INTERNATIONAL

INVESTING IN HEALTHCARE AND LIFE SCIENCES

A guide to key legal and regulatory issues in health and life sciences transactions

June 2022

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INTRODUCTION

Today's global healthcare marketplace is marked by unprecedented transformation. This presents both challenges and opportunity to today's market participants. We know how important it is to structure cross-border investments and transactions to account for complex and ever-shifting regulations.

Within this dynamic environment, McDermott's health lawyers wield a deep knowledge of how healthcare services, medical technology and pharmaceuticals are delivered around the world, and how the laws that affect those entities and that help drive action are creating the market of tomorrow.

We're passionate about our role in shaping the alliances that will lead to next-generation digital health technologies, new pharmaceuticals and superior healthcare delivery.

If you're doing something that's never been done before, or looking to do something better than it's ever been done before, we're here to help. Together, we're pushing boundaries and knocking down barriers to usher in a new age of healthcare.

LEGAL AND REGULATORY

As a leading law firm for healthcare and life sciences, we help clients find creative and unexpected solutions for cross-border transactions and investments. Our cross-practice team affords you unmatched legal experience while balancing local, regulatory, technological and structural needs.

We have developed this guide as a step in your journey to global healthcare and life sciences collaborations and stand ready to help you implement a practical and operational approach.

Together, we can transform healthcare.

What you'll discover for each jurisdiction:

- The impact of COVID-19 on the provision of healthcare and life sciences
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AUSTRIA

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

The pandemic has had a significant effect on healthcare and life sciences in Austria. Some of the changes in law and policy are most likely to be in force during the pandemic only. Such temporary changes may include, for example, new compliance rules in the procurement of medical protective equipment; provision of certain COVID-19-related medical services for (specialised) physicians and paramedics; no supervision by physicians in certain COVID-19-related medical services; no CE mark for standard face masks; and strict behavioural rules and testing requirements for staff members in hospitals.

Telemedicine, however, has experienced a boost that will outlive the pandemic. Although it has not been explicitly regulated (neither before nor during the pandemic), it has now been largely accepted that physicians are not required to provide their services in person in every case but can do so remotely

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

Full medical care may be provided only by physicians (*Ärzte*) or dentists (*Zahnärzte*) in private practices or hospitals (*Krankenanstalten*). Physicians may cooperate in the form of a group practice (*Gruppenpraxis*) or in a primary healthcare unit (*Primärversorgungszentrum*). Only doctors admitted to practice may hold an ownership interest in a group practice or primary healthcare unit. Outpatient clinics (*Ambulatorien*) are considered hospitals. There are no limitations as to who may become a shareholder of a hospital, but legislation may set out regulations with respect to notification requirements and/or compliance with a "fit and proper" test.

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

More than 99 percent of the Austrian population is medically insured in the statutory health insurance system (SHI). SHI covers "adequate and appropriate" (*ausreichend und zweckmäßig*) medical and other healthcare for patients insured in the SHI. Under SHI:

- Any treatment by outpatient physicians with a contract with one or more statutory health insurers (*Kassenvertrag*) is covered
- Treatment by physicians without *Kassenvertrag* (private physicians: *Privatärzte*) is covered to the extent the treatment is considered "adequate and appropriate", and coverage is capped at the amounts fixed in the *Kassenverträge*
- Treatment in hospitals is covered to the extent the treatment is considered "adequate and appropriate". Patients might be required to bear costs for food
- The services of all other care providers and facilities (*e.g.*, nursing care providers and facilities) are covered by SHI if these services are part of a so-called benefits catalogue (*Leistungskatalog*) of the respective health insurer or may be covered on a case-by-case basis

In most healthcare sectors there are no public procurement proceedings for awarding permissions or entering into agreements with SHI funds. Generally, any provider who meets the legal requirements is admitted, yet is subject to the same conditions as any other comparable provider in the relevant region. Formal public procurement tenders usually only take place where there is no free choice of providers, *e.g.*,

for certain drugs such as drugs intended for use in surgeries.

4. Drug Approvals and Reimbursement

Marketing authorisation for drugs is substantially regulated by European Union (EU) law. Under certain conditions, drugs may be authorised in a centralised EU procedure handled by the European Medicines Agency (EMA).

Orphan drugs and most biologics must be authorised through the EMA. The marketing authorisation granted by the European Commission is valid throughout the EU, and therefore also in Austria.

Drugs can also be authorised by the competent Austrian authority (*Bundesamt für Sicherheit im Gesundheitswesen*, or BASG) if the drug is only to be authorised in Austria, or if several EU Member States work together to grant authorisations in several Member States. Most marketing authorisations for drugs require preclinical and clinical testing, but there are exemptions to this rule (*e.g.*, bibliographic authorisation). Expedited approval procedures are also available, such as conditional approval or the priority-medicines (PRIME) procedure.

Like most EU Member States, Austria regulates drug distribution and pricing to a certain extent. Drugs to be reimbursed automatically by SHI are listed in the Reimbursement Code (*Erstattungskodex*). Drugs are included in the Reimbursement Code through a decision by the Umbrella Organisation of the Social Insurance Providers (*Dachverband der Sozialversicherungsträger*) following an application and negotiations on efficiency and pricing.

5. Devices Certification and Reimbursement

In 2017, new EU Regulations on medical devices were adopted. While the EU Regulation for in vitro diagnostic medical devices will be applicable from May 26, 2022, the EU Medical Device Regulation 2017/745 (MDR) entered into force on May 26, 2021.

Due to these EU Regulations, Austria was required to renew its national legislation, the Medical Devices Act (*Medizinproduktegesetz*). Provisions that were regulated directly by the EU were repealed. Provisions that are subject to national regulation were developed.

The new legal framework extends the scope of the medical devices regime to certain products that do not have a medical purpose (*e.g.*, contact lenses).

Another important change is that manufacturers are required to have at least one person responsible for compliance who has the necessary expertise in the field of medical devices.

As before, a medical device must undergo a conformity assessment procedure to confirm that it complies with the essential requirements before being placed on the market with a CE marking. The type of conformity assessment procedure to be used depends on the medical device's risk class. Medical devices of higher than Class I risk (Classes IIa, IIb and III, in vitro diagnostics devices for self-testing) are subject to certain conformity assessment procedures by a notified body. Regarding the classification of medical devices, some amendments have been adopted.

Thus, under the new Regulations, it will become more difficult to place medical devices on the EU market, but still less challenging than placing a drug on the market.

There is no statutory reimbursement scheme for medical devices in Austria. Reimbursement by SHI is largely subject to individual negotiation.

6. Regulation of AI and Software as a Medical Device

Under certain conditions, artificial intelligence (AI) and software are considered to be a medical device (SaMD) and are therefore subject to the requirements of EU medical device regulations and the Austrian Medical Devices Act. According to the new MDR, SaMD are no longer classified as low-risk devices.

The use of artificial intelligence in healthcare is also subject to restrictions regarding medical services, restrictions on advertising, and statutory and non-statutory anti-corruption provisions.

7. Telemedicine and Teleconsultation

Telemedicine and teleconsultation are permissible if certain requirements are met. There is certainly a strong interest in the market for these services, but regulations are strict. Due to the COVID-19 pandemic, there has been greater reliance on telemedicine and authorities have been more receptive to the use of telemedicine as part of patient care.

Telemedicine has been explicitly included in the current government programme.

8. Anti-Kickback Rules and Incentives to Doctors

Statutory and professional rules forbid kickbacks and incentives to physicians and other healthcare professionals. Any such actions are illegal under professional rules and may be sanctioned under recently enacted criminal law.

Cooperation between different healthcare providers and sectors, however, is permitted and even promoted by the relevant public authorities to improve service quality and reduce cost.

9. Merger and Foreign Investment Control

Companies in the healthcare sector may qualify as critical infrastructure within the meaning of Sec. 25a of the Austrian Foreign Trade Act (*Außenwirtschaftsgesetz*). The acquisition of a participation of 25 percent or more of the business of such an undertaking (asset deal) by non-EU/EEA/Swiss nationals may require prior approval by the Austrian Ministry for Economic Affairs (currently the Federal Ministry for Digital and Economic Affairs).

10. Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

There are currently no pending or anticipated changes in the relevant provisions directly related to healthcare and life sciences law.

However, there are changes regarding assisted suicide. Due to a decision of the national Constitutional Court, Austria was required to amend its laws on assisted suicide. The draft version of a Disposition of Dying Act (*Sterbeverfügungsgesetz*) is currently in discussion but has not yet been passed.

The purpose of this law is to allow seriously ill people to commit suicide in certain circumstances by providing them with drugs for self-administration at their voluntary and competent request.

DENMARK

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

COVID-19 has affected various aspects of the Danish healthcare system, including:

- Extraordinary measures for clinical trials

- Implementation of a faster process for review and approval of vaccines and medicines in the response against COVID-19
- Implementation of virtual and digital solutions for consultations within the healthcare sector
- Development of healthcare technology to better combat the challenges of COVID-19 (*e.g.*, oxygen robot monitors supplying oxygen based on a patient's current condition and robotic room disinfection systems)
- Introduction of measures to counteract problems regarding supply, including granting authorisation to the Danish Medicines Agency (DMA) to regulate the prices of medicines and medical devices as necessary and the introduction of less stringent language requirements for labelling and instructions for use of CE-marked face masks
- Development of various projects that aim to mitigate the adverse health effects of the COVID-19 pandemic in Denmark

In April 2021, the Danish Government adopted a recovery and resilience plan that includes a strategy for making the Danish healthcare system more resilient and better prepared for unexpected crises like COVID-19. This plan includes ensuring strategic storage of medicine, which would reduce the vulnerability of supply chains. Furthermore, Denmark will strengthen the digitalisation of the health system, making it ready for future health challenges.

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

In Denmark, the public healthcare system operates across three levels: (i) the state, (ii) the regions and (iii) the municipalities. The state is responsible for overall regulatory and supervisory functions in healthcare. The regions are responsible for hospital care, including emergency care and psychiatry, and for health services provided by general practitioners and specialists in private practice. Municipalities are responsible for certain other health and social services, including disease prevention and health promotion, rehabilitation outside of the hospital setting, home nursing, school health services and other services for elderly people.

In addition, municipalities co-finance regional rehabilitation services and training facilities.

Apart from the public healthcare system, Denmark has a number of private hospitals and health clinics. There are no particular restrictions on the ownership of private hospitals or clinics in Denmark.

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

The Danish healthcare system is based on a principle of free and equal access for all citizens.

In Denmark, healthcare services are financed mainly by general taxes and are supported by a system of central-government block grants, reimbursements and equalisation schemes.

All residents in Denmark have access to the public healthcare system with a national health card, and most services are provided free of charge. Danish legislation ensures that diagnosis and treatment is provided within certain time limits and establishes a free choice of hospital for patients. Citizens in need of hospital care may, within certain limits, freely choose any public (and some private) hospitals.

The regions provide primary care mainly through general practitioners and specialists operating in

private clinics under agreements between the Regions' Salary and Rate Commission (RTLN) that acts for the five regions, the Organisation of General Practitioners in Denmark (PLO) and the Association of Specialist Doctors (FAPS). Hospital care is provided at hospitals owned and operated by the regions and some private hospitals contracted by the regions.

Amgros (the regions' joint procurement body) secures the supply of medicines and hearing aids to public hospitals and hearing clinics through efficient procurement and tendering procedures. Amgros also develops and conducts tendering procedures for selected medical devices.

The Danish regions established the Medicines Council to ensure fast and homogeneous use of new and existing medicines across hospitals in the regions and to support Amgros in price negotiations and calls for tender. The Medicines Council evaluates new medicines and issues recommendations and treatment guidelines to the regions. Hospital administrations usually adhere to this advice and guidance, and the Medicines Council is considered critical to ensuring that hospitals have access to medicines.

4. Drug Approvals and Reimbursement

Medicines must be approved by the European Medicines Agency (EMA) or the DMA and must be included on the medical register before marketing can commence. The applicant for and holder of a marketing authorisation must be established or represented in Denmark or another EU/EEA country. Generic medicines may be authorised using an abridged procedure.

Medicines are pharmacy-reserved unless determined otherwise. As such, medicines can, as a starting point, only be dispensed at pharmacies on prescription.

The regions purchase the medicines used for treating patients at hospitals from the hospital pharmacies under framework supply agreements secured by Amgros. Medicines at the regional hospitals are provided free of charge to patients. Patients treated in the primary care sector must purchase their own medicine at private pharmacies.

The pricing of pharmacy-reserved medicines is the same at all pharmacies and generally determined by the manufacturer/importer. The pharmacy sale price is calculated using the pharmacy purchase price as determined by the manufacturer/importer plus a percentage and a fixed amount. No price approval is required by the authorities.

Reimbursement of medicines purchased by patients in the primary care sector is determined by the DMA, based on recommendations made by the Medicines Reimbursement Committee. Generally, the DMA will consider reimbursement based on an application from the company that brings the medicine onto the Danish market.

Several types of reimbursement may be granted under section 152 of the Danish Health Act. Pre-approved reimbursement means that medicines that have achieved "general reimbursement" when they are marketed in Denmark may be prescribed by physicians directly to patients at reimbursed prices.

There are three types of general reimbursement:

- *General reimbursement for prescription-only medicines*: All citizens receive reimbursement from the Danish regions. The reimbursement is automatically deducted from the price charged at the pharmacy
- *Conditional reimbursement for prescription-only medicines*: This is granted only in certain cases. To obtain reimbursement, it may be a condition that the medicine is prescribed to

certain patient groups, or for the treatment of specific diseases.

- *Conditional reimbursement for over-the-counter medicines*: Reimbursement is only granted if the medicine is dispensed on prescription to certain categories of person, *e.g.*, persons suffering from a specific disease

A doctor may apply to the DMA for individual reimbursement of medicines that are not generally reimbursed on behalf of an individual patient.

5. Devices Certification and Reimbursement

Together with the MDR, which entered into force in May 2021, the Danish Act on Medical Devices constitutes the regulatory framework for the monitoring, pricing and reimbursement of medical devices in Denmark. After the MDR entered into force, all executive orders and guidelines related to medical devices were updated to reflect and support the new regulation.

Medical devices are not to be authorised by the DMA but must be CE-marked before placement on the market. The DMA supervises medical devices marketed in Denmark.

For medical devices in Classes II and III, a "Notified Body" must be involved in the documentation and certification process. A Notified Body is a private entity authorised by the relevant authorities to review and assess whether a manufacturer's technical documentation meets the legal requirements. If the requirements are met, the Notified Body issues a certificate allowing the manufacturer to place a CE mark on the product. As for medical devices in Class I, the manufacturer is usually responsible for the certification process.

For medical devices, there is no system under which companies may apply for general reimbursement of costs. However, if certain requirements are met, end users have the right to full or partial reimbursement of costs for medical devices from the municipalities of Denmark.

6. Regulation of AI and Software as a Medical Device

The definition of a medical device includes software and apps that have a medical purpose and are intended to be used for diagnostic or therapeutic purposes. If considered to be a medical device, such software and apps are subject to the requirements of the MDR.

Software and apps are assessed in Denmark by the DMA based on the Danish executive order on medical devices and on the basis of the EU Commission's Guidelines on the Qualification and Classification of stand-alone software.

The majority of apps that are CE marked as medical devices are currently classified as Class I.

7. Telemedicine and Teleconsultation

Denmark is viewed as a frontrunner in relation to telemedicine, with unique nationwide projects.

Denmark does not have legislation that deals with telemedicine and teleconsultation specifically. The current legal framework for e-health in Denmark is found primarily in the Danish Health Act, the Authorisation Act, the Act on the Processing of Personal Information and the Act on Medical Devices, as well as supplementary executive orders.

Several telemedicine projects are currently being pursued. For example, the agreement between the RTLN and PLO provides that General Practitioners will be reimbursed for telemedicine services and are

obliged to offer it. The parties provide a solution that enables patients to schedule video appointments to be carried out using the My Doctor (*Min Læge*) app.

Other solutions, such as artificial-intelligence-driven platforms, have been introduced to facilitate remote treatment for patients.

8. Anti-Kickback Rules and Incentives to Doctors

The interaction of healthcare professionals (HCPs) with the industry is primarily regulated by Danish national rules regarding advertising, economic advantages, and affiliations between HCPs and the healthcare industry. Industry standards are set out in ethical codes issued by the Ethical Committee for the Pharmaceutical Industry (ENLI) and the Association for the MedTech Industry (*Medicoindustrien*). The ethical codes are only applicable to companies that have submitted to the authority of these industry bodies.

Under Danish legislation regarding promotion of pharmaceuticals and medical devices, economic advantages must not be offered or given to individual HCPs for advertising purposes or otherwise to promote the sale of a medicinal product or a medical device, unless such a gift is of insignificant value and can be used in the HCP's business. Other exceptions to the prohibition on economic advantages permit payment for services as well as hospitality and sponsorship. Pharmaceutical and medical device companies may provide financial support in the form of payment of the reasonable costs of dining, travelling and accommodation when an HCP attends educational and promotional activities with a scientific or professional purpose.

The legal framework regarding transparency for pharmaceutical and medical device companies' relationships with HCPs is provided in the Danish Health Act and the specific rules are set out in an executive order.

