INVESTING IN HEALTHCARE & LIFE SCIENCES

An International Guide to Regulatory and Transactional Issues Across the Sector

September 2023*

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McDermott Will & Emery

McDermott Will & Emery

SPECIAL REPORT

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INTRODUCTION

As macroeconomic forces and geopolitical dynamics continue to shape the M&A and investment climate globally, health and life sciences transactions continue to remain high priority sectors presenting both high growth and defensive asset strategies.

As the market has tightened, understanding the regulatory environment for investments has become even more important. Now, more than ever, investors want to pick sectors and companies well placed to take advantage of changes in regulation, pricing and government policies.

A deep understanding of the regulatory environment and front loading of diligence to spot changes around the corner, vulnerabilities in portfolios and opportunities to deliver scale across multiple jurisdictions is essential.

Within this dynamic environment, McDermott's international health and life sciences team wield a deep knowledge of how healthcare services, medical technologies, biopharma and life sciences tools and services are delivered across the world, and how the laws that affect these industries will drive changes for the markets of tomorrow.

We're passionate about our role in supporting our clients in building deep insights on regulatory, reimbursement and strategic issues and in shaping the alliances that will lead to next-generation changes in how healthcare is delivered to patients internationally.

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 health and life sciences transaction team gives unmatched legal experience while balancing local, regulatory, technological and structural needs.

We have developed this Guide as a step to understanding the policies and regulatory issues that are shaping global healthcare and life sciences M&A and collaborations. Our approach is to work in partnership with our clients to give practical and thoughtful advice to help guide and structure their investments.

Together, we can transform healthcare.

What you'll discover for each jurisdiction:

1. Forthcoming changes in healthcare and life sciences law
2. Ownership or equivalent restrictions in relation to the provision of healthcare services
3. Award of public contracts and reimbursement
4. Drug approvals and reimbursement
5. Devices certification and reimbursement
6. Regulation of AI and software as a medical device
7. Payments to Healthcare Professionals and Incentives
8. Telemedicine and teleconsultation
9. Merger and foreign investment control

FRANCE

1. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

ROLL-OUT OF TELEMEDICINE

Given recent legislative updates allowing the reimbursement of "telesurveillance" activities and associated digital medical devices, telemedicine will be further rolled out in France with the support of public authorities.

REGULATION OF HEALTH PRODUCT PROMOTION ON SOCIAL NETWORKS

With the Influencers Law dated June 9, 2023 (Law n° 2023-45), France became the first European country to regulate the activities of influencers on social networks, including in the healthcare sector. This law aims to provide a framework for commercial influencer activities and tackle abuses by influencers on social networks. It notably provides a definition of "influencers" and "influencers' agencies" and requires the execution of an agreement when compensation for influencer services exceeds a certain amount. With respect to the health sector, the law expressly prohibits the promotion of certain practices (*e.g.*, plastic surgery) and requires influencers to comply with the rules governing the advertising of health products (drugs, medical devices and *in vitro* diagnostic medical devices). This law will have an impact on the way actors in the healthcare industry interact with influencers and promote their products on social networks.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

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

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 nonprofit organizations.

A law dated May 19, 2023, n°2023-378, aims to enhance regulation of healthcare facilities. The law restored the requirement to obtain approval (*agrément*) from the Regional Health Agencies (*Agence Régionale de Santé*) (ARS) prior to the opening of dental, ophthalmological and orthoptic health centers. Such approval will be granted temporarily and will become definitive one year later, after a compliance inspection from the ARS if necessary.

Healthcare facilities also will have to better inform patients of the names and qualifications of the practitioners on their premises, via the facility's website. They will be prohibited from asking patients to pay in full for treatment before it is carried out, and will have to inform patients if they are no longer covered by the French health insurance system.

Centers that already existed on May 19, 2023, will have six months to apply for authorization. No center will be able to provide care without an authorization at

the end of a 30-month period following promulgation of the law.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

Every person born in France, working in France or regularly living in France can benefit from statutory health insurance (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 favorable 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% of the applicable fees. The remaining 20% 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 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% reimbursement rate is based on the prices fixed by the Ministry of Health rather than the price allocated by the private facility.

4. DRUG APPROVALS AND REIMBURSEMENT

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

Marketing authorizations for drugs generally require preclinical and clinical testing, except for certain specific circumstances (*e.g.*, bibliographic authorization). Expedited approval procedures are also available, such as conditional approval or the priority medicines (PRIME) procedure.

In France, medicinal products cannot be placed on the market if they have not received a prior French or centralized marketing authorization (MA). French MAs are granted by the French Medicine Agency (*Agence Nationale de Securité du Médicament, et des produits de santé*) (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 medical rendu*), which is

evaluated by the French High Health Authority (*Haute Autorité de Santé*) (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% to 65% or, in certain circumstances, 100%) depending on the drug's efficacy compared with other therapies that are already on the market.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

EUROPE-WIDE PROVISIONS

The Medical Devices Regulation EU 2017/745 (MDR), which came into force on May 26, 2021, applies to the certification of medical devices and replaces the previous Medical Device Directive (MDD). The MDR applies directly in the EU Member States.

The EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) came into force on May 26, 2022.

In 2023, transition periods for compliance with the MDR and the IVDR were extended because of concerns about the impact to patient safety from delays in certification. Accordingly, legacy devices may benefit from time-limited grace periods allowing continued marketing of the device provided certain conditions are satisfied.

Under the MDR, medical devices are classified according to the device's risk, with Class I being the lowest risk and Class III the highest. Class I devices are self-certified by manufacturers, but higher classes require certification by a third-party notified body.

Under the IVDR, *in vitro* diagnostic (IVD) devices are also classified into three risk classes (A, B and C), with class A being the lowest risk. Under prior IVD legislation, most devices were only self-certified, meaning that many products now require certification under the IVDR.

FRENCH PROVISIONS

French law has been updated to comply with EU requirements applicable to *in vitro* medical devices. By an Order n°2022-1086 dated July 29, 2022, the French Public Health Code provisions related to *in vitro* medical devices and research involving humans were modified, notably to include the following:

- Definition of *in vitro* medical device, accessories and scope of the EU Regulation,
- Appointment of the ANSM as the competent authority for put on the market, put in service and provision of *in vitro* medical devices,
- Exclusion of performance studies from the general framework applicable to research involving human persons.

Once CE-marked, a medical device can be commercialized within the European Union, including France, but this does not mean that it will be reimbursed by the SHI. In France, there are different reimbursement schemes depending on a medical device's conditions and place of use. In addition to the existing mainstream reimbursement schemes, there are early and temporary coverage pathways for medical devices that meet certain conditions.

With respect to traditional reimbursement pathways, the following procedures apply:

- If a medical device is intended for individual use outside the hospital (*en ville*), it will be reimbursed only if it is registered on the List of Reimbursable Products and Services (*Liste des Produits et des Prestations Remboursables*) (LPPR). In order to be registered on the LPPR, the medical device is subject to an assessment by a specific HAS commission (CNEDiMTS) (assessment of

clinical benefit) and an assessment by the French Economic Committee of Health Products (*Comité Economique des Produits de Santé*) (CEPS) (determination of the reimbursement tariff with the manufacturer). Based on the opinions of both the CNEDiMTS and the CEPS, the Ministry of Health will decide whether and to what extent the medical device will be reimbursed.

- Digital medical devices intended for remote medical monitoring (*télésurveillance*) are now reimbursed if they are registered on the List of Remote Medical Monitoring Activities (*Liste des activités de télésurveillance médicale*) (LATM) following an assessment performed by the CNEDiMTS. As a prerequisite, and in addition to the CE-mark, the digital medical device must have a certificate of compliance with the interoperability and security standards in force issued by the Digital Health Agency (*Agence Numérique en Santé*) (ANS). In order to assist applicants with the reimbursement process, the ANS has opened (since August 2022) an office (*guichet*) dedicated to digital medical devices for telesurveillance in order to verify their compliance with the digital health doctrine.
- If a medical device is used at the hospital, it will be financed through a global budget allocated to the Standard Stay Groups (*Groupes Homogènes de Séjours*) (GHS). By exception, some innovative and expensive medical devices indicated for rare diseases are included in a specific list, *liste en sus*, and as such benefit from an alternative coverage.
- If a medical device is intended to be used by a healthcare professional as part of a medical service (*acte professionnel*), the medical device will be reimbursed as part of the reimbursement of the medical service as a "whole service."

Prior to reimbursement under traditional pathways, some medical devices may, under certain conditions, benefit from early and temporary coverage under the following schemes:

- **Innovative package** (*Forfait Innovation*): alternative and transitional coverage of innovative healthcare technologies in the early stages of clinical development.
- **Transitory coverage** (*Prise en charge transitoire*): reimbursement scheme for presumed innovative healthcare products with a therapeutic or disability-compensating purpose and falling within the scope of the LPPR.

With respect to digital medical devices, decree n° 2023-232, dated March 30, 2023, introduced early coverage for two categories of digital medical devices:

- Digital medical devices for therapeutic use, ultimately intended to be registered on the LPPR,
- Digital medical devices for remote medical monitoring (*télésurveillance*), ultimately intended to be registered on the LATM.

This early coverage scheme allows innovative digital medical devices to be reimbursed on an alternative basis for a non-renewable one-year period while awaiting traditional reimbursement through registration on the LPPR or LATM.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

EUROPE-WIDE LAW

SaMD

Software with a medical purpose is generally regulated as a medical device under the MDR or IVDR and must be certified as conforming to the MDR's safety and other requirements before being placed on the market.

Prior to the MDR, software as a medical device (SaMD) was regulated under the MDD and was commonly classified as a Class I device and certified under the basic conformity assessment procedure (self-certification). Under the MDR, many SaMD products are now classified in higher-risk classes (up-classed), meaning that certification is required from third-party notified bodies.

In 2023, the transitional arrangements under the MDR were extended so that up-classed SaMD may benefit from time-limited grace periods permitting continued marketing of the device under the MDD rules provided conditions are satisfied.

AI

The MDR and IVDR do not contain artificial intelligence (AI) specific provisions. Instead, AI algorithms and software are regulated as SaMD.

In 2021, the European Commission published a draft regulation on AI that is expected to come into force no earlier than 2024. The current draft provisions propose that AI legislation will be applied in addition to MDR for AI that is SaMD. This may require an additional certification under the AI regulation.

FRENCH LAW

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

In any event, any medical device 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 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 aiding in understanding hygieno-dietary measures).

In October 2022, the HAS used AI to assess the experience of hospitalized patients. HAS is now working on an analysis tool that would enable healthcare establishments to exploit their own patients' comments.

In January 2023, two French committees (*Comité consultatif national d'éthique pour les sciences de la vie et de la santé* (CCNE) and the *Comité national pilote d'éthique du numérique* (CNPEN)) published an opinion on the ethical issues arising from the use of AI systems for medical diagnosis (AISMD). This

opinion includes 16 recommendations and seven points of vigilance. The committees consider that AISMD should always be used as a priority for the purpose of a proven improvement in care, ahead of any other organizational, economic or managerial interests.

Further, in January 2023, the French Data Protection Authority (*Commission nationale de l'informatique et des libertés*) (CNIL) announced the creation of a specific department dedicated to AI that will notably focus on the entry into force of the EU Regulation on AI.

7. PAYMENTS TO HEALTHCARE PROFESSIONALS AND INCENTIVES

The French regime of anti-kickback rules prohibits 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. Two ministerial orders dated August 2020 set the thresholds, which vary depending on the categories of activities concerned. A failure to comply with the regulation can lead to criminal sanctions. For illustrative purposes following an investigation launched by the French economic administration (*Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes, DGCCRF*) in 2021, the URGO Group has been sentenced to 6,6 million euros in January 2023 for failure to comply with the French anti-kickback rules. The manufacturer distributed gifts to pharmacists in the French territory to increase its profits and its market shares. The DGCCRF continues to investigate the pharmacists involved in the illegal practices.

