic ▪ Decision of the Chief Executive Officer of the FAMHP, dated 1 April 2020, on various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic ▪ Decision of the Chief Executive Officer of the FAMHP, dated 8 April 2020, amending the various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic ▪ Ministerial Decree of 2 May 2020 amending the Ministerial Decree of 23 March 2020 on special measures in the context of the SARS-CoV-2 pandemic on the basis of on Book XVIII of the Code of Economic Law ▪ Royal Decree nr. 20 of 13 May 2020 on temporary measures in the fight against the COVID-19 pandemic and to ensure continuity of care in compulsory medical care insurance **Guidance documents:** ▪ Addendum to the Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic (https://www.fagg.be/sites/default/files/content/national_guidance_corona_20200429c_clean.pdf - version of 29 April 2020) ▪ Conditions for the supply and release of surgical masks (https://www.fagg.be/sites/default/files/content/20200512_fagg_conformiteit_chirurgische_maskers.pdf - version of 12 May 2020) ▪ FAMHP Circular - The manufacture, outsourcing and reprocessing of medical devices and their accessories within care facilities to tackle shortages in the fight against the SARS-CoV-2 pandemic (https://www.fagg.be/sites/default/files/content/afmps_circulaire-omzendbrief_fabricage_fabrication_meddev.pdf) ▪ Information on the Alternative Test Protocol (ATP) for surgical face masks (https://www.fagg.be/sites/default/files/content/atp_chirurgische_maskers_20200428_def.pdf - version of 28 April 2020) ▪ Guidance for the reprocessing of surgical masks and filtering facepiece respirators (FFP2, FFP3) during the Coronavirus disease (COVID-19) Public Health Emergency (https://www.fagg.be/sites/default/files/content/national_guidance_mask_reprocessing_finalversion1_0_0.pdf)

Belgium

Matters	Summary
Specific COVID-19 legislation	**Guidance documents:** ▪ Guidance on the Management of Clinical Investigations during the COVID-19 (Coronavirus) pandemic (https://www.fagg.be/sites/default/files/content/guidance_during_covid19_pandemic_for_ci.pdf - version of 30 April 2020) ▪ Guidelines for in-house fabrication of respiratory devices accessories using 3D printing (https://www.fagg.be/sites/default/files/content/guidance_afmps_3d_printing.docx - version 2 May 2020) ▪ Guidance on how COVID-19 tests should be made available in Belgium (https://www.fagg.be/nl/news/coronavirus_hoe_moeten_tests_in_belgie_beschikbaar_worden_gesteld)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	I. Since 25 March 2020, the minister of health and the FAMHP can take special individual and/or collective measures to **address shortages of medicines** in the framework of the COVID-19 pandemic (Royal Decree of 24 March 2020 on special measures to address shortages of medicines in the framework of the SARS-CoV-2 pandemic). They have the competence to: ▪ restrict or prohibit the export of any medicinal product or starting material ▪ limit the supply of a medicine to a maximum quantity per patient ▪ limit the supply of a medicine or raw material to pharmacies to a fixed quantity per pharmacy ▪ reserve the supply of a medicine for hospital dispensaries ▪ order the redistribution of stocks of a medicinal product or a starting material, either by way of a return to the wholesaler or by way of direct redistribution among pharmacies ▪ commandeer stocks of a medicinal product or a starting material to redistribute it ▪ authorize and regulate the delivery of medicines by doctors or other healthcare professionals ▪ order that the stock of medicines at wholesalers can only be sold or delivered according to the instructions of the FAMHP They can only take such measures if they can demonstrate their necessity, proportionality and adequateness. Moreover, the measure taken must be limited in time. The Belgian State is obliged to compensate the damage resulting from the measures taken. The FAMHP teams continuously monitor the availability of medicines in Belgium. They are in contact with pharmaceutical companies to speed up deliveries and increase production capacity. The FAMHP has also accelerated the necessary administrative procedures. Currently, the FAMHP has already taken the following measures to address shortages of medicines: ▪ The supply of medicines and raw materials on the list drawn up by the FAMHP (see Annexes to the Decision of 8 April 2020 of the Chief Executive Officer of the FAMHP on various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic) is only permitted to wholesalers, pharmacies and hospitals established in Belgium. Other deliveries are prohibited, with the exception of deliveries to the FPS Public Health within the framework of building up strategic stocks. However, the Chief Executive Officer of the FAMHP can allow exceptions. Exports within and outside the EEA are permitted, but must be reported in advance to the FAMHP. The FAMHP can oppose export outside the EEA within three working days.

Belgium

Requisition powers

- Has the government established any powers to requisition assets and premises?
- Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?
- Is it controlling the distribution of medicinal products/medical devices?

- To avoid over-ordering and misallocation of stocks, wholesalers must limit the quantities of medicines and raw materials on the list (see Annexes to the Decision of 8 April 2020 of the Chief Executive Officer of the FAMHP on various urgent measures regarding specific medicines to combat shortages of medicines in the context of the SARS-CoV-2 pandemic) to those corresponding to last year's sales in the same period, plus a maximum of 50 %. Larger quantities may be supplied if this does not compromise the supply to other wholesale distributors, other persons authorised to supply medicines to the public, or other hospitals, and if this has been previously notified to the Chief Executive Officer of the FAMHP. In any case, the wholesale dealer must deliver in accordance with the specific allocation key or instructions imposed by the Chief Executive Officer of the FAMHP.
- Hospitals and pharmacies (both hospital pharmacies and pharmacies open to the public) that have a stock of medicines on the list that exceeds the sales volume of one month for that pharmacy or hospital by more than 50 % must report this surplus stock to the FAMHP with a view to possible re-distribution.
- Strategic stocks of the following medicines are/will be built up: hydroxychloroquine, Kaletra, Rocuronium (curare), Sufentanyl Mylan, Atracurium besilate, Rocuroniumbromide, Hydroxychloroquine; Morfine, Midazolam, Fentanyl, Paracetamol IV and Chloroquinefosfaat.
- Controls are introduced on the distribution of the following medicines: Esmeron, Nimbex, Morphine Sterop, Rapifen, Dipidolor Sufenta, Fentanyl and Hypnomidate. The companies involved must adhere to a quantity/quota per hospital, based on the distribution key that takes into account the number of beds in intensive care for COVID-19 patients. The medicines will continue to be ordered, distributed and invoiced as usual.
- For a number of medicines, derogations for the import of foreign batches have been/will be granted by the FAMHP to pharmaceutical companies. These medicines include clarithromycin, norepinephrine, sufentanil, alfentanil and hypnomidate.
- Available stocks of Hydroxychloroquine, Chloroquine and Kaletra (lopinavir + ritonavir) are quarantined in order to control their distribution and allow better monitoring of their use.
- Pharmacies open to the public are only supplied with the amount of Plaquenil, chloroquini phosphas and Kaletra necessary to meet medical prescriptions for chronic patients.
- General practitioners have been recommended to restrict the prescription of Plaquenil, chloroquini phosphas and Kaletra.
- The FAMHP sets quotas for a range of medicines for which there are no shortages (yet) in order to avoid excessive orders or overstocking. The website of the FAMHP does not mention on which medicines exactly quotas have been set. These quotas are evaluated and assessed on a weekly basis.
- Only a doctor can decide to treat the patient with oxygen. Doctors may only prescribe oxygen if this is a medical necessity or in palliative settings. Only (hospital) pharmacists can order oxygen supplies. Pharmacists may only order oxygen if the patient has a medical prescription for these supplies.
- FAMHP has asked the usual producers on the Belgian market to increase their production and speed up deliveries and it has also searched, and found, other producers in order to obtain additional supplies. In addition, FAMHP has organizsed the supply of raw materials in order start up local production in Belgium where possible.

Belgium

Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	In addition, the FAMHP investigates the possibility of using veterinary medicines in humans. Stocks of Proposure, a sedative containing propofol that is marketed for veterinary use, have already been supplied to hospitals. II. Besides a legal framework for medicines shortages, also measures are taken to address **shortages of certain medical devices and personal protective equipment** (Ministerial Decree of 23 March 2020 on special measures in the context of the SARS-CoV-2 pandemic on the basis of Book XVIII of the Code of Economic Law and the amending Ministerial Decrees of 27 March 2020 and 7 April 2020). The retail sale of the products listed in the Ministerial Decree is only permitted by licensed pharmacies in so far as they have been prescribed by a healthcare professional. Registered distributors may only sell the listed medical devices to other registered distributors of the products concerned, licensed pharmacies, hospitals and authorised healthcare professionals. Wholesalers may only sell the listed personal protective equipment to other wholesalers in the products concerned, licensed pharmacies, hospitals, licensed healthcare professionals and companies that need them within the framework of Book 9, Title 2 of the Codex on well-being at work, and in volumes that can reasonably be foreseen for use within the next month. Manufacturers and wholesalers may also sell the listed personal equipment to companies which are obliged by legal or regulatory provisions to use this equipment in the manufacture, processing, storage or warehousing of their goods or in the exercise of their activities. Moreover, the Minister of Health and the FAMHP have the competence to limit sales and sales volumes, for both small and medium-sized enterprises and for the wholesaler; and limit the sale of these products to sales to hospitals and patients. On a proposal of the FAMHP, the Economic Inspection Authority can order the redistribution of stocks of these products, either by returning them to the wholesaler or by direct redistribution between pharmacies. The Economic Inspection Authority can also claim these products and authorised to sign requisition orders. The list of medical devices and PPE's has been amended by the Ministerial Decrees of 7 April 2020 and 2 May 2020. Moreover, Royal Decree of 17 March 2020 prohibits the provision, commissioning and use of **rapid self-tests** for the measurement or detection of COVID-19 antibodies, such as IgG, IgM and IgA, for six months as from 18 March 2020. However, other tests for the detection of the virus causing COVID-19 or for the detection of antibodies against COVID-19 produced for professional use (ie. use by healthcare professionals) is still allowed. These tests do not have to be approved by the FAMHP but the placing on the market of these tests must be notified to the FAMHP via the following link: https://www.vas.ehealth.fgov.be/webmedseip/nl/.
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	The NIHDI has announced that the price decreases foreseen from 1 April will be postponed. Due to the delay in the adoption of the legal and regulatory provisions for the savings measures for the pharmaceutical budget, and because of the urgency imposed by COVID-19 control, the Minister has indicated that the decided savings measures concerning the pharmaceutical products cannot be implemented in time. The exact date of entry into force of these savings measures cannot be determined yet. It is important to note that health care providers are not allowed to pass on costs related to personal protective equipment - such as gloves, face masks etc. - to their patients. The government will provide for financial assistance to help health care providers to cover these COVID-19-related costs.

Belgium

Public procurement

- Has the government adopted exceptional public procurement measures?
- Have procedural requirements been relaxed for COVID-19 related medicines and devices?
- Are sanctions foreseen for unfilled orders?

The existing public procurement rules must be respected, also with regard to medicine and devices. However, the existing rules provide the possibility to use the negotiation procedure without prior publication in the event of unforeseeable urgency (Law of 17 June 2016 on Public Procurement, art. 42, §1, 1°, b). In this way, the public authority can award the contract in a flexible and fast manner. In the context of the current crisis, it is conceivable that this procedure could apply, for example, in case of urgent purchase of material or in case of need for quarantine measures in case of risk of contamination.

The federal government has stated in a communication that it will adopt a flexible attitude with regard to (federal) public procurement. If the delay or non-performance is due to COVID-19, the federal authority will not impose any fines or penalties. Similar measures have not yet been announced at the Flemish/Walloon or local level. However, if fines for delay have been withheld or penalties have been imposed, the contractor may still obtain a full or partial refund of these fines and penalties if the delay is due to unforeseeable circumstances or if there is a disproportion between the fine or penalty and the extent of the delay or defective performance (Royal Decree of 14 January 2013 laying down the general rules for the implementation of public contracts, art. 50-51).

Legal deadlines

- Have legal/administrative deadlines been suspended/relaxed?
- Have these measures had an impact on MA approvals, public procurement, etc.?

All deadlines foreseen in the law of 14 July 1994 on compulsory insurance for medical care and benefits are suspended, except for time limits relating to benefits and maternity insurance and control services (see Royal Decree nr. 20). This law foresees, among others, the applicable time limits to amend the list of reimbursable benefits. These time limits have been suspended since 13 March 2020 and the end date of the suspension still needs to be determined.

Other deadlines are not suspended or relaxed as a general rule. The authorities will rather take the individual elements and context of each case into account before they allow any suspension or relaxation of deadlines.

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

Medical devices in general

- In a circular, the FAMHP laid down terms and conditions for the manufacture, outsourcing and reprocessing of medical devices and their accessories for care facilities (A care facility is every recognised hospital falling within the scope of the law of 10 July 2008 on hospitals and other care facilities coordinated). These provisions are applicable to medical devices in the sense of Directive 93/42/EEG, Directive 98/79/EG, Regulation 2017/745 and Regulation 2017/746. The circular establishes a framework to increase opportunities for healthcare institutions to collaborate with external companies on alternative solutions to address proven shortages of the material necessary for patient health, on the one hand through the "in-house" production of certain medical devices and, on the other hand, through reprocessing of single use medical devices.

In-house medical devices are medical devices that may only be used in care facilities and cannot be put on the market. Care institutions can call on external companies for the design, production, packaging and labelling of these in-house devices. Under the conditions set out in the circular, no national derogation for their use has to be requested from the FAMHP.

Reprocessed medical devices are medical devices are single-use medical devices but which can be reused under certain conditions. The reprocessing of these medical devices can be carried out by the care institution itself or outsourced, provided that the conditions set out in the circular are met.

Belgium

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

(see: https://www.fagg.be/sites/default/files/content/afmps_circulaire-omzendbrief_fabricage_fabrication_meddev.pdf)

- The FAMHP has also issued guidelines for in-house fabrication of respiratory devices accessories using 3D printing (https://www.fagg.be/sites/default/files/content/guidance_afmps_3d_printing.docx). These guidelines must make it possible to ensure patient safety when using these products. It contains an overview of potential risks related to the undocumented use of 3D printing technologies. The hospital and its subcontractor are expected to perform a risk analysis and this overview should help them with this analysis. The criteria set out in the circular remain applicable.

Face masks

- Surgical face masks always have to bear a CE-mark in Belgium. However, during the COVID-19 crisis, surgical face masks without a CE mark can be accepted if the face masks comply with other international standards (such as USA: ASTM F2100 or China: YY 0469:2011 and YY/T: 0969-2013). The test certificates based on these other international standards must be able to guarantee a quality comparable to the European standard EN 14683 (see Belgian guidance document on the conditions for the supply and release of surgical masks).
- Surgical face masks are often not accompanied with the necessary declarations, certificates and test reports according to European or international standards. Under normal circumstances, these masks are not released for use because the quality and efficiency cannot be guaranteed. Due to the high need in this crisis situation and in order to reduce the large shortages of masks, these masks can now be subjected to a simplified test protocol, the "Alternative Test Protocol" (ATP), which only takes into account the test results of two important parameters: Bacterial Filtration Efficiency and Differential Pressure. Depending on the results of this test, face masks can be used either as surgical face masks or only as comfort masks.

If the test indicates that the face masks can be released as *surgical face masks*, the following conditions apply:

- the masks may only be used during the crisis period;
- the end-user is explicitly informed that the masks are not tested in full compliance with the EN 14683 standard;
- the end-user is informed about the ATP and its application; and
- the information about the masks released in this way is fully transparent and consultable via the FAMHP website.

If the test indicates that the face masks cannot be released as surgical face masks but only as *comfort masks*, the following conditions apply:

- the end-user is explicitly informed of the fact that the masks has been downgraded as a *comfort mask* and that it is consequently not suitable for use as a surgical mask; and
- on the packaging a warning shall appear that the mask is not suitable for use as a surgical mask.

The FAMHP will make the test results of the masks publicly available. The list of released batches will be regularly updated (see https://www.fagg.be/nl/MENSELIJK_gebruik/gezondheidsproducten/medische_hulpmiddelen_hulpstukken/algemeenheden/guidance_1).

see: https://www.fagg.be/sites/default/files/content/informatie_over_het_alternativetest_protocol_atp_def.pdf.

Belgium

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- For PPE masks, documents such as the EU declaration of conformity and the EU-type examination certificate issued by a notified body must be present in order to demonstrate the conformity of products. In view of the exceptional situation, the Federal Public Service Economy takes into account deviations from these rules for CE marking and conformity assessment as described in the European Recommendation 2020/403.

Exceptionally, masks that do not bear the CE marking can therefore be accepted, provided it is ensured that such products are made available **only to health professionals during the current crisis** and do not enter regular distribution channels.For the evaluation of the conformity assessment certification of face masks, the Federal Public Service Economy now exceptionally takes into account certification or test reports according to equivalent international standards. (European Union: EN 149+A1:2009 FFP2 and FFP3; Australia: AS/NZS 1716:2012 P3, P2; Brazil: ABNT/NBR 13698:2011 PFF3, PFF2; China: GB 2626-2006 KN100, KP100, KN95, KP95; Japan: JMHLW Notification 214, 2018 DS/DL3, DS/DL2; Korea: KMOEL-2017-64 Special, 1st Class; Mexico: NOM-116-2009 N100, P100, R100, N99, P99, R99, N95, P95, R95; USA: 42 CFR 84 N100, P100, R100, N99, P99, R99, N95, P95, R95).

Conformity can be demonstrated by test reports or by a certificate from a third party. If sufficiently documented (certificates, test reports according to a standard, accredited laboratory and all documents can be linked to the batch or goods concerned), this can be accepted as an alternative.

The Federal Public Service Economy is furthermore aware that Chinese face masks are currently being tested by Chinese inspection bodies / laboratories according to European Standard EN 149. Normally, this can only be done by European notified bodies, but if the inspection body figures on the following list from the Chinese authorities, these certificates will be accepted: https://www.cnas.org.cn/english/findanaccreditedbody/04/896740.shtml. Certificates from laboratories that are not on the list will not be accepted

In addition, as a large number of the FFP2 and FFP3 masks do not even have the necessary certificates and test reports to demonstrate unequivocally that they meet the requirements of the relevant standards (as set out under point 1 above), it was furthermore decided that FFP2 and FFP3 masks will only be subject to a simplified testing protocol with only a limited number of essential requirements assessed: the Alternative Test Protocol (ATP). Masks that only meet the requirements of the ATP:

- cannot be put into free circulation;
- cannot be used to comply with the provisions of the Welfare Act and the Codex on Well-being at Work (i.e. the employer's obligation to provide safe equipment to employees and to take measures to ensure the safety of its employees).
- can only be used during this crisis period;
- require special warnings, information and user instructions to be placed on the packaging.

Belgium

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

FFP masks that do not meet the requirements of the ATP, are downgraded as comfort masks. The following conditions then apply:

- the end-user is explicitly informed that the masks have been downgraded and are not suitable as FFP masks;
- a warning to that effect shall appear on the packaging;
- these masks may NOT be used as FFP masks, but only as comfort masks.

Alcohol gels

- Persons authorized to supply medicinal products are now, for a period of 6 months from 18 March 2020, authorised to prepare alcohol gels containing at least 70% alcohol and place these products on the market if these products are intended for human hygiene as part of the fight against the spread of COVID-19. However, these hand alcohol gels may only be sold to healthcare professionals (Royal Decree of 18 March on the preparation and marketing of hand alcohol gels for human hygiene as part of the fight against the spread of COVID-19).

Clinical trials

- Have special measures been adopted?
- What are the main changes?

I. The FAMHP, the Clinical Trial College and the Belgian Association of Research Ethics Committees (BAREC) have issued a Belgian Guidance on the Management of Clinical Trials during the COVID-19 pandemic. This document must be read in conjunction with the European Guidance on Clinical Trials issued on 20 March. The Belgian guidance will be regularly updated in line with the evolution of the pandemic.

The Guideline indicates that priority will be given to any (new) clinical trial application related to the treatment or prevention of COVID-19 infections. For multi-country COVID-19 related trials, the guidance draws attention to the accelerated Voluntary Harmonisation Procedure. For national COVID-19 related trials, it strongly recommends the accelerated CTR Pilot because a single review by the selected evaluating EC (without possible local EC's) is sufficient.

The accessibility of healthcare facilities can be restricted due to COVID-19 measures. When the participating patient cannot go to the investigator site, home nursing and/or contact via phone may be required. Direct shipment of trial medication from sponsor to patient is still not allowed in Belgium, but the medication can be directly shipped to the trial participant under the responsibility of the principal investigator. It is also allowed to send the shipment from the distributor to the patient provided that all the conditions prescribed in the European and the national guidance are respected and that the distributor (not the courier service) is not allowed to work with the details of the clinical trial's participant but just with the trial number of each participant. The trial participant names, address and contact details may never be provided to the sponsor and the distributor. The distributor can only have access to the trial participant's number in order to track the shipment and its preparation, storage at the distributor site. Only the courier service will be able to have the details (name, address) of the trial participants communicated by the PI staff. The only link between distributor and courier service must be the trial participant number.

Only trial medication which is suitable for transport, storage at home and administration at home use is eligible for direct shipment. Moreover, special training must be provided to the participant, care giver, nurse or physician on the home administration of the trial medication. This training must be documented. Documentation is paramount. The responsibilities of each party in the direct shipment of trial medication have to be documented.

Remote source data verification (e.g. providing sponsor with copies of medical records or remote access to electronic medical records) is currently not allowed in Belgium. No exceptions are made to the general prohibition in Belgium.

