Investing in European Healthcare

What's on the Horizon for 2022?

Regulatory and Legal Changes

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SPECIAL REPORT

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For more information, please contact your regular McDermott lawyer, or:

SHARON LAMB
PARTNER

slamb@mwe.com
Tel +44 20 7577 6943

DR. STEPHAN RAU
PARTNER

srau@mwe.com
Tel +49 89 1271 2320

HAMID YUNIS
PARTNER

hyunis@mwe.com
Tel +44 20 7570 1438

EMMANUELLE TROMBE
PARTNER

etrombe@mwe.com
Tel +33 1 81 69 15 35

For more information about McDermott Will & Emery visit mwe.com

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SPECIAL REPORT

INTRODUCTION

Today's global healthcare marketplace is marked by unprecedented transformation. The seismic shifts in healthcare delivery and drug development during COVID-19 have, in 2021, continued to demonstrate the power and capacity for changes in the market. A deep understanding of future regulatory and political risks is more important than ever. Within this dynamic environment, McDermott's international health lawyers are passionate about our role in shaping the alliances that will lead to next-generation digital health technologies, new pharmaceuticals and superior healthcare delivery.

In this European guide, you will find an overview of regulatory changes in 2021 and an insight on issues on the horizon in 2022.

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.

United Kingdom	Germany	France
Foreign Investment Control: Under the National Security and Investment Act 2021, a new standalone regime was introduced for the scrutiny and intervention in, acquisitions in certain sensitive sectors of the economy. The Act comes into force in 2022 and introduces a mandatory regime for mandatory sectors, including advanced robotics, artificial intelligence, synthetic biology **NHS Legislative changes**: In 2021, the UK government introduced the Health and Care Bill which includes a range of changes to NHS bodies, the introduction of integrated care boards, changes to pricing of healthcare services and the procurement of NHS services. Separate regulations are to be published for the selection of providers of NHS services. **Medicines and Medical Devices Act**: In 2021, the government introduced the Medicines and Medical Devices Act. The new act is framework legislation which gives the Secretary of State wide powers to adopt a new regulatory framework for medicines and medical devices. In September 2021, the UK government published a consultation on the future regulation for medical devices setting out proposed options for a new regulatory framework. **Brexit related changes**: On 1 January 2021, the UK left the European Union ushering in a new legislative framework for the UK. Most European legislation was transferred to standalone UK legislation. The impact on Brexit has significantly affected health and life sciences services, particularly with respect to recruitment, marketing of medicines and medical devices, customs and tariff changes, appointment of authorized representatives and importation and supply chain. **Procurement**: On 15 December 2020, the UK government published a procurement Green Paper setting out significant changes to procurement law and divergence from the EU procurement directive. This remains under consultation. **Data Protection**: Although the EU GDPR was retained in the UK as standalone data protection legislation post Brexit, the UK government in August published a consultation version for international transfers of data. In September, the government also published a consultation on the future data protection regime for the UK.	**Foreign Investment Control**: Under the German foreign investment control regime, the Federal Ministry for Economic Affairs and Energy may in certain circumstances review whether foreign investments in the healthcare and life sciences sector are likely to affect public order or security. The regime has over the past years been and continues to be subject to significant change. Based on recent reforms, foreign investments in health infrastructures of special public interest, such as large hospitals or selected drug and medical device manufacturers, might have to be notified to and cleared by the ministry prior to closing of the transaction. Further tightening of the regime is expected soon. **Whistleblowing**: Germany is currently implementing the EU Whistleblower Directive. The Federal Ministry of Justice has submitted a corresponding draft bill that goes significantly beyond the requirements of the directive and is controversially discussed in the German government and among experts. The directive has to be implemented by 17 December 2021. Germany may be struggling to meet that deadline due to the federal elections and upcoming new legislative period. **IT Security Guidelines**: The Federal Association of Panel Doctors has issued an IT security guideline for medical practices that becomes fully binding as of 1 January 2022. The guideline provides for technical and organizational standards that have to be observed by doctor's practices, including medical care centers. Such standards vary according to the size of the respective practice. **Clinical Trials**: The German legislator is in the process of amending the Federal Medicinal Product Act (*Arzneimittelgesetz*) and the Federal Drug and Active Ingredient Manufacturing Ordinance (*Arzneimittel- und Wirkstoffherstellungsverordnung*) to the framework of the Clinical Trial Regulation (Reg. (EU) No. 536/2014) that is expected to become applicable on 31 January 2022. **Supply Chain**: The Federal Supply Chain Sourcing Obligations Law (*Lieferkettensorgfaltspflichtengesetz*) will likely enter into force on 1 January 2023. It sets out particular duties of care for large companies with the purpose of respecting human rights and environmental standards globally. Once it has entered into force, the new law will likely have substantial implications on global life sciences companies.	**Telemedicine:** New laws on telemedicine and notably telesurveillance are expected to be adopted in 2022, broadening the scope of what is currently permitted. **Medical Cannabis**: An experimentation of medical cannabis has started in March 2021 to assess the opportunity to generalise the use of cannabis-based medicines in France. Results are expected in September 2023. **Bioethics and reproduction**: A new bioethics law came into force on August 2, 2021. It extended medically assisted reproduction to women couples and to single women and gave new rights to children born from this procedure. It contained other provisions, notably on the self-preservation of gametes for non-medical reasons, on embryo research and on stem cell research. **Medical Devices and Clinical Trials**: Recent changes to the legislation on medical devices and clinical trials on medicines for human use may bring some unexpected challenges to French operators and researchers. **COVID-19**: Numerous laws have been adopted in the course of the COVID-19 pandemic and will likely be subject to further discussion and amendment.