The Danish rules regarding affiliation mean that an HCP's affiliation with a pharmaceutical or medical device company must be reported and disclosed to the DMA. "Affiliation" includes any professional or financial relationship with a pharmaceutical company. Generally, all types of relationship are covered by the rules, as well as activities for which the HCP does not receive payment. Information about financial support will be published on the DMA's website for a period of two years. In May 2021, the rules were updated, expanding the group of companies covered by the rules, the obligation to report economic support, as well as the obligation to make notifications or obtain permission to establish an affiliation.

9. Merger and Foreign Investment Control

On 4 May 2021, the Danish Parliament adopted the bill for a so-called investment screening act introduced by the Danish Minister for Industry, Business and Financial Affairs.

This constitutes an entirely new regime in Danish legislation, as thus far foreign direct investment in Denmark has been subject to very limited regulation.

The overall object of the new act is to prevent, through screening and possible intervention, foreign direct investment and special financial agreements from posing a threat to national security or public order in Denmark.

The screening programme consists of a sector-specific, mandatory approval scheme for investment and conclusion of special financial agreements in sectors assessed as particularly sensitive in relation to national security or public order, combined with a cross-sectorial, non-mandatory notification scheme in sectors other than those that are particularly sensitive.

The act came into force on July 1, 2021. However, the act does not apply to foreign direct investment or special financial agreements executed prior to September 1, 2021.

10. Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

Overall, there is increasing political attention to the life sciences sector in Denmark. The Government has launched its new strategy for the Danish life sciences industry, comprising 38 new initiatives in seven main fields. The initiatives aim, in particular, to improve the conditions for research and development (R&D) and the use of health data, to secure a highly skilled workforce, and set the scene for international expansion. Among other things, the Government has extended the possibility to receive an R&D expenditure deduction of up to 130 percent up to and including 2022. In early September 2021, the Government announced its intention to make the R&D expenditure deduction permanent. Further, a new health agreement between the government, regions and municipalities will work as a framework for future cooperation in the Danish healthcare system. According to the new health agreement, 21 health clusters will be established, where politicians and professionals will agree on the cooperation between hospitals, general practices and the local health services in the municipalities.

Further, some interesting highlights include:

Medical Cannabis Pilot Programme

The political parties have entered into an agreement to continue the Medical Cannabis Pilot Programme. The current Medicinal Cannabis Pilot Programme, whereby doctors may prescribe products containing medicinal cannabis to patients, will be extended by four years, *i.e.*, until December 31, 2025. Further, it has been agreed that the scheme for companies to obtain a license to cultivate, manufacture and export medicinal cannabis products in and from Denmark will be made permanent.

Treatment Council

On January 1, 2021, the Treatment Council became operational. Early in 2021, a process manual and procedure guidelines were published. This means that the Council is now open to receiving evaluation suggestions. The first candidates were expected to complete the process by the end of 2021.

Pharmacy Act

Section 11(5) of the Pharmacy Act has been amended. This means that access to patient-attributable information related to the prescribing of medicinal products from the Danish Medicines Statistics Register is no longer reserved for a defined group of persons. Consequently, information on the prescribing of medicinal products, including information identifying the prescriber and information identifying the patient, can in certain circumstances be obtained by anyone, without consent, when the information is viewed as relevant for scientific or statistical studies of significant societal importance.

FRANCE

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

The pandemic has affected all aspects of the French healthcare system, including the following:

- Telemedicine has grown exponentially during the COVID-19 crisis. Teleconsultations will be fully reimbursed by the French statutory health insurance scheme (SHI) until the end of 2021, a measure that will likely be extended (see section 7 below)

- The e-health sector, including digital health, medtech and biotechnology start-ups, has bloomed and investment in the field is expected to increase significantly. France has amended its foreign investment control framework accordingly (see section 8 below)
- The pandemic emphasised the need for simplified administrative approval for health products. As a result, the Social Health Insurance Financing Act for 2021 (*loi de financement de la sécurité sociale pour 202*1), has replaced the procedure for exceptional use of unauthorised medicines (*authorisations temporaire d'utilisation*) and off-label use of medicine (*recommendations temporaire d'utilisation*) with two regimes: early access authorisation for innovative products and compassionate-access authorisation for therapeutic needs not yet covered. The current bill for SHI financing for 2022 (*projet de loi de financement de la sécurité sociale pour 2022*) has been adopted by the French National Assembly but is still under review by the Senate. The bill aims to (i) include telesurveillance in SHI and implement a flat rate for such activities, (ii) introduce a new system of access to certain new drugs, (iii) integrate industrial aspects into price setting of health products, (iv) facilitate access to expensive drugs and medical devices in hospitals, and (v) create a system of advance payment adapted to innovations in the field of digital health
- Transitional measures were implemented for ongoing and COVID-19-related clinical trials during the first waves of the pandemic to enable the conduct of such trials (*e.g.*, delivery of experimental drugs at home, collection of data via teleconsultations). An *ad-hoc* national steering committee for therapeutic trials and other research on COVID-19 (CAPNET) was created to regulate clinical and preclinical studies relating to COVID-19 and to accelerate those that fall within the scope of national priorities, and which are most promising. Such clinical trials may thereby benefit from a "National Research Priority Label" delivered by CAPNET

2. Ownership or Equivalent Restrictions Regarding the Provision of Healthcare Services

Healthcare services in France can be provided either by independent physicians through their private practices (outpatients) or during a hospitalisation in public or private healthcare facilities (inpatients).

Private inpatient healthcare facilities can be owned by physicians or non-physicians. Subject to the grant of administrative permits, these facilities do not differ from commercial companies. Certain outpatient healthcare facilities are subject to ownership and control restrictions and can be owned or predominantly owned and operated only by physicians. Finally, some healthcare facilities are operated by not-for-profit organisations

3. Award of Public Contracts and Reimbursement

Every person born in France, working in France or regularly living in France can benefit from SHI. SHI provides reimbursement of outpatient and inpatient treatments.

Physicians: Prices are fixed by national physician agreements between SHI and physicians' associations. Physicians can apply higher prices under specific conditions. If a physician is not part of the national physician agreement, he or she can set prices freely. National reimbursement rates apply to services provided by physicians except when the physician is not part of the national physician agreement, in which

case lower rates apply. Healthcare services are reimbursed at more favourable rates if provided within the mandatory care pathway (*parcours de soin*).

Public healthcare facilities: Applicable prices are fixed annually by the Ministry of Health. SHI generally reimburses 80 percent of the applicable fees. The remaining 20 percent can be covered by private insurance.

Private healthcare facilities: There are two types of private facilities:

- *Private facilities under contracts*: Most private healthcare facilities enter into contracts with the local health agency (*Agence Régionale de Santé*, or ARS) and health services are reimbursed as if they were performed in a public facility
- *Other private facilities*: For the few facilities that do not enter into contracts with the ARS, prices are not fixed. For these facilities, the applicable 80 percent reimbursement rate will be based on the prices fixed by the Ministry of Health rather than the price allocated by the private facility

4. Drug Approvals and Reimbursement

Medicinal products cannot be placed on the market if they have not received a prior French or centralised marketing authorisation (MA). French MAs are granted by the French Medicine Agency (*Agence Nationale de Securité du Médicament*, or ANSM). MAs are granted upon demonstration of quality, safety and efficacy. Any variation to the terms of the MA must be reported to or approved by the ANSM, depending on the nature and significance of the variation.

Whether the SHI reimburses a medicinal product depends on its degree of efficacy (*service médical rendu*), which is evaluated by the French High Health Authority (*Haute Autorité de Santé*, or HAS).

The general director of the French National Union of Health Insurance (*Union Nationale des Caisses d'Assurance Maladie*) decides the reimbursement rate (generally from 15 percent to 65 percent or, in certain circumstances, 100 percent), depending on the drug's efficacy compared with other therapies that are already on the market.

5. Payments to Healthcare Professionals and Incentives

Anti-kickback rules currently prohibit companies that manufacture or market health products, or provide health services, from directly or indirectly offering any benefits in cash or in kind to healthcare practitioners. Healthcare practitioners are also prohibited from receiving such benefits.

Exceptions to this prohibition include remuneration for research activities, grants in cash or in kind that are allocated to research activities, and hospitality offered at promotional, professional and scientific events to HCPs by companies operating in the health sector. Such companies will ask the relevant professional association for authorisation to offer any benefit (other than for negligible value) to an HCP for implementing any contract exceeding a specific threshold with an HCP (contract types are defined by ministerial order). Below this threshold, a declaration will be sufficient. In August 2020, two ministerial orders set the thresholds, which vary depending on the categories of activities concerned (*e.g.*, research grants above EUR 5,000 or hospitality above EUR 2,000 must be authorised). The full application of the updated version of the anti-kickback regulation came into force on October 1, 2020 and has spurred multiple institutional guidelines for industry. A failure to comply with the regulation can lead to criminal sanctions.

6. Regulation of AI and Software as a Medical Device

The use of medical devices, regardless of whether they involve AI, is substantially regulated by EU law. AI-powered medical devices (MD) are notably subject to MD regulation, data protection regulations (including the GDPR and the French regime on automated decision making) and bioethics rules. The new MD regulation which came into force on May 26, 2021 notably implemented a specific rule for standalone MD software. Other rules may apply, as there is no comprehensive regulatory framework. The European Commission has proposed harmonised rules regarding AI applications that would pre-empt national regulatory frameworks, although monitoring and enforcement would remain the responsibility of Member States.

In any event, any MD must be CE marked prior to placement on the market. As AI-powered medical devices are built on the basis of experience and accumulation of observations, the quality and quantity of the incoming data and the learning ability of the AI software are crucial elements for the device's operation. Therefore, the actual CE marking process of certifying the conformity of a medical device prior to its placement on the market seems incompatible with the reality of AI-powered devices. The permanent evolution of said devices due to their ability to learn would in theory require a continuous evaluation to assess the service provided. The HAS published a press release in October 2020 disclosing a new assessment scheme for AI-powered medical devices, which sets out a roadmap to adapt to these specificities. Companies operating medical devices are required, amongst other obligations, to provide detailed information on the incoming data used to develop the learning ability of the software. In February 2021, the HAS published a functional classification chart for software according to its use (*e.g.*, screening function, diagnosis, prevention and aid in understanding hygieno-dietary measures).

7. Telemedicine and Teleconsultation

Compared to other European states, the French legal framework for telemedicine is relatively advanced. After a period of experimentation, telemedicine is now fully integrated in the practice of medicine. Telemedicine includes five types of activities, ranging from teleconsultation (*i.e.*, remote consultation between patient and physician) to tele-expertise (*i.e.*, remote solicitation by a medical professional of the opinion of colleagues with particular skills) and preliminary medical reviews conducted by emergency services. Telecare was added in July 2019, to connect pharmacists or paramedics with patients (*e.g.*, to enable remote nurse care). Teleconsultation must be carried out by video transmission (as opposed to a telephone call). However, given the pandemic, teleconsultations by phone have been permitted in specific cases (*e.g.*, where there is no access to the internet). A recent amendment to a national Convention opens discussion on permitting teleconsultations by phone in certain cases. Since September 2019, teleconsultation may also be performed in pharmacies at booths that may be connected to medical devices.

Teleconsultation became eligible for SHI reimbursement in September 2018. To be reimbursable, the teleconsultation must be performed under specific conditions. It must be conducted within the mandatory care pathway and the physician must be an independent doctor adhering to the national physician agreement, who already knows the patient. These conditions were amended recently. By way of example, prior knowledge of the patient is not required in some cases, *e.g.*, if the patient resides in a high-density area. Teleconsultations may, in certain

cases, be reimbursed when conducted outside the mandatory care pathway, provided that they are performed in a local organisation such as a care home (*centre de santé*). Due to COVID-19, the SHI financing Act for 2021 has extended full reimbursement of all teleconsultations until December 31, 2021. The bill for SHI financing for 2022 aims to integrate telesurveillance into SHI before the year's end.

8. Foreign Investment Control

Under current law, foreign investment in relation to activities "in the protection of public health" and AI are considered strategic or sensitive and may require prior government authorisation. Legislative changes in 2020 extended the activities that are considered strategic or sensitive to include activities relating, *inter alia*, to biotechnologies, food safety and additive manufacturing. In addition, these changes resulted in increased sanctions for noncompliance with foreign investment regulation. In July 2020, a decree also lowered the threshold of control applying to non-EEA entities' investments in public corporations transacting in those sensitive sectors, from 25 percent to 10 percent. This measure was temporary and was prolonged by a decree until December 31, 2021.

9. Forthcoming Changes in Healthcare and Life Sciences Law

Advertising by HCPs: The prohibition on HCP advertising was finally repealed by a decree dated December 22, 2020. In its ruling of September 17, 2021, the Paris Court of Appeal further tackled the restrictions on access to advertising by French pharmacists and held that the restrictions were not applicable to EU pharmacies, stating that they were incompatible with market practice.

Extension of the telemedicine framework: The current SHI bill may further the development of telemedicine by extending the telesurveillance regime and facilitate reimbursement of related MDs.

New regulation and reimbursement guidelines are expected for digital health MDs. The French president also announced a plan to implement a fast-track market access procedure for innovative digital MDs, similar to the process in Germany. The new regulation on in vitro diagnostic MDs (subject to an ongoing proposal for extension) and on clinical trials, will come into force in 2022.

GERMANY

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

COVID-19 has had a significant impact on global health markets, including Germany.

The various restrictions on public life that have accompanied the pandemic have led to an acceleration in the digitisation of the health sector. Germany in particular has seen increased use of telemedicine, medical apps and other digital health services, and the German legislature has recently liberalised the relevant legal basis for these services. Telemedical services by a physician are now permitted without the requirement of a prior in-person meeting and include the option to prescribe drugs and provide certificates for sick leave. Pilot projects for digital healthcare services have been transferred into the regular payment system and, accordingly, digital healthcare services may now be reimbursed by public and private payers.

Other measures to alleviate the impact of the pandemic in Germany have included the granting of certain emergency powers to governmental

authorities. In particular, the German government has been enabled to set up and implement emergency plans, *e.g.*, to obtain products of immediate need such as face masks, ventilators and medicines.

Healthcare providers, care-home facilities and hospitals in particular have been provided with additional funds.

With regard to COVID-19 testing, the Ordinance Regulating the Dispensing of Medical Devices (*Medizinprodukte-Abgabeverordnung*, or MPAV) has been amended several times since the beginning of the pandemic. Under the MPAV, diagnostics for COVID-19 self-testing may now be dispensed to the general public.

Besides increasing digitisation, the pandemic has heavily emphasised the existing scarcity of human resources in the healthcare sector in Germany, especially prevalent among in all nursing professions. The government is currently actively addressing this scarcity.

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

There are no ownership restrictions for hospitals. The German hospital market consists of public community or state hospitals, private not-for-profit hospitals and private for-profit hospitals.

There are some ownership restrictions in the outpatient health services sector. Prior to 2004, physicians were only allowed to render outpatient services when working in their own practices or clinics, or in partnership with other physicians. No investor was entitled to directly or indirectly own shares in any such clinics or partnerships. Today, outpatient physician services can also be rendered in medical care centres (*Medizinische Versorgungszentren*, or MVZ). MVZ are often established in the legal form of limited liability companies and operate with employed physicians. MVZ are not required to be owned by physicians. They may also be owned by hospitals, local communities, not-for-profit organisations and, under certain conditions, so-called non-physician dialysis services providers. Investors aspiring to own MVZ usually choose hospitals as their preferred vehicle. Since 2019, local market-share restrictions (far below any antitrust threshold) have applied to hospital-owned MVZ rendering dentalcare services.

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

Around 90 percent of the German population are covered by public/statutory health insurance (SHI). To provide healthcare services to SHI patients, the following requirements must be met:

- Physicians (or MVZ; see section 2, above) providing outpatient services must be admitted to practice under a certain regulatory regime which only applies to the outpatient sector, i.e., the Admission Boards of Panel Doctors Associations (*Zulassungsausschüsse der Kassenärztlichen Vereinigungen*). In addition to medical qualification, a strict needs assessment applies. As most German regions are considered to have an oversupply of physician services, a physician or MVZ aiming to render services to SHI patients usually needs to buy a retiring physician's practice in order to be eligible to treat SHI patients.
- In order to be entitled to accept and treat SHI patients, hospitals must be included in the so-called hospital plan of the relevant German federal state.

- All other care service providers (*e.g.*, nursing care facilities) must enter into care agreements with the SHI funds

In most healthcare sectors, no public procurement proceedings exist for awarding permissions or entering into agreements with SHI funds. Generally, any provider who meets the legal requirements is admitted, yet subject to the same conditions as any other comparable provider in the relevant region.

4. Drug Approvals and Reimbursement

Marketing authorisation for drugs is substantially regulated by EU law. Under certain conditions, drugs may be authorised in a centralised EU procedure handled by the European Medicines Agency (EMA). The EU marketing authorisation is valid throughout the European Economic Area (*i.e.*, the current 27 EU Member States plus Norway, Liechtenstein and Iceland). Drugs may also be authorised by the competent national authority if the drug is only to be authorised in that member state, or if several EU Member States cooperate to grant authorisations.