Belgium

Clinical trials

- Have special measures been adopted?
- What are the main changes?

Furthermore, the government is collaborating with the pharmaceutical industry in the fight against COVID-19. As part of the collaboration the Belgian health regulator has committed to approve COVID related clinical trials within **four days**. The government has also agreed to the establishment of a Belgian Unit to combat infectious diseases. This unit must facilitate the start-up of phase 1 clinical trials and human challenge clinical studies in optimal circumstances in order to accelerate research on COVID-19. The financing hereof will be provided by a public private partnership worth EUR 40 million.

II. The European Commission has also approved a € 4 000 000 Belgian direct grant scheme for the Brussels-Capital region to support COVID-19 related research and development projects in Brussels. This scheme must provide incentives to companies to direct their activities to research and production of certain products, like vaccines, drugs or disinfectants, or treatments, which are most crucial in the current circumstances. In particular, the scheme covers industrial research and experimental development projects and supports 80% of the eligible costs for the duration of the project. Furthermore, undertakings are encouraged to cooperate with each other or with research organisations by benefitting from a 15% bonus when the R&D research project is carried out in cross-border collaboration with research organisations or other undertakings, or when the research project is supported by more than one Member State. (see https://www.concurrences.com/en/bulletin/news-issues/preview/the-eu-commission-approves-eur4-million-belgian-scheme-to-support-covid-19)

III. The FAMHP has issued a national guidance on the Management of Clinical Investigations during the COVID-19 (Coronavirus) pandemic. This guidance should help sponsors of clinical trials for medical devices to manage these trials in the COVID-19 context. Due to the COVID-19 crisis, the visits to healthcare facilities are restricted, an increased demand for health services exists and the availability of investigation staff is often changed. In addition, patients may be required to self-isolate, which makes the maintenance of medical oversight more difficult or even impossible.

- Therefore, the guidance contains a list of possible changes of the trial that sponsors can implement during the COVID-19, such as the conversion of physical visits into phone or video visits or the extension of the duration of the investigation. The involved investigators must agree with these changes. The possible changes mentioned in this guidance can also be initiated by the investigator sites contacting the sponsor. Before the ongoing trial can be changed, also the overall well-being and best interests of the participant must be taken into account.
- The safety of the participant is always of primary importance. Therefore, any changes to the ongoing trial must be based on risk assessment performed by the sponsor in collaboration with the principal investigators. The sponsor must reassess these risks as the situation develops.
- The competent authorities and Ethics Committees must be informed if (i) a new event is likely to have a serious effect on the benefit-risk balance of the trial whereby it is possible that immediate actions are required by the sponsor and investigator to protect the subjects against immediate hazard and (ii) changes are likely to affect the safety or well-being of the participants and/or the scientific value of the investigation but do not require immediate action from sponsor or investigator.
- If re-consent of the participant is needed for the implementation of new urgent changes in the ongoing trial, alternative ways of obtaining such re-consents should be considered during the pandemic e.g. contacting the participants via phone or video-calls and obtaining oral consents supplemented with email confirmation.

Belgium

Clinical trials

- Have special measures been adopted?
- What are the main changes?

- Remote source data verification (e.g. providing sponsor with copies of medical records or remote access to electronic medical records) is still not allowed as it might infringe trial participants' rights. In addition, provision of redacted/ de-identified pdf files will not be acceptable as it puts disproportionate burden on site staff.
- The guidance also indicates that absolute priority is given to any clinical investigation relating to the treatment or prevention of COVID-19 infection or a COVID-19 related illness.
(see https://www.fagg.be/sites/default/files/content/guidance_during_covid19_pandemic_for_ci.pdf)

Czech Republic

Matters	Summary
Specific COVID-19 legislation	On 12 March 2020, the government issued Decision No. 69/2020 Coll., on Declaration of the State of Emergency. This enables the government and other responsible authorities to effectively adopt various decisions and take other measures to address the coronavirus crisis, including the possibility to limit certain fundamental rights and freedoms to the necessary extent. In connection therewith and/or under the Act on Protection of Public Health, a set of general and specific crisis measures has been enacted by the responsible authorities, including measures: ▪ reinforcing the protection of Czech state borders and significantly limiting the right to enter or leave the Czech Republic ▪ closing schools and universities ▪ limiting the right of free movement and prohibiting public gatherings ▪ limiting the operation of various types of enterprises (such as restaurants, retail stores and casinos) ▪ regulating grocery shopping times ▪ obligating persons to wear face masks in public ▪ introducing quarantine rules, including specific rules of quarantine for healthcare providers (HCPs) ▪ obligating HCPs to take measures to prevent COVID-19 spreading, to ensure sufficient capacities to provide treatment to COVID-19 patients and to engage in relevant reporting activities ▪ prohibiting hospital patient visits ▪ obligating telecommunication services providers and banks to collect certain localization data of infected persons ▪ providing economic support to entrepreneurs damaged by the state of emergency and related measures and postponing tax payments ▪ criminalizing the spreading of the COVID-19 disease ▪ putting certain regions into total quarantine for a limited time period The number of related laws and rules is very broad; new rules are adopted and the old are changed, terminated or prolonged on a daily basis.

Czech Republic

Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	During the state of emergency, the state may, for a necessary time and to the necessary extent, limit or interfere with the ownership or related rights of natural persons and legal entities. At this moment, no measure has been taken to convert hotels or other premises into hospital or medical centers. However, various types of medical facilities have been ordered to adjust their activities to have enough capacity for the treatment of COVID-19 patients. The distribution and sale of medicinal products and medical devices is controlled in the following ways: ▪ In the beginning of March 2020, the Ministry of Finance set out maximum prices of FFP3-type respirators, which is CZK 175 (approx. EUR 7) if produced in the EU, or CZK 350 (approx. EUR 14) if produced outside of the EU. On 6 April 2020, the Ministry of Health lifted the ban on the export and cancelled limitations set out for the sales of FFP3 respirators (from 6 March 2020 to 6 April 2020, the respirators could not be sold to anyone except for the state and Czech-based distributors, which could supply such products only to the state and its organizational units). Instead, the Government has ordered specific Czech-based companies manufacturing and/or distributing FFP3 type respirators to provide the Ministry of Health with preferential supplies thereof. ▪ In addition, the Ministry of Health issued a ban on exports of personal hygiene products for hand disinfection outside of the Czech Republic, with the exception of reasonable quantities for personal use. ▪ Further, on 17 March 2020, the government has issued Regulation No. 104/2020 Coll., on Prohibition of Distribution of Pharmaceuticals in connection with the SARS-CoV-2 virus epidemic prohibiting the distribution of any registered medicinal products dedicated to the Czech market abroad, whether to other EU Member States or to third countries. The Government has later narrowed this export ban significantly. Based on the amendment to the above-referred Regulation, as of 2 April 2020, only the registered medicinal products dedicated to the Czech market and enlisted in the Annex of the Regulation, as amended, shall be subject to the export ban for the duration of the State of Emergency. ▪ Recently, the Ministry of Health limited the possibilities of prescriptions of the medicinal product plaquenil, which could be potentially effective against COVID-19. Most HCPs are completely prohibited from prescribing the medicinal product, while HCPs from certain specialist areas (such as dermatovenerology, infections, rheumatology, etc.) may only prescribe the medicinal product in strictly enumerated cases and in stipulated quantities.
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	No specific pricing and reimbursement rules have been adopted so far. For the regulation of prices of FFP3 respirators, please see above.

Czech Republic

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	No specific rules regarding public procurement have been adopted so far.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	Thus far, the only time requirements that have been relaxed in the area of pharmaceutical law on the national level relate to the obligation to ensure regular safety and technical controls (STC) of medical devices. Pursuant to the declaration of the State Institute for Drug Control of 19 March 2020, no sanctions will be used for the use of medical devices without a valid STC, provided that: ▪ the previous STC expired no earlier than three months prior and the state of emergency is still in place ▪ carrying out the STC is not necessary for the further safe use of the medical device ▪ the manufacturer (directly or through a servicing organization) did not prohibit the use of the medical device without a valid STC ▪ records of the medical devices used without a valid STC are kept

Czech Republic

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

In addition to the above, the Ministry of Health has issued several extraordinary decisions to grant approvals of the introduction on the Czech market of various items that could help to eliminate the spread of COVID-19 or to treat patients, including:

- various disinfection preparations (*IPA lékárenská dezinfekce, Lihová lékárenská dezinfekce* and Anti-COVID)
- the experimental medicinal product remdesivir, which is currently being served to first patients
- the non-registered medicinal product "HYDROXYCHLOROQUINE-SULFAAT TEVA", which shall be provided to patients hospitalized for COVID-19 at the time they are released from hospitals
- medical oxygen, which may be temporarily produced from other active substances than those specified in the registration documentation and filled in tanks that are not in compliance with the manufacturing authorization

In line with the Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat, the medical devices and personal protective equipment without CE marking may be placed on the Czech market upon the prior approval of the competent authority. The competent Regional Inspectorate of the Czech Trade Inspection is competent to approve marketing of personal protective equipment manufactured in or imported to the Czech Republic which does not bear the CE marking. Placing on the market of such medical devices should be subject to prior approval of the Czech State Institute for Drug Control.

Further, the Association of Innovative Pharmaceutical Industry (**AIFP**) decided to relax the industry rules governing donations and grants to institutions. Where provided to directly fight the epidemic and for related healthcare, necessary and appropriate donations may be provided to institutions, organizations or associations comprised of HCPs and/or providing healthcare without the need to evidence an unsolicited request. Under the same conditions, items of medical utilities may be provided to HCPs regardless of otherwise applicable limits.

Clinical trials

- Have special measures been adopted?
- What are the main changes?

The Czech State Institute of Drug Control has issued and regularly updated its Opinion on Clinical Trials On Medicinal Products and Ongoing Clinical Trials and To-Be-Commenced Clinical Trials in Light of the COVID-19 Epidemiological Situation.

In this opinion, the State Institute for Drug Control discourages sponsors from commencing new clinical trials or enrolling new trial subjects (patients) in ongoing clinical trials. With respect to ongoing clinical trials, it recommends in particular:

- to replace the physical follow-up visits of patients on site by telephone/virtual visits, where feasible, while ensuring the personal data protection
- to implement the centralized and/or remote monitoring instead of on-site monitoring visits, where feasible, while ensuring the personal data protection
- to postpone carrying out the audits, if not necessary

In addition, the opinion specifies the conditions under which the home delivery of investigational medicinal products (IMP) could be permissible, depending on the type of a particular IMP. In any case, the IMP should be supplied to the trial subject's home directly from the site and upon the prior approval of the investigator. Sending the IMP from the sponsor directly, albeit via third party, is not acceptable since the sponsor may not have access to trial subject's identification details (such as their addresses).

France

Matters	Summary
Specific COVID-19 legislation (as modified)	▪ Decree No 2020-73 dated 31 January 2020 (as modified) ▪ Order of 13 March 2020 authorizing, by way of derogation, the temporary placement on the market and use of certain hydro-alcoholic products used as disinfectant biocides for human hygiene (as modified) ▪ Order of 17 March 2020 supplementing Order of 14 March 2020 laying down various measures to combat the spread of COVID-19 ▪ Order of 19 March 2020 supplementing the Order of 14 March 2020 laying down various measures to combat the spread of COVID-19 ▪ Order of 23 March 2020 prescribing the organizational and operational measures of the health system necessary to deal with the COVID-19 epidemic within the framework of the state of health emergency (as modified) ▪ Law No. 2020-290 of 23 March 2020 as an emergency response to COVID-19 (as modified) ▪ Decree No. 2020-293 of 23 March 2020 prescribing the general measures necessary to deal with COVID-19 within the framework of a state of health emergency (as modified) ▪ Ordinance No. 2020-319 of 25 March 2020 on various measures to adapt the rules for public procurements ▪ Ordinance No 2020-306 of 25 March 2020 relating to the extension of time limits during the period of health emergency and the adaptation of procedures during this same period (as modified) ▪ Ordinance No 2020-460 of 22 April 2020 on various measures adopted to deal with the COVID-19 ▪ Inter-ministerial Instruction No DGT/DGS/DGCCRF/DGDDI/2020/55 of 23 April 2020 relating to the implementation of the European Commission Recommendation (EU) 2020/403 of 13 March 2020 ▪ Exceptional measures applicable to clinical trials during COVID-19 (ANSM website)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	**Has the government established any powers to requisition assets and premises?** **Yes**. Following the publication of the law dated 23 March 2020, the French government is authorized to take measures that, in principle, fall within the scope of the law. Article 2 of Law No. 2020-290 of 23 March 2020, declaring a state of health emergency to manage the current COVID-19 health crisis, includes a new Article L. 3131-15 in the French Public Health Code allowing the government, for the sole purpose of guaranteeing public health, to take some emergency measures, including: ▪ order measures to quarantine persons likely to be affected by COVID-19 ▪ order measures for the placement and maintenance in isolation at their home, or at any other suitable accommodation, of persons affected by COVID-19 ▪ order the requisition of all goods and services necessary for the fight against the health crisis, as well as any person necessary for the operation of these services or the use of these goods ▪ take temporary measures to control the prices of certain products made necessary to prevent or correct the tensions observed on the market for certain products ▪ take all measures to make available appropriate medicines to patients for the eradication of the health crisis

France

Requisition powers

- Has the government established any powers to requisition assets and premises?
- Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?
- Is it controlling the distribution of medicinal products/medical devices?

Pursuant to Article 12 of Decree No. 2020-293 of 23 March 2020, the French Government requisitioned the stocks of several types of respiratory protection masks and anti-projection masks stored or produced in France, at least until the end of the state of health emergency. This restriction does not apply per se to masks imported by companies since 24 March 2020. However, imported masks may also be subject to total or partial requisition; companies wishing to import more than five million of masks per quarter are therefore required to notify the Minister of Health, who may, if necessary, requisition all or part of the products

This restriction does not apply to masks imported by legal entities since 24 March 2020. However, imported masks may be subject to total or partial requisition. Legal entities wishing to import more than 5 million masks per quarter are therefore required to notify the minister of health, who may, if necessary, requisition all or part of the products.

Article 12-1 of Decree No 2020-293 of 23 March 2020 authorizes the State to order the requisition of:

- the raw materials necessary for the manufacturing of the above-mentioned masks
- any healthcare or medico-social establishment and any goods, services or persons necessary for the operation of such establishments, including healthcare professionals
- any goods, services or persons necessary for the functioning of the regional health agencies, the French National Agency for Medicines and Health Products (ANSM) and the National Public Health Agency
- medical biology laboratories and/or the equipment and staff necessary for carrying out additional SARS-CoV-2 test
- some establishments to meet accommodation or storage needs resulting from the health crisis (with the exception of restaurants and drinking establishments for example)

Article 7 of the Order of 23 March 2020 allows the directors of the regional health agencies to authorize, under certain conditions, healthcare establishments to carry out a care activity other than that for which they have been authorized.

Two orders, dated 13 and 23 March 2020, temporarily authorize pharmacists, pharmaceutical companies, cosmetic products companies, biocide product companies and classified installations for the protection of the environment to produce and market biocidal products (hydroalcoholic solutions).

At the request of the French government, the industrial groups Air Liquide, PSA, Schneider Electric and Valeo have formed a consortium to produce more respirators, and the government has asked this group of French manufacturers to study the possibility of increasing production to allow the supply of 10,000 respirators in 50 days, from early April to mid-May.

Is the government converting hotels into hospitals / medical centers for quarantine and self-isolation?

Yes. The French Prime Minister mentioned a few days ago the possibility to use hotels for isolating COVID-19 patients. At this stage, we are not aware of any official measures in this respect.

Moreover, it is to be noted that pursuant to Article 9 of the Order of 23 March 2020, a military hospital has been urgently installed next to the Mulhouse hospital: intention is to help emergency services in the region that are overloaded due to the spread of the COVID-19. Also, pursuant to Article 10 of the Order of 23 March 2020, the French armed forces may be used to transport persons infected with the COVID-19 to other healthcare establishments, in order to provide better care for them.

France

Requisition powers	**Is the government controlling the distribution of medicinal products / medical devices?**
▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	**Yes**. The government has taken several measures to control the distribution of medicinal products, medical devices and biocides in the context of COVID-19: ▪ Maximum prices for the sale of hydroalcoholic gels and of some surgical masks that qualify as medical devices are imposed on companies and pharmacies. ▪ Certain categories of masks (see above), as well as the raw materials necessary for the manufacture of these masks, have been requisitioned to ensure availability and priority access to healthcare professionals and patients. ▪ The off-label use of hydroxychloroquine and lopinavir/ritonavir combination is authorized for patients suffering from COVID-19, under the responsibility of a physician. The export by wholesaler-distributors of medicines containing the lopinavir/ritonavir combination or hydroxychloroquine is prohibited. ▪ The off-label dispensation of the medicine Rivotril® in injectable form is authorized by retail pharmacies for the treatment of patients affected or likely to be affected by COVID-19 whose clinical condition justifies it upon presentation of a medical prescription bearing the wording "Prescription Outside MA in the context of COVID-19." ▪ The dispensation of paracetamol in injectable form is authorized by hospital pharmacies (PUI) upon presentation of a medical prescription bearing the wording "Prescription for COVID-19." ▪ The delivery of paracetamol by pharmacies, without medical prescription, is temporarily limited (one box of paracetamol (500 mg or 1g) per asymptomatic patient, and two boxes (500 mg or 1g) for patients with symptoms (pain and/or fever)). Internet sales of paracetamol, ibuprofen and aspirin medicines are suspended. ▪ Delivery, by pharmacies, of medicines containing nicotine and used in the treatment of tobacco addiction is temporarily limited to the number of boxes necessary for a 1 month-treatment, and internet sales of such medicines are suspended. ▪ The off-label use of certain medicines for veterinary use is allowed in hospitals on human beings. Such medicines, the list of which is set by ANSM, have identical active ingredients, compositions, dosages and routes of administration to those of medicines for human use. ▪ The substitution (under specific conditions) of a medical device by the service provider, the distributor or the dispensing pharmacist is now authorized in the event of a proven shortage of a medical device necessary for the continuity of a patient's care.
Pricing and reimbursement	**Has the price and reimbursement procedures for medicinal products and medical devices been affected?**
▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	**Yes**. Due to COVID-19, the French health authorities prioritize health products to be assessed for price and reimbursement. In practice, the relevant Committee will evaluate, as a priority, medicines indicated in the treatment of COVID-19, as well as first applications for reimbursement (first-time registration or extension of registered indication) for medicines in oncology, paediatrics or serious diseases where there is an unmet medical need. Likewise, the relevant Committee will review, as a matter of priority, medical devices and health technologies that have no equivalent in the treatment of serious diseases or where there is no alternatives and for which an application for a first registration for reimbursement or reimbursement for a new indication is filled. This includes COVID-19 products.

France

Public procurement

- Has the government adopted exceptional public procurement measures?
- Have procedural requirements been relaxed for COVID-19 related medicines and devices?
- Are sanctions foreseen for unfilled orders?

Has the Government adopted exceptional public procurement measures?

Yes. Following Ordinance No. 2020-319 dated 25 March 2020, the government has adopted several exceptional public procurement measures:

- Except where the services covered by the public procurement cannot be delayed, the time limits for the receipt of applications and offers in procedures under way will be extended by a period fixed by the contracting authority sufficient to allow economic operators to submit their applications or offers.
- Where the competitive tendering procedures laid down in the documents relating to the consultation cannot be complied with by the contracting authority, the latter may amend them during the procedure in accordance with the principle of equal treatment of candidates.
- Public procurement contracts expiring between 12 March 2020 and 24 July 2020 may be extended beyond the period provided for in the contract where the organization of a competitive tendering procedure cannot be implemented.
- Public purchasers may modify the conditions of payment of the advance to the public tender holders.
- Several measures are provided for in the event there are difficulties in the performance of the contract (extension of time limits for the performance of the contract by the holder, no penalty where the holder demonstrates that it does not have sufficient means to perform the contract, etc.).

The French Ministry of Economy has also published some recommendations according to which public purchasers, with regard to the exceptional character of the crisis, will not hesitate to acknowledge that the difficulties encountered by their co-contractors are attributable to an act of God (force majeure) or other theories.

Have procedural requirements been relaxed for Covid-19 related medicines and devices?

No. Except for the measures mentioned above, at this stage, we have not identified any specific procedural requirements that have been relaxed for COVID-19 related medicines and public procurement contracts.

Are sanctions foreseen for unfulfilled orders?

No. The above-mentioned legal provision expressly mentions that where the holder is unable to execute all or part of the contract, in particular, where it demonstrates that it does not have sufficient means, the holder may not be sanctioned, have contractual penalties or be held contractually liable on that ground.

France

Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	**Have legal / administrative deadlines been suspended / relaxed?** **Yes.** Following an ordinance dated 27 March 2020, amended by Ordinance dated 15 April 2020, legal/administrative deadlines have been relaxed. ▪ Any authorizations(e.g. health data hosting authorization as per the French Digital Health Agency website) expiring between 12 March 2020 and 24 June 2020 (unless the state of emergency is extended) will be automatically extended until at least 24 July 2020. ▪ During the period between 12 March 2020 and 24 June 2020 (unless the state of emergency is extended), the time limits for any act, appeal, legal action, formality, registration, declaration, notification or publication prescribed by a law or regulation that were due to expire will be suspended. ▪ Moreover, the time limits imposed by the French administration that should have started to run between 12 March and 24 June 2020 are postponed as of 24 June 2020, provided that the time limit, imposed in accordance with the law to comply with measures of any kind, has not expired, and does not result from a court decision. However and as a derogation, the administration (including ANSM, DGCCRF, etc.) could, where justified, decide for the immediate application of such measures within a time limit that it determines taking into account the constraints linked to the state of health emergency. At this stage, existing exemptions from the above-mentioned regime for administrative time limits, which relate to the French Public Health Code, concern only measures taken by the nuclear safety authority. **Have these measures had an impact on MA approvals, public procurement, etc.?** **Yes**. These measures have had an impact on marketing authorization approvals, as well as any other administrative measures related to medicines and medical devices. The impact of these measures on public procurements is described in the section above.