Italy

Foreign Investment Control: At the end of 2020, important regulatory measures regarding Italian foreign investment control regulations (known as the Golden Powers) were enacted: (i) a revised list and definition of critical and strategic assets in sectors relevant for the purposes of these regulations, the life sciences and healthcare sector, and (ii) 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) have been extended through the entire emergency period. Further developments are expected at the end of the emergency period.

Medical Devices Delegation: In April 2020, legislation was approved for a delegation to the Italian Government to issue legislative decrees to adapt the national regulatory framework to reflect of the EU Medical Devices Regulations, within the next 12 months. According to the principles and criteria established by the Delegation Law, the Government will have, among other things, to:

- arrange for the reorganization and coordination of activities among the entities responsible for the governance of medical devices, and establish the mechanism necessary to implement the reimbursement system in the medical devices sector (that could have a significant financial impact on operators);
- establish a sanctioning system for breach of the provisions of the Medical Devices Regulations;
- make medical device purchasing procedures more efficient by strengthening Health Technology Assessment procedures; and
- introduce the obligation for companies that produce or market medical devices to pay a share of no more than 0.75% of their turnover resulting from sales of medical devices and large equipment, net of value-added tax, to the National Health Service for the purpose of financing the system for governance of medical devices.

COVID-19: Numerous laws have been adopted in the course of the COVID-19 pandemic to boost digital health activities and they will likely be subject to further developments. We mention, in particular: (i) two decrees issued by the Ministry of Health providing the possibility for doctors to issue e-prescriptions for drugs reimbursed and not reimbursed by the National Health Service; and (ii) the new National guidelines for the provision of telemedicine services, that represents the up-to-date national reference for provision of telemedicine services, that Italian regions are implementing to allow and recognize certain digital services at the Regional Health System's expenses.

Medicine Reimbursement: On December 23, 2020, the Italian Agency of Medicines ("AIFA") issued Guidelines for the compilation of the dossier to support the request for reimbursement and pricing of a medicine, pursuant to the Ministerial Decree of August 1, 2019, that set out new criteria for the price negotiation procedure between the AIFA and the marketing authorization holder

Netherlands

Healthcare Provider Licensing: In June 2020, the Dutch Senate adopted two bills changing the licencing system for healthcare providers (and their sub-contractors) and the transparency requirements to enhance the enforcement of applicable rules and regulations. The bill will enter into force in 2022 but there will be a transition period of two years for the existing healthcare providers to adapt to the new requirements.

Medical Records: A new guidance on access to medical records by next of kin from the Royal Dutch Society for the Advancement of Medicine was approved on 26 November 2020.

Proposed legislation: In addition, the following bills have been sent to the House of Representatives for evaluation:

- A bill on digital exchange of data in healthcare has been approved by the Council of Ministers.
- In March 2020, a bill introducing a Transparency Register for Healthcare was submitted. Every transaction between manufacturer and doctor of 50 euros or more is registered.
- Members of the House of Representatives have proposed an amendment to the Healthcare Quality, Complaints and Disputes Act to increase the involvement of healthcare employees in decisions made by healthcare institutions that affect the way in which healthcare is provided.
- A bill on the transfer of statutory duties regarding merger control and the control of significant market power from the Dutch Healthcare Authority to the Netherlands Authority for Consumers and Markets (the Dutch competition regulator). The bill will also amend the thresholds for prior mandatory notification.