Marketing authorisations for drugs generally require preclinical and clinical testing, unless in specific circumstances (*e.g.*, bibliographic authorisation). Expedited approval procedures are also available, *inter alia*, by way of conditional approval or the priority medicines (PRIME) procedure.

Like most EU Member States, Germany regulates drug distribution and pricing to a certain extent. Pharmacy-only drugs are not allowed to be dispensed outside a licensed pharmacy. Prescription-only drugs are subject to a statutory pricing scheme.

The reimbursement of drugs within the SHI regime is subject to German social security law. SHI and the private insurance system differ to some extent. SHI funds generally only reimburse prescription-only drugs, with some exceptions.

5. Devices Certification and Reimbursement

After a three year transition period, the Medical Devices Regulation EU 2017/745 (MDR) entered into force on May 26, 2021, replacing the previous Medical Device Directive (MDD). The MDR applies directly in the EU Member States. In Germany, it is complemented by the Federal Medical Devices Implementation Act (*Medizinprodukte-EU-Durchführungsgesetz*, or MPDG) that replaced the previous Federal Medical Devices Act (*Medizinproduktegesetz*, or MPG).

For in vitro diagnostics (IVD), the previous IVD Directive has not been merged into the MDR, but shall be replaced by a new EU regulation, the IVDR, on May 26, 2022. In Germany, the MPG will continue to apply to IVD on a transitional basis until May 25, 2022. Thereafter, the MPDG shall extend to IVD.

Unlike drugs, medical devices do not require a genuine marketing authorisation but are subject to a certification procedure. Before being placed on the market, a medical device must undergo a conformity assessment procedure in order to confirm that it complies with the essential requirements under the MDR. The applicable conformity assessment procedure depends on the risk class of the respective medical device. Medical devices of Risk Class I are subject to a basic conformity assessment procedure that does not require the involvement of a notified body. Medical devices of higher risk classes are required to have certain aspects certified by a notified body, which is a private entity vested with regulatory competencies. After successful completion of the conformity assessment, the manufacturer affixes the CE mark to the device. The CE mark entitles the

manufacturer to place the product on the market in the CE zone, which currently covers the EEA plus Turkey. Switzerland is considered a third country, as the previous mutual-recognition agreement with the EU was not renewed. For this reason, Swiss companies will in future need a legal representative in the EU.

The MDR modifies the risk classification system for medical devices, resulting in many devices being up-classified to higher-risk classes. In that light, and as a result of increased requirements in the conformity-assessment procedure, there are now higher hurdles for placing medical devices on the market in the EU.

At the same time that the EU regulator has stuck to a certification system (rather than a genuine authorisation procedure), market approval of medical devices will continue to be significantly less challenging than the approval procedure for drugs.

6. Regulation of AI and Software as a Medical Device

Software and digital applications may in certain circumstances qualify as medical devices. If so qualified, they would be subject to the MDR or applicable IVD regulations (IVD Directive or IVDR), including related Member State laws.

Before the MDR came into force, software as a medical device was generally classified as a Class I device. Accordingly, it has been certified under the basic conformity assessment procedure (self-certification). Under the MDR, many medical software products are now classified in higher-risk classes. Therefore, manufacturers must regularly obtain their CE certificates from notified bodies.

The transition scheme under the MDR allows for manufacturers of Class I medical devices to benefit from a grace period that enables them to continue to market their products under the previous MDD regime until 2024 if they had issued a declaration of conformity before the MDR has become applicable.

MDR and IVDR do not contain any specific provisions on AI. Therefore, for AI-based medical software, the general provisions on software as a medical device apply.

The European Commission published a draft regulation on AI on April 21, 2021. The regulation is expected to come into force no earlier than 2024. As things currently stand, the draft regulation shall not be linked to the EU medical devices regime but will apply in parallel. AI systems shall be subject to regulatory requirements that increase with the level of risk associated with them. High-risk AI, including certain AI systems for medical technology, shall be subject to comprehensive legal obligations imposed on the respective operator.

7. Telemedicine and Teleconsultation

For a long time, in the teleconsultation sector, the German market lagged behind those of other countries because of restrictive and inconsistent regulations. Moreover, physicians and their professional associations were reluctant to accept the legalisation of telehealth services and the use of digital applications for the diagnosis or treatment of patients.

Since 2019, this has changed for the better and at great speed. Even before the onset of the pandemic, Germany had set the legal basis for telemedicine, including video consultation by physicians, and its coverage by private and public payers. Likewise, public licensing of medical apps was anticipated to allow SHI to cover licensed medical apps prescribed by a doctor. Even though the laws had already been adopted in 2019, their practical implementation sharply accelerated during the pandemic. The number of video consultations, online prescriptions, and other

types of remote treatment and consultation are increasing rapidly. Accordingly, restrictions once in place on the advertisement of remote consultation and treatment have to some extent been lifted. Physicians are now also allowed to issue a certificate for sick leave in a video consultation.

Regardless, telemedicine is still subject to numerous restrictions under German law. According to German professional laws, remote treatment can only take place if, among other things, the use of the telecommunication medium is medically justifiable, *i.e.*, no further medical examinations are necessary to obtain a direct and comprehensive picture of the patient and the patient's disease or condition. Moreover, telemedicine is subject to particular data protection and information technology security challenges.

8. Anti-Kickback Rules and Incentives to Doctors

Germany has introduced a number of healthcare compliance regulations over the past decades that prohibit, *inter alia*, kickbacks and other incentives to healthcare professionals for referrals or prescriptions. Any such incentives are unlawful and may also be subject to criminal sanctions.

As things currently stand, corporations are not subject to criminal charges; however, there are controversial debates on the implementation of a corporate criminal law regime. A corresponding Draft Act on Association Sanctions (*Verbandssanktionengesetz*) has so far not passed the German parliament.

Apart from healthcare compliance regulations, cooperation among players in the health sector is restricted by various provisions under public health insurance law, advertising law and professional regulations.

9. Merger and Foreign Investment Control

In Germany, the Federal Cartel Office (*Bundeskartellamt*, or FCO) is the competent authority for the enforcement of the merger control provisions stipulated in the Federal Act against Restraints of Competition (*Gesetz gegen Wettbewerbsbeschränkungen*). Relevant M&A transactions (concentrations) are subject to mandatory pre-closing notification/clearance if the parties involved exceed certain turnover thresholds. Following recent legal reforms, the FCO now has the right to oblige a company to notify any merger (regardless of whether the applicable thresholds are exceeded) in specific circumstances. This is the case in particular where a sector enquiry by the FCO has shown that further mergers in that sector may significantly impede competition.

Under the German Foreign Trade and Payments Act (*Außenwirtschaftsgesetz*) and its complementing ordinance (*Außenwirtschaftsverordnung*), the German Federal Ministry for Economic Affairs and Climate Action (*Bundesministerium für Wirtschaft und Klimaschutz*, or BMWi) may in certain circumstances review whether foreign investments are likely to affect public order or security. In recent years, German foreign investment control (FIC) has become increasingly strict in the health sector, in particular where foreign investments relate to products or infrastructures essential for the combatting of the pandemic. Depending on the business activities of the domestic target company, foreign investment may be subject to a notification obligation and clearance of the transaction by BMWi may qualify as a statutory closing condition. In the absence of a notification obligation, BMWi may initiate *ex officio* investigations within five years after signing. To mitigate the risk of intervention, and in the interest of deal certainty, foreign investors may apply, on a

voluntary basis, for a clearance certificate after the signing of the transaction.

10. Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

Recent changes in German health policy and legislation that may affect investment in the domestic healthcare and life science sectors include the following:

- Laws and regulations implementing the Clinical Trial Regulation (Reg. (EU) No. 536/2014) that became applicable on January 31, 2022
- Laws implementing the EU Whistleblower Directive (Dir. (EU) 2019/1937), expected with some delay in the coming weeks
- Rollout of the electronic prescription regime, originally planned for summer 2021 but postponed for an indefinite period of time
- Amendments to the Federal Patent Act (*Patentgesetz*), some of which shall come into force in May 2022
- The Federal Supply Chain Sourcing Obligations Act (*Lieferkettensorgfaltspflichtengesetz*), setting out particular duties of care for large companies with the purpose of respecting human rights and environmental standards globally, shall enter into force on January 1, 2023
- New IT security guidelines for medical practices issued by the Federal Association of Panel Doctors (*Kassenärztliche Bundesvereinigung*) that have become fully binding as of January 1, 2022. The guidelines provide for technical and organisational standards that must be observed by doctors' practices, including MVZ. The standards vary according to the size of the respective practice

ITALY

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

The COVID-19 crisis has had a deep impact on the healthcare sector in Italy, including the following:

- Increased use of digitalisation, particularly the spread of telemedicine and the digitalisation of prescriptions for medicines and services to be supplied and paid for by the National Health Service (NHS)
- Introduction of certain derogations to the requirements for placing certain medical devices onto the market
- Provision of special rules concerning the performance of clinical trials for medicines to be used to treat COVID-19 and all other medicines, particularly those aimed at implementing digital services and remote clinical trials
- Simplification and acceleration of procurement rules governing the purchase of goods and services, including public healthcare facilities, by public entities

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

In Italy, there are no specific ownership or equivalent restrictions in relation to the provision of healthcare services.

Healthcare facilities, including hospitals, may be owned by public or private investors.

Healthcare facilities must meet specific requirements to be authorised to operate and must fulfil additional

conditions to operate within the NHS and treat patients at the NHS' expense.

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

The Italian healthcare system is mainly public. The NHS was created to provide universal and uniform healthcare coverage to the entire Italian population and it is financed by general taxation. The relevant responsibilities and powers are shared between the central government (the Ministry of Health) and the Italian regions.

In December each year, the Italian Parliament approves the annual Budget Law (*Legge Finanziaria*), which determines the amount of financing for the NHS. This health funding is then allocated among the regions, mostly on an age-adjusted capitation basis, which finances the Regional Health System (RHS) of each region. Thanks to this financing system, most healthcare services are provided free of charge to patients, and the regions reimburse the cost to the healthcare facilities. Healthcare facilities that intend to operate within the NHS/RHS must be accredited by the relevant Italian region, and must enter into agreements with the local health authorities specifying the terms and conditions of the provision of healthcare services to patients at the RHS' expense.

Public healthcare facilities must tender for the procurement of medicines and services. Exceptionally, under certain conditions, direct negotiation of agreements with private parties is also permitted.

4. Drug Approvals and Reimbursement

No medicines may be placed on the Italian market without a marketing authorisation (MA) from the Italian Medicines Agency (AIFA) or the European Medicines Agency (EMA), according to the centralised procedure provided for by Regulation (EC) No. 726/2004. To receive an MA in Italy, the applicant must be established in the European Union and have an appointed representative in Italy. Under the national MA procedure, the AIFA issues its decision on the authorisation within 210 days of the application being filed (although this period is suspended if additional documents are required). In exceptional circumstances, the authorisation may be granted on the condition that the applicant fulfils additional obligations (often related to the safety of the medicine), which are then assessed annually.

For certain categories of products, such as certain homeopathic medicines, herbal medicines and follow-on products (generic and biosimilar medicinal products), the authorisation procedure is simplified. For example, if the request for MA concerns a generic version of a reference medicine that has been authorised for at least eight years in Italy or the European Union, the applicant is not required to provide the results of the pre-clinical and clinical trials. In the case of biosimilar medicines, the applicant is required to provide the results of pre-clinical or clinical trials related to the aspects that, for the peculiar characteristics of these products, vary compared to the reference medicine (*e.g.*, raw materials or production processes). The results of other tests contained in the reference medicine's dossier are not required.

The MA is valid for five years from its publication in the Official Gazette and can be renewed following a re-evaluation of the risk-benefit balance. After the first renewal, the MA is valid for an unlimited period unless the AIFA/EMA decides, on justified pharmaco-vigilance grounds, to proceed with one additional five-year renewal. The MA will lose its efficacy if the medicine is not placed on the market within three years of the MA issuance, and if the medicine has not

been marketed for three consecutive years (sunset clause).

Following the issuance of the MA and upon the request of the MA holder, negotiations start with AIFA to assess whether the medicine can be reimbursed by the NHS and, if it can, to set the relevant price. In certain cases, the negotiation procedure may be launched by AIFA. Negotiations between the MA holder and AIFA shall be conducted according to criteria set out by law, which include, *inter alia*, the added therapeutic value and therapy costs of the new medicine compared to medicines already distributed for the same indication. The last step to allow a medicine to be supplied at the RHS' expense is the inclusion of the medicine in the *Prontuario Terapeutico* (therapeutic formulary) of each region.

5. Devices Certification and Reimbursement

The placing of medical devices on the market in Italy is permitted only for devices bearing the CE mark. The procedures and requirements for obtaining the CE mark vary depending on the class of the relevant device, and are set out in the EU Medical Devices Regulation 2017/745 (MDR), that became applicable on May 26, 2021 and replaced the national legislation implementing the Directive 93/42/EEC.

In addition, all medical devices to be placed on the Italian market shall be submitted to the Ministry of Health and reported in a dedicated register (*Banca dati dei dispositivi medici*) that is publicly available. This registration will continue to be mandatory until the European Database on Medical Devices (EUDAMED) is no longer fully operational. To be purchased by public entities (*i.e.*, at the NHS' expense), medical devices must also be included in another register, called the *Repertorio generale dei dispositivi medici*, governed under Ministerial Decrees December 21, 2009 and December 23, 2013 (for in vitro diagnostic medical devices (IVDMDs)).

There is no statutory reimbursement scheme for medical devices in Italy. Only medical devices purchased by public healthcare facilities (following tender) and provided to patients by such facilities are reimbursed by the RHS. To be purchased by public healthcare facilities at the RHS' expense, medical devices are allocated to certain existing categories of homogeneous products. If they do not fall within existing categories, specific "health technology assessment procedures" are performed to prove their additional value for patients.

In April 2021, the Parliament approved Law No. 53/2021, that provides for a delegation to the Italian Government to issue legislative decrees to adapt the national regulatory framework to the provisions of the MDR and In Vitro Diagnostic Regulation (IVDR), within the following 12 months. According to the principles and criteria established by the Delegation Law, the Government will be required to, among other things:

- Arrange for the reorganisation and coordination of activities among the entities responsible for the governance of medical devices, and establish the mechanism necessary to implement the payback system in the medical devices sector, according to Law Decree 78/2015 (which could have a significant financial impact on operators)
- Establish a sanctioning system for breach of the provisions of the MDR and IVDR
- Make medical device purchasing procedures more efficient by strengthening health technology assessment procedures
- Introduce the obligation for companies that produce or market medical devices to pay a share of no more

than 0.75 percent of their turnover resulting from sale of medical devices and large equipment, net of value-added tax, to the NHS for the purpose of financing the system for governance of medical devices.

6. Regulation of AI and Software as a Medical Device

There are no specific laws in Italy applicable to artificial intelligence. The use of AI in healthcare raises many issues, including classification of the relevant application as a medical device, data protection and responsibility issues that are currently regulated according to the general principles of Italian and EU law.

The MDR, under Rule 11, provides new classification rules for "software as a medical device". Under the MDR, software as medical device is generally assigned a higher class of risk.

In order to provide clarifications and examples to manufacturers, the Medical Devices Coordination Group published new guidance in October 2019 on the qualification and classification of software as a medical device under the MDR.

7. Telemedicine and Teleconsultation

Italian law does not specifically regulate telemedicine and teleconsultation.

In December 2020, the State-Regions Conference endorsed the "national guidelines for the provision of telemedicine services" drafted by the Ministry of Health. Henceforth, these guidelines shall serve as the national reference for provision of telemedicine services, with this updated version replacing the previous guidelines of 2014.

Thanks to the guidelines, healthcare services provided remotely are officially a part of the NHS.

Each Italian region must implement the guidelines in its respective RHS, in some cases by updating previously enacted rules.

8. Anti-Kickback Rules and Incentives to Doctors

Both the applicable law and the professional codes of conduct of pharmaceutical industry associations forbid kickbacks and incentives to physicians and other healthcare professionals (HCPs). Such actions are subject to criminal sanction.

Cooperation between HCPs and pharmaceutical companies is, however, permitted in compliance with applicable legal and ethical regulations.

The Italian Parliament is discussing a bill that requires pharmaceutical and medical device manufacturers to publicly disclose all payments to, or agreements with, HCPs (called the Sunshine Act). However, the legislative procedure has not been finalised to date.

9. Merger and Foreign Investment Control

Foreign investment control regulations were introduced in Italy for the first time in 2012 and granted the Italian Government authority to impose conditions on, or veto, transactions involving Italian companies carrying out strategic business, regardless of state interest in such business.

The healthcare sector was drawn into the abovementioned regulations for the first time in 2019, when "*critical infrastructure, whether physical or virtual, including ... health" and "critical technologies and dual-use items, including artificial intelligence, robotics, semiconductors, cybersecurity, aerospace, defense, energy storage, quantum and*

nuclear technologies, as well as nanotechnologies and biotechnologies" were mentioned (via citation of Art. 4, letters a) and b) of EU Regulation 2019/452) amongst sectors subject to foreign investment control.