France

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

Has the government relaxed regulatory rules?

Yes.

- Expired FFP2 masks

The Ministry of Labor authorizes, under certain conditions, the use of FFP2 masks with an expiry date not exceeding 24 months.

- Importation of non-CE marked masks, glasses and protective visors to France

Pursuant to an inter-ministerial Instruction dated 23 April 2020, the French Government authorizes the importation to France of non-CE marked masks, glasses and protective visors (whether personal protective equipment or medical device), under certain conditions (which differ depending on whether the product qualifies as PPE or a medical device and whether or not it is intended for healthcare professionals) - provided that these products comply with certain foreign standards recognized as equivalent to the standards that usually apply.

- Use of non-CE marked In Vitro medical devices (IVDs)

Where difficulties in the supply of IVDs prevent medical biology laboratories from carrying out enough examinations to face the health crisis, non-CE-marked IVDs may be used, under restrictive conditions.

- Importation of medicines to France

In order to deal with medicine related supply tensions, medicines with an importation authorization and which list is set by ANSM may be imported to France by the National Public Health Agency without carrying out the finished products' controls required by the French public health code

- Reimbursement conditions for remote consultations

The conditions for the reimbursement of remote medical consultations for COVID-19 infected patients, long duration diseases patients and patients over 70 years of age and pregnant women have been relaxed.

In this context, remote medical consultations will be reimbursed by the French social security system even if they are (i) outside the coordinated care pathway, (ii) conducted by a physician who never saw the patient in a physical consultation before and (iii) performed with any of the technological means currently available to carry out a video consultation (e.g., secure sites or apps, via computers, tablets or smartphones) or by way of an exception performed by telephone without video connection.

Freelance midwives, speech therapists, occupational therapists, psychomotor therapists and masseur-physiotherapists are also, by way of derogation, authorized to conduct remote consultations.

France

Clinical trials

- Have special measures been adopted?
- What are the main changes?

Have special measures measures been adopted?

Yes, special measures relative to clinical trials have been adopted by the French authorities.

- For **new and ongoing clinical trials**:

  ANSM requests clinical trials sponsors to re-evaluate the relevance of setting up new clinical trials, given the priority given to COVID-19 clinical trials.

  ANSM invites clinical trials sponsors to assess the risks associated with the interruption of treatment versus the risks associated with their continuation in a context where the teams at the research sites are heavily solicited. According to the Agency, priority must be given to patients with progressive, life-threatening pathologies. Thus, continued inclusion in a clinical trial may be considered in situations of uncovered medical need and subject to taking into account the potential risks associated with the risk of concomitant COVID-19 infection.

- **For COVID-19 clinical trials**: ANSM, the French Ministry of Health (DGS) and the French ethics committees (CPPs) have put in place fast-track procedures for the initial assessment of the applications. Thus, as an exception to the provisions of article L. 1123-6 of the French Public Health Code and until a date to be set by decree but no later than 31 December 2021, CPPs in charge of processing COVID-19 clinical trials' applications are no longer selected randomly but are directly designated by the French Ministry of Health.

- The French Data Privacy Authority (**CNIL**) is also indicating that its services process these requests for authorization as a matter of priority and within extremely short timeframes in the event that the planned data processing does not comply with the existing fast-track procedures.

What are the main changes?
The main change is the possibility of using fast-track procedures (with the ANSM, ethics committees and the CNIL) to set up COVID-19 clinical trials.

Germany

Matters	Summary
Specific COVID-19 legislation (as modified)	▪ Act on the Protection of the Population against Epidemic Emergencies on a National Scale of 27 March 2020 ▪ COVID-19-Hospital-Relief-Act of 27 March 2020 ▪ Announcement according to Sec. 79 § 1 of the Drug Act of 26 February 2020 ▪ Announcement according to Sec. 79 § 1 of the Drug Act of 16 March 2020 (label waiver for a pneumococcal vaccine) ▪ Bavarian Infection Protection Act of 25 March 2020 (non-exhaustive list)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ Yes, statutory instruments are available and could be used as measures of last resort by regulators on the level of the federal states, as recently invoked by the state of Bavaria which on 16 March 2020 declared a state-wide state of emergency. State Disaster Relief Acts (e.g. in Bavaria Art. 9 BayKSG) empower local enforcement authorities to seize citizens' property. Further measures can be taken authorized through the Federal Infectious Diseases Protection Act (IfSG). Already now, medical clinics in Bavaria have to report their inventory of ventilators to authorities (order issued by the Bavarian secretary of health on 17 March 2020). ▪ In Bavaria, one vacant hotel near Munich will be converted to treat 120-180 Covid19 patients, according to reporting of 3 April 2020. Except for Bavaria, at present, there is only an earlier unspecific and legally non-binding "plan" on the subject of hotel conversion. On 17 March 2020, the federal and state governments decided on an emergency plan for hospitals in Germany to combat the spread of the coronavirus. The resolution states that "additional capacities can be built up for the numerous easier treatment procedures by upgrading, expanding and converting rehabilitation facilities, hotels or larger halls". ▪ Not yet, but based on the aforementioned Act on the Protection of the Population against Epidemic Emergencies on a National Scale, the Federal Ministry of Health has proposed on 6 April 2020 and 7 April 2020, respectively, two regulations. The draft regulation of 6 April 2020 ("SARS-CoV2 Drug Supply Regulation") provides that: ▪ medical supplies, including medicinal products, their active substances and excipients, medical devices, diagnostics, personal safety equipment and disinfectants, may become subject to direct oversight by the Ministry of Health ▪ pharmaceutical companies may be required to report to the Ministry of Health the existing stock, production, distribution and prices of such concerned medical supplies ▪ the Ministry of Health may restrict the trade, dispensing and pricing of such medical supplies. Where necessary to ensure the continued supply of the public, the Ministry of Health may prohibit the sale of such products and compel manufacturers to supply such medical supplies to the government (federal, state, or local) or other entities instead. The price for such compelled supplies will be set by the government, and shall be linked to the regular sales price The draft emergency regulation proposed by the Ministry of Health on 7 April 2020 ("Medical Need Health Care Assurance Ordinance - MedBVSV") provides: ▪ that the Federal Ministry may procure, store, manufacture and market products of medical need directly or through commissioned bodies; and ▪ for numerous exemptions from pharmaceutical legislation requirements, notably regarding labelling, package leaflets, expiration dates and so on

Germany

Matters	Summary
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Under the aforementioned draft regulation of 6 April 2020 (draft SARS-CoV-2 Drug Supply Regulation), among other measures: ▪ pharmaceutical companies may be required by the Ministry of Health to supply products at a price set by the government (see above) ▪ pharmacies are granted more latitude when filling prescriptions by allowing, if necessary, the dispensing of medicines of a different manufacturer, different size, or different strength than prescribed; and ▪ certain compounding requirements are relaxed to the extent necessary for pharmacies to ensure the supply of the public with medicinal products (including controlled substances), medical devices and other pharmacy-typical products.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	The effects of COVID-19 do not per se allow for a deviation from public procurement law. However, a more lenient approach may apply during an interim period. ▪ procurements which cover an urgent need to contain the corona pandemic (e.g. procurement of respiratory masks, servers or buildings/conversion work to create new hospital beds, etc.), urgency justifies the implementation of accelerated procedures. ▪ Procurements to meet an extremely urgent demand to contain the corona pandemic, for which it can be proven that even the accelerated procedures take too long, **directs awards** pursuant the negotiated procedure without a call for tenders are justified. For instance, the German government has initiated under these rules on 2 April 2020 a procurement for the supply of personal safety equipment. With a view to incentivize the ramp-up of domestic production, only personal safety equipment manufactured in Germany qualifies.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ According to a proposal for an MDR amendment from the EU Commission of April 3, 2020 (2020/0060(COD)), the key date of 26 May 26 2020 is to be pushed back by one year to 26 May 2021 throughout the MDR. This would in the first place change the date of the MDR application to 26 May 2021, but also the timelines for the CTS and (anyway in doubt) Eudamed. The deadline for making available and putting into service of certain legacy devices taking advantage of the transition period until 25 May 2025 (Art. 120(4)) will also be deferred by one year.

Germany

Matters	Summary
Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	▪ On 20 March 2020, the German FDA (**BfArM**), in coordination with the Health Ministry, announced by general ruling that certain deviations from the content of the marketing authorization would be permitted for alcoholic medicinal products authorized exclusively for hand disinfection. This measure is limited until 30 June 2020 and serves to ensure the supply of these drugs, whose virucidal effect and safety are still guaranteed. Similarly, three general decisions by the competent authority on biocidal products taken on 4 March 2020, 20 March 2020, and 2 April 2020, have allowed the manufacturing and placing on the market of hand disinfectants containing certain biocidal active substances without a product registration and under relaxed manufacturing and labelling requirements. ▪ Exemptions **from the marketing authorization requirement for medicinal products, or from any other compulsory licenses**: Individual case by case exemptions on the level specific MAs or other specific permits may be granted by competent state authorities through special administrative orders. So far local authorities have only occasionally taken advantage of the conferred exemption authority (State of Saxony, order of Apr. 1: MA and label waiver for a pneumococcal vaccine). Regarding medical devices, German Health Ministry, by letter of 13 March 2020, instructed the heads state-level surgeon generals that specific protective equipment (FFP masks, medical masks, protective gowns) shall be deemed to have clearance for being placed on the market even without CE mark if those products had obtained marketing approval (may be lawfully marketed) in the U.S., Canada, Australia or Japan (China is not mentioned). Otherwise (in the absence of CE marking or recognition of the aforementioned third-country approvals), "suitable bodies", which may be Notified Bodies, are to inspect conformity with EU safety/protection standards. Notified Bodies Dekra and IFA have published a condensed checklist for inspecting basic technical EU compliance of COVID-19 pandemic face masks.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	▪ Sponsors may probe options for re-organizing studies in a way that investigational products are administered to study patients in the patients' homes (possibly assisted by study nurses) rather than at the study centers. According arrangements with regulators and IRBs might be legally supported by the EU guidance on Clinical Trial Management of 27 March 2020 jointly issued by EMA, CTFG, CTEG, GCP Inspectors Working Group, supplemented by an according BfArM guidance. A number of measures may be considered: # Remote Monitoring / Visits / Auditing, # Shipment of study medication ex trial center or ex sponsor site, or through licensed pharmacies, directly to subjects for at-home application, # facilitated Informed Consent (orally obtained), # transfer of patients, # leniency of Protocol Deviations.

Hungary

Matters	Summary
Specific COVID-19 legislation	▪ Governmental Decision No. 1101/2020 (III. 14.) on Further Necessary Measures Regarding Protection Against COVID-19 Pandemic ▪ Governmental Decision No. 1109/2020 (III. 18.) on the Professional Support for the Emergency Operation of Certain State-Owned and Private Companies of Strategic Importance ▪ Governmental Decree No. 48/2020 (III. 19.) on the Measures to Prevent Pandemic Resulting Mass Epidemic with Danger for Safety of Life and Properties and to Decline its Consequences, and to Protect Health and Life of Hungarian Citizens ▪ Governmental Decree No. 63/2020 (III. 24.) on the Measures Regarding Medical Researches to Prevent Pandemic Resulting Mass Epidemic with Danger for Safety of Life and Properties and to Decline its Consequences, and to Protect Health and Life of Hungarian Citizens ▪ Governmental Decree No. 64/2020 (III. 24.) on the Measures Regarding the Export of Certain Medicinal Products to Prevent Pandemic Resulting Mass Epidemic with Danger for Safety of Life and Properties and to Decline its Consequences, and to Protect Health and Life of Hungarian Citizens ▪ Governmental Decree No. 67/2020 (III. 26.) on the Measures Regarding Medicine Supply During the Prevention of Pandemic Resulting Mass Epidemic with Danger for Safety of Life and Properties and to Decline its Consequences, and to Protect Health and Life of Hungarian Citizens ▪ Governmental Decree No. 72/2020 (III. 28.) on the Hospital Commander and the Protection of the Medical Health Supplies ▪ Governmental Decree No. 82/2020. (IV. 3.) on the Measures to be taken regarding Medical Devices and Personal Protective Equipment during the State of Emergency ▪ Governmental Decree No. 83/2020. (IV. 3.) on Healthcare Measures to be taken during the State of Emergency
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ Governmental Decision No. 1101/2020 was issued to set up an action committee **(Committee)** to protect and secure the operation of companies of strategic importance. The Committee identified the relevant companies and prepared to take control over those companies if needed. ▪ We are not yet aware of any measures of the government of Hungary that may aim to convert hotels into hospitals/medical centers for quarantine and self-isolation. However, some hospitals in the capital city of Budapest and certain Hungarian country towns have been nominated as centers for quarantine. In addition, all hospitals in Hungary have implemented special measures due to the pandemic and they have been preparing for the acceptance of patients with COVID-19. Furthermore, the construction of a mobile epidemic hospital has started in a Hungarian country town called Kiskunhalas. ▪ Pursuant to Governmental Decision 1109/2020, the Committee will place military personnel at companies of strategic importance to facilitate effective communication and cooperation between the companies, the government and the Committee. ▪ Military personnel have already visited certain pharmaceutical companies with manufacturing facilities in Hungary and a pharmaceutical wholesaler; however, further actions have not yet been taken. ▪ The Committee might have an impact on the operation of pharmaceutical companies and wholesalers and, consequently, on the production and distribution of medicinal products and/or medical devices in the near future.

Hungary

Requisition powers

- Has the government established any powers to requisition assets and premises?
- Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?
- Is it controlling the distribution of medicinal products/medical devices?

- Although it is not related to the Committee and the military personnel, it must be noted that Governmental Decree No. 64/2020 laid down an export ban for the hydroxychloroquine-sulfate active substance and medicinal products manufactured with this substance, with the following exceptions:
  - the export of the medicinal products intended for humanitarian aid based on international obligations and subject to the specific authorization of the government of Hungary
  - the export of the medicinal products of which an adequate amount is available in Hungary subject to a certificate issued by the State Healthcare Center confirming this fact
  - The National Institute of Pharmacy and Nutrition (**OGYÉI**) also published a decision on the same export ban based on the Medicine Economy Act.
- On 3 April 2020, the OGYÉI confirmed the shortage of medicinal products containing propofol and prohibited the export of such medicines from Hungary from 12:00 AM on 3 April 2020 until six months to prevent supply disruption.
- Medical Devices and Personal Protective Equipment (**PPE**):
  - The competent authority for PPEs (i.e. the Work Safety Department under the competence of the Technology and Innovation Ministry of Hungary) published information on its official website regarding the implementation of Regulation (EU) 2020/402 of 14 March 2020, based on which the exportation of certain PPE products outside of the EU shall be subject to an export authorization. These products include protective spectacles and visors, face masks, mouth-nose-protection equipment, protective garments, gloves as listed in annex 1 of the Regulation. In Hungary, the competent authority that issues the export authorization is the Department of Commerce, Military Engineering, Export Control and Precious Metal Certification of the Budapest Government Office. Authorizations are valid until 6 weeks from the promulgation of the Regulation.
  - According to the European Commission's decision, Hungary obtained the customs tariff and VAT exemption for imported face masks, ventilators and other protective health care supplies imported from outside the EU due to the state of emergency. Exemption shall not automatically apply to all protective health care supplies as only products distributed free of charge can be exempted from taxation.
  - Hungary has recently received significant quantity of face masks and other PPE from China.
- Governmental Decree No. 72/2020. (III. 28.) on the Hospital Commander and the Protection of the Medical Health Supplies laid down that hospital commander may be assigned in Hungary to certain healthcare institutions providing inpatient health care services to monitor the use of medical health supplies. The hospital commander may make recommendations to protect the health care supplies which must be implemented by the head of the given healthcare institution. However, it is important to note that the hospital commander shall not make any recommendations and decision on professional medical issues. If it is necessary to protect the medical health supplies, the head of the health care institution may terminate the agreements concluded for personal and property protection of the given institution. In case of such termination, the director of the health care institution must conclude an agreement for protection of the medical health supplies. However, instead of the conclusion of such agreement, or where appropriate together with this agreement, the Hungarian Defence Forces may be involved to ensure the protection of the medical health supplies.

Hungary

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	▪ According to Governmental Decree No. 67/2020, if the approval of OGYÉI is missing, the National Health Insurance Fund of Hungary (**NEAK**) may submit a request directly to OGYÉI for a resolution regarding whether the requests for the subsidy of medicinal products under special consideration may be accepted and approved by NEAK. ▪ We are not aware of any further information on price and reimbursement issues regarding the state of emergency due to COVID-19.

Public procurement
 	
▪ Has the government adopted exceptional public procurement measures?
▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices?
▪ Are sanctions foreseen for unfilled orders?
	▪ Section 4 of Governmental Decree No. 48/2020 (**Decree**) laid down special rules specifically on procurements in connection with the protection against COVID-19. In addition, the Public Procurement Authority of Hungary published information in Hungarian regarding the Decree mentioned above and the state of emergency affecting public procurements.
	▪ If a public procurement is related to medicines and medical devices that may be in connection with the protection against COVID-19, the rules of the above Decree will be applied for their procurement as well. Please see the following examples of the major issues of the Decree:
	  ▪ The economic operator may accomplish the procurement differently from the general rules of public procurements, if the prime minister approved it in the frame of individual exemption, based on the request for a procurement regarding the protection against COVID-19.
	  ▪ If the value of the procurement in connection with the protection against COVID-19 may reach or exceed the national amount limits, the economic operator may be entitled to accomplish this procurement with the request for three offers, if possible.
	  ▪ If a framework agreement/contract is in force as the result of centralized public procurement, the procurement in connection with COVID-19 and through this agreement will take precedence. In addition, the economic operator will be exempted from paying the fee for the entities entitled to conduct centralized procurements.
	  ▪ Framework agreements may be amended to the extent and in the manner required by the emergency.
	  ▪ In case of exceptional urgent cases, an economic operator may be directly invited to tender regardless of the rules set out in the above Decree.
	▪ We are not aware of any sanctions for the infringement of the above Decree. However, if the Decree may not be applied, other relevant legislations, e.g., Act CXLIII of 2015 on Public Procurement, and their sanctions will be applicable in respect of the infringement's nature.
	▪ The Decree No. 82/2020. (IV. 3.) laid down that if a central budgetary institution (**institution**) or a company operating under the majority state interest (**company**) may conduct procurement to acquire medical devices and personal protective equipment (**devices**) to fulfill the nationwide demand on medical device AND the acquired devices may be stored in the central storage of the National Healthcare Services Center (**ÁEEK**), the company and the institution shall be considered as the representative of the ÁEEK in such procurements. These provisions shall be applied for the ongoing procurements as well.

Hungary

Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ Extraordinary judicial vacation has been introduced in the Hungarian courts during the state of emergency. However, this will not affect the administrative deadlines of the national authorities. There is no information available on whether the relevant authorities (OGYÉI, NEAK and the Public Procurement Authority of Hungary) may have amended their general administrative deadlines. However, please see some changes in the following cases. ▪ Public healthcare certificates: Should the validity of public healthcare certificates expire after 1 March 2020 during the state of emergency due to COVID-19, the validity of public healthcare certificates will be extended by 90 days after the expiration date (the competent authority is NEAK). ▪ The clinical trial requests related to the treatment or prevention of COVID-19 will be evaluated in an expedited procedure by OGYÉI (the competent authority). ▪ According to Governmental Decree No. 67/2020, the treating physician will notify OGYÉI of the prescription of medicines with prescription for an unauthorized indication (off-label use) retrospectively, within 90 days after the end of the state of emergency at the latest.

Relaxation of regulatory rules
 	
▪ Has the government relaxed regulatory rules?
	▪ Prescription of medicines:
	  ▪ Specialists' medical recommendations for medicines and medical aids to be prescribed with increased and special reimbursement will remain valid for the duration of the state of emergency and for 90 days after the end of the state of emergency.
	  ▪ Healthcare providers should provide patients with more prescriptions. Consequently, patients may receive the quantity available in the pharmacy and be able to purchase the missing amount later.
	▪ Visiting ban: Medical sales representatives and persons monitoring clinical trials will not visit institutions providing inpatient and outpatient care or general practitioners.
	▪ Public healthcare certificates: Please see our input indicated under the section "Legal deadlines."
	▪ Governmental Decree No. 67/2020 laid down the following:
	  ▪ The existence of patient care interests deserving special consideration* must be presumed during the state of emergency.
	  ▪ OGYÉI may determine the shortage of medicines based on the available information without the notification submitted by the marketing authorization holder or the distributor to OGYÉI on the shortage. OGYÉI will publish the list of medicines affected by the shortage.
	  ▪ OGYÉI will publish a list of the substances of "medicines with prescription for an unauthorized indication" (off-label use). OGYÉI has already published this list with the following substances: hydroxychloroquine-sulfate, chloroquine, remdesivir, lopinavír, ritonavir, ruxolitinib, azithromycin and oseltamivir. If a medicine or a substance is not included in this list, their prescription or use for an unauthorized indication for the purpose of the treatment of COVID-19 will be authorized by OGYÉI based on a request submitted. OGYÉI will process this request with priority.
	  ▪ For the above substances neither preliminary notification, nor prior authorization of the OGYÉI is required to off-label use for the treatment of diseases caused by COVID-19, as written above. However, a retrospective notification on off-label use shall be submitted to OGYÉI within 90 days after the end of the state of emergency.