8. 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 COVID-19 pandemic, teleconsultations by phone have been permitted in specific cases (*e.g.*, where there is no access to the internet). An 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 have been further amended. For 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 organization such as a care home (*centre de santé*). Because of COVID-19, the SHI Financing Act for 2021 extended full reimbursement of all teleconsultations until December 31, 2021.

As of October 2022, teleconsultation is no longer fully reimbursed by SHI. Further, the Social Security Financing Bill for 2023 created a specific qualification of "teleconsultation companies," which are required to obtain coverage by the SHI. In order to obtain such a qualification, teleconsultation companies must meet cumulative conditions:

- They must obtain approval (*agrément*) from the Ministers of Social Security and Health.
- They must operate as a commercial company governed by the French Commercial Code.
- Their purpose must be (whether or not on an exclusive basis) the offer of teleconsultation services.
- They must not be under the control of a supplier, distributor or manufacturer of drugs or medical devices, with the exception of devices enabling teleconsultation.
- Their activities must comply with rules governing the protection of personal data and interoperability and security standards.

In June 2023, the HAS published good professional practice guidelines and assessment methods for teleconsultation companies.

The new provisions applicable to teleconsultation companies will enter into force on a date fixed by a decree, at the latest on December 31, 2023. To date, such decree has not been published yet.

With respect to telesurveillance, France has become the first country in the European Union to reimburse (outside experimentations) telesurveillance solutions that provide clinical benefits or improve the organization of care. Two decrees (n° 2022-1767 and n°2022-1769) dated December 30, 2022, permit the reimbursement of telesurveillance by the SHI subject to certain conditions. Under this new framework, the remuneration of remote medical monitoring performed by a healthcare team and the remuneration of the associated digital medical device are combined (see section 5). As mentioned in section 5 above, a new transitional coverage system was also set up to grant reimbursement for one year for presumed innovative therapeutic or disability compensation medical devices.

9. MERGER AND FOREIGN INVESTMENT CONTROL

Under current law, activities "in the protection of public health" and AI are considered strategic or sensitive, and foreign investment related to these may require prior government authorization. Legislative changes in 2020 extended the activities that are considered strategic or sensitive to include activities related to biotechnologies, food safety and additive manufacturing, among others. These changes also resulted in increased sanctions for noncompliance with foreign investment regulation. In July 2020, a decree lowered the threshold of control applying to non-EEA entities' investments in public corporations transacting in those sensitive sectors, from 25% to 10%. This measure was temporary and was prolonged by a decree until December 31, 2023, because of the

energy crisis (Decree n°2022-1622 dated December 23, 2022).

GERMANY

1. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

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

- Paper on Key Issues issued by the Federal Ministry of Health together with all health ministers of the federal states in Germany on July 10, 2023, which will form the basis for a comprehensive hospital reform (*Eckpunktepapier zur Krankenhausreform*)
- The German Whistleblower Protection Act implementing the EU Whistleblower Directive (Dir. (EU) 2019/1937), which entered into force as of July 2, 2023
- Rollout of the digitization strategy proposed by the Federal Ministry of Health, comprising the Draft Digital Act (*Entwurf eines Digitalgesetzes*) and Draft Health Data Use Act (*Entwurf eines Gesundheitsdatennutzungsgesetz*), both issued in June 2023
- The Act to Combat Supply Shortages and Improve the Supply of Medicines (*Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz*), amending several laws affecting market access for pharmaceuticals and pricing and reimbursement laws, enacted in June 2023
- 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, applicable as of January 1, 2023
- The Hospital Relief Act (*Krankenhauspflegeentlastungsgesetz*), which supports telemedicine services and became applicable on December 29, 2022
- Amendments to the drug pricing and reimbursement laws by the Act on Financial Stabilization of the Statutory Health Insurance System (*GKV-Finanzstabilisierungsgesetz*), enacted in November 2022.

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 nonprofit 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 centers (*Medizinische Versorgungszentren*) (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, nonprofit organizations 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 (which are far below any antitrust threshold) have applied to hospital-owned MVZ rendering dental care services.

In June 2023, the Federal Council (*Bundesrat*) formally requested the Federal Government (*Bundesregierung*) to issue a draft MVZ Regulation Act (*MVZ-Regulierungsgesetz*) introducing labelling obligations for MVZ owners on practice signs, an MVZ registry and territorial restrictions of the right to establish a dental MVZ with regard to physician group-related planning areas. The proposed regulations are currently subject to controversial discussions in practice.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

Around 90% 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 that 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, but is subject to the same conditions as any other comparable provider in the relevant region.

4. DRUG APPROVALS AND REIMBURSEMENT

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

Marketing authorizations for drugs generally require preclinical and clinical testing, except for certain specific circumstances (*e.g.*, bibliographic authorization). Expedited approval procedures are also available, such as 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 obligatory prescription by a physician and 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

EUROPE-WIDE PROVISIONS

The Medical Devices Regulation EU 2017/745 (MDR), which came into force on May 26, 2021, applies to the certification of medical devices and replaces the previous Medical Device Directive (MDD). The MDR applies directly in the EU Member States.

The EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) came into force on May 26, 2022.

In 2023, transition periods for compliance with the MDR and the IVDR were extended because of concerns about the impact to patient safety from delays in certification. Accordingly, legacy devices may benefit from time-limited grace periods allowing continued marketing of the device provided certain conditions are satisfied.

Under the MDR, medical devices are classified according to the device's risk, with Class I being the lowest risk and Class III the highest. Class I devices are self-certified by manufacturers, but higher classes require certification by a third-party notified body.

Under the IVDR, *in vitro* diagnostic (IVD) devices are also classified into three risk classes (A, B and C) with class A being the lowest risk. Under prior IVD legislation, most devices were only self-certified, meaning that many products now require certification under the IVDR.

GERMAN PROVISIONS

In Germany, the MDR and IVDR are complemented by the Federal Medical Devices Implementation Act (*Medizinprodukte-EU-Durchführungsgesetz*) (MPDG) that replaced the previous Federal Medical Devices Act (*Medizinproduktegesetz*) (MPG). The German regulator also has issued the Ordinance on Operators of Medical Devices (*Medizinproduktebetreiberverordnung*) (MPBetreibV), which governs the operation and use of medical devices.

German law recognizes digital health applications (*Digitale Gesundheitsanwendungen*) (DiGA) as a special category of reimbursable medical devices. DiGA are low-risk medical devices (class I or IIa) whose main function is essentially based on digital technologies and which fulfil specific medical purposes for the patient or in the supply of care by healthcare providers. To be reimbursable by the SHI, DiGA must be certified as a medical device and included in the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*) (BfArM) register. They are reimbursable if a medical prescription or the approval of the respective SHI is available in the specific case.

For a DiGA to be included in the BfArM register, the manufacturer must apply and be able to prove that the DiGA meets the safety, functionality and quality requirements of a medical device; is designed in accordance with the applicable data protection law; and guarantees sufficient data security according to the state of the art. The manufacturer also must provide evidence for the positive supply effects that can be achieved with the DiGA. The BfArM evaluation period is designed as a fast track and takes three months after receipt of the complete application.

In the first 12 months after inclusion on the BfArM register, the manufacturer can freely determine the price of the DiGA. After that period of time, the price is a regulated reimbursement amount. Reimbursement by private health insurance slightly differs from the SHI regime.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

EUROPE-WIDE LAW

SaMD

Software with a medical purpose is generally regulated as a medical device under the MDR or IVDR and must be certified as conforming to the MDR's safety and other requirements before being placed on the market.

Prior to the MDR, software as a medical device (SaMD) was regulated under the MDD and was commonly classified as a Class I device and certified under the basic conformity assessment procedure (self-certification). Under the MDR, many SaMD products are now classified in higher-risk classes (up-classed), meaning that certification is required from third-party notified bodies.

In 2023, the transitional arrangements under the MDR were extended so that up-classed SaMD may benefit from time-limited grace periods permitting continued marketing of the device under the MDD rules provided conditions are satisfied.

AI

The MDR and IVDR do not contain artificial intelligence (AI) specific provisions. Instead, AI algorithms and software are regulated as SaMD.

In 2021, the European Commission published a draft regulation on AI that is expected to come into force no earlier than 2024. The current draft provisions propose that AI legislation will be applied in addition to MDR for AI that is SaMD. This may require an additional certification under the AI regulation.

GERMAN LAW

Germany has not enacted a specific law on SaMD or AI yet. In November 2022, the federal government published a statement on the draft EU Artificial Intelligence Act (draft AI Act). One major concern is that the existing regulations for medical devices and *in vitro* diagnostic medical devices have not been adequately considered in the draft AI Act, and that there would be inconsistencies among these regimes.

7. TELEMEDICINE AND TELECONSULTATION

Germany has not established a standalone regulatory regime for telemedicine services. Telemedicine services are generally permissible if they are in accordance with medical guidelines and the state of scientific knowledge.

For a long time, the German teleconsultation market lagged behind those of other countries because of restrictive and inconsistent regulations. Physicians and their professional associations also were reluctant to accept the legalization 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 COVID-19 pandemic, Germany had set the legal basis for telemedicine, including video consultation by physicians, and its coverage by private and public payors. 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 increased 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 of this shift, telemedicine is still subject to many 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.

Since January 2021, Germany has introduced an electronic patient file (*elektronische Patientenakte*) (ePA). The purpose of ePA is to store all of a patient's relevant health data, including medical history, treatment data and vaccination records, electronically in one place with, and to the extent justified by, the patient's consent. On that basis, ePA shall facilitate medical treatment and expedite research and development.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

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

Currently, 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. Currently, the federal government does not seem likely to pursue this project further.

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*) (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 particularly the case 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*) (BMWK) may in certain circumstances review whether foreign investments are likely to affect public order or security. In recent years, German foreign investment control has become increasingly strict in the health sector. 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 BMWK may qualify as a statutory closing condition. In the absence of a notification obligation, BMWK 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.

UNITED KINGDOM

1. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

The impact of Brexit has led to several changes in law for the United Kingdom. While 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, have and will continue to arise as a consequence of the United Kingdom formally leaving the European Union following the end of the Brexit transition period.

The new NHS Health and Care Act 2022, in force on July 1, 2022, introduced a raft of changes to the commissioning and delivery of public healthcare in England. The act mandated the integration of local NHS bodies in order to promote a greater degree of joined-up care by healthcare commissioners and providers, through the adoption of 42 regional "integrated care systems." The act placed these systems, which had previously only existed in shadow form, onto a statutory footing. It also introduced 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.

The act also gives the Secretary of State for Health new powers, including 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 is 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 Medicines and Healthcare Products Regulatory Agency (MHRA), has consulted on changes to the UK clinical trial regulations with a view to creating an attractive regulatory environment for the conduct of clinical trials in the United Kingdom. New legislation is currently being prepared that is expected to accelerate the clinical trial process and deliver an overhaul of trial regulation. This approach is consistent with the wider life sciences ambitions that the government set out in its Life Sciences Vision (published in July 2021), which is intended to enhance the United Kingdom's status as a go-to destination for the development of new healthcare products and innovation.

On the medical devices landscape, there were further delays to the introduction of a revised medical device regulatory framework. As a consequence of Brexit, the UK did not adopt the EU Medical Device

Regulations 2017 and the current law remains that based on a 1993 directive. The UK has proposed a new framework which is very similar to the EU regime but there have been delays in that introduction. In the meanwhile, there have also been extensions to the use of EU CE marks in the UK.

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 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 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 companies wholly owned by these individuals). In addition, for certain elective and other services, patients are entitled to choose providers who meet commissioner criteria for consultant led services (a policy also known as "patient choice.")