At the end of 2020, significant regulatory measures regarding Italian foreign investment control regulations (known as the golden powers) were enacted and (i) included a revised list and definition of critical and strategic assets in sectors relevant for the purposes of these regulations, including the life sciences and healthcare sector, and (ii) extended the COVID-19 emergency rules providing for a temporary broadening of the scope of notification duties (which, amongst other things, also involve intra-EU transactions) through the entire emergency period. Further developments are expected at the end of the emergency period.

In particular, the new list of strategic assets and relationships relating to the health sector that may trigger the foreign investment control regulation includes the following:

- Critical technologies for the supply of health services, including provision of services by remote access
- Critical technologies for the analysis of data and the use of biological know-how for health, diagnostics, prognostics, therapy and relevant follow-up
- Critical bioengineering technologies and nanotechnologies used in pharmaceutical and medical devices, diagnostics, and the prognostic and therapy sectors, as well as in the chemical and agri-food sectors
- Activities of strategic importance carried out in the health sector (including those relating to supply of drugs, medical equipment and devices, and relevant research and development (R&D) activities (i) involving the use of the technologies listed above or (ii) by entities with an annual net turnover of at least EUR 300 million and at least 250 average annual number of employees

With regard to merger control regulation, in Italy the control of the concentration of undertakings for competition purposes is enforced by the Italian Competition Authority (*Autorità Garante della Concorrenza e del Mercato*, or ICA) according to Law no. 287/1990. In particular, a proposed concentration of undertakings must be submitted to the ICA prior to its implementation if certain thresholds concerning the annual turnover achieved in Italy are exceeded by the undertakings concerned in the transaction.

10. Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

Recent changes in policy and legislation that may affect investments in the healthcare and life sciences sectors focus on the following areas:

- *Negotiation of medicine prices*: The Ministry of Health set out new criteria for the price negotiation between MA holders and AIFA on August 1, 2019, replacing the previous regulation. On December 23, 2020, the AIFA issued guidelines for the compilation of the dossier to support the request for reimbursement and pricing of a medicine, pursuant to the new decree, thus providing very important operational guidance
- *Introduction of the payback mechanism in the medical devices sector*: The payback is a mechanism requiring companies to refund to the NHS certain sums proportional to the quantity of products sold to the NHS. In 2015, this mechanism (originally concerned with pharmaceutical products only) was extended to medical devices, but it has not yet been

applied because certain implementing measures are still outstanding. Last year, some of these measures were taken and the application of the payback mechanism to the medical devices sector is expected in the near future.

NETHERLANDS

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

The COVID-19 pandemic has had a significant effect on the healthcare system of the Netherlands. Even though a large proportion of Dutch inhabitants have been vaccinated, the rise in infections has led to a prioritisation of COVID-19-related healthcare services at the expense of so-called regular healthcare. The Dutch government is considering providing booster vaccines as the extensive COVID-19 testing programme has not curbed a rise in infections. In an effort to minimise infections, there also has been a significant rise in teleconsultation both by general practitioners and by hospitals.

Manufacturers, purchasers and suppliers may only supply CE-marked mouth masks and gloves to healthcare providers as of October 1, 2021. Until June 1, 2022, healthcare providers may use mouth masks and gloves without CE marking if they still have them in stock.

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

A healthcare provider must obtain a licence to provide healthcare services. These services are reimbursed by either healthcare insurers (basic healthcare) or the Dutch state (long-term care). The licensing procedure has changed as of January 1, 2022. In order to improve monitoring compliance with quality regulations, under certain conditions licensed healthcare providers as well as their subcontractors need to notify their activities to the appointed authorities.

Healthcare professionals must be registered in accordance with the Individual Healthcare Professions Act.

For specific forms of healthcare, a provider with a licence is not allowed to distribute profits. Sub-contractors fall outside this prohibition.

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

All residents in the Netherlands must take out basic healthcare insurance. Healthcare insurers have a duty of care, which means that they cannot refuse to provide basic insurance for any individual. In order to provide for affordable, high-quality, timely and accessible healthcare, insurers conclude annual contracts with healthcare providers to ensure basic care for their clients. In most situations, invoices are paid directly to the providers. Insurers receive monthly premiums and, depending on the insured population, compensation from the government. Under certain circumstances, insured individuals must pay deductibles as well as a maximised own-risk payment. Academic hospitals receive additional contributions from the government. If insured individuals receive non-contracted care, insurers are not obliged to fully reimburse the costs.

With regard to long-term care, healthcare providers also contract separately with insurers' subsidiaries, mostly on an annual basis. An independent institution decides per patient whether there is a need for long-

term care. The coverage is paid fully by public money raised through taxation.

4. Drug Approvals and Reimbursement

A registration and marketing authorisation (MA) is required to stock, sell, distribute, deliver, make available within or import drugs into the Netherlands.

If the centralised procedure for obtaining an MA via the European Medicines Agency (EMA) does not apply, the Dutch Medicines Evaluation Board (MEB) is responsible for registering drugs and delivering the MA for marketing the drugs in the Netherlands.

The MEB decides whether a drug must be available by prescription only from a doctor or specialist (PO) or whether a drug is available over the counter (OTC) without prescription. OTC drugs are divided into three categories: (i) pharmacy-only drugs (PH) with a relatively mild potential risk, (ii) pharmacy-and drugstore-only drugs (PDO) with a relatively low potential risk, and (iii) general sales drugs (GS) with very low risk that are also available via sales channels such as supermarkets or service stations.

The Ministry of Health, Welfare and Sports (MoH) has the option to determine the maximum allowable prices for drugs biannually. When purchasing drugs, pharmacists may not pay more than the maximum prices.

Dutch healthcare insurers will only reimburse a registered drug if it is included in the Drug Reimbursement System. The Ministry of Health and the Healthcare Institute of the Netherlands decide together which drugs fall within the standard healthcare insurance coverage and whether they are either fully or partially reimbursable. OTC drugs are not reimbursable.

5. Devices Certification and Reimbursement

In order to place a medical device on the Dutch market, the device must comply with the requirements of the Medical Device Regulation (MDR), the Dutch Medical Devices Decree and the In Vitro Diagnostic Medical Devices Decree. The Health and Youth Care inspectorate is the relevant authority.

For marketing purposes in the Netherlands, a medical device must comply with the essential requirements of Annex I of the MDR and labels and instructions must be in the Dutch language. If the medical device complies with the essential requirements and the correct procedures have been followed, the medical device must bear the CE mark confirming its conformity. Class I device manufacturers can assess the conformity of the product themselves. Medical devices Class IIa, IIb and III must be inspected by an independent and accredited organisation that is designated by the government (notified body).

Manufacturers must be established in the European Union or must have an authorised representative in the European Union and must register with the European Database on Medical Devices (EUDAMED).

There are various laws and regulations in the Netherlands for the reimbursement of medical devices. Most medical devices are reimbursed based on the Dutch Health Insurance Act. The Healthcare Insurance Regulations describe which medical devices qualify for reimbursement under basic healthcare insurance coverage. Healthcare insurers assess whether a new medical device is covered by basic healthcare insurance and, therefore, if it qualifies for reimbursement. Healthcare insurers may set additional conditions for reimbursement, such as a requirement for their grant of permission prior to use. Healthcare insurers also assess whether a device has been proven to be effective.

6. Regulation of AI and Software as a Medical Device

Artificial intelligence (AI) and big data in healthcare and the legal and ethical questions that they raise are hot topics in the Netherlands.

E-health apps are considered to be medical devices and must comply with the Medical Devices Regulation (MDR) from May 26, 2021.

The EU General Data Protection Regulation (GDPR) and the Dutch Processing of Personal Data in Healthcare (Additional Provisions) Act regulate the use of software and medical apps in the healthcare sector and the associated use of medical and non-medical data.

7. Telemedicine and Teleconsultation

In the Netherlands, the government is encouraging the healthcare sector to expand telehealth. As such, the Ministry of Health published an Assessment Framework "deployment of e-health by healthcare providers" in 2018, which provides standards and related assessment criteria with respect to telehealth.

In principle, teleconsultation is reimbursable by Dutch healthcare insurers, provided that certain conditions are met. Dutch law is rather restrictive in relation to online prescriptions. It is prohibited for a prescriber to prescribe drugs to any individual if the prescriber has not met the individual in person, does not know the individual or does not have access to the individual's medical history. The Ministry of Health has noted that the prohibition regarding prescriptions does not apply to healthcare professionals who are established in other EU Member States. This view is in line with the EU e-Commerce Directive and the EU Cross-Border Healthcare Directive.

However, due to the COVID-19 pandemic, the Ministry of Health decided to allow online prescription of drugs in situations where the prescriber has not met a patient in person, at least early 2022.

8. Anti-Kickback Rules and Incentives to Doctors

Dutch inducement rules prohibit the promising, offering or giving of money, valuable services or goods with the "apparent purpose" of promoting the prescription, provision, or use of a drug or the sale of a medical device. Exceptions apply, for instance, for gifts of limited monetary value that can be used for professional practice. There are detailed rules for calculating fines for infringements, which take into account the size of the undertaking.

Undertakings with registered offices outside of the Netherlands can be fined if they infringe the inducement rules and the infringement has a manifest effect in the Netherlands.

Under the applicable self-regulatory framework on financial relationships between the industry and medical professionals, payments to healthcare professionals (excluding general practitioners) exceeding EUR 500 must be notified in a transparency register.

9. Merger and Foreign Investment Control

Apart from certain utilities sectors, the Netherlands has a liberal policy towards foreign investment. There is no general requirement for prior approval of investments made by foreign legal entities or foreign natural persons in the healthcare sector.

A new bill on investment control, the Investment Screening Bill (*Wet Veiligheidstoets investeringen, fusies en overnames (Wet Vifo*, or ISB)), is pending but is intended to have retroactive effect from September8, 2020 onwards. The bill includes a filing obligation for any acquirer where the target is

involved in vital processes or working with sensitive technologies in the Netherlands. The healthcare sector is not defined as a vital process in the current draft bill. However, additional vital processes can be added, but any addition must be confirmed by formal law.

If a proposed merger or acquisition involves a healthcare provider that employs 50 or more individuals that provide healthcare, a prior notification to the Dutch Healthcare Authority (NZa) is mandatory. The NZa is also the designated regulator capable of taking measures if a healthcare provider or healthcare insurer has significant market power.

Mergers in the healthcare sector are subject to lowered turnover thresholds for notification to the Dutch Competition Authority (ACM). A transaction has to be notified if (i) the worldwide turnover of all undertakings concerned is more than EUR 55 million, and (ii) at least two of the undertakings achieve a turnover of more than EUR 10 million in the Netherlands.

10. Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

As of 2022, the Act on Healthcare and Care Providers (Accreditation) Act (*Wet toetreding zorgaanbieders*, or WTZa) and accompanying acts (including *Aanpassingswet* WTZa, or AWTZa) will enter into force. The WTZa will change the licensing system for healthcare institutions in order to improve supervision and awareness of the applicable quality rules and regulations. The WTZa will replace the current licensing system as laid down in the Care Institutions (Accreditation) Act (*Wet Toelating Zorginstellingen*, or WTZi). The WTZi will remain in force in relation to the profit distribution ban for specific healthcare providers.

The most significant changes include the following:

- Within six months after the WTZa enters into force, existing healthcare providers must notify the health inspectorate (IGJ) about the care they provide. The notification is an administrative procedure that includes completing a form from the IGJ
- Some healthcare providers are also obliged to obtain a licence under the WTZa. For obtaining and keeping such licence, they must fulfil certain conditions, amongst others relating to the governance structure. Insofar as the existing healthcare provider has already applied for a licence under the WTZi, the provider will automatically receive an accreditation under the WTZa. Other healthcare providers must apply for such licence. For existing and new healthcare providers, there is a transition period of two years to comply with the licensing conditions
- Healthcare providers must comply with the quality standards as laid down in the Healthcare Quality, Complaints and Disputes Act (*Wet klachten en geschillen zorg*, or Wkkgz), public reporting and financial transparency requirements, and requirements regarding client representation
- Under certain conditions, the aforementioned obligations are also applicable to subcontractors that provide healthcare
- New guidance from the Royal Dutch Society for the Advancement of Medicine, on access to medical records by next of kin, was approved on November 26, 2020
- In May 2020, a proposal was published that, *inter alia*, amends the current Dutch GDPR implementation act (*Uitvoeringswet AVG*) with respect to the transfer of personal data from medical records to parties other than healthcare providers in cases of bankruptcy, retirement or the death of a

healthcare provider. This proposal is still under consultation

In addition, a number of bills have been sent to the House of Representatives for evaluation. These include:

- A bill on digital exchange of data in healthcare has been approved by the Council of Ministers
- A bill introduced in March 2020 to establish a Transparency Register for Healthcare was submitted. Every transaction between manufacturer and doctor of EUR 50 or more is registered. In June 2021, the Dutch Data Privacy Authority issued advice to the House of Representatives criticizing this bill. According to the Dutch Data Privacy Authority a registration in the Transparency Register for Healthcare is a considerable intrusion on the privacy of the individual practitioner. They have doubts about whether the transparency of the register is necessary and whether access to the register could not be limited to the health inspectorate (IGJ)
- An amendment to the Healthcare Quality, Complaints and Disputes Act, proposed by members of the House of Representatives to increase the involvement of healthcare employees in decisions made by healthcare institutions that affect the way in which healthcare is provided
- A bill on the transfer of statutory duties regarding merger control and the control of significant market power from the Dutch Healthcare Authority to the Netherlands Authority for Consumers and Markets (the Dutch competition regulator). The bill will also amend the thresholds for prior mandatory notification

In July 2021, an Order in Council was issued that aims to strengthen the ability to combat various forms of fraud (*inter alia*, in the healthcare sector) by the use of the Personal Records Database (*Basisregistratie Personen*). This Order in Council has been criticized from a privacy perspective. The consultation period ended September 7, 2021.

In May 2021, a temporary bill on COVID-19 access certificates was passed. This bill makes it possible, when taking measures to combat COVID-19, to introduce rules on a required test certificate indicating if a person was infected with the coronavirus at the time the test was taken.

In February 2021, the Dutch Data Protection Authority issued advice about a proposed Order in Council in relation to the consultation of client data via an electronic exchange system in connection with the triage or treatment of COVID-19. The Dutch Data Protection Authority raised serious objections to this proposal. No definitive Order in Council has been issued yet. As prompt availability of medical data of COVID-19 patients in emergencies is deemed necessary, this data is currently exchanged based on a tolerance arrangement pending an appropriate legal basis.

POLAND

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

Several changes in the Polish healthcare system have occurred as a result of the pandemic, including:

- Removal of regulatory obstacles regarding telemedicine, and vast use of all e-health related solutions aimed to substitute for face-to-face contact with healthcare professionals (e-consultations, e-prescriptions, e-sick notes)
- Increased legislation to avoid shortages of COVID-19 diagnosis and treatment products, medical devices, drugs and biocides, and to limit access to seasonal-flu vaccines to high-risk patients only (in both the public and private sectors)

- Use of fast-track regulatory procedures by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) aimed at accelerating the authorisation of new products related to the COVID-19 pandemic
- Establishment of new healthcare facilities and adaptation of non-healthcare facilities (*e.g.*, stadiums) as temporary COVID-19 hospitals
- Decrease of treatments not directly linked to treatment of COVID-19, particularly in oncology, cardiology and neurology
- Introduction of incentives for doctors and other healthcare professionals involved in the treatment of COVID-19 patients, aimed at increasing the efficiency and capacity of the system; these measures include increasing salaries, simplifying the recruitment of foreign medical staff from outside the EU, delegating trainee doctors to work in infectious diseases hospitals and increasing the working age of men in medical professions
- Introduction of new regulations on public procurements for services, supplies or construction works necessary to fight the pandemic in case of rapid and uncontrolled spread of the disease, or if required for the protection of public health

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

There is no strict differentiation between the private and the public sector in Poland's healthcare market. Currently, the private sector dominates the provision of services in primary care, outpatient care, rehabilitation and long-term care, whilst hospitals remain the domain of the public sector. However, this is different for highly specialised single-specialty hospitals, *e.g.*, hospitals for eye surgery.

Healthcare service providers have a highly differentiated ownership structure. Primary medicine (first-contact doctors) and dentistry are almost exclusively provided by individual doctors and dentists. The same applies to the plastic surgery sector and aesthetic dermatology.

Healthcare institutions operate as companies, state-funded establishments (*e.g.*, military healthcare) and independent public healthcare providers (mostly hospitals). Public healthcare institutions may be established by the State Treasury or by local government (provincial authorities). Public entities must hold at least 51 percent of the shares in a healthcare provider established as a company and must maintain a voting majority.

The shares of a medical university clinic may only be held by the university (minimum of 51 percent of the shares), the State Treasury and/or the local government.

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

More than 80 percent of the Polish population is medically insured under the statutory health insurance system, which covers outpatient and hospital care. However, the private insurance sector is growing significantly and currently covers more than 3 million people, which is an increase of 13.1 percent compared to last year.

The largest payer for services offered in private hospitals is the National Health Fund (*Narodowy Fundusz Zdrowia*, or NFZ), which in 2016 accounted for 62 percent of private hospital revenues, with patients financing 35 percent and insurers only 3 percent of private hospital revenues.

In order to render publicly financed medical services, healthcare facilities are required to sign contracts with regional NFZ branches. The content and pricing mechanisms of these contracts and the award processes are strictly regulated. As a rule, public and private healthcare facilities are treated equally in terms of access to contracts with NFZ.