Hungary

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

***** *Patient care interests deserving special consideration mean a situation where a medicinal product that does not have a valid marketing authorization in Hungary offers the potential of successful treatment, and no medicinal product currently on the Hungarian market has the capacity of achieving such success, and if access to a medicinal product with marketing authorization for a specific indication is inhibited to an extent where it would likely delay the treatment prescribed for the patient, hence causing a disproportionately great risk of irreversible health impairment.*

- According to Governmental Decree No. 63/2020, the information required by law may be provided to the person with full legal capacity involved in a non-interventional trial ("trial") relating to the COVID-19 pandemic through telecommunication devices. The person may also provide or withdraw their consent to participate in the trial through a telecommunication device.
- The dissemination of Direct healthcare professional communications (**DHPCs**) according to OGYÉI's decision: DHPCs and important risk minimization guidelines should only be disseminated electronically where possible. They should also be provided to the professional associations requested to assist in the digital dissemination. However, as long as dissemination by post is possible, OGYÉI will disregard the submission of the confirmation receipts to OGYÉI. Therefore, drug safety materials may be delivered by regular mail. Personal distribution of DHPCs is not considered appropriate during this period.
- Rules of Decree No. 83/2020:
  - The Minister of Interior and the Minister of Human Capacities may access and process – maximum until the end of the state of emergency - the personal data managed by the patient care and the public health administration body and processed in the Electronic Healthcare Service Platform.
  - The alcohol required for the manufacture of biocide products used for disinfection may be obtained as an active substance from any sources.
  - The certification on the payment of the given administrative fees may not be examined by OGYÉI as a precondition for the assessment of an application submitted.

Hungary

Clinical trials

- Have special measures been adopted?
- What are the main changes?

OGYÉI is the relevant authority regarding clinical trials. OGYÉI publishes information on the continuity of clinical trials during the coronavirus pandemic in compliance with the harmonized EU-wide recommendation on the conduct of clinical trials during the COVID-19 pandemic.

- General and specific considerations are included in OGYÉI's recommendation related to certain issues such as the authorization practice, study visits, monitoring and the supply of investigation medicinal products.
- The following are some examples of major measures raised by OGYÉI's recommendation:
  - The most important issue is to ensure the continuity of clinical trials.
  - In-depth risk assessment of ongoing trials will be performed and measures will be taken to prioritize the patient's safety and data validation. In case of conflict, the patient's safety must be the priority.
  - Risk assessment must be repeated and properly documented, if needed.
  - The use of electronic patient information and consent forms is not allowed.
  - If wet ink signature may only be obtained with difficulty, alternative documentation tools (such as printed email) may be applied.
  - Based on the risk assessment, the sponsor and the principal investigator will consider postponing or stopping the site visits, or will perform them via telephone.
  - Visits performed in a patient's home are not supported by OGYÉI.
  - A patient's enrolment will be considered stopped during the state of emergency.
  - OGYÉI does not support the study drug being provided by the sponsor directly to the patient's home, as the sponsor does not know the patient's personal data (name, address, etc.).
  - If the transfer of study drugs requiring special storage conditions must be changed, the way of the amended transfer will be documented (e.g., in a refrigerator bag). However, OGYÉI will not be notified of this amendment.
  - OGYÉI will evaluate the clinical trial requests related to the treatment or prevention of COVID-19 in an expedited procedure.

Italy

Matters	Summary
Specific COVID-19 legislation	▪ Decree of the President of the Council of Ministers dated 1 April 1 2020 implementing Decree-Law No. 19 dated 25 March 2020 on urgent measures to deal with the epidemiological emergency by COVID-19 ▪ Decree-Law No. 19 dated 25 March 2020 on urgent measures to deal with the epidemiological emergency caused by COVID-19 ▪ Order of the Head of the Civil Protection Department No. 655 dated 25 March 2020 on further urgent measures for the emergency relating to the health risk connected with the occurrence of diseases from transmissible viral agents ▪ Decree of the President of the Council of Ministers dated 22 March 2020 on further measures to implement Decree Law No. 6/2020 introducing urgent measures for the containment and management of the epidemiological emergency caused by COVID-19 ▪ Order of the minister of health and the minister of internal affairs dated 22 March 2020 prohibiting all persons from moving from one municipality to another, except for proven urgent professional needs or health reasons ▪ Decree Law No. 18 dated 17 March 2020 on measures to strengthen the national health service and provide economic support to families, workers and businesses in connection with the COVID-19 epidemiological emergency ▪ Workplace Safety Protocol signed on 14 March 2020 by trade unions and industry associations ▪ Decree of the President of the Council of Ministers dated 11 March 2020 on further measures to implement Decree Law No. 6/2020 introducing urgent measures for the containment and management of the epidemiological emergency caused by COVID-19 ▪ Decree of the President of the Council of Ministers dated 9 March 2020 on further measures to implement Decree Law No. 6/2020 introducing urgent measures for the containment and management of the epidemiological emergency caused by COVID-19 ▪ Decree of the President of the Council of Ministers dated 8 March 2020 on further measures to implement Decree Law No. 6/2020 introducing urgent measures for the containment and management of the epidemiological emergency by COVID-19 ▪ Decree-Law No. 9 dated 2 March 2020 on urgent supporting measures for families, workers and businesses in connection with the epidemiological emergency caused by COVID-19 ▪ Decree-Law No. 6 dated 23 February 2020 on urgent measures for the containment and management of the epidemiological emergency caused by COVID-19
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	Pursuant to Decree Law No. 18 dated 17 March 2020, the head of the Department of Civil Protection can order the requisition, either for use or title, of health and medical-surgical facilities and equipment, as well as movable properties of any kind belonging to public or private persons necessary to deal with the health emergency, and also to ensure their supply to healthcare structures located in the Italian territory and to increase the number of specialized beds in wards for hospitalization of patients affected by said disease. Furthermore, pursuant to the above Decree Law prefects may order the requisitioning of hotels or other buildings with similar characteristics to house individuals under health surveillance. Decree Law No. 18 dated 17 March 2020 also provides for ad hoc funding through non-repayable and operating grants, as well as subsidized loans, to ensure the manufacturing and supply of medical devices and personal protective equipment in light of the inadequate availability of same during the COVID-19 emergency period. To this end, the Decree Law authorizes the expenditure of EUR 50 million for 2020 and entrusts an extraordinary commissioner, appointed by decree of the President of the Council of Ministers, with the task of approving the disbursement of the relevant funding.

Italy

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	We are not aware of any legislative/regulatory provision affecting the price and reimbursement procedures for medicinal products and medical devices.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	CONSIP, the Italian central purchasing entity, has been appointed the "responsible body" for public procurement activities related to the health emergency. Pursuant to Article 63, paragraph 2, letter c), of Legislative Decree No. 50/2016 on Code of Public Contracts, COMSIP has been allowed to carry out negotiated procedures without prior publication of the tender notice, aimed at entering into framework agreements for supplies required by healthcare structures. In particular, in order to deal with the strong demand for and the shortage of medical devices intended for the current health emergency, CONSIP, in accordance with the Department of Civil Protection's directives, has already awarded several urgent negotiated procedures, among which are those for the supply of medical devices for intensive and sub-intensive care, swabs and diagnostic kits, personal protective equipment and electro-medical equipment. Moreover, with Order No. 655 dated 25 March 2020 the Head of the Civil Protection Department introduced the possibility for Local Authorities to award public contracts for the supply of services/equipment in derogation from the deadlines and methods for the publication of the tender notice provided for by Articles 60, 61, 72, 73 and 74 of Legislative Decree No. 50/2016 on Code of Public Contracts. We are not aware of any specific sanctions for unfulfilled orders other than those that normally apply under the Legislative Decree No. 50/2016 on Code of Public Contracts.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	Article 103 of Decree Law No. 18 dated 17 March 2020 provides for the suspension of all terms of administrative proceedings pending at, or started after, 23 February 2020 until 15 April 2020. With the circular letter dated 23 March 2020, the Ministry of Infrastructures and Transports clarified that the above suspension also applies to procurement procedures for the award of public contracts.

Italy

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

With Decree Law No. 18 of 17 March 2020, the Italian Government introduced exceptional measures allowing the manufacturing, import and placing on the market of surgical masks for medical use (medical devices) and personal protection equipment in derogation from the existing legislation.

Pursuant to Article 15 of the Decree Law, manufacturers, importers and those who place on the market surgical masks intending to make use of the above-mentioned derogation, must send to the National Health Institute (*Istituto Superiore di Sanità*) a specific application along with a self-certification whereby they certify, under their own exclusive responsibility, the technical characteristics of the masks and declare that the same fulfill all safety requirements established by the in-force regulations. No later than three days from the issue of the self-certification, manufacturers and importers must also provide the National Health Institute with all elements useful to validate the surgical masks that are the subject of the self-certification.

Within three days from the receipt of the above-mentioned elements, the National Health Institute will express its opinion on whether the surgical masks comply with the in-force regulations. If the National Health Institute resolves that the surgical masks do not comply with the applicable in-force regulations, the relevant manufacturer will immediately cease their production and the importer will be prevented from placing them on the market.

The above-mentioned procedure also applies to personal protection equipment, with the only difference being that for these products the authority responsible for receiving/reviewing the self-certification and the supporting documentation and for assessing compliance with the in-force regulation is the National Institute for Insurance against Accidents at Work (*Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro (INAIL)*).

The possibility to make use of said derogation is limited to the duration of the state of emergency resulting from the COVID-19 outbreak (currently, six months from 31 January 2020) with the consequence that, at the end of the emergency period, companies intending to manufacture, import and place on the market surgical masks and personal protection equipment will comply with standard rules.

Italy

Clinical trials

- Have special measures been adopted?
- What are the main changes?

On 12 March 2020 the Italian Medicine Agency (**AIFA**) published guidelines addressed to pharmaceutical companies, non-profit sponsors and CROs for the management of clinical trials in light of the containment measures adopted by the Council of Ministers and the Ministry of Health preventing trial subjects from reaching the relevant clinical sites.

In view of the above-mentioned measures and in order to guarantee, where possible, the continuity of the trials while reducing contacts between medical staff and patients, the guidelines also provide for the following exceptions to/derogations from the existing rules on clinical trials.

- As regards the submission of applications for authorization and substantial amendments to clinical trials, the postponement of deadlines for the filing of paper documentation and the introduction of specific procedures for the submission of documentation relating to clinical trials for the treatment of COVID-19.
- In light of the difficulties of patients in reaching trials sites, and in order to guarantee therapeutic continuity, the possibility, subject to notification to the competent ethics committees, of carrying out certain clinical trial activities (e.g., delivery of investigational products, performance of medical examinations, management of adverse reactions) outside of the same sites and, therefore, directly at the patient's home or at a healthcare establishment other than the authorized trial site.
- As regards the conduct of the trial outside of the site and the administration of investigational drugs at the patients' home, the possibility of using third-party providers to deliver drugs directly from the hospital pharmacy to trial subjects, in accordance with the instructions of the hospital pharmacy and the principal investigator, and provided that safety conditions applicable to the transport, storage and administration of investigational products are complied with.
- The application, under the principal investigator's responsibility, of exceptional measures for the remote monitoring and clinical management of patients by the trial site's staff, as well as the possibility for the sponsor to directly enter into contracts with companies/providers specializing in services for the clinical management of patients, without prejudice to the need to obtain the specific opinion of the Data Protection Authority in case such forms of monitoring involve sensitive data.
- Last, the possibility for the sponsor to reimburse directly any exceptional costs incurred by trial subjects in light of the measures aimed at protecting them.

The validity of the above-mentioned measures is limited to the COVID-19 emergency period.

Moreover, Decree Law No. 18 of 17 March 2020 allows the AIFA to access all data of clinical trials and compassionate use programs on medicines for patients with COVID-19 in order to improve the coordination and analysis capability of available scientific evidence. The Decree Law No. 18 also provides that the relevant study protocols will be subject to the preliminary assessment by the AIFA's Technical Scientific Committee and to the opinion of the Ethics Committee of the National Institute for Infectious Diseases Lazzaro Spallanzani of Rome, in its capacity as the single national ethics committee.

Kazakhstan

Matters	Summary
Specific COVID-19 legislation	▪ The Code on Population Health and Healthcare System No. 193-IV (**Healthcare Code**). The Healthcare Code provides general regulations for quarantine and special protection measures. ▪ The Law on State Emergency No. 387-II (**State Emergency Law**). The State Emergency Law sets forth grounds for requisitions of assets and premises. ▪ The State Property Law No, 413-IV (**State Property Law**). The State Property Law sets forth a procedure for the requisition of assets and properties. ▪ Minister of National Economy Order No. 239 dated 20 March 2015 On the Quarantine Procedure (**Order 239**). ▪ Presidential Decree No. 285 dated 15 March 2020 On State Emergency in the Republic of Kazakhstan (**Decree 285**). Decree 285 introduced the state emergency in Kazakhstan from 16 March until 15 April 2020 because of COVID-19, protection measures, including quarantine, and ordered the provision of the required state funds for protection measures from state financial and asset funds. ▪ Presidential Decree No. 286 dated 16 March 2020 On Economic Stability Measures (**Decree 286**). Decree 286 granted the government the right to adopt measures to support the local economy, including a simplified procurement procedure. ▪ Governmental Resolution No. 127 dated 20 March 2020 On Implementation Special Procurement Rules (**Resolution 127**). Resolution 127 implemented simplified procurement rules on acquisition goods and services while the state of emergency is in place. The procurement can be performed through the request of bids or from a single source. ▪ Prime-Minister Decree No. 10-p dated 27 January 2020 on Establishment of Special Interministerial Commission On Protection Against COVID-19 (**Commission**). ▪ Prime-Minister Decree No. 14-p dated 29 January 2020 On Adoption of the Plan on Protection Measures Against COVID-19.
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ The State Emergency Law sets forth grounds for requisitions of assets and premises. ▪ We are not aware of any measures of the Kazakhstani government that may aim to convert hotels into hospitals/medical centers for quarantine and self-isolation. All centers for quarantine are located in state hospitals and state residences. No construction of mobile epidemic hospitals has started in Kazakhstan. ▪ Pursuant to Decree 285, military personnel took under their protection anything of strategic importance to facilitate effective communication. ▪ The Commission might impact on the operation of local pharmaceutical companies and wholesalers and, consequently, on the production and distribution of medicinal products and/or medical devices in the near future. ▪ The police monitor unauthorized sales of face masks and antiseptics and confiscate them from unofficial traders.

Kazakhstan

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	We are not aware of further information on price and reimbursement issues regarding the state of emergency due to COVID-19.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ Resolution 127 laid down simplified procurement rules on acquisition goods and services, specifically on procurements in connection with the state of emergency against COVID-19. ▪ All acquisitions may be procured through requests of bids or from a single source. Resolution 127 does not provide special rules on acquisitions of medicines and medical devices. ▪ The procurement rules for acquisition medicines and medical devices No. 1729 dated 30 October 2009 provides a special procedure on acquisition of medicines and medical devices during epidemic and/or state emergency. This procedure presumes that single state distributor acquires the medicines and medical devices though a request of bids. According to information published on the website of single state distributor for medicines and medical devices SK-Pharmacia LLP, since 19 March 2020, the latter acquires medicines with or without marketing authorization in the Republic of Kazakhstan through this procedure. If the medicines and medical devices have no local marketing authorization, the supplier has to submit a permit from the Ministry of Healthcare on the importation of such products. An epidemic is one of the grounds to obtain such permit. ▪ The Administrative Code and the Criminal Code may apply to offenders of Resolution 127.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ A major portion of state officials has been sent to remote work because of the state of emergency. The quarantine introduced in Nur-Sultan, Almaty, Karaganda, Aktau and five other small towns closed all state offices, excluding central governmental offices. However, it is unclear whether the state of emergency and quarantine will affect the administrative deadlines of the national healthcare authorities. ▪ Since 19 March 2020, the National Center for Expertise of Medicines and Medical Devices works remotely and accepts all documents through the governmental digital communication service egov.kz and through emails. There are no publications in open sources suggesting that the National Center for Expertise of Medicines and Medical Devices will suspend its work or its administrative procedures. ▪ SK-Pharmacia LLP is continuing with the procurement of medicines and medical devices as discussed above. There are no publications in open sources suggesting that SK-Pharmacia LLP will suspend its operations during strict quarantine on 31 March-5 April 2020, which was introduced in Nur-Sultan, Almaty, Aktau, Karaganda and five other small towns in the Karaganda region.

Kazakhstan

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	There has been no relaxation of regulatory rules except those discussed above by the government, the Commission or the Ministry of Healthcare.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	No changes to the clinical trial procedure have been introduced. We understand that Kazakhstan expects the creation of a COVID-19 vaccine; then, it may establish a simplified clinical trial for this vaccine. As an alternative, if the COVID-19 vaccine has the Eurasian Economic Union (EAEU) marketing authorization, this authorization will apply to Kazakhstan under the EAEU Treaty.

The Netherlands

Matters	Summary
Specific COVID-19 legislation	▪ Ministerial regulation of the Minister for Medical Care of 28 January 2020, with reference 1643096-201442-PG, under Article 20 of the Public Health Act (Regulation 2019-nCOV); ▪ Decree of the Ministry of Health, Welfare and Sport of 19 March 2020, with reference 1664163-203347-GMT, establishing the designation of the competent authority regarding Regulation 2020/402 with regard to the export of personal protective equipment ▪ Ministerial regulation of the Minister of Infrastructure and Water Management of 28 March 2020, with reference IENW/BSK-2020/57427, establishing the emergency measures with regard to gene therapy against COVID-19 (**Temporary Regulation Gene Therapy**) ▪ Emergency orders of the president of the security region, such as the emergency order of the president of the security region Flevoland establishing provisions to avoid further circulation of the coronavirus/COVID-19 dated 26 March 2020 ▪ Temporary regulations on alternative handling of permit applications gene therapy relating to the fight against COVID-19.
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ Since 28 January 2020, COVID-19 has been added to Group A of the Dutch Public Health Act. The Public Health Act regulates the fight against and prevention of infectious diseases in the Netherlands. The Public Health Act authorizes the president of the security region to take measures against COVID-19, such as having a person hospitalized for isolation, putting persons under quarantine or closing down buildings or sites. ▪ In the Netherlands, it appears that hotels have not been converted into hospitals or medical centers for quarantine and self-isolation. However, to relieve hospitals, the venue Ahoy in Rotterdam has been turned into a temporary care location for patients with and without COVID-19. ▪ On 26 March 2020, the minister for medical care announced that there would be no export ban with regard to the export of medicines within the EU. The export of medicines outside the EU is also allowed in principle. However, due to the entry into force of Regulation 2020/402, exports of personal protective equipment outside the EU are subject to an authorization. Due to the current shortage of personal protective equipment, the Health and Youth Care Inspectorate (**IGJ**), in principle, will not issue the export license.

The Netherlands

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	▪ Reference is made in the section "Legal deadlines" to the Medicine Prices Act. The minister for medical care postponed the change of the maximum prices of medicines for six months. Furthermore, the minister for medical care announced that the maximum prices of medicines would be released in the event that there is, or may be, a shortage of medicines and the price of such medicines may be an obstacle. ▪ The Ministry of Health, Welfare and Sport made arrangements with the Working Group Medicine Shortages, which includes pharmacies, drugstores and wholesalers, regarding the delivery and sale of medicines with and without prescriptions. This means that patients can have their usual amount of medicines, but not for longer periods of time. ▪ The minister for medical care is examining the possibility of giving firms and wholesalers a sales guarantee and applying more flexible rules relating to the joint procurement of sensitive medicines. Moreover, the minister for medical care spoke to several market parties regarding medicine provision. For instance, the minister for medical care asked healthcare providers to consider changing the market conditions when concluding agreements with manufacturers or pharmacies. ▪ The Central Office for Drugstore Companies has advised drug stores to limit over-the-counter sales of paracetamol to a maximum of two packs and to only place paracetamol behind the drugstore's counter. ▪ The Dutch government instituted a national approach regarding the distribution of personal protective equipment. The GGD GHOR Nederland, in cooperation with the Regional Consultation Immediate Care, is responsible for such distribution.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ It appears that the Dutch government has not (yet) adopted national exceptional public procurement measures relating to COVID-19 and has not (yet) relaxed any procedural requirements regarding public procurement for COVID-19 medicines and devices.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ Due to the amendment of the Medicine Prices Act, the maximum prices for medicines in the Netherlands would have been lowered from 1 April 2020. However, the minister for medical care postponed the change of the maximum prices for six months. The new date is now 1 October 2020. ▪ The Dutch Healthcare Authority extended the deadline for the application for the quality budget 2020 of healthcare providers from 1 April 2020 to 30 April 2020. ▪ It appears that these measures have not had an impact on MA approvals or public procurement.