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

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% of the market.

The NHS marketplace is underpinned by legislation, with national and regional integrated care system payor bodies (NHS England and Integrated Care Boards) 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 to procurement rules following Brexit have been proposed, and the UK government is in the final stages of setting the overarching new procurement legislation and, in tandem, a "provider service regime" that will have particular application to NHS healthcare services. These changes are anticipated to take effect at the end of 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 the new statutory NHS payment scheme, which allows for local modifications and variations. Under the NHS Constitution, patients may exercise "patient choice" when choosing a provider for elective services provided that the chosen provider meets commissioner criteria for those services.

4. DRUG APPROVALS AND REIMBURSEMENT

Marketing authorization for drugs is heavily regulated in UK law. Prior to Brexit, the procedure for marketing authorizations was regulated by both EU and UK law. As a consequence of Brexit, a separate

marketing authorization is required in the United Kingdom. As part of the United Kingdom's post-Brexit regulatory system, community marketing authorizations will be converted to UK marketing authorizations. Transitional provisions allow the United Kingdom to authorize 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 cooperation 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 the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS), which took effect on January 1, 2019 (replacing the previous comparable PPRS Scheme) and will be in place until December 31, 2023. The VPAS sets out permitted growth of the NHS-branded medicines spend (set at 2% 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 VPAS is automatically subject to statutory regulations 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 VPAS. As the current VPAS is due to expire at the end of 2023, some pharmaceutical industry associations are calling for a different approach that would emphasize investment and growth in addition to pricing and access. The critical voices in the industry argue that the unforeseen increased post-pandemic NHS demand has resulted in dramatic rises in rebate payments, posing major challenges for the UK life science sector.

Negotiations between the government and the pharmaceutical industry regarding a mutually beneficial scheme are expected to conclude this fall. The new scheme is expected to come into force when the current scheme expires at the end of 2023.

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 MHRA has been the regulator of medical devices in the United Kingdom. The MHRA undertakes responsibilities historically managed through the EU system, including vigilance reporting. Because of the timing of Brexit, the United Kingdom did not adopt the EU Medical Device Regulation 2017/345 (EU MDR), which applied in the European Union from May 2021. Instead, the United Kingdom continues to follow the earlier EU Medical Device Directive regulatory regime that was implemented in the United Kingdom by the Medical Devices Regulations 2002 (MDR 2002), with certain modifications that the United Kingdom introduced as standalone UK legislation to reflect the United Kingdom'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 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 new regime that would take effect in summer 2025.

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. In 2023, the UK announced an extension to the period during which CE marking will continue to be recognized in the United Kingdom. This means that certificates issued by EU notified bodies will continue to be valid for a transitional period (currently until June 30, 2028, or June 30, 2030, depending on the classification of the device).

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 centralized procurement and purchasing system for medical devices and other supplies to NHS providers. NHS providers are reimbursed through the NHS payment scheme for health services they provide. The NHS payment scheme includes the cost of most medical devices, but in certain cases, high-cost devices are excluded from the NHS payment scheme 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 healthcare professionals are required to use their own knowledge for the care, the tool may not be a device.

In the European Union, the EU MDR, 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 will continue to be based on the EU Medical Device Directive implemented in the United Kingdom by the MDR 2002, which has 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 organizations must also meet certain mandatory standards published by NHS Digital.

The United Kingdom currently lacks specific legislation for governing AI use and relies on existing laws (such us the UK Data Protection Act 2018 or MDR 2002). However, the government aims to foster AI development by creating a "proportionate, light-touch and forward-looking" regulatory framework.

On March 29, 2023, the UK government introduced a white paper outlining its "pro-innovation" approach to AI regulation. The framework is based on five core principles, emphasizing safety, transparency, fairness, accountability and redress. Instead of enacting new legislation, existing sector-specific regulators will develop guidelines for implementing these principles within their domains. Additionally, voluntary "AI assurance" standards and toolkits will aid in responsible AI adoption. This approach contrasts with the EU AI Act and will potentially allow for adaptability as technology and risks evolve. The UK government aims to swiftly implement this framework across relevant sectors, with sector-specific regulators building upon it.

In recent years, the DHSC has published various guidance and codes of practice in relation to AI and digital health services, setting 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. On October 17, 2022, the MHRA published the Software and AI as a Medical Device Change Programme Roadmap that sets out information on each work package and a timetable for implementation.

In March 2023, the UK government published a white paper detailing plans for implementing a "pro-innovation" approach to AI regulation. This approach contrasts with a separate standalone regulatory regime proposed in Europe. Instead, the UK proposes to publish cross-sectoral principles that would be required to be implemented and taken into account by existing regulators in different sectors. In other words, no new general AI legislation would be introduced but regulators may change their existing regulation of technologies in different sectors.

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 that it is assessing how it can regulate services currently outside its remit, such as digital health services based overseas that provide services to UK patients. To date, however, it is unclear how such regulation would work in practice, and no guidance or changes to the CQC's regulatory remit have been formally proposed.

In 2022, the CQC announced major changes to the framework it uses to regulate providers. By the end of 2023, the CQC will move from an inspection-based framework to a broader continual assessment that collects evidence on an ongoing basis.

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. As mentioned above, however, the Health and Care Act 2022 gives the Secretary of State for Health the power 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. 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.

There also 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 Health and Care Act 2022 removed some powers of the CMA in the context of health and social care, including, notably, CMA's historic powers with respect to 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.

There is, however, evidence of 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. The National Security and Investment Act 2021 has also established a mandatory foreign direct investment regime for the United Kingdom. The act focuses on particular industry sectors, including advanced robotics, AI, critical suppliers to government, critical suppliers to

emergency services and engineering biology. The act requires companies to notify the UK government of any relevant mergers and acquisitions and a wider range of transactions (that may include minority investments, acquisitions of voting rights, and acquisitions of land or intellectual property assets) that fall within the regime. The act gives the UK government the power to review (and call in) relevant transactions. Failure to comply may result in heavy turnover-based fines, criminal liability and the transaction being voided. This new regime is already having a sizeable impact on certain life sciences investments in the United Kingdom, particularly those that involve manufacturing of certain biologics and vaccine related drugs.

UNITED STATES

1. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

More than halfway through 2023, many important items remain pending in the US Congress. With a split Congress and White House, progress remains somewhat elusive, creating a need for larger legislative packages toward the end of the calendar year. Congressional priorities include transparency and consolidation, must-pass reauthorizations and funding the government.

TRANSPARENCY AND CONSOLIDATION

Congress has focused heavily on transparency and consolidation in healthcare, which has been an area of general bipartisanship. Five committees across the US House of Representatives and the US Senate have held hearings and considered a variety of legislation to require disclosures of certain information related to hospital prices, the role of pharmacy benefit managers (PBMs), insurance prices and diagnostic laboratory pricing, among other issues. Legislative efforts have also included disclosure of information related to hospital ownership, including a focus on private equity involvement in the healthcare sector. The House Energy and Commerce, Education and Workforce, and Ways and Means Committees have all considered and passed very similar pieces of legislation, largely with bipartisan support. The Senate Health, Education, Labor and Pensions, and Finance Committees have done the same. The House is expected to combine (and harmonize) the three committee bills into one package to bring to the floor in September 2023. While the Senate timeframe is less clear, legislation on these issues likely will pass before the end of 2023.

MUST-PASS LEGISLATION

Congress has a series of programs that must be reauthorized before the end of the fiscal year (September 30, 2023). These include pandemic preparedness, opioid and substance use disorder programs, National Health Service Corp and Children's Hospital Graduate Medical Education. While these have historically been bipartisan efforts, House Republicans have struggled to maintain support from Democrats on some of these issues because of the insertion of controversial provisions into otherwise neutral policies. The Senate seems to be working together more efficiently on these issues. As a result, the House and Senate will need to spend substantial time negotiating their differences to garner sufficient bipartisan support in both chambers for these policies to pass. This may warrant a short-term reauthorization of these important programs.

FUNDING THE GOVERNMENT

Federal funding runs out on September 30, 2023, and Congress has made very little progress in passing any of the 12 appropriations bills. House Republicans propose significant cuts in overall spending and

controversial provisions in many of the funding bills. This is causing House Democrats to oppose these measures. The Senate is working at a slower pace and is not proposing deep cuts to federal funding. So far, these efforts are bipartisan. Again, the House and Senate will need to broker these differences, likely requiring support from both Republicans and Democrats to ultimately move forward. It is highly likely that Congress will pass a continuing resolution to fund the government at current levels as the September 30, 2023, deadline approaches, although the length of a potential continuing resolution is unclear.

REGULATORY ACTIVITY

The Biden Administration continues to pursue regulatory actions in healthcare. The Centers for Medicare and Medicaid Services (CMS) is actively working to implement the Medicare Drug Pricing Negotiation Program, but faces many lawsuits questioning the validity of the program. With the COVID-19 public health emergency (PHE) officially ended, the administration is also working to address the post-PHE regulatory landscape, including a focus on payment and coverage for telehealth and virtual care services. There also continues to be an effort to address health equity throughout many of the administration's regulatory proposals.

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. Some restrictions do exist at both the federal and state levels, however. Individual state licensing regimes for health services and healthcare facilities can 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 for completing these types of transactions.

Increasingly, public officials are questioning the benefits of the expansion of private capital in healthcare. The increased concerns and scrutiny have resulted in proposed and enacted legislation in some states to create approval or review processes that could negatively impact the flow of private capital into the healthcare sector. These efforts remain few in number but could increase over time.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

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 enroll in Medicare and Medicaid, which can be a burdensome process but generally does not involve competitive bidding. Other programs, however, such as Medicare Advantage and Medicaid managed care, do require private organizations to compete for participation. 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 65 million people. Medicare-eligible beneficiaries may choose either to receive insurance coverage directly from the federal government under so-called "Original Medicare," or to enroll in a Medicare Advantage plan, under which their Medicare benefits are administered by a private commercial insurance entity that shares risk on the cost of care by taking a capitated payment from Medicare for their beneficiaries' 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 many drugs are not eligible for coverage under Original Medicare.

Original Medicare has typically been paid on a fee-for-service basis, under which providers submit claims and receive payment 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 enroll in order to participate in Medicare. Enrollment may also require accreditation by an approved non-government agency or government agency for certain 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 primarily administered by 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

Individuals who 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 enroll and comply with the private reimbursement regimes, which are mandated through participation agreements between the providers and 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 enrollment 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 enrollees. 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, diagnostic testing services), there is no general "device" benefit category. As a result, payment for devices used in patient care may only be reimbursed when 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 finalized 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

The US 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 temporarily waived this requirement during the COVID-19 pandemic and extended this temporary waiver through November 11, 2023 (see our summary here). The DEA plans to issue one or more final rules before November 11, 2023, addressing telemedicine prescribing of controlled substances.

Although the COVID-19 PHE ended May 11, 2023, certain Medicare reimbursement flexibilities related to telehealth have been extended through December 31, 2024 (see our summary here). The impact of the PHE's end on commercial programs continues to play out in state-level changes addressing telehealth coverage and reimbursement requirements, 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 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. It is also 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, telemedicine is typically categorized into three modalities:

- Live, synchronous audio-visual interactions (*e.g.*, a patient speaking directly to a provider)

- Store-and-forward technology (*e.g.*, a patient sending an image of a clinical concern to a healthcare professional for review)
- 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. However, there is a significant amount of variation in the types of healthcare professionals that are permitted to provide services via telehealth, the modalities deemed sufficient to prescribe and the 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 telemedicine evolves with the utilization of more technology, including AI, these variations may multiply along with the many use cases being developed.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

The healthcare industry is subject to several 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 willful 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. States also have their own fraud and abuse laws, which often mirror and sometimes extend beyond federal law.