Contracts with NFZ are concluded for a relatively short period (usually from one to five years). In principle, this should work to new market players' advantage, but in practice it creates instability and lack of predictability for future operations.

NFZ conducts detailed inspections of the beneficiaries of public funds and in some cases refuses to pay for services, particularly those exceeding their allocated quota.

4. Drug Approvals and Reimbursement

Marketing authorisations for some advanced drugs are issued centrally by the European Medicines Agency (EMA). For all other drugs, the URPL issues marketing authorisations for Poland using either the EU decentralised procedure (DCP) or mutual-recognition procedure (MRP) or using the national procedure.

Marketing authorisations for innovative drugs require full pre-clinical and clinical testing. A limited number of studies are required to register generic products. Such registration can take place after the expiry of the applicable data exclusivity period (generally eight years from the issuance of the first marketing authorisation within the EU, plus two years of market exclusivity, which can be extended by a further year when new indications have been added).

Pricing for drugs available only on prescription is strictly regulated and depends on the outcome of reimbursement and price negotiations between marketing authorisation holders (or their representatives, where marketing authorisation holders are seated outside the European Economic Area) and the Minister of Health. The Minister of Health issues a list of the reimbursable drugs every quarter.

Poland's distribution system for drugs (and medical devices) is strictly regulated via licensing (applicable to wholesale distributors and pharmacies), permitted distribution methods (upstream distribution is prohibited), and detailed obligations relating to the reporting of title transfers and physical movement of products throughout the supply chain.

5. Devices Certification and Reimbursement

In Poland, there is legislative work in progress on a new national law on medical devices aimed to supplement the EU Medical Device Regulation (2017/745) (MDR) which entered into force in May 2021.

The reimbursement system applicable to medical devices differs from the one applicable to drugs. From a hospital perspective, purchase of equipment is part of the total annual budget and thus a part of overall spending on its operation. Patients that purchase medical devices prescribed by a doctor have their payments reimbursed in arrears, but the regulatory framework is about to be simplified (to allow e-prescriptions).

6. Regulation of AI and Software as a Medical Device

A significant number of Polish start-ups are developing medical software. The main regulatory obstacles are lack of certainty concerning the status of medical data and the possibility of secondary use.

These issues are currently being discussed in Poland, but have not been resolved by any specific legislation.

As a rule, medical software can be classified as software as a medical device (SaMD), which is subject to the requirements of EU medical device directives and the Polish Medical Device Act of May 20, 2010, concerning the notification procedure before the URPL.

The MDR has been in force since May 2021, replacing the Medical Devices Directive. The regulation provides for changes in the classification of medical devices and in the rules for assessment of the risk connected with placing products on the market. The MDR extends the scope of the medical devices regime to certain products that do not have a medical purpose.

As a rule, under the MDR, it has become more difficult to place medical devices on the EU market, but it will still be less challenging than marketing a drug.

7. Telemedicine and Teleconsultation

The principal regulatory obstacles to telemedicine have been removed.

The pandemic has significantly accelerated development of the telemedicine and e-health sector in Poland. The introduction of e-prescriptions, e-referrals and e-sick notes has facilitated, to a large extent, cooperation between patients and doctors. Limited access to medical facilities has put more emphasis on the use of remote medical advice. At the start of the pandemic, upwards of 80 percent of medical consultations took place remotely.

8. Anti-Kickback Rules and Incentives to Doctors

Professional rules forbid doctors and other healthcare professionals from receiving kickbacks and incentives. Under certain circumstances, providing and accepting incentives, or exceeding the allowance threshold, can be treated as a criminal offence.

Cooperation between the private and public sectors exists and is encouraged as a method of improving service quality and reducing costs. Such cooperation is a well-established practice in the field of clinical trials.

9. Merger and Foreign Investment Control

Public founders must hold at least 51 percent of shares in the healthcare provider established as a company and must maintain a majority of votes.

The shares of a medical university clinic may only be held by the university (minimum 51 percent of shares), the State Treasury and/or the local government.

10. Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

On March 29, 2019 NFZ published its strategy for the years 2019 through 2023. Its main goals for the four-year period include supporting service providers in building efficiency (for example, through the development and implementation of a system for accreditation and digitalisation) and a focus on innovation.

However, implementation of the strategy ceased to be the priority of healthcare institutions following the start of the COVID-19 pandemic. A new, emerging focus area is the provision of mental health services for both adults and children, which has grown in

demand given greater public awareness, and as a result of the isolation of individuals during the pandemic.

It is expected that further developments in the Polish healthcare sector will be spurred on by means of private and public sector partnerships. These developments will require predictability, stability and openness. By way of example, projects featuring non-commercial clinical trials of biochemical molecules (in particular in the field of oncology), are already being implemented and there is significant potential to replicate these and undertake other projects in other clinical fields.

The private healthcare market in Poland is forecast to continue to grow. According to data provided by the Polish Chamber of Insurance, for the first half of 2020, Poles spent almost half a billion zlotys (approximately EUR 225 million) on health services and insurance.

SPAIN

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

The pandemic has affected many aspects of the Spanish healthcare system, including:

- The adoption of urgent/emergency procurement procedures to ensure rapid letting of contracts to source essential supplies and equipment
- New methods of home delivery of medicines for chronic and high-risk patients
- Adoption of technology at an accelerated rate, including greater use of telemedicine, precipitating a fall in the number of face-to-face appointments and a rise in appointments conducted remotely by telephone, email and video
- A new way of conducting clinical trials remotely
- Emergency control over stock of certain essential medicinal products and medical devices
- Substantial use of medical devices for diagnosis

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

Spain has no specific corporate restrictions on the type of legal entity that may develop medical care centres (*i.e.*, outpatient or inpatient medical facilities).

As a general principle, only registered doctors may provide medical services and only registered pharmacists may dispense drugs.

Both the legal entity rendering medical services and the healthcare practitioner must be authorised and registered in Spain in order to render these services, but no specific type of company is required.

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

The National Health System (NHS) primarily comprises hospitals fully sustained by public funds. Private hospitals generally render services for insured patients and for self-pay patients.

Private hospitals (inpatient and outpatient) can become public health providers through public procurement proceedings that award public services to private providers (*contratos de concesión de servicios*). These contracts may include both the management of hospital beds and other types of services.

Public procurement processes take place for drugs, medical devices, and medical inpatient and outpatient

services, including services for clinical labs, home respiratory therapies and home-care services.

Reimbursement for medical services (inpatient and outpatient) is carried out according to the terms of the corresponding tender launched by the regional healthcare systems. Those terms usually include both availability and demand-based payments.

4. Drug Approvals and Reimbursement

Drugs must be authorised before they can be placed on the Spanish market. Marketing authorisations are granted through four different procedures heavily regulated by European law. The Spanish Agency of Medicinal Products and Medical Devices (AEMPS), as well as the respective European Member States' drug agencies, are in charge of granting national marketing authorisations for drugs in Spain and can do so under the national, mutual recognition or decentralised procedures. The latter two procedures allow for the grant of coordinated authorisations in several EU Member States.

Some drugs (such as orphan drugs and most biologics) must be authorised by a centralised EU procedure handled by the European Medicines Agency (EMA), and this authorisation is valid throughout the European Union. Marketing authorisations for innovative drugs require pre-clinical and clinical testing.

Although national authorities are free to set the prices of drugs and to designate the treatments they wish to reimburse under their social security systems, the European Directive on drug pricing aims to ensure that national pricing and reimbursement decisions are made in a transparent manner. Once a drug has its marketing authorisation, national authorities decide whether to provide and reimburse it on the NHS, and set its price. The current tendency with innovative drugs is the signing of risk-sharing arrangements with the laboratories, where the reimbursement is based on the efficacy of the drug.

If the authorities refuse to make the drug available on the NHS, the marketing authorisation holder is free to set the price and must notify the authorities accordingly. Authorities may impose a different price for any public-interest reason.

5. Devices Certification and Reimbursement

The manufacture, import (from non-EU countries), grouping or sterilisation of medical devices is subject to administrative authorisation from the AEMPS.

Medical devices imported from other EU countries can be used in Spain. However, they can only be placed on the Spanish market if they meet the requirements set out in the regulations. To import devices from non-EU countries, a specific authorisation from the AEMPS is required.

Only CE-marked medical devices can be marketed or put into service in Spain. This is not applicable to custom-made devices or to devices under clinical research.

A CE marking can only be placed on products 1) where there is evidence that they comply with the essential requirements set out in applicable regulations and 2) that have followed the applicable evaluation procedures. These procedures differ depending on the nature of the product. Devices that already have CE marks according to the rules applicable in other EU countries benefit from a presumption of conformity in Spain. However, if the Spanish health authorities consider that a device, used for its intended purpose, may compromise the health or safety of patients, they can take measures to withdraw it from the market or restrict its commercialisation under the safeguarding clauses included in applicable EU directives.

A CE mark on Class I products is directly set by its manufacturer. However, for other categories, a CE mark must be accredited by the notified bodies, which carry out the corresponding evaluation procedures. In Spain, currently, the notified body is the AEMPS.

Any entity that places Class III, Class IIb or Class IIa devices on the market, or puts them into service in Spain for the first time, must report this activity to the AEMPS. Any subsequent changes to the information that has been reported to the AEMPS (or the relevant regional authorities) must also be reported.

Any entity established in Spain that is responsible for the initial commercialisation of Class I devices or custom-made devices in the EU must be registered with the AEMPS.

Distributors of medical devices must communicate such activity to the regional authorities where they are established.

The introduction of medical devices to the NHS is subject to public procurement proceedings.

6. Regulation of AI and Software as a Medical Device

Under certain conditions, medical software is considered a medical device (SaMD) and is therefore subject to the requirements of EU medical device directives and related Member State laws. SaMD may be classified under different medical device categories depending on its functionality and risk level and will be required to comply with the attendant obligations. If SaMD is aimed at helping or supporting a diagnosis, it is considered a Class IIa medical device, and it must undergo conformity assessment procedures carried out by a notified body and must receive a CE mark in order to be placed onto the European and Spanish markets.

It is worth noting that Regulation 2017/745 sets forth the same classification and requirements (applicable from May 2021) as rule 11 of its Annex VIII. Innovative devices, such as AI chatbots or similar devices, may be subject to individual negotiation for exclusivity reasons if the market lacks the specific know-how, tools or means to ensure that the right technology is procured.

7. Telemedicine and Teleconsultation

COVID-19 has led to an exponential increase in the telemedicine and teleconsultation sector in Spain. Currently, despite the lack of a specific legal framework, public and private healthcare institutions practice a degree of telemedicine, either through the monitoring of patients, triage or virtual consultation. The activity displayed by regional health authorities and the support and impetus from the industry could lead to further developments in telemedicine and teleconsultation. Regional regulations can be expected in the near future, followed by a national framework.

8. Anti-Kickback Rules and Incentives to Doctors

Spanish law adopts an incompatibility regime that prevents those with the power to prescribe or authorise the dispensing of drugs from having a direct economic interest in the marketing of drugs and medical devices. In addition, kickbacks and incentives to physicians and other healthcare professionals are forbidden and may be sanctioned under criminal law.

Industry codes and certain laws issued by regional authorities promote (albeit with strict rules) cooperation between different healthcare providers and the drug industry to improve data collection, drug safety and efficacy, and quality of service. Self-regulation and private enforcement have proven to be an effective tool to enforce a compliance culture

within pharmaceutical and medical devices companies.

9. Merger and Foreign Investment Control

The National Markets and Competition Commission (CNMC) is the authority entrusted with the enforcement of merger control and has the final decision on the majority of merger control cases.

In 2020, the Spanish government introduced a new screening mechanism for certain investments made in Spanish companies by non-EU and non-EFTA investors, which may require prior authorisation from the Spanish Council of Ministers. The sectors affected by the restrictions include critical infrastructure, critical technologies (including biotechnology), supply of critical inputs, sectors with access to sensitive information, media, and other sectors that may affect public security, public order or public health.

The screening mechanism applies to direct and indirect investments in Spanish companies made by non-EU and non-EFTA investors, even when investments are made through legal entities incorporated in the EU if those are beneficially owned by non-EU and non-EFTA residents (*i.e.*, when non-EU and non-EFTA residents ultimately possess or control, directly or indirectly, more than 25 percent of the share capital or voting rights of the investor, or otherwise exercise control, directly or indirectly, over the investor).

10. Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

New regulation on medical devices is expected to be approved in the near future. A draft has already been released for public information. In addition, legislation on veterinary medicines is also pending repeal by a new regulation, which has already been released for public information.

Spain is also facing rising demand for precision medicine, and genetic testing has experienced steady growth.

In addition, there is constant pressure over prices for new drugs, which may lead to shortages in specific drugs (including orphan drugs).

SWITZERLAND

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

Amongst the notable effects of the pandemic on healthcare and life sciences in Switzerland is an emergency regime for the supply and marketing of essential medical goods. The legislation and implementing regulation enacted to tackle the so-called special situation have imposed obligations on manufacturers, distributors and laboratories to report their current stocks of COVID-19 testing kits. The law also allows for emergency procurement and allocation of testing capacities, as well as exceptions to the ordinary course of marketing authorisation procedures for medicinal products and conformity assessment for medical devices.

As part of the logistical reorganisation of the healthcare system, specific COVID-19 healthcare units, inter-hospital patient transfers and closer collaboration between public and private hospitals have been implemented.

Additionally, efforts to develop teleconsultation (video consultation, in particular) and telemonitoring for COVID-19 patients, as well as the launching of digital tools (*e.g.*, contact tracing apps), have gained momentum. The increased use of digital platforms

during the pandemic will likely have a lasting and enabling effect on telemedicine.

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

There are no ownership or equivalent restrictions pertaining to the operation of inpatient or outpatient medical care facilities. However, physicians practicing under the umbrella of a legal entity (usually a limited liability company or stock corporation) in outpatient care must themselves hold a professional license to practice and perform healthcare services personally under their own professional responsibility.

Hospitals or other inpatient service providers require an operating licence granted by the canton in which they operate. The requirements are laid down in the cantonal legislation.

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

Costs of healthcare services are reimbursed by mandatory public health insurance, which is available to all Swiss residents and offered by private health insurers. In addition, non-compulsory supplementary private health insurance is widespread.

Depending on the method of treatment (inpatient or outpatient), the reimbursement scheme varies significantly. As a general rule, the applicable tariff structures are negotiated between the tariff partners, *i.e.*, representatives of health insurers and professional associations (the so-called primacy of negotiation, *Verhandlungsprimat*). The reimbursement scheme for costs of outpatient treatment is separated into the services performed by healthcare professionals and the reimbursement of the prescribed medicinal products. Patients are free to choose their physician, save where they have adhered to a specific insurance model offering only limited choices (*e.g.*, HMO schemes). The services of hospitals and other inpatient service providers are only reimbursable by public health insurance if the institutions are listed by the canton in which they operate. Treatments are reimbursed in the form of a flat fee designed to cover the costs of all reimbursable services provided by the hospital, including the costs of medication. All listed public and private hospitals are subject to public procurement proceedings.

4. Drug Approvals and Reimbursement

The distribution of medicinal products in Switzerland requires marketing authorisation issued by the Swiss Agency or Therapeutic Products (Swissmedic). The marketing authorisation holder must have its registered address, registered office or a branch office in Switzerland. There is no mutual recognition of EU marketing authorisations. However, if a medicinal product or procedure is already authorised in a country having equivalent medicinal product control, the results of examinations carried out for this purpose will be considered. In specific situations (*e.g.*, medicines containing known active ingredients), a simplified procedure applies. Certain formulations produced by pharmacies do not require a marketing authorisation.

The data protection period for new medicinal products is ten years. An additional protection period of three years applies to new indications, new modes of administration, new preparation forms or new dosages, and may be extended to ten years for new indications when a significant clinical benefit can be expected and the indication is supported by extensive clinical studies. A ten-year data protection period may be granted for medicinal products designed for

paediatric use. Vital orphan drugs are eligible for a 15-year data protection period.

Costs for medicinal products prescribed by a physician in outpatient treatment are reimbursed based on the maximum price set out in the positive specialty list (LS). In addition to reimbursement of listed medicinal products, public health insurance will exceptionally reimburse the costs of unlisted medicinal products that are either authorised by Swissmedic or imported from a country with an equivalent market authorisation scheme.

5. Devices Certification and Reimbursement

In contrast to medicinal products, medical devices do not require a marketing authorisation in Switzerland but may be placed on the market if the manufacturer is able to demonstrate that the device has undergone the prescribed conformity assessment procedures. The type of conformity assessment procedure to be used depends on the medical device's risk class. The current regime on medical devices closely mirrors the EU's Regulation (EU) 2017/745 on medical devices.

Since the mutual recognition agreement (MRA) between Switzerland and the EU has not yet been updated to account for the revised European and Swiss medical device regulations, the free circulation of medical devices between Switzerland and the EU under the previous regimes has been partially suspended. Whilst CE-marked medical devices may still be placed on the market without any domestic conformity assessment required, importing medical devices marketed under a foreign manufacturer's name into Switzerland is hence subject to regulatory duties placed on foreign manufacturers and importers. *Inter alia*, foreign manufacturers must appoint an authorised representative bearing responsibility for device compliance (though the current Swiss regulation provides for device class-specific transitional periods for EU/EEA manufacturers).