The Netherlands

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- The IGJ announced that it would temporarily give manufactures and suppliers of medical devices the opportunity to supply medical devices without a CE mark or without completing the required assessment procedure to prevent supply shortages of medical devices. The IGJ will only allow such request if the manufacture or supplier satisfy certain criteria: (i) the healthcare institution must ask explicitly for the alternative device; (ii) the healthcare institution bears the responsibility for the use of such device; and (iii) there are no approved alternatives available.
- The Inspectorate SZW has temporarily created scope for introducing non-CE marked personal protective equipment (**PPE**), such as FFP1, FFP2 and FFP3 mouth and nose masks, into the Dutch market, provided that such materials meet the health and safety requirements and such PPEs aim to protect the healthcare professionals against COVID-19. The Inspectorate SZW is the Dutch market surveillance authority for the products falling within the scope of Regulation (EU) 2016/425. The Inspectorate SZW works together with the LCH (*Landelijk Consortium Hulpmiddelen*) to evaluate the non-CE marked PPEs. The LCH is the central procurement and distribution point for PPEs and medical devices. The manufacturers of non-CE marked PPEs must notify such PPEs to the LCH by sending an email to middelencorona@nfu.nl.
- The IGJ can temporarily grant permission to license holders to deliver medicines with different (non-Dutch) packaging. According to the minister for medical care, the following requirements must be met: (i) there is a shortage and the availability of the product is necessary for the continuity of patient care; and (ii) there is no alternative medicine available on the Dutch market.
- The IGJ is adopting a more flexible attitude regarding the enforcement of the Individual Healthcare Professions Act. This means that healthcare institutions are allowed to assign support personnel, such as non-registered doctors, in the event of a personnel shortage due to COVID-19.
- In order to prevent problems relating to the delivery of medicines causing medicine shortage, the IGJ allows pharmacists to exchange their medicine supplies amongst themselves. The following conditions must be met: (i) the requesting pharmacist must submit the request for medicines in writing; (ii) the requesting pharmacist must be able to demonstrate the provision and the receipt of such medicines afterwards; (iii) the supplying pharmacist must keep proper records; (iv) the pharmacist must organize the transport of the medicines in such way that the good quality of the medicines remains.
- The IGJ announced that, under certain conditions, medicines may be stored outside the pharmacy in temporary COVID-19 care centres. The following conditions must be met (i) the responsible pharmacist and the location must be notified to the IGJ; (ii) the storage space must be safe and good, safeguard the quality of the medicines and not be accessible for unauthorized parties; (iii) the records must be kept properly; and (iv) the medication of patients must be monitored on the basis of a complete and actual medication file.

The Netherlands

Clinical trials

- Have special measures been adopted?
- What are the main changes?

The following measures have been adopted:

- Due to the entry into force of the Temporary Regulation Gene Therapy, the decision-making period for permit applications relating to clinical trials for gene therapy with regard to COVID-19 is temporarily accelerated. There is now a 28-day decision-making period, instead of 120 days.
- The Central Committee on Research Involving Human Subjects (**CCMO**) facilitates an accelerated review of research files concerning studies on COVID-19 (the so-called fast-track procedure).
- Besides the CCMO, a number of accredited Multicentre Research Ethics Committees (MRECs) have also set up a fast-track procedure for the accelerated review of research files on the occurrence and/or treatment of COVID-19.
- From 20 March 2020, and until further notice, all submissions to the CCMO must be submitted digitally. The obligation for accredited MRECs and the CCMO to sign decrees with a so-called wet signature has been suspended.
- The research dossiers for gene therapy and medicinal products containing GMOs must be submitted to the relevant authority directly. The relevant authorities are the CCMO, as the review committee, the Ministry of Health, Welfare and Sport, as the competent authority, and the Ministry of Infrastructure and Water Management (GMO Office).
- A premature termination of the study must be reported to the review committee as soon as possible, but at the latest within 15 days.
- A (partial) suspended trial for reasons of subject safety must be reported immediately to the review committee. Temporary halts for other reasons must be reported within 15 days.
- A deviation from the protocol or a protocol modification due to urgent safety measures to eliminate immediate hazards to the subject must be reported immediately to the review committee. The prior approval of the review committee is not required.

The procedures for notifications to the Dutch competent authority both during and after the study, as well as for submitting a substantial amendment to the review committee, have not be changed due to COVID-19.

Poland

Matters	Summary
Specific COVID-19 legislation	▪ Act of 2 March 2020 on specific arrangements for the prevention, counteraction and combating of COVID-19, other infectious diseases and the resulting emergencies (link) ▪ (Not yet in force — still subject to works in Parliament) Draft Law of 26 March 2020 Act amending the Act of 2 March 2020 on specific arrangements for the prevention, counteraction and combating of COVID-19, other infectious diseases and the resulting emergencies and certain other acts (link to the bill) ▪ Regulation of 20 March 2020 of the minister of health on declaring the state of the epidemic in the Republic of Poland (link) ▪ (Not yet in force — still subject to works in Parliament) Draft Law of 26 March 2020 amending certain healthcare-related laws in connection with prevention and combating of COVID-19 (link) ▪ Amendment of the Regulation of 20 March (link)

Requisition powers
 	
▪ Has the government established any powers to requisition assets and premises?
▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?
▪ Is it controlling the distribution of medicinal products/medical devices?
	▪ During the state of epidemic, there is an order for the provision of immovable property, premises and land indicated in anti-epidemic plans.
	▪ No, but a number of hospitals are being converted to hospitals treating infectious diseases to treat patients who are infected with COVID-19.
	▪ Yes, the sale and distribution of medical devices has been limited and, problematically, it is subject to three different regimes:
	  ▪ There is a list of medicinal products/medical devices that are subject to an "export ban" and may not be exported or sold abroad without notifying the chief pharmaceutical inspector, who can oppose such export of such products or devices.
	  ▪ The minister of health is authorized to issue a list of medicinal products and foodstuffs intended for particular nutritional uses that may only be sold to a pharmaceutical wholesaler (this is the current regulation). However, once the Draft Law of 26 March 2020 amending certain healthcare-related laws in connection with the prevention and combating of COVID-19 is adopted, the above-mentioned regulation will be stricter — the pharmaceutical wholesalers will need to be located in Poland (this provision is still subject to works in Parliament).
	  ▪ An entrepreneur is obliged to notify the voivode no later than 24 hours before the intended export or sale outside Poland of products such as protective goggles, TYVEK-type overalls, FFP2/FFP3 masks, surgical masks, shoe protectors, latex and nitrile gloves, hand sanitizer, and surface and room disinfectants. The voivode may submit a request to the prime minister to ban the export or sale of these products outside of Poland.
	  ▪ The export or sale of ventilators or cardiomonitors outside of Poland is prohibited.

Poland

Pricing and reimbursement
 	
▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?
	▪ The minister of health will define the maximum prices of medicinal products with certain availability specified in the Pharmaceutical Law, medical devices and foodstuffs for special nutritional purposes, which can be used in connection with combating COVID-19.
	▪ Significant changes in this respect are provided in the Draft Bill of 26 March (not yet in force). The most important changes are as follows:
	  ▪ Lists of reimbursed products valid from 1 March 2020 are valid until 31 August 2020. Consequently, the validity period of reimbursement decisions, which expire before 1 July 2020, is extended until 31 August 2020.
	  ▪ Reimbursement decisions issued until the date of entry into force of the act, which were intended to enter into force on 1 May 2020, will enter into force on 1 September 2020.
	  ▪ The time limits for proceedings initiated and not completed (i) before 8 March 2020, and (ii) in the period from 8 March 2020 to 15 August 2020 will be suspended by law until 31 August 2020.
	However, during the period of suspension of the proceedings, the minister of health may take any steps to issue new administrative decisions — it is difficult to predict what kind of actions the minister will undertake because no new or amended reimbursement decisions may be issued before 1 September.

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ The provisions of the Public Procurement Law will not apply to contracts for goods or services that are necessary to counteract coronavirus. A condition for this exclusion of provisions is the existence of a high probability of the rapid and uncontrolled spread of the disease or a requirement to protect public health. The exemption from the application of public procurement provisions in the above case has been limited in time — it will be in force for 180 days from 8 March 2020. In addition, changes can be made to a public procurement contract if COVID-19 affects its performance. The parties are allowed to introduce changes to the contract related to deadlines, the scope of the contract and the contractor's remuneration provided that the increase in prices included in each subsequent change does not exceed 50% of the value of the original contract. If the public procurement contract includes beneficial regulations for the contractor, the change may be introduced in accordance with such regulations. However, the circumstances related to COVID-19 cannot constitute a sole basis for the withdrawal from the contract.

Legal deadlines
 	
▪ Have legal/administrative deadlines been suspended/relaxed?
▪ Have these measures had an impact on MA approvals, public procurement, etc.?
	(These provisions are still subject to works in Parliament.)
	▪ Administrative deadlines will be suspended or withheld in the following cases, among others:
	  ▪ deadlines that need to be met to be eligible for legal protection before a court or authority
	  ▪ deadlines for the performance of actions creating rights and obligations for oneself or the other party
	  ▪ statute of limitations
	  ▪ statutory time limits, the omission of which results in a definite loss of right
	In addition, deadlines in legal proceedings in civil and administrative cases, among others, are suspended or withheld.

Poland

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	According to a draft resolution of the Council of Ministers, the minister of health will be authorized to make purchases of personal protective equipment to use them for the needs of personnel providing healthcare services, including sanitary transport in connection with preventing the spread of SARS-CoV-2 virus and the COVID-19 disease caused by it. Personal Protective Equipment (PPE) may be made available for use before the completion of the conformity assessment and without affixing the CE marking no later than 30 days after the end of the epidemic.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	It is recommended to take into account the current epidemiological situation and the fact that the medical staff of hospitals are involved in activities related to SARS-CoV-2 infections in the supervision of clinical trials (monitoring and audit). It is recommended that changes resulting from the need to adapt to the epidemiological situation should be treated as immediate security measures in accordance with Article 37y of the Pharmaceutical Law: "(1) When any event occurs that could affect the safety of the clinical trial subjects, the sponsor or investigator shall abandon the clinical trial in accordance with the applicable clinical trial protocol. In that case, the sponsor and the investigator shall take appropriate measures to ensure the safety of the clinical trial subjects. (2) The sponsor shall immediately inform the President of the Office and the bioethics committee of this situation and the safety measures taken. In view of the current situation, it is acceptable to send this information by e-mail. The information on immediate safety measures shall include a detailed assessment of the risks resulting from the changes." An analogical approach has been recommended for the clinical trials of medical devices. In view of the above, the president of the Office for Registration recommended considering the appropriateness of submitting new applications for starting a clinical trial of a medicinal product and applications for authorization to conduct a clinical trial of a medical device in this situation. It has also informed that the activities of the clinical trial inspection are suspended until the end of April 2020 and the decision to resume the inspection process will be made depending on the epidemiological situation.

Russia

Matters	Summary
Specific COVID-19 legislation	▪ Federal Law No. 67-FZ "On Amending Article 60 of the Federal Law No. 61- FZ "On the Circulation of Medicines" and Article 38 of the Federal Law 323-FZ "On the Fundamentals of Citizens' Health Protection in the Russian Federation" as of 26 March 2020 (**Federal Law No. 67-FZ**) ▪ Federal Law No. 98-FZ "On Amending Certain Legislative Acts of the Russian Federation on the Issues Related to Prevention of and Response to Emergencies" as of 1 April 2020 ("Federal Law No. 98-FZ) ▪ Federal Law No. 105-FZ "On Amending Article 15-1 of the Federal Law "On Information, Information Technologies and the Protection of Information" and the Federal Law "On the Circulation of Medicines" as of 3 April 2020 ▪ Decree of the President of the Russian Federation No. 187 "On the Retail Sale of Medicines" as of 17 March 2020 ▪ Decree of the President of the Russian Federation No. 206 "On the Announcement of Non-working Days in the Russian Federation" as of 25 March 2020 ▪ Decree of the President of the Russian Federation No. 239 "On measures to ensure sanitary and epidemiological welfare of the population in the Russian Federation in connection with the spread of COVID-19" as of 2 April 2020 ▪ Decree of the Government of the Russian Federation No. 223 "On the Introduction of a Temporary Ban on the Export of Certain Types of Products from the Russian Federation" as of 2 March 2020 ▪ Decree of the Government of the Russian Federation No. 299 "On Amending the Rules on the State Registration of Medical Devices" as of 18 March 2020 ▪ Decree of the Government of the Russian Federation No. 419 "On the implementation of the decision of the Council of the Eurasian Economic Commission as of 16 March 2020 No. 21 and amending the list of medical devices, the sale and import of which on the territory of the Russian Federation and other territories under its jurisdiction shall be exempted from value added tax" as of 2 April 2020 ▪ Decree of the Government of the Russian Federation No. 430 "On the peculiarities of circulation of medical devices, including state registration of a series (batch) of medical device" as of 3 April 2020 ▪ Decree of the Government of the Russian Federation No. 431 "On establishing the peculiarities of the circulation of medical devices, restrictions on the wholesale and retail sale of medical devices and the list of such devices" as of 3 April 2020 ▪ Decree of the Government of the Russian Federation No. 440 "On the extension of validity of permits and other peculiarities of licensing activities in the year 2020" as of 3 April 2020 ("Decree of the Government No. 440"); ▪ Decree of the Government of the Russian Federation No. 441 "On the peculiarities of the circulation of medicines, which are intended for use in case of threat of an emergency, liquidation of an emergency and for the purposes of medical assistance to persons affected by emergencies, prevention of emergency situations, prevention and treatment of dangerous diseases, diseases and injuries resulting from exposure to favorable chemical, biological, radiological factors" as of 3 April 2020 ("Decree of the Government No. 441"); ▪ Decree of the Chief State Sanitary Physician of the Russian Federation No. 6 "On Additional Measures to Reduce the Risks of the Spread of COVID-19" as of 13 March 2020

Russia

Specific COVID-19 legislation	▪ Order of the Ministry of Health of the Russian Federation No. 171 "On a Temporary Procedure for Organizing the Work of Medical Institutions in order to Implement Measures to Prevent and Reduce Risks of the Spread of COVID-19" as of 16 March 2020 ▪ The plan of priority measures (actions) to ensure the sustainable development of the economy due to the spread of a new coronavirus infection (approved by the government of the Russian Federation on 17 March 2020) ▪ Information of the Government of the Russian Federation "On Measures to Protect Public Health from a New Coronavirus Infection" as of 19 March 2020 ▪ Information of the Chamber of Commerce and Industry of the Russian Federation as of 24 March 2020 explaining the procedure for issuing reports on force majeure circumstances ▪ Letter of the Ministry of Health of Russia No. 20-1/*И*/2-3651 regarding the conduct of clinical trials of medicines in connection with the spread of COVID-19 as of 27 March 2020
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	As of 8 April 2020, there is no state of emergency in the Russian Federation and there are no governmental powers related to requisition assets and premises. Days from 30 March 2020 to 30 April 2020 have been declared non-working days in Russia. The Russian network of private medical clinics, Medsi, has decided to convert its multidisciplinary hospital into an infectious diseases hospital to help patients who become infected with a new type of coronavirus and patients with pneumonia. The Russian government imposed a temporary ban on the export of a number of protective equipment and medical devices from the country. These include medical masks, gloves and white coats, bandages, cotton wool, disposable chemical protective overalls and, especially, durable shoe covers. The ban on export is valid until 1 June 2020 and it does not apply to international humanitarian assistance and the export of disposable goods by citizens for personal use. On 30 March 2020, the president of the Russian Federation ordered reserves of artificial lung ventilation apparatus in medical institutions in Russia to be replenished, as well as the creation of additional stocks of medicines used to combat COVID-19 and its complications. According to Federal Law No. 98-FZ, the peculiarities of circulation, including the state registration, of medical devices and the state registration of medicines that are intended for use in military operations, emergencies, the prevention of emergency situations, the prevention and treatment of dangerous diseases, during diseases and injuries resulting from exposure to adverse chemical, biological, radiation factors, etc., will be established by the government of the Russian Federation. Under Federal Law No. 98-FZ, in case of an emergency situation or when there is a threat of the spread of a dangerous disease, the Russian government has the right to restrict the wholesale and retail sale of medical devices included on the list determined by the government for a period not exceeding 90 calendar days from the date of adopting the relevant decision.

Russia

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Federal Law No. 67-FZ, which entered into force on 26 March 2020, allows the Russian government to set up maximum selling prices for manufacturers of certain medicines and medical devices. The same opportunity is provided in relation to the marginal wholesale and retail markups of the actual selling prices of manufacturers of these medicines and medical devices. The Russian government will determine the list of medical devices and the list of medicines that are not included on the List of Vital and Essential Medicines that will fall under state regulation. The government will be able to exercise the right to set up maximum selling prices and mark-ups in the following cases: ▪ an emergency situation ▪ a threat of the spread of a dangerous disease ▪ detection of the growth of retail prices for medicines and medical devices by at least 30% in the regions within 30 calendar days after the government decides to track the prices
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	The Russian government has introduced the temporary suspension of the "third one out rule" in the process of public procurement for a number of medicines and medical devices determined by the Ministry of Industry and Trade and the Ministry of Health of Russia. This rule imposes a ban on the participation of a foreign product in the public procurement tender if there are two or more participating suppliers offering products originating from the Eurasian Economic Union and manufactured by unaffiliated manufacturers. The list of medicines and medical devices, to which the "third one out rule" will not temporarily apply, will soon be adopted.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	Currently, legal/administrative deadlines are uncertain. The Chamber of Commerce of the Russian Federation indicated that regional chambers of commerce might issue reports on force majeure circumstances if there are appropriate personnel. This document attests the existence of force majeure circumstances that do not allow obligations under contracts entered into between Russian legal entities to be fulfilled. In respect of international contracts, a force majeure certificate may confirm force majeure circumstances. The Chamber of Commerce of the Russian Federation and its regional units issues it. This service is free of charge from 26 March 2020. In accordance with the Decree of the Government № 440, the state registration of medicines and the state registration of medicines for veterinary use shall be extended by twelve months, if their validity expires (has expired) in the period from 15 March 2020 to 31 December 2020.

Russia

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- The president of the Russian Federation approved distance selling of over-the-counter (OTC) medicines and medical devices. Distance selling means any sale that does not entail a visit to the pharmacy by the purchaser (e.g. online sales, home deliveries) and can be carried out by pharmacy organizations licensed to engage in pharmaceutical activities and authorized by the Federal Service for Surveillance in Healthcare. The procedure for distance selling, the rules for delivering OTC medicines to the population is yet to be established.
- Moreover, a new law has been passed, specifying the President's initiative, that allows the distance sale of medicines, with the exception of prescription ones, as well as medicines that are subject to strict record keeping and storage and alcohol-containing medicines with a volume fraction of ethyl alcohol of more than 25%. In case of an emergency and when there is a threat of spread of a dangerous disease, the Government of the Russian Federation is entitled to establish a temporary procedure for the distance sale of all medicines (with the exception of narcotic and psychotropic medicines, as well as alcohol-containing medicines with a volume fraction of ethyl alcohol of more that 25 %). The latter provision is valid until 31 December 2020.
- Following the initiative of the Ministry of Economic Development of Russia, the Council of the Eurasian Economic Commission exempted importation of goods necessary to prevent the spread of coronavirus infection from customs duties. The duty-free import regime applies to personal protective equipment, vaccines, laboratory reagents, boxes and stretchers for transporting patients, bags for transporting hazardous biological waste, blood transfusion systems, tubes for artificial lungs ventilation, syringes and catheters, materials used for the production of personal protective equipment, disinfectants. The measure applies to goods imported from 16 March 2020 to 30 September 2020.
- The Ministry of Industry and Trade of the Russian Federation and the Ministry of Economic Development of the Russian Federation together with the Federal Service for Accreditation issued the following recommendations to certification bodies and applicants for mandatory certification:
  - postpone the inspection control procedure for up to 6 months in relation to valid certificates of conformity for serial production, if the next scheduled inspection control must be within the period related to the spread of COVID-19,
  - in respect of valid certificates of conformity for serial production that expire within the period related to the spread of COVID-19, certification bodies that periodically evaluated such certified products may issue a new serial certificate taking into account the positive results of the latter periodic evaluation of such certified products, etc.

