Hogan Lovells

COVID-19 resources for life sciences and health care companies

Last updated on 31 August 2022

Helping you make the world healthier

Despite the professional and personal challenges that each of us is faced with due to the COVID-19 pandemic, the life sciences and health care industry world-wide is rallying to find solutions that enable us to respond to, treat, and prevent the spread of COVID-19, and as advisors we are proud to have been called upon to support you in these efforts.

We recognize the extreme challenges of moving your business and efforts forward through uncertainty in local, regional, and international efforts to address these critical public health needs. In the following pages, you will find a compilation of the guidance, client alerts, and thought leadership that our Global Life Sciences and Health Care team has published to date to address the COVID-19 crisis, along with key contacts for each subject matter.

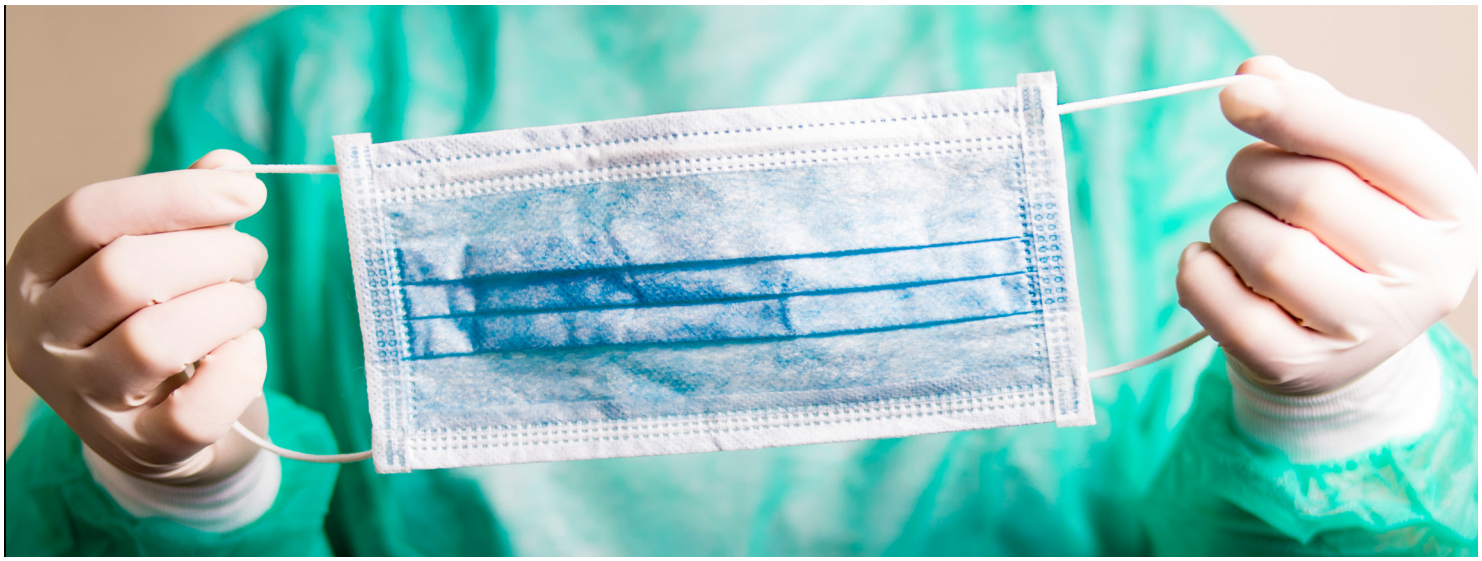
If you have questions or need support, please do not hesitate to get in touch with the key contacts listed in this guide or the Hogan Lovells lawyers with whom you regularly work.

Life Sciences and Health Care Leadership Team

Steve Abrams
Partner, Philadelphia
T +1 267 675 4671
steve.abrams@hoganlovells.com

Lynn Mehler
Partner, Washington, D.C.
T +1 202 637 6419
lynn.mehler@hoganlovells.com

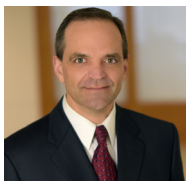
Jane Summerfield
Partner, London
T +44 20 7296 2000
jane.summerfield@hoganlovells.com



Clinical trials

We are starting to see clients consider and address a number of clinical trial-related issues and concerns caused by COVID-19 and the containment efforts including issues with travel restrictions and reimbursement, clinical trial vendors, study conduct, and supply chains. We have also assisted many of our pharmaceutical, biotechnology, and medical device clients with the development and initiation of clinical studies and expanded access programs for therapeutic products and medical devices intended to treat COVID-19 infections.