The US 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 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, which provide patient data to telemedicine companies to enable those companies to fraudulently bill for services furnished to the patients. The OIG has indicated that it will carefully review telehealth and virtual-care services as an area of priority, and has already published reports assessing telehealth services furnished to patients during the pandemic. The data included in these reports likely will be used to guide future telehealth policies and enforcement actions. The OIG also recently released a new toolkit designed to help analyze telehealth claims to assess federal healthcare program integrity risks (see our summary here). The OIG intends for the toolkit to be used by public and private parties, including Medicare Advantage plan sponsors, private health plans, State Medicaid Fraud Control Units and other federal healthcare agencies. The adoption of the toolkit's framework could result in further enforcement action against telehealth and other virtual care providers.

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 they 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 CFIUS's focus 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 utilization 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.

AUSTRIA

1. 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 as described in the following sections.

A recent decision by the national Constitutional Court required Austria to amend its laws on assisted suicide. The Disposition of Dying Act (*Sterbeverfügungsgesetz*) has been in force since January 1, 2022. 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.

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 on who may become a shareholder of a hospital, but legislation may set out regulations with respect to notification requirements or compliance with a "fit and proper" test.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

More than 99% 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, the following protocols apply:

- Any treatment by outpatient physicians with a contract with one or more statutory health insurers (*Kassenvertrag*) is covered.
- Treatment by physicians without *Kassenvertrag*, or 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 authorization for drugs is substantially regulated by EU law. Under certain conditions, drugs may be authorized in a centralized EU procedure handled by the European Medicines Agency (EMA). The EU marketing authorization is valid throughout the European Economic Area (EEA) (*i.e.*, the current 27 EU Member States plus Norway, Liechtenstein and Iceland). Drugs may also be authorized by the competent national authority (the competent Austrian authority is the Austrian Federal Office for Safety in Health Care) if the drug is only to be authorized in that Member State, or if several EU Member States cooperate to grant authorizations.

Marketing authorizations for drugs generally require preclinical and clinical testing, except for specific circumstances (*e.g.*, bibliographic authorization). 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 by a decision of the Umbrella Organisation of the Social Insurance Providers (*Dachverband der Sozialversicherungsträger*) following an application and negotiations on efficiency and pricing.

The Austrian Pharmacy Act (*Apothekengesetz*) and the Austrian Medicinal Products Act (*Arzneimittelgesetz*) were amended recently. The Austrian Pharmacy Act now more clearly reflects the free choice of pharmacy and includes a definition on the "supply of medicinal products by means of distance selling" that explicitly includes the "deposit." The changes to the Austrian Medicinal Products Act are more extensive, but they are mainly adaptations of

the national law to the Regulation (EU) No. 536/2014 and regulate the responsibilities and national procedures within the framework of the procedures specified by the Regulation. This concerns the organization of the interaction of the national medicinal products authority, the Austrian Federal Office for Safety in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen*) (BASG) with the relevant ethics committees.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

EUROPE-WIDE PROVISIONS

The Medical Devices Regulation EU 2017/745 (MDR), which came into force on May 26, 2021, applies to the certification of medical devices and replaces the previous Medical Device Directive (MDD). The MDR applies directly in the EU Member States.

The EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) came into force on May 26, 2022.

In 2023, transition periods for compliance with the MDR and the IVDR were extended because of concerns about the impact to patient safety from delays in certification. Accordingly, legacy devices may benefit from time-limited grace periods allowing continued marketing of the device provided certain conditions are satisfied.

Under the MDR, medical devices are classified according the device's risk, with Class I being the lowest risk and Class III the highest. Class I devices are self-certified by manufacturers, but higher classes require certification by a third-party notified body.

Under the IVDR, *in vitro* diagnostic (IVD) devices are also classified into three risk classes (A, B and C) with class A being the lowest risk. Under prior IVD legislation, most devices were only self-certified, meaning that many products now require certification under the IVDR.

AUSTRIAN PROVISIONS

At the end of June 2021, the new Austrian Medical Devices Act 2021 (*Medizinproduktegesetz 2021*) (MPG 2021) was promulgated and is now fully in force for both medical and *in vitro* diagnostic devices. The MPG 2021 supplements the European regulations and basically regulates the national competences and procedures, language requirements and sanctions.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

EUROPE-WIDE LAW

SaMD

Software with a medical purpose is generally regulated as a medical device under the MDR or IVDR and must be certified as conforming to the MDR's safety and other requirements before being placed on the market.

Prior to the MDR, software as a medical device (SaMD) was regulated under the MDD and was commonly classified as a Class I device and certified under the basic conformity assessment procedure (self-certification). Under the MDR, many SaMD products are now classified in higher-risk classes (up-classed), meaning that certification is required from third-party notified bodies.

In 2023, the transitional arrangements under the MDR were extended so that up-classed SaMD may benefit from time-limited grace periods permitting continued marketing of the device under the MDD rules provided conditions are satisfied.

AI

The MDR and IVDR do not contain artificial intelligence (AI) specific provisions. Instead, AI algorithms and software are regulated as SaMD.

In 2021, the European Commission published a draft regulation on AI that is expected to come into force no earlier than 2024. The current draft provisions propose that AI legislation will be applied in addition to MDR for AI that is SaMD. This may require an additional certification under the AI regulation.

Neither the MPG 2021 nor any other Austrian act specifically regulates AI as a medical device.

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. Because of 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 program.

However, since Austria is officially no longer in a pandemic state and all pandemic-related measures have been lifted, certain aspects of telemedicine are viewed more critically by healthcare professionals. For example, prescriptions that have been sent via e-mail may no longer be accepted by pharmacies.

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 2 no 1, Anlage Teil 2 Z 1 of the Austrian Investment Control Act (*Investitionskontrollgesetz*) (InvKG). The acquisition of a participation of 10% or more of the business of such an undertaking (asset deal) by non-EU/EEA/Swiss nationals (be it a company or an individual) may require prior approval by the Austrian Ministry for Economic Affairs (currently the Federal Ministry for Digital and Economic Affairs).

The InvKG henceforth forms the new regime for the control of foreign direct investment (FDI) and thus replaces Section 25a of the Foreign Trade Act 2011 (*Außenwirtschaftsgesetz 2011*). The revision of the Austrian FDI regime is based on European Regulation (EU) 2019/452 establishing a framework for the screening of foreign direct investments into the European Union.

DENMARK

1. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

Overall, there is increasing political attention to the life sciences sector in Denmark. In 2021, the government launched a life sciences industry strategy, comprising 38 new initiatives in seven main fields. The initiatives' aim, in particular, is to improve the conditions for research and development and the use of health data, secure a highly skilled workforce and support international expansion.

Another interesting highlight is the anticipated revision of health research regulation. The draft is currently in hearing. The changes aim to ease the process in the health research area and to widen patients' and test subjects' right of self-determination. The proposal consists of eight main areas, including the following:

- **Use of real-time data in research.** Currently, researchers may only use sensitive bioinformatic data that has already been generated in electronic patient files (*i.e.*, data that has already been generated at the time of the approval of the research project). Under the proposal, the Danish National Center for Ethics may grant permission for ongoing access to sensitive bioinformatic prospective data.
- **Low-risk studies.** Researchers would no longer be required to collect informed consent from patients in low-risk health science studies, *i.e.*, health research aiming to collect knowledge on the most effective treatment of known standard treatments.
- **More information and self-determination for patients and test subjects.** Under the proposal, the Danish National Center for Ethics may impose conditions on a study's responsible researcher to inform citizens that a study has been approved for which it is not a prerequisite that consent be collected, and that the researcher intends to use biological material from the citizen for this specific research. The researcher may be obliged to inform citizens of the possibility to withdraw from the study.
- **Transparency on economic interests in research using artificial intelligence (AI).** To ensure transparency regarding financial interests in health data scientific research using AI (more specifically, sensitive bioinformatic imaging diagnostic data from patient records), the competent committee will, in connection with notification of the project, have to assess the amount and payment to the researcher and the sponsor as well as the content of the relevant contractual clauses between the two.
- **Formal legal basis for hypothesis-generating studies.** It is proposed to list the conditions for the committees' assessment of exploratory studies in extensive data sets aimed at generating new hypotheses in the health sciences. The purpose is to streamline the framework for hypothesis-generating research where it is difficult to specify in advance expectations for the research project's results and which correlations the research project is expected to identify.

The proposal is expected to enter into force on January 1, 2024.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

In Denmark, the public healthcare system operates across three levels: the state, the regions and 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.

Municipalities also co-finance regional rehabilitation services and training facilities.

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

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

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 equalization 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

Marketing authorization for drugs is substantially regulated by EU law. Under certain conditions, drugs may be authorized in a centralized EU procedure handled by the European Medicines Agency (EMA). The EU marketing authorization is valid throughout the European Economic Area (*i.e.*, the current 27 EU Member States plus Norway, Liechtenstein and

Iceland). Drugs may also be authorized by the competent national authority if the drug is only to be authorized in that Member State, or if several EU Member States cooperate to grant authorizations.

Marketing authorizations for drugs generally require preclinical and clinical testing, except for specific circumstances (*e.g.*, bibliographic authorization). Expedited approval procedures are also available, such as conditional approval or the priority medicines (PRIME) procedure.

In Denmark, the medicines prescribed by doctors to patients in the primary care sector are partially reimbursed by the regions in accordance with the reimbursement thresholds. Reimbursements are divided into general reimbursement of medicines and individual reimbursement.

A medicine that has general reimbursement means that all Danish residents receive reimbursement, which is automatically deducted from the price when buying the medicine at the pharmacy. General reimbursement of medicines is further divided into two subcategories:

- Conditional reimbursement for prescription-only medicines
- Conditional reimbursement for over-the-counter medicines in which the medicine is only reimbursed to specific patient groups or for specific diseases.

It is the medical companies that apply for the general reimbursement.

In 2022, a four-year pilot program began regarding conditional reimbursement for prescription-only medicines on condition of the pharmaceutical company sharing the risk. The pilot program is relevant for medical products that do not currently meet the requirements for conditional reimbursement. The pilot program includes five medicinal products and is granted on a first-come, first-served basis. The program is a revised version of a 2019 pilot program that only included two medical products. The aim of the programs is, however, the same.

Some residents may be granted individual reimbursement for their medical expenses, in which case the grant is given to the patient personally. It is the doctor that assesses the patient's needs and applies for the individual reimbursement to the Danish Medicines Agency on behalf of the patient. There are three types of individual reimbursement: single reimbursement, increased reimbursement and reimbursement of the terminally ill.

The price of pharmacy-reserved medicine is the same at all pharmacies and linked to the pharmacy purchase price, which is fixed freely by the company placing the medicine on the market. The prices of medicines are fixed for 14-day periods. The companies report changes in prices every fortnight to the Danish Medicines Agency. The Danish Medicines Agency places equivalent medicines in substitution groups. Pharmacies are obligated to always offer the cheapest alternative within the substitution group, thereby incentivizing lower prices.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

EUROPE-WIDE PROVISIONS

The Medical Devices Regulation EU 2017/745 (MDR), which came into force on May 26, 2021, applies to the certification of medical devices and replaces the previous Medical Device Directive (MDD). The MDR applies directly in the EU Member States.

The EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) came into force on May 26, 2022.

In 2023, transition periods for compliance with the MDR and the IVDR were extended because of

concerns about the impact to patient safety from delays in certification. Accordingly, legacy devices may benefit from time-limited grace periods allowing continued marketing of the device provided certain conditions are satisfied.

Under the MDR, medical devices are classified according to the device's risk, with Class I being the lowest risk and Class III the highest. Class I devices are self-certified by manufacturers, but higher classes require certification by a third-party notified body.