Personal Records and Data: In July 2021, an Order in Council was issued that aims to strengthen the possibilities to combat various forms of fraud (inter alia in the healthcare sector) by the use of the Personal Records Database. In February 2021, the Dutch Data Protection Authority raised serious objections to a draft Order in Council in relation to the consultation of client data via an electronic exchange system in connection with the triage or treatment of COVID-19. No definitive Order in Council has been issued yet.

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

Switzerland	Poland	Spain	Austria
In Vitro Devices: Key regulatory changes currently underway include the project for a revised regime on in vitro diagnostic medical devices set to apply from 26 May 2022. In April 2021, the Federal Council published the draft for an ordinance on in vitro diagnostic medical devices (IvDO), laying grounds for a reform akin to the European Regulation (EU) 2017/746. To date, it is still unclear if the mutual recognition agreement between Switzerland and EU/EEA will be adapted accordingly. **Electronic Patient Dossiers**: Following the certification of the first operators of electronic patient dossiers (EPD), the nationwide roll-out of a certified electronic health record system is progressing. Accession to a certified EPD operator is currently mandatory for hospitals, birth centres, and nursing homes acting as service providers under statutory health insurance (SHI) laws and will become compulsory for outpatient SHI providers as per legislative amendments expected to apply from 2022. **Future changes**: The following amendments due to enter into force in 2022 include • loosened regulation on cannabis for medical use, • the reform of legislation on genetic testing, and • a revised federal data protection act and implementing data protection ordinance.	**COVID-19**: Several changes in the Polish healthcare system have occurred as a result of the pandemic, including i.a.: widespread use of telemedicine and e-health related solutions, increased legislation to avoid shortages of COVID-19 diagnosis and treatment products, use of fast track regulatory procedures aimed to accelerate the authorisation of new products related to COVID-19 pandemic, establishment of new healthcare facilities and decrease of treatments not directly linked to COVID-19. **Policy Developments**: The National Health Fund implements its strategy for the years 2019–2023. Its main goals for the four-year period include supporting service providers in building efficiency (for example, through development and implementation of a system for accreditation and digitalisation) and a focus on innovation. However, implementation of the strategy slightly seized to be the priority of healthcare institutions because of the COVID-19 pandemic. Also a new, emerging focus area is mental health both of adults and children, because the public awareness and thus demand is growing due to consequence of isolation. **Public Private Partnerships**: It is expected that further developments in the Polish healthcare sector will be spurred on in the upcoming years by means of private- and public-sector partnerships. This will require predictability, stability and openness. Such projects are already implemented in the area of non-commercial clinical trials of biochemical molecules, in particular in the area of oncology, and with a significant potential in other areas too. **Growth of private healthcare**: The private healthcare market in Poland is forecast to continue to grow. According to data provided by the Polish Chamber of Insurance for first half of 2020, Poles spent almost half a billion zlotys (approximately 225 million Euros) on health services and insurance.	**Medical Devices**: New regulation on medical devices is expected to be approved in the near future. A draft has already been subject to public information. In addition, legislation on veterinary medicines is also pending repeal by a new regulation, which has already been subject to public information. **Integrated Patient Services**: Spain is also facing rising demand for integrated patient services (drug supply and healthcare services) and a significant increase in the wellbeing industry for the prevention and prediction of illnesses with the aid of medical devices. In addition, precision medicine and genomic testing activities are in the spotlight. **Drug Pricing Pressure**: Finally, the constant pressure over prices for new drugs may lead to shortages in specific innovative drugs (including orphan drugs) in Spain.	**COVID-19**: In Austria numerous pieces of legislation have been adopted in the course of the COVID-19 pandemic. The changes in legislation were required to facilitate healthcare in order to meet the constantly changing needs during the pandemic, e.g. the possibility to receive prescriptions for medicinal products per email. The healthcare-related acts mostly affected by the changes are the Austrian Physicians Act (*Ärztegesetz*), the Hospitals Act (*Krankenanstaltengesetz*) and the Nursing Act (*Gesundheits- und Krankenpflegegesetz*). Currently it is still not certain which of these amendments will stay in force for the period to come. Nevertheless, most of these acts are only applicable in case of the pandemic. **Medical Devices**: In June 2021, the Austrian parliament adopted changes on the Medical Devices Act to be in line with the EU Medical Device Regulation. The sections for in vitro diagnostic medical devices will become applicable in May 2022.