Russia

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

- The Government of the Russian Federation has established a separate, simplified, procedure for state registration of medical devices with a low degree of potential risk of their use (gloves, shoe covers, medical overalls, masks, respirators, etc.). The registration of such medical devices will be carried out within 5 working days. The applicant must submit only application, technical and operational documentation and a photograph of the medical device, while the submission of the results of clinical and other trials at the time of medical device's registration is not required. However, within five months the applicant will be required to confirm the state registration of his medical device and submit to Roszdravnadzor the documents confirming the results of:
  - technical tests of medical devices
  - toxicological tests of medical devices
  - tests of medical devices in order to approve the type of measuring instrument, etc.
- The Government of the Russian Federation has approved the procedure for the registration of certain medical devices that are intended for use in military operations, emergencies, and the prevention and treatment of dangerous diseases. The list includes 108 items, including: ventilators, extracorporeal membrane oxygenators, surgical suits, insulating suits and disposable masks, thermometers, etc. For initial registration, the applicant must provide the Roszdravnadzor with a copy of a document confirming the applicant's credentials, technical and operational documentation, photographs of a medical device, information about quality and safety, if any. Roszdravnadzor shall investigate the documents within three days and, in the absence of remarks, shall issue a temporary registration certificate to be valid until 1 January 2021. Moreover, it is allowed to put into circulation disposable medical devices, such as gloves, medical masks, gowns, respirators, shoe covers, without their registration in Russia, if there is a registration certificate in the country of their manufacture.
- With respect to some medical devices (filter respirators, medical masks and gloves, gauze, disposable medical kits, protective clothing sets, etc.), the following restrictions are introduced:
  - wholesale of the abovementioned devices will be allowed only to the federal coordinating operator (JSC "Roskhimzashita Corporation") and regional operators (organizations that are licensed to carry out pharmaceutical activities in terms of wholesale of medicines and supply medicines in accordance with the rules, approved by Decree of the Government of the Russian Federation No. 1416 as 26 of November 2018)
  - the retail sale of such devices in stores and sales points which do not have a license to carry out pharmaceutical activities in terms of retail sale of medicines will be prohibited
  - the restriction of the wholesale and retail mark-ups is introduced: the wholesale mark-up should not exceed 10% of the purchase price or the cost of goods, the retail mark-up should not exceed 10 kopecks per unit

Russia

Relaxation of regulatory rules
 	
▪ Has the government relaxed regulatory rules?
	▪ Decree of the Government No. 441 contains a number of measures optimizing the regulatory procedures for the medicines during the period of spread of COVID-19, including:
	  ▪ electronic documents review and submission without hard copies with electronic signature;
	  ▪ establishment of the Working Group in the Russian Ministry of Health which will determine the volume of expertise of the medicines intended for use in emergency situation
	  ▪ reduction of the volume of examinations when introducing changes into the registration dossier related to replacement, addition, exclusion of the manufacturing site of the manufacturer of the active pharmaceutical substance and finished dosage form, as well as change in the primary packaging
	  ▪ exclusion of the examination of the medicine's quality and the examination of the expected benefit to the possible risk of the medicine's use in relation to medicines registered in the Member States of the European Union, the United States of America, Canada or another state according to the list established by the Ministry of Health. The State registration of such medicines shall be carried out by the Ministry of Health within 5 working days
	  ▪ the State registration of medicines intended for use in emergency situation shall be carried out in the period of no more than 20 working days
	  ▪ the Russian Ministry of Health issues to the applicant a registration certificate which shall be valid until 1 January 2021.

Russia

Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	In order to ensure the safety of participants of clinical trials in the Russian Federation and compliance with good clinical practice the Ministry of Health of Russia issued the following recommendations to clinical trial organizers: ▪ Use alternative methods for monitoring patients of a clinical trial (for example, telephone contact, virtual visit or an alternative location for assessment, including local laboratories or centers). ▪ Expand the possibilities of interaction with patients at home, provided that the research organizer is able to ensure the proper level of quality for this process (for example, organize the delivery of medicines to the research participant at home by employees of medical centers or organize the collection of biological samples at the place of residence). ▪ Take measures to minimize the impact on the integrity of the clinical trial to prevent deviations from protocol. ▪ Take measures aimed at providing the maximum possible protection for the personnel involved in the clinical trial. Moreover, on 27 March 2020, the Association of Clinical Research Organizations asked the Russian prime minister to clarify the procedure for the air transportation of pharmaceuticals in connection with the spread of COVID-19. The main issue is how to organize the process of importing medicines and exporting biological samples. The Association of Clinical Research Organizations requested clarification on whether the measure introduced by the Russian government to stop regular and charter flights from 27 March 2020 applies to air cargo.

South Africa

Matters	Summary
Specific COVID-19 legislation	Legislation: ▪ Disaster Management Act 57 of 2002 (accessible here) Regulations: The following regulations have been published in accordance with the declaration of a national state of disaster and the imposition of a Nationwide Lockdown (defined below) across South Africa: ▪ COVID-19 Block Exemption for the Healthcare Sector (accessible here) ▪ Classification of a National Disaster (accessible here) ▪ Disaster Management Act Regulations, published on 18 March 2020 (accessible here) ▪ Amended Disaster Management Act Regulations, published on 25 March 2020 (accessible here) Guidelines: The following guidelines, as it relates to healthcare businesses, have been published in accordance with the declaration of a national state of disaster and the imposition of a Nationwide Lockdown (defined below) across South Africa: ▪ Guidelines for case finding, diagnosis, management and public health response in South Africa (accessible here) Notices and announcements: The following notices and announcements, as they pertain to healthcare businesses, have been made in accordance with the declaration of a national state of disaster and the imposition of a Nationwide Lockdown (defined below) across South Africa: ▪ Competition Act: regulations related to COVID-19 (accessible here) ▪ National Institute for Communicable Diseases (NICD) announcements (accessible here) ▪ South African Health Products Regulatory Authority announcement in relation to medicine and medical device supply challenges (accessible here)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	Measures adopted by the government: ▪ Designated hospitals in each province have been identified to deal with the COVID-19 outbreak. Additionally, a public health management program has been implemented to significantly increase screening, testing, contact tracing and medical management. ▪ Community health teams will focus on expanding screening and testing where people live, focusing first on high density and high-risk areas. ▪ A system for "centralized patient management" for severe cases and "decentralized primary care" for mild cases has been implemented. ▪ The Department of Science and Technology has negotiated the repurposing of various facilities and laboratories to respond to the COVID-19 outbreak. ▪ As stated in the Disaster Management Act Regulations, accommodation used for persons rendering essential services, quarantine, isolation and the lockdown are prohibited from closing and are to remain open.

South Africa

Requisition powers

- Has the government established any powers to requisition assets and premises? Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?

- Is it controlling the distribution of medicinal products/medical devices?

- The government and hospitals operating in the private sector have agreed to accommodate people who may need to be hospitalized to treat COVID-19 even when they cannot afford it.
- Hospitals in both the public and private sector throughout South Africa have closely cooperated with the NICD and the Department of Health (DoH) on an ongoing basis, and have aligned the DoH's clinical protocols for managing COVID-19 patients with their own clinical guidelines. Additionally, hospitals throughout the country have implemented comprehensive measures to detect, identify and appropriately respond to any suspected or confirmed cases of COVID-19[2].
- Throughout the Nationwide Lockdown (defined below), no hospital visits are permitted, except for instances constituting a grave emergency.
- The government is not currently controlling the distribution of medicinal products or medical devices. However, this may change as it was reported on 29 March 2020 that South Africa is facing a shortage of ventilators (more on this report can be accessed here).

Declaration of a Nationwide Lockdown:

- The president of South Africa declared a nationwide lockdown, which will be effective from 23:59 pm on Thursday, 26 March 2020 until 23:59 pm on Thursday, 16 April 2020 (**Nationwide Lockdown**).
- During the Nationwide Lockdown, the movement of all persons outside of their residences will be strictly restricted to performing essential services, obtaining essential goods or seeking medical attention. No other movement of persons may occur during the Nationwide Lockdown. All businesses that are not regarded as essential services will be required to cease operations for the duration of the Nationwide Lockdown.
- It should be noted, however, that healthcare businesses, including health workers in the public and private sectors, paramedics, laboratory services, essential care of the elderly and sick persons (including home-care and old-age homes), pharmacies and those involved in the supplying, manufacturing and transportation of medical and hygiene products, will be regarded as essential services and will be exempt from the restrictions imposed under the Nationwide Lockdown.

Restrictions imposed at ports of entry into South Africa:

- South Africa's main ports will continue to operate. However, berths at Durban and Cape Town, Port Elizabeth and the deep-water Port of Ngqura in the Eastern Cape have been reduced, while Richards Bay and East London are being closed during the Nationwide Lockdown.
- Ports may receive essential cargo whereby medical supplies and food products will be prioritized. All shipments will be subject to sanitization processes to combat the spread of COVID-19.

[2] This has been done by, among other things: (i) ensuring that every person entering their facilities sanitizes their hands; (ii) ensuring that all persons entering their facilities are verbally screened for COVID-19 risks at the main points of entry as a first line of defense, and conducting further screening where indicated; (iii) erecting gazebos or tents at entrances to emergency departments and main hospital entrances where authorized staff members will conduct the relevant screenings; (iv) closing certain entrances to facilities to ensure adherence to hand cleaning and screening; (v) deploying ultraviolet light disinfection robots in those hospitals that do not yet have their own as soon as possible; (vi) restricting visiting times in hospitals and the number of visitors allowed to visit a patient at one time; (vii) screening all staff on a daily basis, including personnel of external service providers in all areas of the business; and (viii) recording all persons entering into hospitals.

South Africa

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Pricing of medical products (including medicines and medical devices): ▪ The Competition Act: Regulations related to COVID-19 control the pricing of essential goods and services during the Nationwide Lockdown, which includes medical products. ▪ The Competition Act: Regulations related to COVID-19 creates strict prohibitions on the excessive pricing of emergency products, services, medical and hygiene supplies to the detriment of consumers or customers. ▪ Contraventions of the Competition Act: Regulations related to COVID-19 carry a fine of up 10% of a firm's turnover and/or a period of imprisonment not exceeding 12 months.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	Exceptional public procurement procedures: ▪ The National Treasury has issued an instruction note (accessible here) to government departments, municipalities and entities to help speed up the procurement of goods and/or commodities required to reduce and control the spread of the COVID-19 virus, which would naturally include medical-related products. ▪ It further lists prices of goods/commodities to curb any opportunistic use of the national disaster to drive profit margins. The instruction note is limited to goods required to limit the spread of the virus and will be terminated at the end of the disaster or when the National Treasury retracts the instruction note. ▪ As of 29 March 2020, no procedural requirements have been relaxed in any sphere, including medication and devices. ▪ Currently, no sanctions are foreseen for unfilled orders.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ A directive issued by the chief justice of South Africa (accessible here) has declared that courts should only remain open for extremely restricted matters. ▪ This includes the filing of papers and hearing urgent applications (mainly related to the Nationwide Lockdown), bail applications and appeals or matters relating to violations of liberty, domestic violence, maintenance and matters involving children. This will be applicable for the duration of the Nationwide Lockdown. ▪ Additionally, on 26 March 2020, the minister of justice and correction services issued a directive that provides that, among other things, time limits imposed by any rules of court will be suspended and will recommence after the termination or lapsing of the period of the national state of disaster.
Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	▪ Parts of the competition regulations allow private hospitals to coordinate their activities and share beds, medical supplies, doctors and nurses without facing charges of collusion, as contemplated under the Competition Act.

South Africa

Clinical trials

- Have special measures been adopted?
- What are the main changes?

- South Africa is one of 10 countries involved in an urgent global trial announced by the World Health Organization to identify the most effective treatment for COVID-19 (the report is accessible here).
- Eight South African health sciences faculties are involved in this program, and the work will involve many of the country's senior clinicians and researchers across specialties such as infectious diseases and intensive care.
- The Southern African Pharmaceutical Regulatory Affairs Association and ethics committees are urgently reviewing potential therapeutics so there are no regulatory delays.

Measures adopted by the South African Health Products Regulatory Authority:

- The adoption of scientific reviews of new medicines and vaccines through a priority review process, the implementation of a special access program for practitioners treating COVID-19 patients and the speedy review of clinical trials for new vaccines or repurposed anti-virals will be implemented.
- The South African Pharmacy Council and Regulatory Affairs Association has not yet issued a statement on whether they will shut down operations. They are proactively working with institutions for research purposes, and to develop a vaccine as a matter of urgency, and they have given approval for Austell Pharmaceuticals to donate 500,000 chloroquine phosphate tablets for use by the DoH. They are also issuing updates on the status of medicinal supplies and calling upon the public not to bulk buy purchases of essential supplies and medical items (accessible here).

Medical research:

- The University of Cape Town, the Council for Scientific and Industrial Research and Biovac have started researching and developing a potential vaccine for COVID-19.
- The Department of Science and Innovation has availed ZAR 12 million and it will redirect an additional ZAR 30 million to further the development of a vaccine for COVID-19.

Spain

Matters	Summary
Specific COVID-19 legislation	▪ Royal Decree 463/2020 of 14 March declaring a state of alarm to manage the current COVID-19 health crisis ▪ Royal Decree Law 7/2020 of 12 March adopting urgent measures to tackle the economic impact of COVID-19 ▪ Royal Decree Law 8/2020 of 17 March on extraordinary urgent measures to deal with the economic and social impact of COVID-19 ▪ Royal Decree Law 16/2020, of 28 April adopting procedural measures to combat COVID-19 ▪ Royal Decree-Law 17/2020, of 5 May adopting proceeding measures to combat COVID-19 ▪ Order SND/233/2020 of 15 March establishing the obligation to provide information regarding the manufacturing of certain sanitary products ▪ Order SND/266/2020 of 19 March adopting measures to guarantee access to the pharmaceutical provision of the Spanish National Health System to the group of special regimes of social security ▪ Order SND/276/2020 of 23 March establishing the obligation to provide information regarding the supply and manufacture of certain medicines ▪ Order SND/293/2020 of 25 March establishing conditions for dispensing and administering of medicinal products ▪ Order SND/321/2020 of 3 April establishing measures to allow the use of bioethanol to manufacture hydroalcoholic solutions and gels ▪ Order SND/326/2020 of 6 April relating to temporary licenses for manufacturing facilities and for product authorizations regarding products critical to protect public health ▪ Order SND/353/2020, of 17 April updating the list of medicines included in Order SND/276/2020, of 23 March ▪ Order SND/354/2020, of 19 April establishing measures to guarantee access to the products recommended preventing COVID-19 infection ▪ Royal Decree-Law 15/2020, of 21 April, on extraordinary urgent measures to deal with the economic and social impact of COVID-19 ▪ Resolution of the National Health System General Directorate, of 22 April establishing the prices to the public of certain products ▪ Resolution of the National Health System General Directorate, of 2 May establishing the prices to the public of certain products ▪ Resolution of the Industry General Directorate, of 23 April regarding PPE related to the healthcare crisis caused by the COVID-19 ▪ Guideline on Order SND/326/2020 with instructions to obtain the temporary operating licenses ▪ Resolution of 20 March on alternative specifications to personal protective equipment (PPE) masks with European CE marking ▪ Recommendations for action in the pharmaceutical production and distribution industry in cases of COVID-19 infection published by the Spanish Agency of Medicines and Medical Devices (**AEMPS**) ▪ Exceptional measures applicable to clinical trials during the COVID-19 emergency ▪ Order SND/344/2020, of 13 April, adopting exceptional measures for the support of the National Health System and the contention of the health crisis caused by the COVID-19.

Spain

Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ Among the measures approved in Royal Decree 463/2020 of 14 March declaring a state of alarm to manage the current COVID-19 health crisis, it has been approved that the Ministry of Health may intervene and temporarily occupy privately owned factories, plants, workshops, holdings or premises, as well as those operating in the pharmaceutical sector; it may also temporarily seize all types of property and impose compulsory service on individuals in cases when this is necessary for the adequate protection of public health. Authorities may also impose compulsory service on individuals that may be essential to achieve the aims of Royal Decree 463/2020 of 14 March. Health authorities may order the requisition of health products (such as masks, gloves, hydroalcoholic solution, etc.). ▪ Health authorities may fit out for their use spaces in public or private premises that meet the necessary conditions to provide healthcare for either medical visits or hospitalization. The above means that the Ministry of Health may occupy, among others, private hospitals or centres for healthcare assistance to manage the COVID-19 health crisis. Health authorities are already using private premises (such as hotels or convention centres) for healthcare assistance. ▪ The authorities have also requested companies manufacturing or importing certain sanitary products and those that have the capacity to produce any of these products (such as masks, gloves, hydroalcoholic solution, etc.) to regularly provide information regarding their stock so the authorities may impose obligations regarding the supply of those products. ▪ It is compulsory to provide information regarding the supply and manufacture of certain medicines (more than 110 active substances are currently controlled). Authorities may request that manufacturers produce more units and/or that they prioritize the manufacture of certain medicines. The Spanish Agency of Medicines and Medical Devices has already established the controlled distribution of the stock of hydroxychloroquine/chloroquine. The marketing authorization holders cannot introduce more hydroxychloroquine/chloroquine units in the market unless agreed by the health authorities.

Spain

Pricing and reimbursement

- Has the price and reimbursement procedures for medicinal products and medical devices been affected?

- Article 7 of Royal Decree Law 7/2020 of 12 March amends Article 94.3 of the revised text of the Law on Guarantees and Rational Use of Medicines and Medical Devices. It is expected that the government will be allowed to regulate the mechanism for pricing non-prescription medicines and medical devices, along with other products necessary to protect the general public health, that are dispensed on Spanish territory in accordance with an objective and transparent general scheme. It also provides for the eventuality that in the event of exceptional public health circumstances, such as the present one, the Interministerial Medicinal Product Pricing Committee may set the maximum amount of sales to the public of these medicines and products for the time that the exceptional circumstances last. Therefore, currently, the committee may adopt such decision for any of these medicinal products or medical devices during the state of alarm.
- The Ministry of Health has approved the procedure to set the maximum sale price to the public of certain medical devices and other health protection products (such as masks or hydroalcoholic solution, etc.). It has also established the information that must appear on the labelling of hygienic masks and some requirements regarding the fulfilment of certain technical specifications. Also, it has clarified that those masks that are not individually packed can only be sold to the public in pharmacies.
  For the moment, the authorities have established the prices to the public (VAT or IGIC included) for the following products:
  - Surgical masks: EUR 0.96 per unit;
    The prices will be applicable from 24 April 2020, but the authorities can review and modify such prices.
  - Antiseptic wash of healthy skin authorized by the AEMPS (biocides):
    - Up to 150 ml: EUR 0.032 per ml;
    - Between 151 ml and up to 300 ml: EUR 0.023 per ml;
    - Between 301 ml and up to 1000 ml: EUR 0.015 per ml.

    The prices will be applicable from 6 May 2020, but the authorities can review and modify such prices.
  - Gels and hydroalcoholic solutions temporary authorized by the Spanish Medicines and Medical Devices Agency (AEMPS). The prices applicable from 24 April 2020 until 5 May 2020 are the following:
    - Between 150 ml and up to 300 ml: EUR 0.018 per ml;
    - Between 300 ml and up to 1000 ml: EUR 0.015 per ml.

    The prices applicable from 6 May 2020 are the following:
    - Up to 150 ml: EUR 0.025 per ml;
    - Between 151 ml and up to 300 ml: EUR 0.021 per ml;
    - Between 301 ml and up to 1000 ml: EUR 0.015 per ml (price not modified).

    The authorities can review and modify such prices.

  The authorities have also established that the prices of the hygienic masks and antiseptic wash of healthy skin authorized by the AEMPS will be established in the next meeting of the Commission adopting such decisions (they are obtaining further information on costs to establish the prices).
  The Spanish Government has also established a 0 % rate of the VAT of the supply of goods, importations, and acquisitions within the EU of the products listed on the Annex of the Royal Law-Decree 15/2020 (which mainly are medical equipment, PPE -some gloves, masks, and coveralls are included-, some medicines and medical devices) provided that the purchasers are public entities, hospitals or medical centres, or social private entities. The above will apply from 23 April and until 31 July 2020.

Spain

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ With regard to services and supply public sector contracts that must be provided on an ongoing basis (such as the supply of medicinal products or medical devices), they can now be suspended if their performance becomes impossible as a result of COVID-19 or the measures taken by the authorities to combat it. The above is subject to the contracting authority, at the request of the contractor and within five calendar days, determining that it is impossible to execute the contract. ▪ In addition, a contract may be extended on its expiration on the same terms if a replacement contract has not been executed as a result of the paralysis of contracting procedures until a new contract is in place for a maximum period of nine months. ▪ Regarding supply and service contracts other than successive execution contracts where the contractor is delayed as a result of COVID-19 or the measures taken by the authorities to combat it, and the contractor offers to meet its obligations if the deadline is extended, the contracting authority: (i) will grant an extension for a period that will be at least equal to the time lost, unless the contractor requests a shorter one; and (ii) pay the additional salary costs actually incurred up to a limit of 10% of the initial contract price (following a request and due evidence by the contractor). In such cases, no penalty will be imposed on the contractor and the contract will not be terminated. ▪ With regard to public works concession and service concession contracts, the de facto situation created by COVID-19 and the measures taken by the authorities will be considered force majeure, entitling the concessionaire to restore the economic balance of the contract by extending its initial duration by a maximum of 15% or by amending the economic clauses included in the contract. This rebalancing will in any case compensate the concessionaires for the salary costs paid during the period of the situation (following a request and due evidence by the contractor). This will only apply if the contracting authority, at the request of the contractor, recognizes that it is impossible to perform the contract. ▪ The above will not apply to contracts for health, pharmaceutical or other services or supplies whose object is linked to the health crisis caused by COVID-19, which will be subject to the emergency procedure. Any contract entered into by the General State Administration or its public bodies and public law entities to cover the need to protect the public and other measures adopted by the Council of Ministers to address COVID-19 constitutes an emergency contract and is therefore subject to the emergency procedure provided for in the Public Sector Contracts Law. ▪ Procedural requirements have not been formally relaxed for COVID-19-related medicines and devices. However, a modification of the Public Procurement Law has been approved in connection to the open simplified procedure to allow that the non-public opening of the offer. ▪ No specific sanctions have been approved in case of unfilled orders.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	▪ As a rule, procedural and administrative deadlines (including periods of prescription or limitation) are suspended and interrupted for the duration of the state of alarm. However, courts, judges or competent bodies may agree to take any action necessary to avoid irreparable damage to the rights and legitimate interests of the parties or interested parties. Therefore, MA approval procedures are suspended until otherwise agreed by the relevant authority. ▪ Public procurement procedures are also suspended. However, the contracting body may decide to continue with the procedures when justified. Regarding such non-suspended procedures, the deadlines to file an appeal and/or continue it are not suspended. However, since 7 May 2020 procurement procedures that can be awarded via electronic means are no longer suspended. Therefore, since such day all the public procurement procedures that can be conducted via electronic means must continue.