Under the IVDR, *in vitro* diagnostic (IVD) devices are also classified into three risk classes (A, B and C) with class A being the lowest risk. Under prior IVD legislation, most devices were only self-certified, meaning that many products now require certification under the IVDR.

DANISH PROVISIONS

The rules in the MDR governing products without a medical purpose have been transposed into national law with no material deviations (*e.g.*, for manufacturers and distributors of products without a medical purpose).

In Denmark, all information (*e.g.*, labelling, user manuals and implant cards, in both printed and electronic form) that is necessary for the safe and proper use of the medical device must be in Danish, when the medical device is made available to the end user or patient. In exceptional cases, the Danish Medicines Agency may grant exemptions from the language requirement and allow the information to be in another language (typically English).

The Danish Medicines Agency is the competent authority in Denmark responsible for implementing supervision and control measures. This includes regulatory supervision, control of performance evaluation for IVD medical devices, inspection and imposition of sanctions.

In Denmark, medical devices purchased by citizens are generally not subject to reimbursement. If necessary for a treatment provided by the regional hospital, the region will make the medical device available to the patient. Examples include pacemakers, tracheal cannulas and endoprostheses. Medical devices are to some extent financially supported by the municipality, such as support for assistive devices for citizens with permanently reduced physical or mental functional capacity (*e.g.*, wheelchair, rollator and orthopedic footwear), home nursing (*e.g.*, plasters, wound dressings and cleansing fluids), medical devices in connection with rehabilitation (*e.g.*, crutches) and to a very limited extent other medical devices prescribed by a doctor (*e.g.*, hearing aids).

To ensure adherence to ethical standards and safety protocols, clinical trials of medical devices in Denmark require approval from both the Danish Medicines Agency and a research ethics committee. Approval from the Danish Medicines Agency is required for all classes, including the low and medium class. These regulatory bodies meticulously evaluate proposed trials, ensuring that they meet the necessary criteria and uphold ethical guidelines specific to medical devices. This also applies for devices without a medical purpose. However, there are exceptions for medical devices that have already obtained the CE marking, denoting conformity with EU regulations. Such devices may be exempt from seeking permission, provided that the purpose of the clinical trials aligns with the original intended use stated during the conformity assessment and CE marking process.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

EUROPE-WIDE LAW

SaMD

Software with a medical purpose is generally regulated as a medical device under the MDR or IVDR and must be certified as conforming to the MDR's safety and other requirements before being placed on the market.

Prior to the MDR, software as a medical device (SaMD) was regulated under the MDD and was commonly classified as a Class I device and certified under the basic conformity assessment procedure (self-certification). Under the MDR, many SaMD products are now classified in higher-risk classes (up-classed), meaning that certification is required from third-party notified bodies.

In 2023, the transitional arrangements under the MDR were extended so that up-classed SaMD may benefit from time-limited grace periods permitting continued marketing of the device under the MDD rules provided conditions are satisfied.

AI

The MDR and IVDR do not contain AI-specific provisions. Instead, AI algorithms and software are regulated as SaMD.

In 2021, the European Commission published a draft regulation on AI that is expected to come into force no earlier than 2024. The current draft provisions propose that AI legislation will be applied in addition to the MDR for AI that is SaMD. This may require an additional certification under the AI regulation.

DANISH LAW

In 2020–2022, the Danish Agency for Digital Government, the Association of Municipalities and the Regions of Denmark initiated 40 flagship projects regarding the use of new technology/AI, largely related to development of AI to treat illnesses or to enhance the overall patient experience regardless of such disease. Such initiatives include AI for faster and improved diagnosis of acute patients, early detection and intervention if a discharged patient experiences worsening health by 24-hours-a-day assessment of the patient and a possibility to alert health staff, and an algorithm to help health staff detecting which eye-patients should be treated, be under observation or be discharged.

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 AI-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 to otherwise 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, traveling 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 Danish Medicines Agency. "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 Danish Medicines Agency'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, and the obligation to make notifications or obtain permission to establish an affiliation.

9. MERGER AND FOREIGN INVESTMENT CONTROL

On May 4, 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. Prior to the bill foreign direct investment was subject to very limited regulation in Denmark.

The overall object of the 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 program 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.

On June 14, 2023, the investment screening act was amended so that applications on foreign direct investments are divided in two phases. Less complex cases will be decided in phase 1, and applications will as a main rule be completed within 45 days. If the phase 1 processing raises concerns that the investment or agreement in question may pose a threat to national

security or public order, the Danish Business Authority will conduct further investigations and request additional information in an additional investigative phase (phase 2), which will take 125 days.

The new two-phase system applies from July 1, 2023, and is in line with the application process in other European countries.

ITALY

1. 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 include the following areas.

IMPLEMENTATION OF THE NATIONAL RECOVERY AND RESILIENCE PLAN

The National Recovery and Resilience Plan (NRRP) is the plan approved by Italy in 2021 to relaunch the economy following the COVID-19 pandemic, as part of the Next Generation EU program. The NRRP is composed of six "missions" focusing on digitization and innovation, education and research, and healthcare, among other topics. Mission no. 6, "Health," allocates more than EUR 15 billion to the health sector, spread over two main areas. The first area is dedicated to the reorganization of community medicine and telemedicine, aiming at strengthening existing structures and creating new centers promoting home care and the use of telemedicine, as well as more effective integration between social and health services. The second area is focused on updating and modernizing the National Health Service's (NHS's) technological and digital structures, completing and disseminating the electronic health record, and enhancing and strengthening scientific research conducted within the NHS. The completion of these reforms, scheduled for 2026, should enhance the Italian healthcare ecosystem in terms of innovation, digitization and effectiveness of care.

INTRODUCTION OF THE PAYBACK MECHANISM IN THE MEDICAL DEVICES SECTOR

The payback is a mechanism introduced by the Law-Decree 78/2015. If the public expenditure for the purchase of medical devices exceeds certain thresholds established by the law, the payback mechanism requires companies to refund to the Italian regions a certain percentage of the amounts they paid, in proportion to the company's turnover. The first implementation of this law only occurred in 2022, when regions started to ask companies to refund high amounts of money related to the years 2015–2018. Following significant litigation, as most companies challenged the regions' requests and the entire system, a new law introduced the possibility for companies to pay a sum equal to 48% of the amounts requested by the regions on condition that the companies waived any litigation and payment was made by July 31, 2023. A technical table has been established by the regulatory authorities and the associations representing companies in this sector to discuss if and how to change the payback system, which some companies consider to be unfair and financially unsustainable.

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. Holding shares of companies owning pharmacies is incompatible with any other activity carried out in the sector of manufacture and promotion of medicines, as well as with the exercise of the medical profession.

Healthcare facilities must meet specific requirements to be authorized to operate and must fulfill additional conditions to operate within the NHS and treat patients at the NHS's expense.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

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's expense.

Public healthcare facilities must tender for the procurement of products (including medicines and medical devices) and services. As an exception, under certain conditions, direct negotiation of agreements with private parties is also permitted. Public procurement legislation was recently reformed by Legislative Decree 36/2023 (Italian Public Procurement Code), which applies to tenders launched as of July 1, 2023. The purpose of the new legislation is to simplify and speed up the procurement process, for instance by permanently increasing the thresholds under which the direct negotiation of public contracts, without the launch of a call for tender, is allowed.

4. DRUG APPROVALS AND REIMBURSEMENT

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

Marketing authorizations for drugs generally require preclinical and clinical testing, except for specific circumstances (*e.g.*, bibliographic authorization). Expedited approval procedures are also available, such as conditional approval or the priority medicines (PRIME) procedure.

Following grant of the marketing authorization, drugs are automatically placed in a class (named Cnn, meaning non-negotiated class) reserved for medicines not yet assessed by the Italian Medicines Agency (AIFA) from a price and reimbursement perspective. Pending the AIFA's decision on price and reimbursement, drugs in Class Cnn can be marketed after the AIFA has been notified of their ex-factory price and the retail price freely set out by the

marketing authorization holder. In this case, the price may be paid by patients or hospitals with their local budgets.

The Italian Ministry of Health set out new criteria for the price negotiation between marketing authorization holders and the 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 important operational guidance. Simplified procedures for the price negotiation of parallel imported medicines and equivalent or biosimilar medicines have subsequently been introduced.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

EUROPE-WIDE PROVISIONS

The Medical Devices Regulation EU 2017/745 (MDR), which came into force on May 26, 2021, applies to the certification of medical devices and replaces the previous Medical Device Directive (MDD). The MDR applies directly in the EU Member States.

The EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) came into force on May 26, 2022.

In 2023, transition periods for compliance with the MDR and the IVDR were extended because of concerns about the impact to patient safety from delays in certification. Accordingly, legacy devices may benefit from time-limited grace periods allowing continued marketing of the device provided certain conditions are satisfied.

Under the MDR, medical devices are classified according to the device's risk, with Class I being the lowest risk and Class III the highest. Class I devices are self-certified by manufacturers, but higher classes require certification by a third-party notified body.

Under the IVDR, *in vitro* diagnostic (IVD) devices are also classified into three risk classes (A, B and C), with class A being the lowest risk. Under prior IVD legislation, most devices were only self-certified, meaning that many products now require certification under the IVDR.

ITALIAN PROVISIONS

At the national level, Legislative Decrees No. 137 and No. 138 (and subsequent implementing decrees) were adopted in August 2022 to adapt the national regulatory framework to the MDR and the IVDR, respectively. These regulations include specific provisions on the national medical devices database, clinical investigations (application procedures, facility requirements, *etc.*), advertising of medical devices, and penalties for infringement of the MDR and IVDR and the relevant national legislation.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

EUROPE-WIDE LAW

SaMD

Software with a medical purpose is generally regulated as a medical device under the MDR or IVDR and must be certified as conforming to the MDR's safety and other requirements before being placed on the market.

Prior to the MDR, software as a medical device (SaMD) was regulated under the MDD and was commonly classified as a Class I device and certified under the basic conformity assessment procedure (self-certification). Under the MDR, many SaMD products are now classified in higher-risk classes (up-

classed), meaning that certification is required from third-party notified bodies.

In 2023, the transitional arrangements under the MDR were extended so that up-classed SaMD may benefit from time-limited grace periods permitting continued marketing of the device under the MDD rules provided conditions are satisfied.

AI

The MDR and IVDR do not contain artificial intelligence (AI) specific provisions. Instead, AI algorithms and software are regulated as SaMD.

In 2021, the European Commission published a draft regulation on AI that is expected to come into force no earlier than 2024. The current draft provisions propose that AI legislation will be applied in addition to the MDR for AI that is SaMD. This may require an additional certification under the AI regulation.

No specific national regulations for SaMD or AI in medical devices have been adopted in Italy to date (except for legislation implementing the MDR and IVDR). Discussions are ongoing concerning possible paths to make digital therapeutics subject to prescription or reimbursement by the NHS, as in other EU countries.

7. 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. These guidelines serve as the national reference for provision of telemedicine services, with this updated version replacing the previous guidelines of 2014.

In the following years, the Ministry of Health has issued several decrees to regulate specific aspects of telemedicine. These include the Decrees of April 29, 2022, and Decree No. 77 of May 23, 2022, laying down guidelines for the development of digital home care, and the Decree of September 21, 2022, providing functional and technological standards for delivering telemedicine services as well as the training requirements for healthcare professionals and users.

The purpose of these regulations is to set out a framework of common rules applicable throughout the Italian territory. Then, each Italian region implements these regulations in its respective RHS, providing further operative details.

Within the scope of mission no. 6 of the NRRP, the setting up of a national platform for telemedicine services is planned, and is expected to be operational by the end of 2023. This platform will serve as the central infrastructure ensuring consistency across telemedicine services provided locally and their uniform delivery across the country. The national platform will include systems for collecting and monitoring data produced at the local level, systems for identifying medical devices that can be integrated with the platform, and solutions for profiling various parties involved and establishing their roles and the various authorization levels needed to access and view data.