Medical devices qualify for reimbursement under the Swiss social health insurance regime if they are listed on the lists of aids and equipment (MiGeL), of laboratory analyses (Analysenliste), or included in the lists for dental treatments, preventive medical care or maternity services issued by the Swiss Federal Department of Home Affairs (FDHA). The lists are exhaustive positive lists, meaning that non-listed aids and equipment, analyses, dental and preventive care, or maternity services are not covered by the social health insurance regime, unless they are included in the applicable tariffs for inpatient or outpatient treatment.

6. Regulation of AI and Software as a Medical Device

Swiss medical device regulations are harmonised with the corresponding EU/EEA regulatory framework. Accordingly, medical software is considered a medical device if it is intended by the manufacturer to be used, *inter alia*, for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of a disease.

Applications that conduct medical analyses based on automated processing of data, including solutions employing artificial intelligence (AI), are therefore deemed medical devices.

Use of AI by medical practitioners is still in its infancy and, whilst the use of intelligent medical software is making progress, it is not yet established in clinical practice and there is currently limited use in hospitals. Physicians tend to use medical software to support and verify diagnoses. Arguably, however, physicians are obliged to inform patients about digital innovations.

7. Telemedicine and Teleconsultation

Telemedicine is an established practice in Switzerland and is generally permissible under Swiss law. Since there is no specific legal regime governing telemedicine in Switzerland (apart from a few dispersed cantonal provisions, some with restrictive regimes), telemedicine is subject to the same rules and principles as conventional forms of healthcare. The Swiss Federal Supreme Court confirmed the admissibility of teleconsultation as long as the counselling physician is in a position to take adequate measures depending on the health of the patient.

8. Anti-Kickback Rules and Incentives to Doctors

Under Swiss law, it is prohibited to grant, offer or promise undue material benefits to persons who prescribe or dispense medicinal products or to organisations employing such persons. Under a legislative amendment due to take effect in 2022, this provision will include medical devices. Further, Swiss laws also provide for transparency requirements, whereby discounts and reimbursements granted in respect of products used or services performed for ambulatory treatment must be recorded on the files, invoices and accounting documents of the supplying and purchasing parties. An exemption is provided for certain OTC medicinal products and Class I medical devices. Further, healthcare providers must in principle pass on to the patient (or the insurer paying directly, as the case may be) all direct and indirect discounts or other benefits (*e.g.*, referral fees and kick-backs) granted by the supplier of a medicinal product or medical device or the provider of a healthcare service that is subject to reimbursement by public health insurance in the course of outpatient treatment. Subject to conditions stipulated under the applicable ordinance, healthcare providers and insurers may agree not to pass on parts of the discount in order to improve treatment quality.

9. Merger and Foreign Investment Control

There are currently no foreign investment control restrictions in the Swiss healthcare sector. The largest private hospital group in Switzerland is owned by the South African entity Mediclinic International plc. However, the Federal Council defined parameters for the possible introduction of foreign investment controls to a very limited extent and without addressing the healthcare sector specifically.

10. Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

Key regulatory changes currently underway include the project for a revised regime on in vitro diagnostic medical devices set to apply from May 26, 2022. In April 2021, the Federal Council published the draft for an ordinance on in vitro diagnostic medical devices (IvDO), laying grounds for a reform akin to the European Regulation (EU) 2017/746. To date, it is still unclear if the mutual recognition agreement between Switzerland and EU/EEA will be adapted accordingly.

Further, following the certification of the first operators of electronic patient dossiers (EPD), the nationwide rollout of a certified electronic health record system is progressing. Accession to a certified EPD operator is currently mandatory for hospitals, birth centres, and nursing homes acting as service providers under mandatory statutory health insurance laws and will become compulsory for pertinent outpatient providers as per legislative amendments expected to apply from 2022.

Additionally, as part of a legislative reform of quality criteria for outpatient healthcare under mandatory

health insurance, from January 2022 admission of new physicians to practice thereunder will require at least three years of training at a recognized Swiss training centre in the respective specialty, accession to an EPD operator and proof of defined language skills. Under regulatory amendments that took effect in July 2021, Swiss cantons also have the authority to implement regional quantitative limitations on the number of admitted physicians.

Other major forthcoming amendments due to enter into force in 2022 include loosened regulation on cannabis for medical use, the reform of legislation on genetic testing, and a revised federal data protection act and implementing data protection ordinance.

UNITED ARAB EMIRATES

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

In line with global trends, the pandemic has continued to affect all aspects of the UAE healthcare system, resulting in:

- Decreased M&A activity in 2020, but with a steady increase through 2021, and the entry of mostly foreign service providers and hospital operators to the market, mostly focused on specialized services
- Healthcare asset consolidation
- The adoption of technology at an accelerated rate, including greater use of telemedicine, precipitating a fall in the number of face-to-face appointments and a rise in appointments conducted remotely by telephone, email and video
- The introduction of temporary fast-tracking for the healthcare facility licensing process
- A temporary obligation on insurance providers to cover telehealth services and a lifting of the licensing requirements for the provision of telehealth services, during the COVID-pandemic
- The temporary suspension of lawsuits against healthcare providers

By way of a brief overview, the United Arab Emirates (UAE) is a confederation of seven emirates, the most well-known of which are Dubai and Abu Dhabi. The other emirates are Sharjah, Ajman, Fujairah, Umm al-Quwain and Ras al-Khaimah, often collectively referred to as the “Northern Emirates”.

The Federal Ministry of Health and Prevention (MOHAP) oversees the implementation of federal government policy in collaboration with the local emirate health authorities, such as the Abu Dhabi Department of Health (DOH) and the Dubai Health Authority (DHA). The remaining Northern Emirates rely on the MOHAP to act as their regulator to oversee delivery of healthcare services.

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare

In the UAE, in general, statutory restrictions prevent foreign companies from establishing wholly owned healthcare businesses outside of the economic free zones, and require that such onshore UAE companies have one or more UAE national partners (individual or corporate) who hold at least 51 percent of the company's capital. A 2020 law now allows foreign investors to create an onshore wholly foreign-owned legal entity to establish a healthcare facility, provided that the investor meets certain share capital and other investment financial thresholds.

The key business activities in the healthcare sector that are listed in the “positive list”, thereby allowing

100 percent foreign ownership, are: hospital activities, manufacturing of pharmaceutical materials, manufacturing of chemical and plant pharmaceuticals, medical and dentist clinic activities and other activities in the field of human health.

Approval will be subject to the discretion of the relevant authority (the Department of Economic Development) in the respective local emirate, which will take into consideration the number of hospitals, medical and health centres in the respective area, and other minimum-share capital, investment and financial thresholds. At present, not all seven of the emirates have put in place a process enabling 100 percent onshore ownership; thus, in several emirates foreign investors will need to await such processes before being able to obtain 100 percent ownership.

Ownership restrictions in relation to certain other healthcare activities, such as import and distribution of medical products, remains restricted to a maximum of 49 percent foreign ownership. On the other hand, companies established in free zones are exempt from the 51 percent local ownership requirement, therefore 100 percent foreign ownership is permitted in such economic free zones. The emirates of Dubai and Sharjah have established healthcare-specific free zones, such as the Dubai Healthcare City, Dubai Science Park, and the Sharjah Healthcare City. However, the selling of physical goods, such of medical devices and pharmaceuticals, out of the free zones is complicated by the requirement for such products to be imported onshore, through an onshore licensed importer/distributor.

3. Award of Public Contracts and Reimbursement

For the Emirati population in the emirate of Abu Dhabi, the Abu Dhabi Government provides full medical coverage through the *Thiqa* health insurance program administered by the emirate of Abu Dhabi's insurance company, Daman, and its network of private and public healthcare providers.

UAE nationals in the emirate of Dubai, and separately in the Northern Emirates, have a separate system for medical coverage, provided by their local emirate governments. For example, *Saada* is the health insurance program for UAE nationals in the emirate of Dubai, providing healthcare services through a network of healthcare providers in the private sector and public Dubai Health Authority healthcare centres. Further, the emirate of Dubai unified all government health insurance systems (provided to employees of the Dubai government) under one umbrella, the Unified Health Insurance System (Enaya), which includes the *Saada* program and other government insurance programs.

For expatriates, the emirate of Abu Dhabi was the first emirate to fully implement mandatory health insurance, through Law No. 23 of 2005, which provides a basic level of coverage for all employees and their families.

In the emirate of Dubai, Law No. 11 of 2013 mandates medical insurance coverage for all expatriates, along with their dependents, living in the emirate of Dubai. Employers are required to provide health insurance coverage for their employees that meets the minimum requirements of the law.

For both Emirati national and expatriate insurance, not all healthcare needs are covered. Consequently, many services are still paid for out of pocket or accessed abroad.

In terms of public contracts, the regulation thereof depends on whether the contract relates to the federal government or at the individual emirate levels. Each emirate has specific provisions regulating government procurement activities. Some public contracts will go

through a public tender process while others will be directly awarded.

For most types of government procurement projects, the bidder must have a legal presence in the UAE and ensure that their company, goods, and services are prequalified for procurement tenders.

Public tenders in Abu Dhabi follow the new Public-Private Partnership (PPP) procurement regulations, issued in 2019. The DOH issues tenders related to its public facilities through its website and suppliers will need to register through the Digital Marketplace - Abu Dhabi Government Procurement Gate.

Public tenders in Dubai follow the 2020 law on Contracts and Warehouse Management in Dubai. DHA tenders concerning its public facilities are issued via eSupply, the official Procurement Portal for Dubai Government Tenders. Vendors and suppliers will need to register with DHA Purchasing & Finance Departments

The Northern Emirates each have their own local government procurement process as well. Federal government tenders are mainly issued through the Ministry of Finance, in accordance with the Federal Government Procurement Regulation and Storehouses Management.

4. Drug and Device Approvals and Reimbursement

MOHAP is responsible for the overall regulation of medical products, including medical devices, pharmaceuticals, biologicals and combination products in the UAE. Under the UAE Pharmaceutical Law, all medical products must be approved by MOHAP before they can be imported into the UAE for sale and distribution.

A medical products manufacturer must register its manufacturing site with MOHAP before its products themselves can be registered with MOHAP.

The product registration application must be made by the manufacturer from the country of origin (the market authorisation holder in the case of pharmaceutical products) jointly with the local authorised representative, who is appropriately licensed in the UAE. The local authorised representative must be explicitly designated by the foreign manufacturer to act in the UAE, on behalf of the manufacturer, with regard to the manufacturer's legal obligations and responsibilities.

During the registration process, the price of the pharmaceutical (both the sale price to the pharmacy and the sale price to consumers) will be fixed by MOHAP in accordance with the formulation and considerations set out in law. Attempts by manufacturers and their agents to circumvent the fixed pricing may subject such violators to fines, bans or other legal action.

The company importing the medical product into onshore UAE must be an individual or entity established onshore in the UAE and licensed by MOHAP to import medical products. With regard to an individual, only UAE nationals may apply in their individual capacity to be a registered importer of pharmaceuticals and medical devices.

While in the past only companies wholly owned by UAE nationals could apply for a licence to import medical products, currently companies owned by both a UAE shareholder and a foreign shareholder may also apply for such a licence (under the aforementioned limitation of a maximum of 49 percent foreign ownership).

Medical devices must also be approved by MOHAP before they can be sold or distributed in the UAE. The law defines a medical device as any such device that

is used to diagnose, monitor or treat an illness. UAE laws and regulations make a distinction between devices that provide therapeutic benefit through purely mechanical or non-pharmaceutical means and those devices that have a pharmaceutical component (*i.e.*, devices that dispense a drug therapy). The latter may be subject to pricing controls similar to those of pharmaceuticals.

5. Payments to Healthcare Professionals and Incentives

The MOHAP Code of Ethical Practices for the Promotion and Distribution of Medical Products (Code) provides directives for the ethical promotion and distribution of medical products in the UAE. It covers the minimum standards that should govern the interaction between medical product companies (or their representatives) and healthcare professionals. It aims to ensure that all interactions between such parties are intended to advance healthcare practices and to benefit patients.

For example, the Code determines that the reasonableness of remuneration to a healthcare professional, for participation in a clinical trial, is determined in accordance with the fair-market value of the work performed. Further, compensation or reimbursement made in conjunction with a consulting arrangement is determined as reasonable based on the fair market value of such services.

The Code allows suppliers to offer one type of incentive to pharmacies: a bonus in the form of free-of-charge goods (FOCs). The volume of permissible FOCs is calculated as "a quantity of FOCs up to 15 percent of the invoiced quantity to pharmacies". No other incentives besides this specific type of bonus, FOCs, can be offered to pharmacies, as per the Code.

Further, in the UAE kickbacks are strictly prohibited. These include payments given or received by other healthcare professionals, health facilities or institutions for referring or prescribing tests and/or medications and treatment to patients.

6. Telemedicine, Teleconsultation and Reimbursement

The regulation of telemedicine is fragmented across the emirates, with responsible authorities including MOHAP in relation to the Northern Emirates, the DOH in the emirate of Abu Dhabi and the DHA in the emirate of Dubai.

The DOH Standard on TeleMedicine (DOH Telemedicine Standard) of September 2020, brought Abu Dhabi's telemedicine standards in line with recent federal legislation and current care delivery models. While exemptions to licensure were provided during the COVID-19 pandemic, it remains that a DOH licence is required by the healthcare facility for the provision of telemedicine services, either to provide telemedicine services as a supplemental service or as the primary service. Stand-alone telemedicine providers, however, are not permitted to engage in telemedicine interventions and telediagnostic services. The individual healthcare professional is not required to obtain a specific telemedicine license; merely, the provider must be credentialed/privileged by a healthcare facility with a telemedicine license in order to provide telemedicine services.

The DHA's 2021 telehealth policy sets out the regulatory requirements for licensure of telehealth services. All telehealth services and telehealth platforms operating in Dubai must be licensed by DHA. Telehealth services are licensed under one of the following areas:

- Call centre
- Telebooth

- Add-on services.

In addition to the relevant health authority's telehealth regulation, compliance is required with, amongst others, federal laws regarding telehealth services, the use of information and communication technology (ICT) in healthcare, and medical liability; the National Electronic Security Authority Standards and Guidelines for Cyber Security; the Telecommunications and Digital Government Regulatory Authority for Voice Over Internet Protocol channel requirements related to telehealth; in Dubai, the Dubai Health Insurance Corporation requirements for telehealth approval processes e-claims, reimbursement and documentation; and in Abu Dhabi, the Abu Dhabi Healthcare Information and Cyber Security Standard and various DOH policies (such as the DOH Data Management Policy, DOH Policy on Health Information Exchange, DOH Policy on Digital Health, and DOH Standard for Patient Healthcare Data Privacy).

Both DOH and DHA issued a slew of circulars addressing exemptions and insurance coverage afforded during these current times. For example, DHA General Circular No. 9 of 2020, on teleconsultation DSL Codes, established five new Dubai Service List codes for billing purposes to cater to teleconsultation services, with effect from April 5, 2020. The codes included those for teleconsultation with a general practitioner, specialist, consultant, allied health provider and psychotherapy (psychologist). However, it does not include nursing consultations. As per Policy Directive No. 2 of 2020, all payers must encourage and accept any claims, regardless of whether they had previously not agreed to telehealth services from the same network providers.

7. Regulation of AI, Software and Medical Apps

Artificial intelligence (AI), software and medical applications may be regulated as medical devices, depending on their intended use. MOHAP will evaluate and classify any such products. Further, software and medical apps that aid telehealth must consider the local telehealth regulations mentioned above, as compliance and licensing requirements may be applicable.

In April 2018, DOH issued the Policy on the Use of Artificial Intelligence in the Healthcare Sector of the emirate of Abu Dhabi (the Policy). The Policy sets out minimum acceptable requirements that DOH expects for AI (and its tools) introduced in Abu Dhabi, which includes certification by recognised international agencies, compliance with Abu Dhabi Smart Solutions & Services Authority (ADSSSA) regulations, and auditable validation statements.

Further, in 2022, it is now a requirement that m-health companies obtain DOH accreditation before offering the service to patients in Abu Dhabi. Such companies must also have a Department of Economic Development or Abu Dhabi Global Market licence - in other words, these companies should be established in Abu Dhabi and approved by the DOH.

In the emirate of Dubai, all AI solutions for healthcare must conform to international, UAE federal and emirate of Dubai information laws, regulations and guidelines with respect to human values, patient autonomy, human rights and acceptable ethics. The DHA Policy on Artificial Intelligence in Healthcare (2021) applies to all healthcare facilities and professionals licensed by DHA utilising AI in healthcare services, national and locally based international AI developers that utilise Dubai-based population or patient clinical and nonclinical data to develop AI solutions, UAE-based pharmaceutical

manufacturers, health insurers and public health entities utilising AI solutions for healthcare services in Dubai and all AI solutions used by healthcare researchers involved in human research in Dubai.

8. Foreign Investment Control

UAE competition law requires merger clearance in advance of any proposed merger, acquisition or other consolidation of two or more entities that would result in a market share of 40 percent or more.