Spain

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

The Spanish authorities have approved the following alternative specifications to European CE marking regarding PPE masks in addition to CE marking:

a) CE marking, standard situation.

b) Public acquisition of PPE masks without CE marking for their use by healthcare professionals if they comply with either the following NIOSH or Chinese specifications, and if they are subject to prior approval from the health authorities:

1. NIOSH_USA accepted equivalences:

EU certification	NIOSH certification
FFP2	N95, R95, P95
FFP3	N99, R99, P99, N100, R100, P100

There is a public list of the products with NIOSH certification: https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html

2. KN95_China

c) Commercialization of protection masks without CE marking will be exceptionally accepted provided that: (i) they comply with the specifications mentioned under (b) above; (ii) the relevant health authority approved their commercialization; and (iii) the CE marking procedure is ongoing.

d) CE marking with a technical specification different from the above-mentioned harmonized standards — notified bodies must verify that the specifications are in line with the standards required by Regulation 2016/425.

The Ministry of Health has relaxed the authorisation requirements for manufacturing surgical masks and medical gowns. These measures include: (i) the possibility of granting temporary operating licences to manufacturing facilities, once their premises, quality systems and the documentation of the products to be manufactured has been evaluated, and (ii) the possibility of authorising the use of products that are critical to protect public health and that have not obtained the CE mark, after evaluation of the available documentation and assessment of the health guarantees required in each case. The Ministry of Health has expressly stated that the Government will assume any liability from the relaxation of the established measures.

Spain

Relaxation of regulatory rules

- Has the government relaxed regulatory rules?

The Spanish regulator (AEMPS) has issued a guideline to help companies obtain the temporary operating licenses. These requests shall be processed as a matter of priority and urgency.

The authorities have also allowed the use of bioethanol to manufacture hydroalcoholic solutions and gels provided that it comply with the technical specifications set out in the Annex of Order SND/321/2020.

The authorities have agreed that PPE without CE mark can be sold to public entities and each contracting body will check whether the products are correct. Additionally, authorities have also established a temporary authorization for PPE that without having the CE mark comply with certain standards that guarantee a minim level of safety (the notification body will be the responsible to evaluate it). Said authorizations will be in force until the obtaining of the CE mark or until 30 September 2020. Information must be borne that the product does not have the CE mark and has been temporary authorized. The Annex to the Resolution of the Industry General Directorate, of 23 April, specifies harmonized standards that will be considered sufficient regarding protection masks (FFP2 and FFP3), gloves, protection clothes and ocular and facial protection equipment. Finally, the Resolution also allows the granting of such temporary authorization to those PPE that have a CE mark based on another technical specification according to sections 3 and 4 of the EU Recommendation 2020/403.

The above measures will only apply during the COVID-19 sanitary crisis.

Clinical trials

- Have special measures been adopted?
- What are the main changes?

- Clinical trial COVID-19 measures include:
  - replacing patients' appointments in person with telephone appointments and/or rescheduling the appointments
  - interrupting the treatment
  - accessing the medicinal products under treatment (supplying the patient with more medicinal products than usual, supplying individuals authorized by the patients and home delivery)
  - updating the monitoring plans of the clinical trial for the next four months and prioritizing centralized and remote monitoring
  - transferring patients from one center to another
  - prioritizing the evaluation of clinical trials addressed to treat or prevent coronavirus
- The measures on clinical trials taken during this period have to be included in the clinical trial file. The implementation of these measures does not require the prior approval of AEMPS or the Ethical Committee, except for the measure in the second bullet point above. During the four months after the date the COVID-19 emergency in Spain ends, the sponsor will send AEMPS and the Ethical Committee a report of the exceptional measures taken.
- The AEMPS has updated the initial recommendations on clinical trials and recommends the implementation of fee exemptions and the simplification of contracts between sponsors and participating sites. In non-commercial clinical trials, the Spanish regulator considers that the contract may be replaced by a document of agreement issued by the management body of those sites.
- The health authorities have limited the supply of medicinal products by public hospitals to patients (as a rule, they can only provide treatment for two months). However, such restriction does not apply to patients of clinical trials. In addition, the authorities have approved that patients who are part of clinical trials can receive the medicinal products at home.

Sweden

Matters	Summary
Specific COVID-19 legislation	The government has proposed measures to mitigate the economic impact and the infection spread: ▪ Governmental Decree (2020:127) on temporary traveling ban to Sweden ▪ Government Bill (2019/20:136) on credit guarantees to air carrier companies ▪ Introducing crisis package proposal for jobs and transition ▪ Governmental Decree (2020:115) on education in certain school forms in the school system to prevent spread of infection ▪ Government Bill (2019/20:151) on additional measures of temporary reductions of the taxation of employers ▪ Government Bill (2019/20:142) on credit guarantees for loans to companies ▪ Government Bill (2019/20:146) on student income during extraordinary events in peacetime ▪ Government Bill (2019/20:143) on temporary measures to facilitate the execution of general meeting of shareholders and general assembly of the association ▪ Government Bill (2019:20:132) on respite for deducted preliminary tax, employer's contributions and VAT ▪ Governmental Decree (2020:126) on appointing the National Board of Health and Welfare as the national purchasing center for medical supplies, protective equipment and certain medical devices, and achieving a good working environment for personnel in healthcare, social services and the Support and Service for Persons with Certain Functional Impairments Act ▪ Governmental Decree (2020:163) on temporary ban on visits to special housing for the elderly to prevent the spread of COVID-19 ▪ Government Bill (2019/20:152) on temporary permit exemptions for the construction of field hospitals ▪ Government Bill (2019/20:144) on the Swedish Parliament to classify COVID-19 as a disease dangerous to society and societal functions under the Swedish Communicable Diseases Act (2004:168)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ The government has not adopted any measures to requisite assets or premises. ▪ The government has not adopted any measures to convert hotels into hospitals. However, field hospitals are being built in collaboration with the Swedish Armed Forces to treat COVID-19 patients. ▪ The government has adopted measures to limit the purchase of prescription drugs to cover only three months' consumption. ▪ In response to the urgent need for medicines, medical devices and medical supplies, the government has decided to reorganize the national supply scheme by appointing the National Board of Health and Welfare (*Socialstyrelsen*) as the national purchasing center for medical supplies to facilitate the supply of equipment across the country. ▪ Normally, it is not permissible to transfer medicines between pharmacies. However, the Swedish Medicines Agency (**MPA**) has imposed reliefs in this regard by allowing pharmacies that need to be closed for an extended period during the ongoing pandemic to transfer medicine to another pharmacy with the same licensee.

Sweden

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Price and reimbursement procedures for medicinal products and medical devices have not been affected.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	▪ No exceptional public procurement measures have been adopted other than the above-mentioned reorganization of the national supply scheme, where the National Board of Health and Welfare was appointed as the national purchasing center for medical supplies to facilitate the supply of equipment across the country. ▪ No procedural requirements have been relaxed for COVID-19 related medicines and devices. ▪ Sanctions for unfilled orders are regulated in each specific agreement between the parties.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	The government has proposed the following measures: ▪ temporary suspension of the deduction from sick pay during the qualifying period ▪ the requirement of a doctor's medical report for an employer is temporarily suspended for the first two weeks of illness ▪ the requirement of a doctor's medical report for the application of sick pay is temporarily suspended from 27 March and during the first 21 days of illness The government has decided that the extradition of public documents at all Swedish authorities must proceed normally with urgency. However, the requisite to deliver urgently has been relaxed to delivering **as soon as possible** for some authorities.

Sweden

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	The MPA has granted emergency licenses for remdesivir (which is still under development) for patients with COVID-19 who have, or are at risk of developing, a complicated disease, i.e., life-threatening breathing problems. The relief means that treating physicians do not need to apply for a license from the MPA for each patient to treat them with remdesivir. The Swedish Work Environment Authority has granted temporary authorization for the use of non-CE marked military grade gas masks (*Skyddsmask 90*) in certain functions outside of the armed forces, such as ambulance services and other emergency rescue services.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	Clinical trial COVID-19 measures include: ▪ Reliefs for delivering trial products to participants directly, allowing clinical trials to proceed as planned. ▪ The Ethical Review Agency has created a procedure to handle requests for granting priority to authorizations of clinical trials regarding COVID-19.

Switzerland

Matters	Summary
Specific COVID-19 legislation	Ordinance on Measures to Combat the Coronavirus (COVID-19) of 13 March 2020 (as amended)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	The government has the power to requisition assets and premises and to convert hotels into hospitals/medical centers for quarantine and self-isolation but has not yet done so. However, the federal government empowered the cantons to require private hospitals and clinics to make their facilities available for the admission of patients. Furthermore, healthcare facilities — in particular, hospitals and clinics, medical practices and dental practices — are prohibited from carrying out non-urgent medical examinations, treatments and therapies (medical procedures). This prohibition will be set aside effective 27 April 2020. Furthermore, a license from the State Secretariat for Economic Affairs (**SECO**) is required for the export of protective equipment from the Swiss customs territory (protective eyewear and visors, gloves, face shields, mouth-nose protection equipment and protective garments). To support the provision of essential medical goods to the cantons and their healthcare facilities, charitable organisations (for example Swiss Red Cross) and third parties (for example laboratories, pharmacies), essential medical goods may be procured if requirements cannot be covered through the normal procurement channels. Laboratories, manufacturers and distributors of in-vitro-diagnostics («COVID-19-Tests») regularly have to notify the Laboratory Spiez their current stock of such tests. The Laboratory Spiez is responsible for the allocation of these tests. The federal government also has the power to request manufacturers to manufacture essential medical goods, to prioritize the manufacturing of such goods or to increase the number of the manufactured goods if the supply with such goods cannot be secured. There is an exhaustive list of medicinal products, medical devices and protective equipment that qualify as essential medicinal goods.

Switzerland

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	No specific pricing and reimbursement rules have been adopted so far.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	No specific public procurement rules have been adopted so far.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	No legal deadlines have been suspended or relaxed with respect to the healthcare sector However, to the extent that the applicable procedural law provides for a stay of the statutory limitation periods or periods set by the court over Easter, such stay was extended to run from 21 March 2020 to 19 April 2020. This has no impact on MA approvals or public procurement except on any subsequent lawsuit in that respect.

Switzerland

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	Yes. Medicinal products that are manufactured with certain specific active substances explicitly mentioned by law for the treatment of COVID-19 patients may, provided an application for authorization of a medicinal product containing one of these active substances has been filed, be placed on the market without authorization pending Swissmedic's decision on authorization. When examining applications for authorization, Swissmedic may permit a relaxation of the relevant requirements for such medicinal products under the law on therapeutic products on the basis of a risk-benefit analysis. Amendments to the authorization for a medicinal product authorized in Switzerland containing a specific active substance listed by law that is used to prevent and treat COVID-19 in Switzerland may be made immediately after filing a corresponding amendment application. Swissmedic may permit a relaxation of the relevant requirements for such amendments. Swissmedic may on the basis of a risk-benefit analysis permit changes to the manufacturing process approved within the framework of the authorization of medicinal products used to prevent and treat COVID-19 in Switzerland. Swissmedic has established the criteria according to which the Responsible Person may grant an early market release for medicinal products used to prevent and treat COVID-19 in Switzerland. Furthermore, Swissmedic may authorize the placing on the market and use of medical devices that have not undergone a conformity assessment procedure, provided their use for preventing and combating COVID-19 in Switzerland is in the interests of public health or patient safety or health and provided, taking account of their intended purpose, their fulfilment of the essential requirements and their effectiveness and performance are adequately proven. When assessing the risks, Swissmedic shall in particular take account of the procurement needs identified by the Federal Office for Public Health for preventing and combating COVID-19 in Switzerland.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	No. However, joint guidance from Swissmedic and swissethics on the management of clinical trials with medicinal drug products in Switzerland during the COVID-19 pandemic has been issued. The authorities will prioritize applications for clinical trials with medicinal drug products to treat COVID-19 or substantial amendment applications to existing clinical trials necessary as a result of COVID-19. During the COVID-19 pandemic period, the delivery of study medication directly to the study patient from the trial site might be permissible, provided that the study drugs are suitable for use at home. Changes in the distribution of the study medication have to be notified to Swissmedic and swissethics for their information. The guidelines also deal with other issues related to clinical trials such as the patient's informed consent.

Turkey

Matters	Summary
Specific COVID-19 legislation	▪ Presidential Circular No. 2020/3 regarding the postponement of meetings and organizations ▪ Amending Communique on Prohibited Goods and Goods Subject to Prior Approval (**Communique**) ▪ The Ministry of Health's Circular on COVID-19 Measures for Health Service Providers ▪ The Ministry of Health's Instruction Letter to Pharmacies Regarding COVID-19 Measures ▪ Announcements, instructions and guidelines of the Turkish Pharmaceuticals and Medical Devices Agency (**TİTCK**) ▪ Amending Decrees on Import Regime (regarding respirators)
Requisition powers	
▪ Has the government established any powers to requisition assets and premises?	No. The ministries, however, have been tightening their measures and increasing their inspectional activities. In this regard, although the Turkish government has not yet authorized the public authorities to requisition assets and premises, it may be possible for the government to adopt measures that are generally more restrictive in the immediate future due to the increase in COVID-19 cases.
▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation?	No specific regulation converting hotels into hospitals/medical centers has yet been introduced. Certain hotels, however, on their own initiative, have been providing accommodation services to healthcare personnel with no charge during the COVID-19 outbreak.
▪ Is it controlling the distribution of medicinal products/medical devices?	The distribution of medical devices/pharmaceuticals is not directly restricted. On 26 March 2020, however, the TİTCK required hospitals to make unit dosage notifications through the Pharmaceuticals Track & Trace System for certain pharmaceuticals used for the treatment of COVID-19. In other words, the TİTCK will track these pharmaceuticals and it may possibly introduce restrictions for the distribution of such pharmaceuticals as a measure to combat COVID-19 effectively. In addition, further to the amendments to the Communique, the export of medical devices such as ventilators, oxygen concentrators, intubation tubes and other respirators are now subject to the TİTCK's prior approval. Accordingly, persons wishing to export the mentioned medical devices must apply to the TİTCK electronically for approval. Nevertheless, according to the Amending Decrees on Import Regime, the Ministry of Trade remitted additional customs tariffs applicable to the respirators (13%), disposable medical masks (20%) and ethyl alcohol used for disinfectant liquids (10%).

Turkey

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	No specific price and reimbursement procedure for pharmaceuticals and medical devices has yet been adopted. As noted above, however, the ministries have already been taking certain measures such as customs restrictions and the tracking of pharmaceuticals. In this regard, it may be possible for the Turkish government to adopt certain price and reimbursement measures in the future due to the increase in COVID-19 cases.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	No sector-specific public procurement measures have yet been adopted. The government has not adopted any exceptional public procurement measures. However, the COVID-19 outbreak may trigger emergency provisions embedded in the legal framework. In other words, the urgency stemming from the pandemic enables public tender authorities to use expedited emergency procurement procedures as opposed to lengthy and scrutinized open tender procedures. For your reference, please find brief explanations regarding these procedure changes below. Under normal circumstances, much of the public procurement is done through open tenders and direct procurement. ▪ Open tenders, as regulated under the Public Tender Law, are complicated and thoroughly regulated processes that impose time-consuming safeguards such as tender announcements, seeking bonds from participants, awarding tenders and executing the contract between the procurement authority and the winning tenderer. Open tender processes are frequently appealed and put to judicial review throughout the process, which may lead to tenders being canceled. The process may take months. ▪ On the other hand, direct procurement, as regulated under Article 22 of the Public Tender Law, is a simplified procurement process. Direct procurement is only available in prescribed circumstances, including but not limited to: (i) the purchase of emergency, patient-specific or perishable medical consumables or supplies; and (ii) the rent or purchase of real estate per a public entity's needs. The procurement is expedited since the procurement authority is not obligated to prepare tender documents, make an announcement or set up a tender committee. In some cases, it is even possible not to have a technical specifications document or to execute a written contract at the end of the procurement. This process can be completed within days as opposed to months. Under the emergency circumstances of COVID-19, a public procurement method called "bargaining tender," regulated under Article 21 of the Public Procurement Law, is available to address the outbreak. Public authorities frequently use this method to address urgent procurements. The emergency of COVID-19, however, activates Article 21(b) of the Public Procurement Law, which is reserved for infectious disease outbreaks when time is of the essence for the completion of the procurement. Accordingly, public authorities can use this tool when the procurement is: (i) related to the emergency of the infectious disease; and (ii) the procurement should be completed as soon as possible. Bargaining tenders do not have to be announced in principle, as only invited companies submit bids to the tenders, and the participants may not have to post a performance bond under certain conditions.

Turkey

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	As noted above, there is no sector-specific guidance or relaxed procedures for public procurements in relation to pharmaceuticals or medical devices. Having said that, given the increase in COVID-19 cases in Turkey, the Turkish authorities may shed light on this matter in the immediate future.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	Further to the amendments to certain laws effective as of 25 March 2020, all time limits regarding the origination, exercise and termination of any rights, including but not limited to the statute of limitations, peremptory terms for filing legal actions, commencing enforcement proceedings, warnings, notices, submissions, complaints, objections and mandatory administrative application timelines, and other timelines under certain laws (e.g., the Code of Administrative Procedure), are suspended from 13 March 2020 to 30 April 2020. Having said that, the TİTCK did not provide any guidance on whether these measures apply to the administrative timelines under the healthcare legislation. For the TİTCK's announcements on regulatory rules, please see the section "Relaxation of regulatory rules" below.
Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	In principle, all medical devices placed on the Turkish market must be registered with the Product Tracking System. For the registration process, applicants must submit certain documents relating to the medical devices. Some of these documents (e.g., EC certificate and conformity certificate) must be apostilled and physically submitted to the TİTCK. The TİTCK announced that it will not initially require the physical submission of these documents and it will grant a 60-day extension period. If the documents cannot be submitted within the extension period, the TİTCK may grant 60 more days upon the applicant's extension application. The TİTCK will also accept the submission of documents that do not have to be submitted physically (such as the ISO 13485 certificate or authorized distributorship certificate) if the apostillization procedures for these documents could be completed in a timely manner. The TİTCK also announced that the effective period of approvals for off-label use or the use of the pharmaceutical procured from abroad (name patient sales) is extended to 30 June 2020 if the approvals expire between 1 March 2020 and 30 June 2020. It is worth noting that the TİTCK has been very active recently, publishing official announcements on regulatory requirements on a daily basis. Therefore, we expect the TİTCK to provide further guidance on how the regulatory requirements should be interpreted during the COVID-19 outbreak.

Turkey

Clinical trials

- Have special measures been adopted?
- What are the main changes?

The TİTCK announced changes to clinical trial procedures during the COVID-19 outbreak. The TİTCK's measures generally aim to reduce the workload of research centers and ensure the safety of volunteers:

- The TİTCK requires sponsors to regularly conduct risk assessments, coordinate their clinical trial organizations and make updates when necessary. In this respect, the TİTCK states that sponsors must initially evaluate whether clinical trials should be temporarily suspended or terminated early, depending on the nature of the clinical trial.
- If an event occurs that affects the safety of volunteers, sponsors or principal investigators must take the necessary emergency safety measures to protect volunteers. Accordingly, safety measures taken against the COVID-19 pandemic can be implemented without the Ethics Committee's approval or the TİTCK's authorization.
- Sponsors or principal investigators may make changes to the monitoring activities during the clinical trials. In this regard, monitoring activities at the research center may be postponed and/or rescheduled. The TİTCK also allows remote monitoring if physical monitoring at the research center is unfeasible, which is subject to Law No. 6698 on Protection of Personal Data and the confidentiality principles of clinical trials.
- The TİTCK allows investigational products and clinical trial supplies to be stocked for a longer period so that a sufficient amount of materials can be supplied to research centers in case of possible scenarios such as import restrictions or quarantine. The TİTCK also requires volunteer visits to research centers to be postponed if feasible, recommending telephone calls as an alternative.
- The TİTCK stated that research meetings will be held online and it will not grant approval for face-to-face trainings or meetings regarding good clinical practices and clinical trials.
- The TİTCK will not require physical documentation to be submitted for clinical trial applications. It stated that applications would be made electronically.

United Kingdom

Matters	Summary
Specific COVID-19 legislation	Coronavirus Act 2020 The Statutory Sick Pay (General) (Coronavirus Amendment) Regulations 2020
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	The UK government has not yet adopted any formal powers to: ▪ requisition assets and premises. ▪ convert hotels into hospitals / medical centers for quarantine and self-isolation. ▪ control the distribution of medicinal products / medical devices. However, there have been some developments in these areas. **Production of ventilators and CPAP devices:** The UK Government is looking for businesses which can support in the supply of ventilators, CPAP devices and related components across the UK (see here). It has produced a specification of the minimally clinically acceptable ventilator, along with some preferred options, and a CPAP device, to be used in UK hospitals. In the UK, the Civil Contingencies Act 2004 provides the UK Government with particular powers in emergencies such as loss of human life, human illness and injury. We expect the UK government to prefer that manufacturing switches are voluntary but it is not inconceivable that powers under the Civil Contingencies Act could be used or the government may pass specific legislation to deal with the situation. **NHS staff use of hotel accommodation:** For those staff of the UK's National Health Service (NHS) affected by Public Health England's 14 day household isolation policy, the NHS is offering staff the alternative option of staying in NHS-reimbursed hotel accommodation while they continue to work. NHS England and NHS Improvement have established a single process for NHS staff to secure accommodation at hotels within their immediate area, if they have been affected by COVID-19 in some way. The supplier of this service to the NHS is Corporate Travel Management (CTM). CTM has national agreements with a wide number of hotel operators across the country. **Distribution of medicinal products / medical devices:** The NHS has introduced measures to manage the supply shortage. These include the NHS Urgent Medicine Supply Advanced Service (NUMAS), which allows patients whose GP practice is closed to continue receiving their medicines, and Medicines Delivery Service, which supports self-isolating and vulnerable individuals.