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.

In June 2022, Law No. 62 (the Sunshine Act) was approved and requires healthcare companies, including pharmaceutical and medical device manufacturers, to publicly disclose on a dedicated electronic register all payments to or agreements with HCPs, as well as the shareholdings and corporate bonds held by such HCPs. However, to date these obligations are not applicable, since the public register where communications are to be made has not been established yet.

9. MERGER AND FOREIGN INVESTMENT CONTROL

Foreign investment control regulations were introduced in Italy for the first time in 2012. These regulations 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 these 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) among 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. They 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. They also extended the COVID-19 emergency rules providing for a temporary broadening of the scope of notification duties (which, among other things, also involve intra-EU transactions, including acquisitions of control by Italian entities) through the entire emergency period. These emergency measures were made permanent by a subsequent amendment introduced by Law Decree No. 21/2022 of March 21, 2022 (the so-called Ukraine Decree).

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 activities involving the use of the technologies listed above or by entities with an annual net turnover of at least EUR 300 million and on average at least 250 employees annually.

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*) (ICA) according to

Article 16 of Law No. 287/1990 (Italian Competition Act).

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. However, Article 32 of Law No. 118 of August 5, 2022, added a new paragraph 1-bis to Article 16 of Law No. 287/90 with a view to align the Italian merger control regime with the European Commission's recently updated interpretation and application of Article 22 of Regulation No. 139/2004 (European Merger Control Regulation) (EUMR), as enforced in *Grail/Illumina* (as updated by Resolution of the ICA No. 30507 of March 14, 2023, to reflect the national price deflator index registered from 2018 to 2022). More specifically, with the introduction of paragraph 1-bis, the ICA is now allowed to control transactions that do not exceed national merger control thresholds, via request up to six months after closing of the transaction. The rationale for this change rests in the recent increase in the number of predatory and consolidating acquisitions (*i.e.*, "killer acquisitions") that, while below the threshold, are still bound to significantly restrict competition, particularly in the digital economy and in the pharmaceutical sector. Until now, application of the national merger control mechanism was subject to only two cumulative criteria:

- The combined turnover generated in Italy by all the undertakings concerned in the transaction exceeds EUR 532 million.
- The turnover generated in Italy by each of at least two undertakings concerned exceeds EUR 32 million[1].

In addition to this main criteria, Article 16, paragraph 1-bis states that the ICA may ask companies to notify below-the-threshold mergers even after completion, and within 30 days of the request, if three cumulative conditions are met:

- No more than six months have passed since completion of the transaction.
- Either one of the two Italian turnover thresholds provided under Article 16, paragraph 1 (*i.e.*, EUR 532 million or EUR 32 million) is exceeded, or the worldwide aggregate turnover generated by all the undertakings concerned exceeds the EUMR threshold of EUR 5 billion.
- Based on available evidence, the ICA believes there are concrete risks to competition in the national market or in a significant part thereof, including in terms of harmful effects on the development of small enterprises characterized by innovative strategies.

On December 27, 2022, the ICA published a notice setting forth procedural rules and criteria for the application of its newly introduced powers to request notifications for mergers and concentrations falling below the national turnover thresholds triggering mandatory prior notification. The notice provides further guidance to identify below-thresholds transactions that could potentially be subject to a request of notification by the ICA, and clarifies that the parties of such transactions may file a voluntary notification without waiting for a request from the ICA.

[1] On September 6, 2022, the European Commission blocked the acquisition of Grail by Illumina—although the deal didn't meet the turnover threshold of the European Union or any Member State—arguing that the merger would have prevented innovation and competition in the blood-based early cancer detection test market. The legality of the European Commission's new approach to Article 22 is being assessed by the European Court of Justice in this case.

NETHERLANDS

1. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

Following the experience gained during the COVID-19 crisis, an amendment to the Act on Public Health (*Wet Publieke Gezondheid*) (Wpg) was proposed centralizing certain competences regarding the management of necessary operational measures and facilities, such as centers for testing and vaccination. Shifting these competences to the central level would enable the Minister of Health, Welfare and Sport to better manage pandemics and implement the necessary measures in a more uniform way. Currently, the competences to manage the Municipal Health Service (*Gemeentelijke Gezondheidsdienst*) (GGD), which is responsible for the operational measures, lie at the level of municipalities. The amendment also provides for the establishment of a National Facility on Infection Control (*Landelijke Faciliteit Infectieziektebestrijding*) (LFI). The Council of State has been examining the proposal since June 6, 2023, and subsequently the Minister of Health, Welfare and Sport will send the Council of State's advice together with his reaction to the House of Parliament.

A second amendment to the Wpg was proposed introducing a permit requirement and a reporting obligation to perform actions with pathogens that cause certain infectious diseases, such as polio. This amendment is now under evaluation in the House of Representatives.

In addition, preparatory activities for several bills are taking place, including the following.

BILL ON ETHICAL BUSINESS OPERATIONS FOR CARE AND YOUTH CARE PROVIDERS

The bill on ethical business operations for care and youth care providers (*Wetsvoorstel integere bedrijfsvoering zorg- en jeugdhulpaanbieders*) (Wibz) aims to introduce stricter preconditions for the conduct of business in the care and youth assistance sector in order for the public authorities to better guarantee the integrity of care and youth assistance providers' business operations. The bill introduces stricter rules on profit distribution, guarantees for normal market conditions for significant transactions involving parties with a direct or indirect interest, and the prevention of conflicting interests, among other issues. The bill provides a legal basis for additional public enforcement instruments by the Dutch Health Care authority (*Nederlandse zorgautoriteit*) and the Health and Youth Care Inspectorate (*Inspectie Gezondheidszorg en Jeugd*) to hold care and youth aid providers accountable for sound business practices. These enforcement instruments include withdrawal of licenses issued on the basis of the Healthcare and Care Providers (Accreditation) Act (*Wet toetreding zorgaanbieders*) and orders to recover profit distributions from the beneficiary.

The bill is currently being examined by the Council of State, after which the Minister of Health, Welfare and Sport of will send the Council of State's advice together with his reaction to the House of Parliament.

BILL ON MEDICINE PRESCRIPTION AFTER ONLINE CONSULTATION

A bill providing a legal basis for the prescription of medicine to patients after contact via the internet is currently being prepared. According to the current rules, medicines can only be prescribed if the healthcare provider has met the patient in person. Based on the positive results of the temporary

exemption to this rule during the COVID-19 pandemic, the bill will provide the legal basis to continue this practice.

PROPOSED AND POSTPONED REFORM OF THE DRUG REIMBURSEMENT SYSTEM

The Minister of Health, Welfare and Sport proposed a reform of the Drug Reimbursement System resulting in savings of EUR 140 million per year. However, because of criticism, the Minister informed the House of Representatives on May 17, 2023, of his withdrawal of the proposed reform. The reason was its potential negative impact on the accessibility of medicinal products. The main criticism to the proposal was that if manufacturers would not reduce their prices in line with the proposed lowered reimbursement limit, this would result in an additional payment for the patient or a forced switch to a different medicinal product that did fall below the reimbursement limit. Moreover, because of the interaction of the Drug Reimbursement System, the Medicine Prices Act, and the preference and purchasing policies of health insurers, the proposal could have a negative impact on the security of supply of medicinal products if manufacturers only kept fully reimbursed products on the Dutch market. Taking this into account, the Minister indicated that he will continue working on a reform of the Drug Reimbursement System other than via a reduction of the reimbursement limits, and will inform the House of Representatives in early 2024. Later in 2023, the Minister will follow up on the interim changes to ensure the functioning of the Drug Reimbursement System.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

On the basis of the Healthcare and Care Providers (Accreditation) Act (*Wet toetreding zorgaanbieders)* a healthcare institution must have a license to practice healthcare if it provides specialized care or if it employs more than 10 healthcare professionals. These services are reimbursed by either healthcare insurers (basic healthcare) or the Dutch state (long-term care). They must adhere to certain conditions. These conditions include having an independent supervisor within their organization, being able to provide high-quality care, having an internal procedure to deal with incidents and having a client council. The Central Information Point Professions Healthcare (*Centraal Informatiepunt Beroepen Gezondheidszorg*) (CIBG) can start an investigation if there is reason to believe the quality standards are not met.

For certain medical procedures, an extra license is needed according to the Regulation for the designation of special medical procedures (*regeling aanwijzing bijzonder medische verrichtingen*). These include, for example, organ transplantation.

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

For specific forms of healthcare, a provider with a license is not allowed to distribute profits. Subcontractors fall outside this prohibition.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

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 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 maximized 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

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

In the Netherlands, the relevant marketing authorization is granted by the Dutch Medicines Evaluation Board (MEB). Under the Medicines Act (*Geneesmiddelenwet*), medicines in the Netherlands are divided into three categories: pharmacy-only drugs, pharmacy-and-drugstore-only drugs, and general sale drugs or over-the-counter (OTC) drugs.

The Ministry of Health, Welfare and Sport 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 Minister 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.

Marketing authorizations for drugs generally require preclinical and clinical testing, except for specific circumstances (*e.g.*, bibliographic authorization). Expedited approval procedures are also available, such as conditional approval or the priority medicines (PRIME) procedure.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

EUROPE-WIDE PROVISIONS

The Medical Devices Regulation EU 2017/745 (MDR), which came into force on May 26, 2021, applies to the certification of medical devices and replaces the previous Medical Device Directive (MDD). The MDR applies directly in the EU Member States.

The EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) came into force on May 26, 2022.

In 2023, transition periods for compliance with the MDR and the IVDR were extended because of concerns about the impact to patient safety from

delays in certification. Accordingly, legacy devices may benefit from time-limited grace periods allowing continued marketing of the device provided certain conditions are satisfied.

Under the MDR, medical devices are classified according to the device's risk, with Class I being the lowest risk and Class III the highest. Class I devices are self-certified by manufacturers, but higher classes require certification by a third-party notified body.

Under the IVDR, *in vitro* diagnostic (IVD) devices are also classified into three risk classes (A, B and C), with class A being the lowest risk. Under prior IVD legislation, most devices were only self-certified, meaning that many products now require certification under the IVDR.

DUTCH PROVISIONS

The Act on Medical Devices (*Wet medische hulpmiddelen*) (Wmh) lays down the provisions for the application of the MDR and the IVDR, such as the appointment of the competent supervising body (*i.e.*, the Inspection Healthcare and Youth (*Inspectie Gezondheidszorg en Jeugd*) (IGZJ)), operational powers and sanctions. The Wmh and the implementing regulation (*Regeling medische hulpmiddelen)* (Rmh) also implement the topics on which interpretation was left to the Member States, such as the reuse of medical devices meant for a one-time use, the language used in certain documents and the cost of an export declaration. The Rmh also contains the requirement for manufacturers of custom-made devices to submit a list of the types of custom-made devices they provide.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

EUROPEAN-WIDE LAW

SaMD

Software with a medical purpose is generally regulated as a medical device under the MDR or IVDR and must be certified as conforming to the MDR's safety and other requirements before being placed on the market.

Prior to the MDR, software as a medical device (SaMD) was regulated under the MDD and was commonly classified as a Class I device and certified under the basic conformity assessment procedure (self-certification). Under the MDR, many SaMD products are now classified in higher-risk classes (up-classed), meaning that certification is required from third-party notified bodies.

In 2023, the transitional arrangements under the MDR were extended so that up-classed SaMD may benefit from time-limited grace periods permitting continued marketing of the device under the MDD rules provided conditions are satisfied.

AI

MDR and IVDR do not contain artificial intelligence (AI) specific provisions. Instead, AI algorithms and software are regulated as SaMD.