9. Forthcoming Changes in Healthcare and Life Sciences Law

The UAE has a complex patchwork of laws that impact the development of digital transformation. There are industry-specific laws in addition to laws covering specific technologies (such as internet of things (IoT)). There are relevant telecommunications laws and regulations. In addition to this are cybersecurity and IT security regulations and guidelines that govern both the UAE public and private sectors.

In general, it is not permitted to store, develop or transfer data and health information outside the country that is related to health services provided within the country, except in limited cases.

One of the most impactful provisions of the 2019 ICT Health Law was that it mandated that health information and data related to services provided in the UAE could only be processed, generated or transferred outside of the UAE in cases prescribed by virtue of a decision issued by a local emirate health authority, in coordination with MOHAP. A 2021 Ministerial Resolution expressly provides for ten circumstances wherein the transfer of health information and data outside of the UAE may be permissible.

In November 2021, the UAE published the long-awaited UAE Personal Data Protection Law, a GDPR-style data protection law and we await its executive regulations.

We expect to see much more regulatory activity relating to data and IT security as the region's digital transformation programs progress.

Additionally, we expect to see further activity with regard to investment in and localisation of medical products manufacturing and medical research.

In 2021 the authority of the DHA was split, and the new Dubai Academic Health Corporation (DAHC) was created. DAHC's objectives include strengthening Dubai's leadership in medical education and scientific research and the DHA positioning itself as the unified regulator for the emirate of Dubai, including its free zones, such as the Dubai Healthcare City. The DAHC is an academic health system, with financial and administrative independency. Further, the DAHC seeks to enhance the capabilities of Dubai's healthcare sector to prevent and treat diseases and epidemics. The new corporation also aims to develop educational and professional programmes for healthcare personnel and promote strategic public-private sector partnerships to meet its objectives.

UNITED KINGDOM

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

The pandemic has continued to affect all aspects of the UK healthcare system, resulting in:

- The adoption of technology at an accelerated rate, including greater use of telemedicine, precipitating a fall in the number of face-to-face appointments and a rise in appointments

conducted remotely by telephone, email and video

- The introduction of a fast-track certification and authorisation process for medical devices and medicines, thereby accelerating the route to market for manufacturers and distributors. Following the conclusion of the EU-UK Trade and Cooperation Agreement, with respect to the UK's withdrawal from the EU (Brexit), the UK largely retained the EU regulatory regime in relation to medical devices whilst also introducing certain modifications as stand-alone UK legislation
- A reduction in levels of elective care, cancer care and non-COVID-related diagnosis and care throughout the pandemic, leaving a considerable backlog of patients requiring treatment
- During the initial pandemic phase, and more recently in January 2022, the public-sector purchasing healthcare services capacity from across private-sector hospitals
- Delays to clinical trials and to development of medicines
- Ongoing implementation of a mass vaccine roll-out programme, including the extension of the roll-out to persons under the age of 18, and booster jabs to tackle variant strains of the virus

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

There are limited barriers to the ownership and/or operation of private healthcare facilities in England. Any provider may operate healthcare facilities if the provider is registered with the Care Quality Commission (CQC) and holds relevant registrations.

Most NHS contracts may be awarded to and/or held by any provider, and current rules prevent discrimination on the basis of ownership.

There are, however, some restrictions on the entities and persons that may hold NHS primary care contracts. Under legislation, only certain types of contracts may be held by general practitioners or other healthcare professionals (or by companies wholly owned by these individuals). In addition, for certain elective and other services, patients are entitled to choose providers that are authorised, by commissioners, to provide these services (a policy also known as "patient choice").

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

The United Kingdom's national healthcare system is the NHS. The NHS is funded through general taxation, and healthcare is provided free at the point of use and without co-payment. Privately purchased healthcare (through insurance or self-paying patients) has, in recent years, accounted for about 11 percent of the market.

The NHS marketplace is underpinned by legislation, with national and local payor bodies (NHS England and clinical commissioning groups) that commission and contract for healthcare services.

All NHS contracts are currently subject to EU, UK and NHS procurement rules, which require that contracts are subject to a tendering regime. Changes are proposed to procurement rules following Brexit and the UK government is currently legislating for changes to the procurement regime, with changes anticipated to take effect in 2023.

In practice, many contracts held by NHS hospitals are not tendered. Private providers commonly provide non-urgent and non-emergency care, including elective, mental health, dental, primary care, diagnostics, pharmacy and community services contracts.

In general, NHS services are reimbursed at rates set out in a statutory mechanism known as the NHS tariff, although the NHS tariff allows for local modifications and variations, which have been used more frequently in recent years, including in relation to NHS system-wide payments. Under the NHS constitution, patients may exercise patient choice when choosing a provider for elective services provided that the chosen provider meets commissioner standards for those services.

The NHS Long Term Plan proposes changes in NHS law. The government has recently introduced new legislation in the form of the Health and Care Act 2022, which became law on 28 April 2022. The Health and Care Act builds on the proposal for legislative change set out in the NHS Long Term Plan and introduces wide-ranging changes for the NHS. The Act paves the way for changes that will: affect the structure of NHS bodies by requiring formal adoption of 'Integrated Care Systems' across England to promote integration that will alter the composition and nature of local commissioning and payor bodies; and will impact the NHS marketplace and the NHS tariff payment regime.

4. Drug Approvals and Reimbursement

Marketing authorisation for drugs is heavily regulated in UK law. Prior to Brexit, the procedure for marketing authorisations was regulated by both EU and UK law. As a consequence of Brexit, a separate marketing authorisation is required in the UK. As part of the UK's post-Brexit regulatory system, community marketing authorisations will be converted to UK marketing authorisations and there are transitional provisions allowing (*inter alia*) the UK to authorise medicines on a fast-track process in reliance upon decisions of the European Medicines Agency (EMA). The EU-UK Trade and Co-operation Agreement includes certain co-operation and facilitation arrangements with respect to medicinal products.

The NHS is the largest purchaser of drugs in the United Kingdom. A range of policies and statutory mechanisms regulate the prices payable by the NHS for drugs. There is no statutory regime for the drug prices payable by private providers.

For branded medicines, the main mechanism for pricing drugs and controlling spending on medicines is a voluntary scheme known as the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS sets out permitted growth of the NHS-branded medicines spend (set at 2 percent per year for the period 2019 to 2023). The scheme requires the industry to make rebate payments if NHS expenditure exceeds the permitted growth. Any company that is not a member of the PPRS is automatically subject to statutory regulations (the Statutory Scheme) under which the Department of Health and Social Care (DHSC) may limit prices and profits of NHS medicines. In practice, most large companies participate in the PPRS. Generic (unbranded, out-of-patent medicines) are covered by the Drug Tariff (produced by an executive arm of the DHSC).

New medicines and technologies are assessed by the National Institute for Health and Care Excellence (NICE) on the basis of clinical and economic evidence. While NICE's role is to make availability decisions, in practice it also influences product prices through cost-effectiveness thresholds. The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE. If NICE is

unlikely to recommend a drug for use, then drug prices and access to the market may be agreed with NHS England (as part of a patient-access scheme or commercial agreement).

5. Devices Certification and Reimbursement

Since January 1, 2021, following Brexit, the Medicines and Healthcare Products Regulatory Agency (MHRA) has been the regulator of medical devices in the United Kingdom and undertakes responsibilities historically managed through the EU system, including vigilance reporting. Due to the timing of Brexit, the United Kingdom did not adopt the EU Medical Device Regulation 2017/345 (EU MDR), which applied in the EU from May 2021, but continues to follow the earlier EU Medical Devices Directives regulatory regime that was implemented in the United Kingdom by the Medical Devices Regulations 2002 (MDR 2002), with certain modifications that the United Kingdom has introduced as standalone UK legislation to reflect the UK's post-Brexit regulatory regime. Under this new standalone UK legislation, the Medicines and Medical Devices Act 2021 (MMDA 2021), the United Kingdom may adopt new regulations that may diverge from the EU legislative regime for medical devices in the future.

Towards the end of 2021, the MHRA conducted a consultation on the future development of medical devices in the United Kingdom, with the intention of developing a regulatory framework for all aspects of medical devices, including to promote access and support innovation, to reform and develop the law, and to promote sustainability. The aim is to amend the MDR 2002 with a bold new regime to take effect in the summer of 2023.

Medical device manufacturers based outside the United Kingdom seeking access to the UK market need to assign a UK responsible person to register and act on their behalf. A new UK certification route known as UK Conformity Assessed marking has been in place since January 1, 2021, although CE marking will continue to be recognised in the United Kingdom and certificates issued by EU notified bodies will continue to be valid for a transitional period (until June 30, 2023).

There is no statutory reimbursement scheme for medical devices in the United Kingdom. Medical devices purchased by NHS providers are subject to procurement law. The NHS currently operates a centralised procurement and purchasing system for medical devices and other supplies to NHS providers. NHS providers are reimbursed through the NHS tariff for health services they provide. The NHS tariff includes the cost of most medical devices; however, in certain cases, high-cost devices are excluded from the NHS tariff and reimbursed separately. As with medicines (see Section 4 above), NICE appraises certain devices that meet its criteria and evaluates clinical effectiveness and budget impact. NHS commissioners are legally obliged to fund treatments that are recommended by NICE.

Separately, the CQC regulates all healthcare services, including online healthcare and telemedicine (to the extent they are not software as a medical device).

6. Regulation of AI and Software as a Medical Device

The MHRA regulates medical technology software and artificial intelligence (AI) tools as medical devices under medical-device legislation. Online software tools, such as symptom checkers, are typically regulated as Class I medical devices. However, if the device allows for diagnosis, it may be a Class II medical device or higher. If the software is only a reference or decision-support tool, and the healthcare

professional is required to use his or her own knowledge for the care, the tool may not be a device.

In the EU, the Medical Device Regulation 2017 (which came into force on May 26, 2021) has changed certain classifications for medical devices. As noted above, the United Kingdom's regime for medical devices, however, will continue to be based on the EU Medical Devices Directives implemented in the United Kingdom by the MDR 2002, which have been amended to reflect the United Kingdom's post-Brexit regulatory regime under the MMDA 2021. This includes clarification on how devices in Northern Ireland will continue to be required to comply with EU medical devices regulation under the Northern Ireland Protocol that was introduced as part of the Brexit arrangements. In addition, software provided to NHS organisations must also meet certain mandatory standards published by NHS Digital.

In recent years, the DHSC has published various guidance and codes of practice in relation to AI and digital health services, which set out principles and expectations for the use and purchase of AI in healthcare in the United Kingdom. It also sets out principles in relation to the use of and access to data.

In 2021, in parallel with its consultation on medical devices, the MHRA consulted on the use of software and AI medical devices, with a view to incrementally introducing an applicable regulatory framework through separate work packages, with the more specific intention of introducing incremental changes between 2021 and 2023. Furthermore, in September 2021, the UK Department of Digital, Culture, Media and Sport announced a ten-year strategy for investment, use and governance of AI, with the intention of making the United Kingdom a "global AI superpower".

7. Telemedicine and Teleconsultation

Telemedicine and teleconsultation, including remote, online and digital health services (which are not medical devices) located in England, are regulated by the CQC, and providers of these services must register with the CQC.

Services are assessed through investigations and other regulatory interventions to check that they are safe, effective, caring, responsive and well-led.

The CQC has stated it is assessing how it can regulate services currently outside its remit, such as digital health services based overseas providing services to UK patients. To date, however, it is not clear how this regulation will work in practice and no guidance or changes to the CQC's regulatory remit has been formally proposed.

8. Anti-Kickback Rules and Incentives to Doctors

In the United Kingdom, financial relationships between pharmaceutical companies and healthcare professionals are governed by the Human Medicines Regulations 2012 and related guidance, which prohibit the use of inducements in connection with the promotion of medicinal products to healthcare professionals. The legislation is supplemented by the UK regulatory guidance published by the MHRA and industry codes that set out detailed guidance about payments to healthcare professionals.

Professional rules (for example, those issued by the General Medical Council) also prohibit doctors from accepting any inducement or gift that may affect or be seen to affect the way the doctor treats patients.

Bribery legislation also applies to payments to doctors and other healthcare professionals.

There are currently no legislative requirements to disclose financial relationships with healthcare professionals, although there are disclosure obligations in medicine and medical device codes of practice. NHS contracts and guidance include an obligation to disclose and publish all financial interests, including gifts and hospitality received by staff.

A Competition and Markets Authority Order also sets out rules about certain payments and share-ownership by doctors in relation to private patient services where such payments and interests may operate as incentive arrangements to influence referrals and care.

9. Merger and Foreign Investment Control

The Competition and Markets Authority (CMA) oversees merger control in the United Kingdom. From January 1, 2021, the CMA has had jurisdiction to review the effects of certain mergers previously reviewed by the European Commission and, accordingly, is taking a more prominent role in reviewing global transaction activity. The recent changes NHS legislation in the Health and Care Act 2022 remove some powers of the CMA in the context of health and social care, notably removing CMA's historic powers in respect of mergers between two NHS provider bodies.

The United Kingdom has historically operated with a liberal approach to foreign investment. The UK government has some powers to intervene under merger controls in relation to mergers that are against the public interest for national security reasons. This power has been exercised on rare occasions and never in relation to healthcare.

Recent developments, however, suggest that there will be increasing intervention from government. In response to COVID-19 and effective from June 23, 2023, the government introduced a new public-interest ground on which it can intervene in mergers in order to maintain the United Kingdom's capability to combat and mitigate public-health emergencies. Furthermore, a new National Security and Investment Act recently established a mandatory foreign direct investment regime for the United Kingdom. The Act has a focus on particular industry sectors, including advanced robotics, AI, critical suppliers to government, critical suppliers to emergency services and engineering biology. The Act will have an impact on certain healthcare and life sciences investments in the United Kingdom.

10. Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

As noted above, the impact of Brexit has led to several changes in law for the United Kingdom, and whilst the United Kingdom has retained EU regulatory regimes that were applicable to the United Kingdom to a large extent, it has also introduced certain modifications to those regimes in the form of standalone UK legislation, which may result in a degree of divergence from EU law in the future. Changes in UK law, including the law relating to the procurement, export and import arrangements for goods and supplies, and to other laws (including some mentioned above), have and will continue to arise as a consequence of the United Kingdom formally leaving the EU following the end of the Brexit transition period.

As noted above, the new NHS Health and Care Act 2022, which became law on 28 April 2022, will precipitate a raft of changes to the delivery of healthcare in England. The Act mandates the integration of local NHS bodies in order to promote a greater degree of joined-up care for healthcare commissioning and in the provision of healthcare. It has other wide-reaching implications, which include:

changes to the NHS marketplace (which will take place alongside new and separate service provider and supplier procurement regimes that are still subject to the legislative process and parliamentary approval); and replacement of the NHS tariff with a new NHS payment scheme.

Furthermore, the Act gives the Secretary of State for Health new powers, one of which includes the power for the first time to introduce regulations that would require manufacturers and commercial suppliers of healthcare products to report payments or benefits that they provide to healthcare providers and others that provide healthcare or connected services in order to promote transparency. We still await draft regulations and the timing for the new disclosure requirements are unclear, but any new regime could reflect the approach used in the US Physician Payments Sunshine Act to promote transparency on payments to healthcare professionals and institutions.

The UK Government (through the MHRA) has recently consulted on changes to the UK clinical trial regulations with a view to creating an attractive regulatory environment for clinical trials and has also set out its wider life sciences ambitions in in its Life Sciences Vision (published in July 2021), which is intended to enhance the UK's status as a go-to destination for the development of new healthcare products and innovation.

UNITED STATES

1. The Impact of COVID-19 on the Provision of Healthcare and Life Sciences

The response to the COVID-19 pandemic changed certain aspects of the delivery of healthcare services in the United States, although many of these changes are temporary. With the Omicron-fuelled spike in infections showing a decline, and political pressure mounting for a return to normalcy, the federal public health emergency is likely to end in 2022. Already, most state emergency declarations and special orders have lapsed.

While the significant growth in telehealth adoption rates have diminished, usage remains far higher than immediately prior to the pandemic. Virtual care models have continued to evolve and investment in digital health in 2021 far exceeded past years' numbers. The interest in virtual-care models seems likely to withstand the impending reversion to pre-pandemic rules, although changes will likely be temporary, leaving significant room for further changes in policy going forward.

While the end of the public health emergency will have a significant impact on the rules for Medicare (see here for a discussion), its impact on Medicaid, Medicare Advantage, and the private insurance and employer plan markets is less clear. Payment systems not directly impacted by the change in Medicare rules will determine their own way forward. Insurers and state regulators are already drawing the contours of care that is permissible and payable virtually, some that are helpful for virtual care models, and some that are distinctly not.

Private investment in the healthcare services sector remains strong, after suffering an initial setback early in the pandemic. Interest in digital health, as noted above, has grown significantly, and the rapid success of some models has created challenging valuations and opportunities for investors looking beyond their traditional theses or goals.

Accordingly, while the end of the COVID-19 public health emergency declarations could impact the virtual care sector, it does not appear that investors view the prospect negatively.