United Kingdom

Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	The UK government has written to suppliers informing them that the National Supply Disruption Response is monitoring the supply situation and will provide solutions where possible. NHS Supply Chain are focussed on the fast and safe supply of both personal protective equipment (PPE) and other critical consumables. It has put in place new delivery processes to give suppliers visibility over orders, and ensure it maximises deliveries to NHS hospitals. **NHS Essential Medicine Supply** NHS England has developed a list of the most critical ITU medicines and Anaesthetic drugs and is liaising with the Association of the British Pharmaceutical Industry (ABPI) to promulgate the list and calling for support from the UK pharma industry to maximise production of these essential products. Additional critical drugs may be added to the list in due course as further clinical policies are developed to support the Covid-19 response. Again, we expect the UK government to prefer that this support is voluntary but it is not inconceivable that powers under the Civil Contingencies Act could be used or the government may pass specific legislation to deal with the situation if the supply of the listed medicines to the UK market was perceived to be at risk. The MHRA has been maintaining its list of medicines that cannot be parallel exported from the UK, which was originally developed in 2019 ahead of a possible no-deal Brexit, but now includes medicines key to the treatment of COVID-19, including morphine, paracetamol, adrenaline and insulin.
Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	The National Institute for Health and Care Excellence (NICE), the health technology assessment body in England that makes reimbursement recommendations, is prioritising all therapeutically critical topics, including all appraisals of cancer medicines, diagnosis of COVID-19 and treatment of COVID-19. (NICE's advisory committees are made up of a lot of frontline NHS staff who cannot fulfil their NICE role due to their more pressing work with patients.) NICE is therefore working on revised timelines for all our other guidance that is not related to COVID-19 or therapeutically critical, progressing guidance and any work they can do without committee engagement. NICE has said it will communicate with its advisory committee chairs, members and stakeholders as soon as possible. The Scottish Medicines Committee (SMC) has cancelled all its scheduled meetings of New Drugs Committees until the end of May 2020 in response to the COVID-19 crisis, in order to release its committee members and staff to support work aligned with COVID-19 resilience. A core SMC team will continue to assess the new medicine submissions that are currently in the system and will work on urgent activities around COVID-19 as required.

United Kingdom

Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	The UK Government has not introduced new legislation on public procurement in response to COVID-19. However, a procurement policy note from the UK government (see here) sets out how contracting authorities may approach procurement activities as they respond to COVID-19 challenges. The guidance summaries key existing provisions under the Public Contract Regulations 2015 which facilitate expedited procurement procedures for public authorities, including: ▪ direct award due to extreme urgency; ▪ direct award due to absence of competition or protection of exclusive rights; ▪ call off from an existing framework agreement or dynamic purchasing system; ▪ call for competition using a standard procedure with accelerated timescales; and ▪ extending or modifying a contract during its term.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	**Extension of deadline for NHS's Data Security and Protection (DSP) Toolkit:** NHSX has pushed the final deadline for DSP Toolkit submissions from 31 March 2020 to 30 September 2020. Organisations can choose to complete DSPT before that date. If they do so, and if they fully meet the standard, those organisations will be awarded 'Standards Met' status, as in previous years. For background, all organisations that have access to NHS patient data and systems must use the toolkit to provide assurance that they are practising good data security and that personal information is handled correctly. **CQC Inspections suspended:** The Care Quality Commission (CQC) has announced that it will be stopping routine inspections, to focus on its primary objective to support providers to keep people safe (see here). **Postponing MHRA Good Practice (GxP) inspections:** The UK's Medicines and Healthcare products Regulatory Agency (MHRA) will only be conducting essential inspections of laboratories, clinical trials, manufacturing, distribution and pharmacovigilance until further notice. However, the MHRA are expecting organisations to maintain GxP compliance (see here). The MHRA will prioritise essential on-site inspections linked to the UK Government's COVID-19 response or any other potential serious public health risk, where these sites cannot be assessed remotely. **Medicines Approvals and Variations:** The MHRA is expediting the assessment of variations and initial applications – it is implementing priority and expedited assessment for national variations (including batch-specific variations) and initial marketing authorisation applications that impact the medicines supply chain. Guidance is in preparation on how to highlight these at the time of submission

United Kingdom

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	**Exemptions from UK MDR:** The MHRA may authorise manufacturers to supply a non-CE marked device in the interest of the protection of health (see here). This will be under regulations 12(5), 26(3) and 39(2) of the Medical Devices Regulations 2002, and is likely to be relevant for manufacturers of ventilators and PPE. The Department of Health and Social Care (DHSC) can grant its approval so that manufacturers may submit applications for exemption from the regulations to the MHRA. The DHSC may grant its approval regarding ventilators as long as they comply with the necessary minimum specifications which have been set out by the UK Government for ventilators (see here). For any other relevant devices such as PPE, the application may be sent directly to the MHRA. **MHRA Guidance for Manufacturers Specials licence holders on 'packing down' medicines:** Facilities with a Manufacturers Specials (MS) licence, may under normal circumstances pack down for their own use or in response to an order from a registered pharmacy, but not for retail sale. However, the MHRA are relaxing rules on packing down for distribution to community (retail) pharmacies, provided certain conditions are complied with (see here).
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	The UK's Health Research Authority (HRA) and MHRA have published guidance on the impact of COVID-19 on medical research in the UK (here and here). The HRA provides guidance on: ▪ New studies relating to COVID-19, including procedures for expedited review. ▪ Amendments to existing studies to address COVID-19 elements, such as adding sub-studies or components to enable epidemiological analysis of COVID-19, or to add patients with COVID-19 to an existing trial. ▪ Amendments to existing studies impacted by the wider COVID-19 response, such as sponsors making changes to how or when patients are seen (to avoid exposing patients or to reduce burden on clinical services), investigational medicinal product (IMP) being sent by courier direct to participants, or halting / closing studies. The MHRA's guidance addresses a range of issues, including: ▪ the MHRA prioritising COVID-19 assessments. ▪ providing investigational medicinal products to trial participants. ▪ remote monitoring for trials. ▪ submitting paperwork for trials that have been halted. ▪ restarting a trial after it has been halted. ▪ reporting of serious adverse events (SAEs) and submission of annual safety reports (DSURs) and end-of-trial notifications. ▪ protocol deviations, serious breaches and waivers.

United Kingdom

Clinical trials	For clinical investigations of medical devices, the MHRA will expedite clinical investigations as follows:
▪ Have special measures been adopted? ▪ What are the main changes?	▪ Any amendments to existing clinical investigations as a direct result from COVID-19. ▪ Any new submissions for clinical investigations that will have a direct impact on the COVID-19 emergency. ▪ Protocol deviations as a result of COVID-19 do not need to be notified to MHRA unless there is an impact on patient safety; however good records of these deviations should be kept. However, all other protocol deviations must be reported as normal.

Ukraine

Matters	Summary
Specific COVID-19 legislation	▪ Law of Ukraine No. 530-IX "On Amending Certain Legislative Acts of Ukraine Aimed at Preventing Emergence and Spread of Coronavirus Disease (COVID-19)" dated 17 March 2020 ▪ Law of Ukraine No. 533-IX "On Amending the Tax Code of Ukraine and other Laws of Ukraine to Support Taxpayers for the Period of Taking Measures Aimed at Preventing Emergence and Spread of Coronavirus Disease (COVID-19)" dated 17 March 2020 ▪ Law of Ukraine No. 540-IX "On Amending Certain Legislative Acts of Ukraine Aimed at Ensuring Additional Social and Economic Guarantees due to Spread of Coronavirus Disease (COVID-19)" dated 30 March 2020 ▪ Law No. 3539-IX "On Amending Certain Laws of Ukraine Aimed at Ensuring Treatment of Coronavirus Disease (COVID-19)" dated 30 March 2020 ▪ Resolution of the Government No. 211 "On Preventing Spread of Acute Respiratory Disease COVID-19 Caused by Coronavirus SARS-CoV-2" dated 11 March 2020 ▪ Resolution of the Government No. 224 "On Approval of the List of Pharmaceuticals, Medical Devices and/or Medical Equipment Required for Taking Measures to Emergence and Spread, Localization and Liquidation of Outbreaks, Epidemics and Pandemics of Coronavirus Disease (COVID-19) Exempt from Import Duty and Importation of which into the Customs Territory of Ukraine are Exempt from Value Added Tax" dated 20 March 2020 ▪ Resolution of the Government No. 223 "On Preventing Export (Sending) of Certain Anti-Epidemic Goods outside the Customs Territory of Ukraine by Citizens" dated 16 March 2020 ▪ Resolution of the Government No. 226 "On Amending Certain Resolutions of the Government" dated 20 March 2020
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	▪ No, as of 23 April 2020 the government has not established any powers to requisition assets and premises. ▪ As of 23 April 2020, no measures aiming to convert hotels into hospitals/medical centers for quarantine and self-isolation have been approved. At the same time, the government is considering the establishment of temporary hospitals to treat COVID-19 patients at convention and sports centers in case the capacities of existing healthcare facilities become insufficient. ▪ Based on Resolution No. 223 dated 16 March 2020, the government prohibited the export of certain personal protective equipment, including masks, gloves, etc.

Ukraine

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	Yes, the price and reimbursement procedures for medicinal products and medical devices have been affected as follows: ▪ Under Law No. 3539-IX, in addition to existing powers to regulate prices, the government was additionally empowered to: (i) set maximum wholesale and retail prices for anti-epidemic goods and socially significant products; and (ii) prohibit the mass buying and selling of the same products at prices exceeding those set by the government during the quarantine. The government establishes the list of anti-epidemic and socially significant products. The government approved such a list on 22 April 2020, but it has not been published yet. ▪ In addition, liability for violating the pricing regulations was increased. The fine for violating the pricing regulations was increased from UAH 85-170 (approx. EUR 3-6) to UAH 1,700 (approx. EUR 57) for individuals, and UAH 2,550 (approx. EUR 86) for companies' officials. Fines for repeated violations within one year as of imposing a previous fine were increased from UAH 170-255 (approx. EUR 6-7) to UAH 2,550 (approx. EUR 86) for individuals, and UAH 3,400 (approx. EUR 115) for companies' officials. If violations of the pricing regulations occurred during the quarantine with respect to anti-epidemic goods and/or socially significant goods, and the price of such goods exceeds the maximum price set forth by the government by 1.2, the amount of the fine is UAH 3,400-4,250 (approx. EUR 115-144) for individuals, and UAH 4,250-5,100 (approx. EUR 144-172) for companies' officials.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	Yes, the government has adopted exceptional public procurement measures and relaxed procedural requirements for COVID-19 related medicines and devices: ▪ Law No. 530-IX dated 17 March 2020 and the Resolution of the Government No. 226 dated 20 March 2020 envisaged an expedited and simplified procedure for the procurement of goods, works and services required to combat COVID-19. Under the same procedure, public procurement entities may procure goods, works and services to combat COVID-19 outside the online ProZorro platform, which is used under the standard procurement procedure. Under the simplified procedure, the procurement entity is authorized to establish its own criteria for selecting successful bidders. The procurement entity must only upload the procurement report, procurement agreement and performance report to the ProZorro platform. ▪ No additional sanctions for unfilled orders have been introduced. In general, liability for unfilled orders should be set forth in the procurement agreement. There is also a high risk of criminal conviction for the failure to supply to public procurement entities, especially in view of the ongoing pandemic.

Ukraine

Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	Yes, legal/administrative deadlines have been suspended/relaxed: ▪ Based on Law No. 3539-IX dated 30 March 2020, most of the court procedural terms established by the law were extended for the duration of the officially declared quarantine (e.g., terms for challenging court decisions, amending claims and the consideration of cases). Where the procedural term is established by the court, it will not be shorter than the term of the officially declared quarantine (for commercial and administrative courts only). The limitation period terms (both general and specific) were also prolonged for the time of the officially declared quarantine. ▪ The above measures did not have any impact on MA approvals, public procurement, etc. At the same time, the Ministry of Health of Ukraine (MOH) is considering the draft order, whereby the legal timelines for the approval of MA/clinical trial applications may be extended due to quarantine. In addition, originals of MA certificates will not be issued until the end of the quarantine (the MA will be confirmed by entering relevant data into the state register of pharmaceuticals). ▪ Based on Law No. 3539-IX dated 30 March 2020, the government must ensure there are expedited legal timelines for approving MA (variation) and clinical trials (significant amendment) applications of pharmaceuticals for treating COVID-19. The government must ensure that MA (variation) applications are approved within seven calendar days and clinical trial (significant amendment) applications are approved within 10 calendar days. To become effective the same timelines must be introduced by the MOH into its orders establishing the procedures for granting MA and clinical trial approvals. As of 23 April 2020, the MOH has not yet introduced the required changes into its orders.
Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	Yes, the government has relaxed regulatory rules as follows: ▪ Based on the Resolution of the Government No. 226 dated 20 March 2020, personal protective equipment, medical devices, in vitro diagnostics and active implantable devices for combating COVID-19 may be placed on the market without conducting conformity assessments set forth in applicable technical regulations. To place products on the market in derogation of technical regulations the applicant must submit to the State Labor Service of Ukraine (for personal protective equipment) or to the MOH (for medical devices, in vitro diagnostics and active implantable medical devices) the application containing information on, e.g., the purpose of importation, the product and its manufacturer. The State Labor Service of Ukraine or the MOH should issue a notification on introducing personal protective equipment and devices into circulation in derogation of relevant technical regulations. ▪ Based on Law No. 3539-IX dated 30 March 2020, the Parliament of Ukraine permitted the off-label use of certain pharmaceuticals. Off-label use is permitted in case a pharmaceutical has proven to be efficient in treating COVID-19 and/or if a pharmaceutical is recommended by the authorities of the US, EU member countries, the UK, Switzerland, Japan, Australia, Canada, China or Israel for the treatment of COVID-19. The Parliament of Ukraine also permitted using unapproved pharmaceuticals if the same are recommended by authorities of states set forth above for the treatment of COVID-19. At the same time, Law No. 3539-IX does not provide guidance on the form in which the same authorities should recommend pharmaceuticals for treating COVID-19 or guidance on how the proven efficiency of a product to treat COVID-19 should be confirmed. Apparently, these criteria must be clarified by the MOH. The use of unapproved pharmaceuticals and the off-label use of approved pharmaceuticals are only permitted subject to obtaining a patient's consent. Such pharmaceuticals must be used in compliance with the clinical protocol approved by the MOH on 2 April 2020.

Ukraine

Clinical trials
 	
▪ Have special measures been adopted?
▪ What are the main changes?
	▪ Yes, the regulator for clinical trials (the State Expert Center of the Ministry of Health of Ukraine (**State Expert Center**)) issued recommendations regarding conducting clinical trials in view of the spread of COVID-19. Among other things, the safety measures that may need to be taken include the following:
	  ▪ replacing personal meetings with phone calls, video calls, use of electronic communication devices, etc.
	  ▪ remote monitoring, provided that it does not create extra burden on trial sites and the subjects consent to their personal information being shared outside the trial site
	  ▪ withdrawal of subjects from trials
	  ▪ temporary halt of a trial/recruitment of new subjects
	  ▪ transfer of participants to other sites
	  ▪ direct-to-patient shipment of trial products
	  ▪ laboratory testing outside the trial site or at a patient's home
	  ▪ visiting patients at their residential addresses by investigators for clinical and diagnostic tests
	  ▪ use of telemedicine technologies
	  ▪ when there is the need to re-consent, investigators may obtain oral informed consent supplemented with email confirmation
	▪ An increase in study protocol deviations in relation to COVID-19 will not be considered serious violations, therefore, there is no need to notify the State Expert Center immediately (unless patients are being put at risk).
	▪ Inspections of clinical trial sites by the State Expert Center scheduled for Q1 2020 were rescheduled to Q2 2020.

Uzbekistan

Matters	Summary
Specific COVID-19 legislation	▪ Directive of the President of the Republic of Uzbekistan "On formation of the special republican commission on the preparation of a program of measures to prevent the entrance and spread of a novel coronavirus in the Republic of Uzbekistan" No. R-5537 dated 29 January 2020 (**Directive**) ▪ Decree of the President of the Republic of Uzbekistan "On primary measures to mitigate negative influence of the coronavirus pandemic on the economy and global crisis phenomena" No. UP-5969 dated 19 March 2020 (**Decree**) ▪ Resolution of the Cabinet of Ministers of the Republic of Uzbekistan "On additional measures for prevention of spread of coronavirus infection" No. 176 dated 23 March 2020 (**Resolution 176**) ▪ Resolution of the President of the Republic of Uzbekistan "On additional measures to prevent a wide spread of coronavirus infection in the Republic of Uzbekistan" No. PP-4649 dated 26 March 2020 (**Resolution 4649**) ▪ Resolution of the President of the Republic of Uzbekistan "On additional measures to support medical workers and employees of the sanitary and epidemiological service that are involved in combating the spread of coronavirus infection" No. PP-4652 dated 26 March 2020 ▪ Resolution of the President of the Republic of Uzbekistan "On additional measures for ensuring supply of the population's needs in medicines, medical devices, medical equipment and first necessity goods" No. PP-4662 dated 27 March 2020 (**Resolution 4662**)
Requisition powers ▪ Has the government established any powers to requisition assets and premises? ▪ Is it converting hotels into hospitals/medical centers for quarantine and self-isolation? ▪ Is it controlling the distribution of medicinal products/medical devices?	The Uzbek government has not established any powers to requisition assets and premises. According to Resolution 176, regional municipalities must establish three bases in every region (four in Karakalpakstan) adapted for a 14-day quarantine regime. State sanatoriums and other recreation facilities, as well as state rest hotels, may be used to establish such bases. Resolution 4649 allows private hospitals to provide medical services to coronavirus-infected patients until 1 September 2020. Hence, private hospitals are allowed to be converted into medical centers for quarantine without formal public procurement requirements/procedures and without obtaining necessary licenses. A private hospital is allowed to provide such services after the execution of the service contract between the hospital and the Ministry of Healthcare of Uzbekistan. It implies that the Uzbek government, represented by the Ministry of Healthcare, will cover the costs of private hospitals for the treatment of patients with coronavirus infections. Resolution 176 mandates the Special Commission[1] to monitor the continual supply of essential medicines, masks and medical devices (for disinfection and other) to the population at fixed prices. The Decree established an anti-crisis fund comprising approximately USD 1 billion. Anti-crisis fund proceeds will be partially used to finance the procurement of medicines and medical devices necessary to combat the spread of coronavirus infection.

[1] Special Republican Commission for the preparation of a program of measures to prevent the entrance and spread of a novel coronavirus in the Republic of Uzbekistan, established by the Directive.

Uzbekistan

Pricing and reimbursement ▪ Has the price and reimbursement procedures for medicinal products and medical devices been affected?	The Directive mandates several state authorities to conduct the daily monitoring of prices for medicines, medical devices and medical equipment, as well as materials and substances used for their production, to prevent artificial price increases due to the coronavirus epidemic. In addition, as stated above, the Special Commission will monitor the supply of essential medicines and medical devices at fixed prices.
Public procurement ▪ Has the government adopted exceptional public procurement measures? ▪ Have procedural requirements been relaxed for COVID-19 related medicines and devices? ▪ Are sanctions foreseen for unfilled orders?	According to Resolution 176, public procurement procedures do not apply to the public procurement of medicines, medical devices, medical equipment, and materials and substances used for their production (as per the list approved by the government) during the epidemic period. Hence, state purchases may proceed to execute direct contracts with suppliers that provide the best offers without formal tender/bidding procedures. Currently, the approved list of such medicines, medical devices and medical equipment is not publicly available.
Legal deadlines ▪ Have legal/administrative deadlines been suspended/relaxed? ▪ Have these measures had an impact on MA approvals, public procurement, etc.?	According to Resolution 4662, customs duties are not imposed on imports of medicines, medical devices, medical equipment, and materials and substances used for their production (a list of which is approved by the state authorities and is not publicly available). Moreover, Resolution 4662 authorized the Special Commission to: ▪ grant certain finished medicines and medical devices with exemption from value-added tax for a period of up to three months ▪ reduce the rates of customs duties and excise tax up to 0% for imports of certain types of essential goods for a period of up to three months (the list of essential goods may be approved by the Special Commission itself) Uzbekistan is planning to adopt a law that would allow imports of medicines used to prevent dangerous infectious diseases without marketing authorizations during epidemiological situations in the country. We expect the adoption of the law in the very near future.

Uzbekistan

Relaxation of regulatory rules ▪ Has the government relaxed regulatory rules?	Please see our comments above.
Clinical trials ▪ Have special measures been adopted? ▪ What are the main changes?	N/A

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