In 2021, the European Commission published a draft regulation on AI that is expected to come into force no earlier than 2024. The current draft provisions propose that AI legislation will be applied in addition to the MDR for AI that is SaMD. This may require an additional certification under the AI regulation.

DUTCH LAW

In the Netherlands, no additional national provisions apply to SaMD and AI at this stage. However, the sector has developed a guideline providing a description of what is considered good professional conduct in the development, testing and implementation of an AI prediction algorithm (AIPA) in the medical sector, including public healthcare. The requirements and recommendations in the guideline

are addressed directly to the developers and testers of the AIPA, the manufacturer of the software that incorporates the AIPA and the care organization that implements this software in its organization. The guideline describes what care providers, citizens and patients, insurance companies and policy-makers (such as the National Health Care Institute and the Dutch Healthcare Authority) can expect from an AIPA developer or manufacturer when they purchase such medical devices, use these devices or have such devices used on them.

7. TELEMEDICINE AND TELECONSULTATION

In the Netherlands, the government is encouraging the healthcare sector to expand telehealth. The Ministry of Health published an assessment framework for "deployment of e-health by healthcare providers" in 2021 that 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 somewhat 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.

As indicated in section 1, a proposal to provide a legal basis for the prescription of medicine to patients after contact via the internet is currently being prepared. Based on the positive results of the temporary exemption to this rule during the COVID-19 pandemic, this proposal will provide the legal basis to continue this practice.

8. ANTI-KICKBACK RULES AND INCENTIVES TO DOCTORS

Dutch inducement rules prohibit promising, offering or giving 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. This applies to all parties that have a commercial interest in the use of a certain medical device and everyone who has control over which devices are used from their profession. 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.

In March 2020, a legislative proposal to lay down in law a Transparency Register for Healthcare was submitted to the House of Representatives. This register would be introduced by amending the Medicines Act, the Medical Devices Act and the Individual Healthcare Professions Act to include the existence of a mandatory public register. Every transaction between manufacturers and doctors of EUR 500 or more would have to be registered. The aim is to ensure that, in the future, patients can be assured that medicinal products or devices are

prescribed because they are the best medical or treatment option for them at the time.

The Council of State issued advice on the legislative proposal in February 2021, criticizing the proposal for not making it sufficiently clear why it is necessary to make the existing Transparency Register mandatory to improve its functioning. In June 2021, the Dutch Data Protection Authority issued advice to the House of Representatives, also criticizing the proposal. It noted that a registration in the Transparency Register is a considerable intrusion on the privacy of the individual practitioner. The Dutch Data Protection Authority doubts whether the transparency of the register is necessary and questions whether access to the register could not be limited to the Inspectorate. Currently, the proposal is being amended by the petitioner, following these criticisms. The Minister of Health, Welfare and Sport expects to be able to give more information on the proposal at the end of 2023.

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.

The Foreign Subsidy Regulation (FSR) applies from July 12, 2023. This includes a notification obligation similar to the one already in place for state aid and concentrations within the European Union. For concentrations, this notification threshold applies when one of the parties has an EU turnover of at least EUR 500 million and the transaction involves foreign financial contributions of more than EUR 50 million. For public procurement procedures, the notification obligation applies if the estimated contract value is at least EUR 250 million and the bid involves a foreign financial contribution of at least EUR 4 million per third country.

As of January 1, 2023, mergers in the healthcare sector are no longer subject to lowered turnover thresholds for notification to the Dutch Competition Authority (ACM). Before this date, a prior notification to the Dutch Healthcare Authority (NZa) was mandatory if a proposed merger or acquisition involved a healthcare provider that employs 50 or more individuals that provide healthcare. The NZa is also the designated regulator capable of taking measures if a healthcare provider or healthcare insurer has significant market power.

The Minister of Health, Welfare and Sport decided to not extend the validity of the Decree on temporary extension of the scope of application of merger control to companies that provide healthcare (*Besluit tijdelijke verruiming toepassingsbereik concentratietoezicht op ondernemingen die zorg verlenen*). A transaction within the healthcare sector now must be notified at the same threshold as transactions in other sectors. This threshold is reached if the worldwide turnover of all undertakings concerned is more than EUR 150 million and at least two of the undertakings achieve a turnover of more than EUR 30 million in the Netherlands. The NZa is monitoring the effects of the removal of the reduced turnover thresholds for merger supervision under the Competition Act. To that end, parties involved in a merger or acquisition involving a healthcare provider are requested to indicate on the notification form whether the concentration would fall under the reduced turnover thresholds and to enclose the most recent annual accounts of the organizations involved in the merger notification.

POLAND

1. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

Recent changes in Polish healthcare and life sciences law include the following:

- New act on the National Oncology Network (Q1 2023), which provides for eligibility criteria that must be met by the hospital in order to be part of the National Oncology Network.
- New act on medical devices (Q2 2022), which introduced new rules for advertising of medical devices and strict sanctions for non-compliance.
- New act on clinical trials on medicinal products for human use (Q1 2023), which regulates liability for damages arising in connection with the conduct of a clinical trial.
- New act on quality in healthcare and patient safety (Q3 2023), which introduces rules regarding monitoring the quality of provided healthcare services.
- Amendment to act on reimbursement of medicinal products, foodstuffs for particular nutritional uses and medical devices (Q3 2023), which introduces increases in official margins of reimbursed products.

Anticipated changes (drafts still in the legislative process that may not necessarily become law in force) include the following:

- Amendment to Pharmaceutical Law Act, which introduces restrictions regarding pharmacies' takeovers.

2. OWNERSHIP OR EQUIVALENT RESTRICTIONS IN RELATION TO THE PROVISION OF HEALTHCARE SERVICES

There is no strict differentiation between the private and 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, while hospitals remain the domain of the public sector. However, this is different for highly specialized 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% 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% of the shares), the State Treasury and/or the local government.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

More than 90% 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 four million people.

The largest payor for services offered in private hospitals is the National Health Fund (*Narodowy Fundusz Zdrowia*) (NFZ), which in 2016 accounted for 62% of private hospital revenues, with patients financing 35% and insurers only 3% of private hospital revenues. The NFZ announced that in 2023 it will pay an additional PLN 200 million (around EUR 45 million) for patients treated in hospitals.

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

Marketing authorizations for drugs generally require preclinical and clinical testing, except for specific circumstances (*e.g.*, bibliographic authorization). Expedited approval procedures are also available, such as conditional approval or the priority medicines (PRIME) procedure.

The drug marketing authorization for a medicinal product in the national procedure in Poland is issued within 210 days of the submission of a complete application. The authorization is first valid for a period of five years and then it can be renewed for an indefinite period of time.

An application for a drug reimbursement is usually processed within 180 days (documents are submitted via an online system). Pricing for drugs available only by prescription is strictly regulated and depends on the outcome of reimbursement and price negotiations between marketing authorization holders (or their representatives, where marketing authorization holders are seated outside the European Economic Area) and the Minister of Health. The Minister of Health issues a list of reimbursable drugs every two months (every three months from 2024).

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

EUROPE-WIDE PROVISIONS

The Medical Devices Regulation EU 2017/745 (MDR), which came into force on May 26, 2021, applies to the certification of medical devices and replaces the previous Medical Device Directive (MDD). The EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) came into force on May 26, 2022. The MDR and IVDR apply directly in the EU Member States.

In 2023, transition periods for compliance with the MDR and the IVDR were extended because of concerns about the impact to patient safety from delays in certification. Accordingly, legacy devices may benefit from time-limited grace periods allowing continued marketing of the device provided certain conditions are satisfied.

Under the MDR, medical devices are classified according to risk of the device, with Class I being the lowest risk and Class III the highest. Class I devices are self-certified by manufacturers, but higher classes require certification by a third-party notified body.

Under the IVDR, *in vitro* diagnostic (IVD) devices are also classified into three risk classes (A, B and C) with class A being the lowest risk. Under prior IVD legislation, most devices were only self-certified, meaning that many products now require certification under IVDR.

POLISH PROVISIONS

In Poland, a new national law on medical devices aimed at supplementing the MDR and IVDR has been in force since May 2022. Among other changes, it introduced stricter rules concerning advertising of medical devices.

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 part of overall spending on its operation. Patients that purchase certain medical devices prescribed or commissioned by a doctor (since July 2023, e-commissions have been introduced) have their payments reimbursed.

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

EUROPEAN-WIDE LAW

SaMD

Software with a medical purpose is generally regulated as a medical device under the MDR or IVDR and must be certified as conforming to the MDR's safety and other requirements before being placed on the market.

Prior to the MDR, software as a medical device (SaMD) was regulated under the MDD and was commonly classified as a Class I device and certified under the basic conformity assessment procedure (self-certification). Under the MDR, many SaMD products are now classified in higher-risk classes (up-classed), meaning that certification is required from third-party notified bodies.

In 2023, the transitional arrangements under the MDR were extended so that up-classed SaMD may benefit from time-limited grace periods permitting continued marketing of the device under the MDD rules provided conditions are satisfied.

AI

MDR and IVDR do not contain artificial intelligence (AI) specific provisions. Instead, AI algorithms and software are regulated as SaMD.

In 2021, the European Commission published a draft regulation on AI that is expected to come into force no

earlier than 2024. The current draft provisions propose that AI legislation will be applied in addition to the MDR for AI that is SaMD. This may require an additional certification under the AI regulation.

POLISH LAW

In Poland there are currently no specific regulations applicable to SaMD and AI. The general EU and Polish regulations apply. Solutions based on AI, such as assisting doctors performing surgeries, are becoming more and more popular and are starting to be covered by reimbursement. Introduction of AI-based procedures is a political priority, as well as training doctors so that they are ready to use these types of procedures in their practices and in hospital management processes.

7. TELEMEDICINE AND TELECONSULTATION

The pandemic 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% of medical consultations took place remotely.

Under the Medical Activity Act, telemedicine healthcare providers must be entered in a public register of healthcare providers (the same rules apply to non-telemedicine providers).

The Regulation on the organizational standard of teleconsultation within primary healthcare imposes several requirements. For example, a patient must be informed of the right to meet a doctor in-person, a patient must be verified, and confidentiality of consultations must be assured.

In 2023, governmental representatives announced that the Polish government plans to counteract the phenomenon of e-platforms appearing on the Polish market, where patients can obtain a prescription almost automatically in 15 minutes without a doctor's diligent examination of whether issuance is in fact justified. Therefore, telemedicine may be subject to future legal limitations in this regard. In July 2023, the Minister of Health introduced limits to the amount of prescriptions per day that can be issued by doctors (300 per day; the limit will not apply to reimbursed drugs).

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 offense.

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% 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% of shares), the State Treasury and/or the local government.

In July 2023, an amendment to the Pharmaceutical Law was proposed and as of 24.08.2023 it is in the

final stage of the legislative process (awaiting the President's decision). It introduces additional restrictions with respect to pharmacy takeovers. Should the amendment become binding law, it would significantly limit takeovers of pharmacies in Poland by non-pharmacists.

SPAIN

1. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

The new medicines law is expected to be approved in the near future together with a complete reform of the regulations on promotional practices in both the medicines and medical devices sectors.

The regulations implementing the EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR) are also pending approval.

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).

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 centers (*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 authorized and registered in Spain in order to render these services, but no specific type of company is required.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

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, such as radiology or clinical labs.

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

Marketing authorization for drugs is substantially regulated by EU law. Under certain conditions, drugs may be authorized in a centralized EU procedure handled by the European Medicines Agency (EMA). The EU marketing authorization is valid throughout the European Economic Area (*i.e.*, the current 27 EU

Member States plus Norway, Liechtenstein and Iceland). Drugs may also be authorized by the competent national authority if the drug is only to be authorized in that Member State, or if several EU Member States cooperate to grant authorizations.