2. Ownership or Equivalent Restrictions in Relation to the Provision of Healthcare Services

There are limited barriers to the ownership and operation of private healthcare services in the United States. Nonetheless, some restrictions do exist at both the federal and state levels. Individual state licensing regimes for health services and healthcare facilities make a national strategy challenging. Participation in government payment systems and private payment systems by healthcare service providers requires enrolling in those systems independent of any applicable state licensure requirements. Moreover, individual US states impose restrictions on the ability of unlicensed persons to practice medicine or employ medical professionals under a doctrine known as the "corporate practice of medicine" prohibition. These prohibitions can extend to other licensed professionals as well, including nurses and therapists.

Investing in healthcare services must also conform to federal and state fraud and abuse laws designed to isolate clinical decision-making and patient choice from the financial incentives associated with care delivery. Because these laws and regulations can exist at both a federal and state level, compliance efforts can be burdensome.

Strategies exist to address these hurdles, but the resulting structures can be complex and confusing to those unfamiliar with the US healthcare market. In addition, changes in ownership can trigger notice or consent requirements from the relevant government oversight agency, which present timing issues and additional administrative burdens on completing these types of transactions.

3. Reimbursement of Public or National Healthcare Services and Award of Contracts

Unlike European jurisdictions, the United States has a significant market for the private reimbursement of healthcare services, which is generally offered by employers. Public reimbursement is largely limited to Medicare (federal health insurance for seniors and individuals with certain disabilities) and Medicaid (state-run insurance for individuals with low incomes). Providers wishing to participate in these programs must satisfy conditions of participation and enrol in Medicare and Medicaid, which can be a burdensome process but generally does not involve competitive bidding. Medicare Advantage, Medicaid managed care and other programs, however, do require private organisations to compete for participation in those programs. Each program is different, with unique requirements that are generally regional.

Government Payors

Medicare is the largest government insurance program, providing insurance for more than 63 million people. Medicare-eligible beneficiaries may choose either to receive insurance coverage directly from the federal government under so-called "Original Medicare," or to enrol in a Medicare Advantage plan, under which plan their Medicare benefits are administered by a private commercial insurance entity that shares in the risk of the cost of care. Medicare beneficiaries can also choose to purchase a prescription drug plan as part of a Medicare Advantage plan or as a standalone plan, as prescriptions are generally not covered under Original Medicare.

Original Medicare has typically been paid on a fee-for-service basis, under which providers submit claims for each reimbursable service. Increasingly, however,

the federal government is exploring value-based purchasing programs and other innovative payment models that seek to link payment rates to quality of care, rather than simply the volume of services provided. Shared risk models, such as Medicare Advantage and the Medicare Shared Savings Program, are increasingly popular and, in some instances, are proving to be cost effective.

Providers of healthcare services must enrol in order to participate in Medicare. Enrolment may also require accreditation by an approved non-government agency or government agency for facilities. Reimbursement from Medicare can be through fee-for-service, bundled services and shared-risk models. Appropriate coding of claims for care rendered and compliance with reimbursement requirements are also mandatory.

Medicaid is administered by the individual states and shares many of the same characteristics as Medicare, although states have additional flexibility with how these programs are implemented and what is paid for.

Private Payors

Americans that do not qualify for Medicare or Medicaid largely receive health insurance from commercial health insurance coverage, either through their employer or the private marketplace created by the Affordable Care Act. Federal law sets standards for commercial health insurance coverage, which is often supplemented by state-specific requirements.

For example, commercial payors may be required to offer coverage and payment parity for telehealth services under applicable state law. Coverage parity refers to laws that require private payors to provide the same coverage for services provided via telehealth as is offered when such services are provided in person, while payment parity refers to laws that require private payors to offer the same reimbursement rates, regardless of whether the service is provided in-person or via telehealth.

Currently, 43 states and the District of Columbia have private payor laws governing telehealth. As with government payment regimes, healthcare service providers that participate in private health payment systems must enrol and comply with the private reimbursement regimes, which are mandated through participation agreements entered by the providers with the payors. While government reimbursement rates are non-negotiable, the reimbursement rates under private payor contracts can be subject to significant negotiation.

Most healthcare providers participate in Medicare, Medicaid and private payment regimes that are relevant in their markets. Accordingly, they must comply with multiple enrolment and reimbursement regimes, which can place a significant administrative burden on providers.

4. Drug Approvals and Reimbursement

The US Food and Drug Administration (FDA) evaluates new drugs and biological products before they can be sold in the United States. For novel therapeutic products, the FDA generally requires substantial clinical and non-clinical data before it will approve or license a product for distribution.

Medicare is the largest third-party payor in the United States. Medicare pays for most outpatient drugs and biological products under Part D (Medicare drug coverage), which involves Medicare paying competing private plans to deliver benefits to enrolees; the plans also establish coverage criteria, formularies and payment rates for therapeutic products. However, a limited number of drugs (*e.g.*, certain physician-administered drugs) are reimbursed under Part B (Medicare medical insurance), which allows Medicare to pay providers directly at rates established by statute or regulation.

Commercial payors may cover drugs or biologics under their pharmacy or medical benefit, depending on the drug and the payor's preference. Subject to certain federal and state laws, commercial payors generally have substantial flexibility when deciding whether to cover and how much to pay for a drug.

5. Devices Certification and Reimbursement

The FDA also regulates the development, manufacturing and distribution of medical devices in the United States. Depending on the device, a manufacturer may need to obtain premarket approval (PMA), clearance (510(k)) or a *de novo* classification before offering the product for sale in the United States.

Medicare is a defined-benefit program, which means the program can only pay for items and services if there is a statutorily defined "benefit category" for such items and services. While there are Medicare benefit categories for certain types of medical devices (*e.g.*, durable medical equipment), there is no general "device" benefit category. As a result, payment for devices is often bundled into the payment for other covered services (*e.g.*, physician office visits, outpatient hospital admissions).

Commercial payors typically take a similar approach to Medicare and, with certain limited exceptions, consider medical devices an expense incurred by providers when furnished as part of a covered service, as opposed to making separate payment for the device itself. However, commercial payors increasingly exercise their discretion to enter into novel arrangements— particularly in the digital health space—to provide coverage for novel digital modalities, where supported by adequate clinical evidence.

6.Regulation of AI and Software as a Medical Device

Depending on its technological characteristics and the indications for which its developer intends to market the product, an Artificial Intelligence (AI) -based or software product may be subject to regulation by the FDA as a medical device.

The FDA's existing regulatory structure for medical devices was not designed with rapidly evolving products in mind. However, in 2019 the FDA issued a white paper announcing plans to consider adapting its existing regulatory framework to promote the development of safe and effective medical devices that use advanced AI algorithms. The FDA's proposed approach would allow developers to make certain modifications to previously cleared or previously approved algorithms based on real-world learning and adaptation without requiring a new clearance or approval for the modified product in many cases. If finalised as outlined in the white paper, the FDA's plans would attempt to better accommodate the iterative nature of AI products while ensuring that the FDA's standards for safety and effectiveness are maintained.

7. Telemedicine and Teleconsultation

In the United States, telemedicine is regulated at the state and federal level and by multiple regulatory bodies. At the federal level, the Centers for Medicare and Medicaid Services (CMS), the federal agency overseeing federal health reimbursement programs, establishes Medicare reimbursement policies (subject to applicable legislation) and has a certain level of oversight over state Medicaid programs. Many of the reimbursement requirements imposed by these programs have been relaxed during the COVID-19 pandemic. In addition, the federal Drug Enforcement Administration (DEA) plays a role in determining,

subject to federal law, whether and how controlled substances may be prescribed via telemedicine. Historically, federal law requires an in-person examination prior to any such prescribing, but the DEA has temporarily waived this requirement during the COVID-19 pandemic.

The end of the public health emergency relative to COVID-19 will result in significant changes to the Medicare reimbursement rules (see here for a summary), but the impact on commercial programs is likely to play out in state-level changes, as these plans are not impacted by Medicare rules. Already, some states have passed laws that create a more inviting environment for virtual care models, while others have taken action making it more difficult. The state-level regulation of telemedicine remains inconsistent.

At the state level, state legislatures and professional licensing boards may create telehealth standards of care that govern telehealth practice. Such standards may relate to licensure requirements, the types of modalities that are permitted, remote prescribing of controlled and non-controlled substances, informed consent, medical recordkeeping, technology, confidentiality/privacy requirements and more. In addition, it is essential to understand that telemedicine practitioners are regulated by both the state where the patient is located and the state where the practitioner is located. This typically requires the provider to be licensed within the state where the patient is located, regardless of where the provider is physically located at the time of the encounter.

Every telemedicine regulatory regime has its own definitions regarding telemedicine. That said, it is typically categorised into three modalities: (1) live, synchronous, audio-visual interactions (*e.g.*, a patient speaking directly to a provider), (2) store-and-forward technology *(e.g.*, a patient sends an image of a clinical concern to a healthcare professional for review) and (3) remote patient monitoring (*e.g.,* mobile applications that track an individual's blood pressure and send readings to a healthcare professional).

There is significant variation in state and federal regimes relative to these modalities. For example, most, if not all, states permit physicians to prescribe non-controlled substances on the basis of a synchronous, audio-visual encounter. Beyond that, there is a significant amount of variation in terms of the types of (1) healthcare professionals that are permitted to provide services via telehealth, (2) modalities deemed sufficient to prescribe and (3) healthcare professionals permitted to use telehealth to prescribe when prescribing is otherwise within the professionals' scope of practice.

These variations make national telemedicine programs challenging to implement. Further, as we see telemedicine evolve with the utilisation of more technology, including AI, these variations can multiply along with the many use cases being developed.

8. Anti-Kickback Rules and Incentives to Doctors

The healthcare industry is subject to a number of fraud and abuse laws. Most notably, this includes federal statutes known commonly as the Anti-Kickback Statute and the Stark Law, which regulate financial relationships within and among healthcare stakeholders, and the False Claims Act, which prohibits providers from submitting false or fraudulent claims to government payment programs. The Anti-Kickback Statute is a criminal law that prohibits the knowing and wilful payment of remuneration to induce or reward patient referrals, while the Stark Law prevents healthcare providers from referring patients for certain services to entities in which they have a financial interest. In addition, states have their own

fraud and abuse laws, which often mirror, and sometimes extend beyond, federal law.

The Department of Justice (DOJ) and the Office of the Inspector General (OIG) have long played a significant role in bringing enforcement actions against healthcare providers for fraud and abuse violations. The DOJ is increasingly bringing enforcement actions against telemedicine providers for, among other things, paying healthcare providers for orders of durable medical equipment, genetic testing or pain medications and for submitting claims for medically unnecessary items or services. Many of these enforcement actions have focused on care that was furnished either without a patient interaction or based upon a brief telephone encounter. Other enforcement actions have focused on brokers of patient data, who provide patient data to telemedicine companies to enable those companies to fraudulently bill for services furnished to the patients. In addition, the OIG has indicated it will be carefully reviewing telehealth and virtual-care services and has already published reports assessing telehealth services furnished to patients during the pandemic. The data included in this report likely will be used to guide future telehealth policies and enforcement actions.

9. Merger and Foreign Investment Control

Investment in the healthcare and life sciences industries in the United States is not subject to specific foreign investment protocols or specific merger or acquisition controls outside of those related to licensure requirements for healthcare facilities and professionals and regulated insurers. Some of these regimes can be burdensome, and are generally state-based. Participation in public and private reimbursement regimes also includes following specific protocols related to change in control transactions.

Some states are more active in overseeing the availability of healthcare resources and require approval of expansions or changes in the control of healthcare services through “certificate of need” laws, which, in addition to other regulatory approvals, require independent government agency approval over a transaction. Like every industry in the United States, healthcare and life sciences transactions are subject to antitrust laws, the enforcement of which has increased in recent years with respect to hospital and physician markets. While state antitrust regimes can also play a role, federal antitrust enforcement generally takes precedent.

In recent years, the role of the Committee on Foreign Investment in the United States (CFIUS) has expanded through legislation, regulation and high-profile action. The focus of CFIUS is on transactions that could impact the national security of the United States, but the broad scope of concern, ranging from critical technologies to critical information, and the increased utilisation of technology in the healthcare and life sciences sectors has made CFIUS much more relevant now than it has been in past years. Compliance with CFIUS requires a careful review of transaction structure and assets and a determination whether a pre-closing filing may be required.

10.Forthcoming and Anticipated Changes in Healthcare and Life Sciences Law

As we begin 2022, Democrats control both the legislative and executive branches of the US federal government, but the country is going into what is expected to be contentious mid-term elections in the fall of 2022. The factors leading toward this volatility include the COVID-19 pandemic, rising inflation, a number of retiring Members of Congress and the impact of Congressional redistricting across the country. Traditionally, the party in control of the

Presidency loses seats in the legislative branch in mid-term elections. The current Democratic majorities in the House and Senate are slim (50-50 in the Senate and a four-vote Democratic margin in the House), which has already complicated the process for Democrats to pass legislation.

Notwithstanding the delicate balance of power in Washington, in response to the pandemic the Biden administration and Congress were able to achieve two significant domestic policy wins with the enactment of the American Rescue Plan in March 2021, which was the latest COVID-19 relief package, and the Infrastructure Investment and Jobs Act in November 2021, which also contained modifications to federal health policy. The House of Representatives also passed the Build Back Better Act, which includes transformational healthcare policy changes, such as Medicare prescription drug negotiation. To date, however, this package has not passed the Senate and is being renegotiated among Senate Democrats to see if the package can advance.

Looking forward in 2022, there is limited opportunity for legislation to advance because it is an election year, which limits time in Washington, DC, as Members of Congress will travel back to their respective districts to campaign. As a result, there will be a sprint to the summer, as the effective deadline for meaningful legislating prior to the lame-duck session after the election. During this time period, efforts are underway to pass an omnibus appropriations bill to fund government for the remainder of fiscal year 2022 which may be a vehicle to include some additional health policies such as Medicaid funding for the territories, telehealth flexibility extensions and (potentially) COVID relief that could include providers. In addition, Congress is looking to advance bipartisan behavioural healthcare legislation, although that could easily slide to the lame-duck session. If the public health emergency draws to a conclusion this summer, the Biden Administration has committed to providing 60-day notice in advance of such action. That would also become a driver for Congress to extend flexibilities such as telehealth, hospital at home, and more, and could become a vehicle for additional health proposals. Finally, at the end of the year, providers are facing significant Medicare payment cuts that are also likely to spur Congressional action during the lame-duck session.

Although Congress may have a small window of time to advance health policy this year, the Biden Administration will continue to advance its agenda through regulations and executive orders. This includes the continuation of the COVID-19 Public Health Emergency. This is important, as many flexibilities are tied to the emergency and once the Biden Administration ends the Public Health Emergency, many of these flexibilities will terminate. The Biden Administration and states need to plan for off ramps for many of these policies, or work to find continuations of these initiatives. Congress may also be needed for some of these efforts. Additionally, the Biden Administration has taken a focus on health care equity and will continue to advance policies to address disparities across the nation, and also continue to build on the Affordable Care Act.

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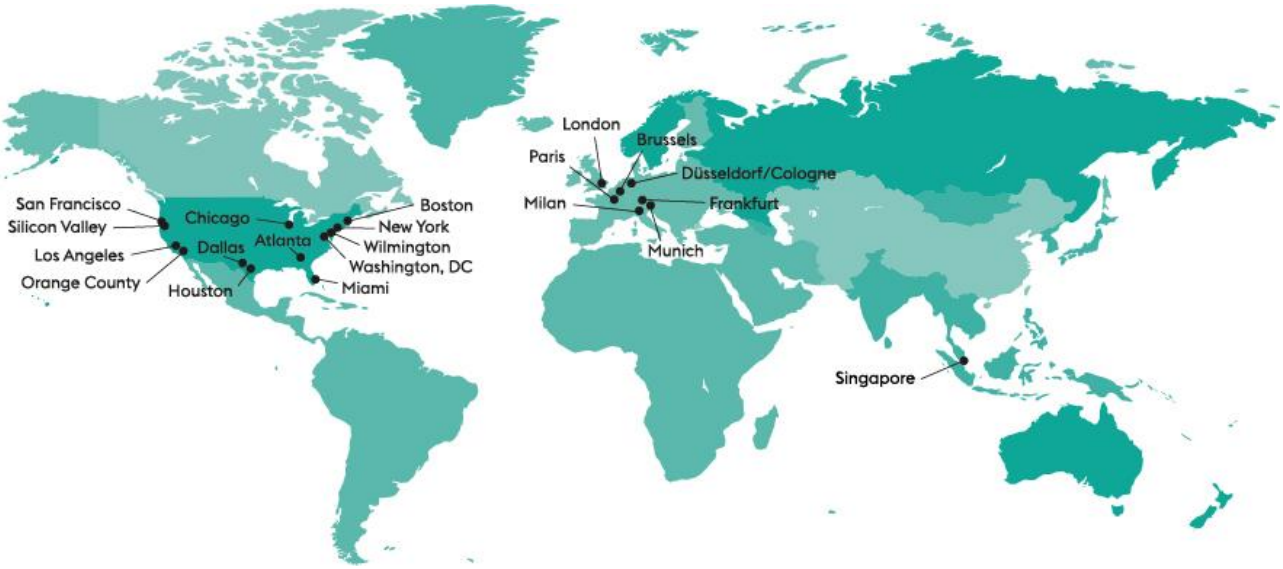

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