Denmark

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

Further, some interesting highlights include:

MDR: Since application of the MDR on 26 May 2021, Danish authorities have both issued and updated a number of executive orders and guidelines which medical device companies should be aware of. These include executive orders on medical devices and products without medical purpose and on fees for medical products. The guidelines cover labelling and instructions and software and apps for medical devices among others. The Danish Medicines Agency has announced that it will strengthen its efforts with regard to inspection of medical device companies, having established a new inspection team specifically for this area.

Rules on industry affiliation and economic support: The new Danish rules on industry affiliations and economic support to healthcare professionals came into force on 26 May 2021. Among other things, the amended affiliation rules expand 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.

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

Treatment Council: On 1 January 2021, the Treatment Council became operational. Early in 2021 a Process Manual and Procedure Guidelines was published. This means that the Council is now open for receiving evaluation suggestions. The first candidates expect to complete the process by end of 2021.

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

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MCDERMOTT HEALTHCARE TEAM

UNITED STATES

DALE C VAN DEMARK
PARTNER
dcvandemark@mwe.com
Tel +1 202 756 8177

MICHAEL RYAN
PARTNER
mryan@mwe.com
Tel +1 202 756 8088

KRISTIAN WERLING
PARTNER
kwerling@mwe.com
Tel +1 312 984 2157

STEPHEN BERNSTEIN
PARTNER
sbernstein@mwe.com
Tel +1 617 535 4062

ERIC ZIMMERMAN
PARTNER
ezimmerman@mwe.com
Tel +1 202 756 8148

UNITED KINGDOM

HAMID YUNIS
PARTNER
hyunis@mwe.com
Tel +1 44 20 7570 1438

SHARON LAMB
PARTNER
slamb@mwe.com
Tel +44 20 7577 6943

GARY HOWES
COUNSEL
ghowes@mwe.com
Tel +44 20 7577 3488

DAVID GIBSON
ASSOCIATE
dgibson@mwe.com
Tel +44 20 7577 6996

BELLA NORTH
ASSOCIATE
bnorth@mwe.com
Tel +44 20 7577 6917

FRANCE

EMMANUELLE TROMBE
PARTNER
etrombe@mwe.com
Tel +33 1 81 69 15 35

ANTHONY PARONNEAU
PARTNER
aparonneau@mwe.com
Tel +33 1 81 69 15 33

ANNE-FRANCE MOREAU
PARTNER
amoreau@mwe.com
Tel +33 1 81 69 15 53

KATYA ASCHER
COUNSEL
kascher@mwe.com
Tel +33 1 81 69 14 91

LAETITIA DE DINECHIN
ASSOCIATE
ldedinechin@mwe.com
Tel +33 1 81 69 14 83

RAPHAËLLE MONJOU
ASSOCIATE
monjou@mwe.com
Tel +33 1 81 69 14 80

LUCIE MARTIN
ASSOCIATE
lumartin@mwe.com
Tel +33 01 81 69 00 00

GERMANY

DR. STEPHEN RAU
PARTNER
srau@mwe.com
Tel +49 89 12712 320

JANA GRIEB
COUNSEL
jgrieb@mwe.com
Tel +49 89 12712 323

SYLVIA PETEREIT-KEMTER
ASSOCIATE
spetereit@mwe.com
Tel +49 89 12712 322

DR. DENIZ TSCHAMMLER
COUNSEL
dtschammler@mwe.com
Tel +49 89 12712 335

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THE MCDERMOTT TEAM THANKS THE FOLLOWING CONTRIBUTORS TO THIS SPECIAL REPORT

SCHÖNHERR RECHTSANWÄLTE GMBH

Dr. Andreas Natterer

Austria

www.schoenherr.eu

BECH BRUUN

Martin Dræbye Gantzhorn, Emil Kjeldahl Bjerregaard Bjerrum

Denmark

www.bechbruun.com

PORTOLANO CAVALLO

STUDIO LEGALE

Elisa Stefanini, Luca Gambini

Italy

www.portolano.it

HOUTHOFF

Greetje van Heezik, Jori de Goffau

Netherlands

www.houthoff.com

WARDYŃSKI & PARTNERS

Joanna Krakowiak

Poland

www.wardynski.com.pl

GÓMEZ-ACEBO & POMBO ABOGADOS, S. L. P.

Irene Fernández Puyol

Spain

www.ga-p.com

WALDER WYSS LTD.

Dr. Michael Isler, Christine Schweikard

Switzerland

www.walderwyss.com

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