Marketing authorizations for drugs generally require preclinical and clinical testing, except for specific circumstances (*e.g.*, bibliographic authorization). Expedited approval procedures are also available, such as conditional approval or the priority medicines (PRIME) procedure.

Drugs must be authorized before they can be placed on the Spanish market. Marketing authorizations 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 authorizations for drugs in Spain and can do so under the national, mutual recognition or decentralized procedures. The latter two procedures allow for the grant of coordinated authorizations in several EU Member States.

Some drugs (such as orphan drugs and most biologics) must be authorized by the EMA. Marketing authorizations 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 authorization, national authorities decide whether to provide and reimburse it on the NHS, and set its price. The current trend for 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 authorization 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

EUROPE-WIDE PROVISIONS

The Medical Devices Regulation EU 2017/745 (MDR), which came into force on May 26, 2021, applies to the certification of medical devices and replaces the previous Medical Device Directive (MDD). The MDR applies directly in the EU Member States.

The IVDR came into force on May 26, 2022.

In 2023, transition periods for compliance with the MDR and the IVDR were extended because of concerns about the impact to patient safety from delays in certification. Accordingly, legacy devices may benefit from time-limited grace periods allowing continued marketing of the device provided certain conditions are satisfied.

Under the MDR, medical devices are classified according to risk of the device, with Class I being the lowest risk and Class III the highest. Class I devices are self-certified by manufacturers, but higher classes require certification by a third-party notified body.

Under the IVDR, *in vitro* diagnostic (IVD) devices are also classified into three risk classes (A, B and C) with class A being the lowest risk. Under prior IVD legislation, most devices were only self-certified, meaning that many products now require certification under the IVDR.

SPANISH LAW

A new Royal Decree on medical devices was recently approved. It supplements the MDR.

The manufacture, import (from non-EU countries), grouping, reprocessing or sterilization of medical devices is subject to administrative authorization 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 authorization 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 commercialization 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 and must be registered in a special registry. Any subsequent changes to the information that has been reported to the AEMPS (or the relevant regional authorities) must also be reported.

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

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

6. REGULATION OF AI AND SOFTWARE AS A MEDICAL DEVICE

EUROPEAN-WIDE LAW

SaMD

Software with a medical purpose is generally regulated as a medical device under the MDR or IVDR and must be certified as conforming to the MDR's safety and other requirements before being placed on the market.

Prior to the MDR, software as a medical device (SaMD) was regulated under the MDD and was commonly classified as a Class I device and certified under the basic conformity assessment procedure (self-certification). Under the MDR, many SaMD products are now classified in higher-risk classes (up-classed), meaning that certification is required from third-party notified bodies.

In 2023, the transitional arrangements under the MDR were extended so that up-classed SaMD may benefit from time-limited grace periods permitting continued marketing of the device under the MDD rules provided conditions are satisfied.

AI

MDR and IVDR do not contain artificial intelligence (AI) specific provisions. Instead, AI algorithms and software are regulated as SaMD.

In 2021, the European Commission published a draft regulation on AI that is expected to come into force no earlier than 2024. The current draft provisions propose that AI legislation will be applied in addition to the MDR for AI that is SaMD. This may require an additional certification under the AI regulation.

SPANISH LAW

Under certain conditions, medical software is considered 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 receive a CE mark in order to be placed onto the European and Spanish markets.

The MDR sets forth in its rule 11 of Annex VIII the same classification and requirements (applicable from May 2021) as Medical Devices Directive (MDD) had. Innovative devices, such as artificial intelligence (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 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 authorize the dispensing of drugs from having a direct economic interest in the marketing of drugs and medical devices. Kickbacks and incentives to physicians and other healthcare professionals also 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-European

Free Trade Association (EFTA) investors, which may require prior authorization 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 European Union if those entities 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% of the share capital or voting rights of the investor, or otherwise exercise control, directly or indirectly, over the investor). It also applies until December 31, 2024, to European investors when they invest in a listed company or the value of the investment is over EUR 500 million. The development rules of this regulation were recently approved by means of Royal Decree 571/2023, dated July 4, 2023, on foreign investment control.

SWITZERLAND

1. FORTHCOMING AND ANTICIPATED CHANGES IN HEALTHCARE AND LIFE SCIENCES LAW

Several recent regulatory changes will likely impact the healthcare and life science sector in the coming years:

- The new medical device ordinances that were adopted in the wake of the Medical Devices Regulation EU 2017/745 (MDR) and the EU In Vitro Diagnostic Medical Devices Regulation 2017/746 (IVDR).
- The new criteria for physicians to practice under mandatory health insurance that came into force in 2022.
- The revised data protection legislation in effect since September 2023.
- The revised regime on human genetic testing that came into force at the end of 2022.
- The liberalized approach to the application of cannabis for medical use since mid-2022.
- The plans to reinvigorate the electronic patient record and digitalization in the provision of healthcare generally.

The old Swiss legislation for medical devices was considered equivalent to the EU framework under the old EU regulation (MDD and IVDD). This principle is anchored in the Mutual Recognition Agreement (MRA) between the European Community (EC) and Switzerland. Accordingly, medical devices that complied with the MDD or the IVDD were allowed to be placed on the market in Switzerland. Conversely, medical devices that complied with the applicable Swiss legislation could circulate freely in all EU Member States.

On May 26, 2021, the revised Medical Devices Ordinance (MedDO) entered into force, and on May 26, 2022, the new Ordinance on In Vitro Diagnostic Medical Devices (IvDO) entered into force, mirroring the European Union's regulations (MDR and IVDR).

However, the MRA was not adapted to the new Swiss regulations for political reasons. Switzerland is now a third country within the meaning of the MRA; there is no mutual recognition. This has major implications for the market.

Since January 2022, admission of new physicians to practice under mandatory health insurance requires at least three years of training at a recognized Swiss

training center in the respective specialty. Swiss cantons are obliged to implement (cantonal or regional) quantitative limitations on the number of admitted physicians by July 2023. These new limitations are currently the subject of lively criticism.

The Swiss legislator adopted a revised Federal Data Protection Act (FDPA) and a new Ordinance to the Federal Act on Data Protection (FDPO). The new legislation entered into force on September 1, 2023. The new framework provides for increased transparency requirements while building on previous concepts of the Swiss data protection regime. It is expected that the EU Commission will renew its adequacy decision on that basis and consequently acknowledge an equivalent level of data protection in Switzerland.

On December 1, 2022, a revised regime on human genetic testing entered into force. Depending on the genetic traits examined, genetic tests are regulated to different degrees. The strictest requirements apply to the use of genetic testing for DNA profiling and in the medical field. In contrast, providers of direct-to-consumer tests enjoy a more liberal environment than before.

On August 1, 2022, the Swiss Narcotics Act (NarcA) was amended to facilitate the use of cannabis for medical purposes. Irrespective of its THC content, cannabis no longer qualifies as a prohibited narcotic, and special authorization by the Federal Office of Public Health (FOPH) is no longer required for the medical use of cannabis. Market participants in the field of medical cannabis can apply for various commercialization licenses from the Swiss Agency for Therapeutic Products (Swissmedic).

Switzerland lacks a coherent environment for the legitimate and secure re-use of health data. In April 2022, the Federal Council announced its plan to develop the electronic patient record (EPD) further, and for it to become an instrument of mandatory health insurance. All health professionals working in outpatient care will be obliged to maintain an EPD. Access for research purposes with the consent of the persons concerned is also planned. On May 4, 2022, one day after the European Commission announced its plans for the European Health Data Space, the Federal Council informed the public that it wanted to enable better use of health data for research. However, it seems that the various projects are not coordinated with one another.

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 license granted by the canton in which they operate. The requirements are laid down in the cantonal legislation.

3. AWARD OF PUBLIC CONTRACTS AND REIMBURSEMENT

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 authorization issued by Swissmedic. The marketing authorization holder must have its registered address, registered office or a branch office in Switzerland. There is no mutual recognition of EU marketing authorizations. However, if a medicinal product or procedure is already authorized 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 authorization.

The data protection period for new medicinal products is 10 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 10 years for new indications when a significant clinical benefit can be expected and the indication is supported by extensive clinical studies. A 10-year data protection period may be granted for medicinal products designed for pediatric 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 authorized by Swissmedic or imported from a country with an equivalent market authorization scheme (so-called individual reimbursement). The government is currently working on a revision of the individual reimbursement scheme.

5. DEVICES CERTIFICATION AND REIMBURSEMENT

In contrast to medicinal products, medical devices do not require a marketing authorization 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 MDR.

Since the MRA between Switzerland and the European Union was not updated to account for the revised European and Swiss medical device regulations, the free circulation of medical devices between Switzerland and the European Union under the previous regimes has been partially suspended. Foreign manufacturers must therefore appoint an authorized representative based in Switzerland (CH-Rep). Certificates of conformity issued by notified bodies in the European Union or European Economic

Area (EEA) are still recognized in Switzerland, whereas certificates of conformity issued by notified bodies in Switzerland are no longer recognized in the European Union or the EEA. As Swissmedic does not have access to EUDAMED, economic operators based in Switzerland must register with Swissmedic and apply for a Swiss Single Registration Number (CHRN), similar to the SRN in Europe.

Medical devices qualify for reimbursement under the Swiss social health insurance regime if they are included on the lists of aids and equipment (MiGeL); lists of laboratory analyses (*Analysenliste*); or 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 harmonized 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 for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of a disease, among other things.

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

So far the regulator sees no need for general regulation of AI. Switzerland is participating in the negotiations for an international convention on AI as a member of the European Committee on AI (CAI), which was set up by the Council of Europe in 2022.

Use of AI by medical practitioners is still in its infancy, and while 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 generally permissible under Swiss law. The Swiss Federal Supreme Court confirmed the admissibility of teleconsultation if the counselling physician is able to take adequate measures depending on the health of the patient. However, the COVID-19 pandemic did not result in the establishment of a wider range of remote consultations. Besides the lack of specific tariffs, safety and liability concerns are often named as inhibiting factors. 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 outpatient tariff is to be modernized after almost 20 years; negotiations are ongoing.

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 organizations employing such persons. Under a legislative amendment due to take effect in 2025, this provision will include medical devices. 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 over-the-counter medicinal products and Class I medical devices. Further, healthcare providers must in principle pass on to the patient (or the insurer paying directly, as applicable) 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 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, in 2020, the Swiss parliament instructed the government to present a legislative project to introduce state control in the case of takeovers of Swiss companies by foreigners. The government later sent a concrete legislative project for consultation, which was eventually reduced in scope to a great extent. Investment control is to be limited to "particularly critical" areas. As examples, the government mentioned armaments, electricity grids, electricity production, telecommunications infrastructure and parts of the health sector. The course that will be taken by parliament and the timeline are still unpredictable.

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SPECIAL REPORT

WHY McDERMOTT

McDermott Will & Emery partners with leaders around the world to fuel missions, knock down barriers and shape markets. With 20+ locations on three continents, our team works seamlessly across practices, industries and geographies to deliver highly effective–and often unexpected–solutions that propel success. More than 1,400 lawyers strong, we bring our personal passion and legal prowess to bear in every matter for our clients and the people they serve.

We strive to offer unparalleled counsel to the world's most respected, innovative and important health organizations as they make their mark on the rapidly evolving healthcare industry. We're deeply passionate about the incredible progress our clients are making and our role in supporting them as they transform the future of healthcare. As a leading international health law firm, our achievements are driven by a deep commitment to our clients and we were honored to see those achievements recognized in industry accolades. McDermott's health team continues to receive top rankings from Chambers USA, Chamber Europe, Legal 500, JUVE and Best Lawyers. This was the 13th consecutive year we received a national Band 1 ranking from Chambers USA, and the fifth consecutive time we were the only nationwide band 1 healthcare firm. We were also named the most active firm for healthcare private equity by pitchbook's league tables for the fifth consecutive year.

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