Key contact



Robert Church
Partner, Los Angeles
T +1 310 785 4646
robert.church@hoganlovells.com

Meredith Manning
Partner, Washington, D.C.
T +1 202 637 6585
meredith.manning@hoganlovells.com

Global

- FDA RWD/RWE regulatory considerations in draft guidance highlight opportunities and challenges
- The global impact of COVID-19 on clinical trials and countermeasure development

Asia

- The impact of COVID-19 on clinical trials and countermeasure development in Japan

Europe

- EDPB's new guidelines – clinical trials in the EU and COVID-19

Belgium

- Belgian AFMPS issues guidance regarding the management of clinical trials during the COVID-19 epidemic

Germany

- Additional German guidance on the management of clinical trials during the COVID-19 pandemic

Italy

- Emergency regulation for COVID-19 clinical trials and compassionate use in Italy

United Kingdom

- UK coronavirus guidance for clinical trials

United States

- FDA proposes annual summary reporting requirements for Right to Try drug sponsors, manufacturers
- HHS offers flexibility on human subjects protection regs during COVID-19 pandemic

Listen on-demand:

How COVID-19 is changing the clinical trials landscape

U.S. regulatory

Given the urgency of the outbreak, we believe Congress and the administration will work together to take additional action to bolster the fight against coronavirus and strengthen confidence in the U.S. economy. Companies and organizations can help the government fight the coronavirus but may need assistance presenting their ideas to policymakers, responding to government orders and requests for proposals, and in connecting with the government officials. That's where we can help.

FDA

- FDA plans to expand remote evaluations, record reviews post-pandemic
- Unapproved stem cell therapies remains a top FDA enforcement priority
- FDA issues new policy for evaluating impact of viral mutations on COVID-19 tests
- 2021 U.S. Regulatory Outlook: Watch For What FDA Does With EUAs – And More
- Election 2020 Snapshot: Impacts of the U.S. election for the life sciences and health care industry
- FDA extends enforcement discretion period for regenerative medicines, citing COVID-19 challenges

Medical Devices

- FDA transition plan for COVID-19 medical devices requests new submissions to agency
- Pandemic accelerates expanding role of real-world evidence in FDA medical device submissions
- CDRH plan for FY-2021 guidance prioritizes cybersecurity, CDS software, COVID-19 updates
- FDA explains how EUA medical devices can electronically comply with AE reporting requirements
- FDA releases enforcement policy for VTM and PBS/saline transport media during the COVID-19 pandemic
- QMS eAudits and remote inspections

Pharmaceuticals and Biotechnology

- PREVENT Pandemics Act to build pandemic capabilities and implications for medical product developers
- FDA sheds light on benefit-risk assessments to inform decision-making throughout product lifecycle
- FDA issues list of essential medicines and countermeasures required under Buy American Executive Order
- FDA cracks down on pharmaceutical firm for misbranding drug as COVID-19 treatment
- Navigating the new 'buy American' drug landscape: opportunities for some, pitfalls for others

Health and Human Services (HHS)

- HHS again permits FDA review of LDTs, updates EUA policy for laboratory developed tests
- MDRP multiple best prices option and territory exclusion update plus Part B discarded drug refund
- National Academies release early draft framework for equitable COVID-19 vaccine allocation
- HHS ends EUA requirement for Laboratory Developed Tests; FDA may continue to assert authority
- Stark Law waivers, HHS-OIG announcement offer health care providers greater flexibility during COVID-19 pandemic
- HHS extends COVID-19 public health emergency determination

American Rescue Plan

- White House announces COVID-19 safety measures for onsite federal contractors
- American Rescue Plan Act's COBRA health care premium subsidy
- Congress passes, and the President signs, a sweeping $1.9 trillion COVID-19 relief package
- House committees move swiftly to pass COVID-19 relief legislation
- More stimulus coming: President-elect Biden lays out immediate plans for additional COVID relief

- Braving a perfect storm: Avoiding legal and reputational risk associated with CARES Act oversight and investigations
- At long last, landmark OTC Drug reform legislation is enacted

Emergency Procurement/ Defense Production Act

- Buy American EO applies domestic preferences for "essential medicines" and "medical countermeasures"
- Emergency government contracting: FEMA issues regulation implementing Defense Production Act
- Emergency Federal contracting tools streamline medical device, drug acquisition

PREP Act

- U.S. courts continue to apply narrower view of PREP Act immunity
- Fifth Amendment to PREP Act Declaration expands "covered persons" to increase workforce authorized to administer COVID-19 vaccines
- HHS issues Fourth Amendment to PREP Act Declaration significantly expanding scope of liability protections

Key contacts

Janice Hogan
Leader, Global Regulatory Practice, Philadelphia
T +1 267 675 4611
janice.hogan@hoganlovells.com

Ronald Wisor
Leader, Health Practice, Washington, D.C.
T +1 202 637 5658
ron.wisor@hoganlovells.com

Lynn Mehler
Leader, Pharmaceuticals and Biotechnology Practice, Washington, D.C.
T +1 202 637 6419
lynn.mehler@hoganlovells.com

Randy Prebula
Leader, Medical Device and Technology Practice, Washington, D.C.
T +1 202 637 6548
randy.prebula@hoganlovells.com

Joy Sturm
Partner, Government Contracts, Washington, D.C.
T +1 202 637 5990
joy.sturm@hoganlovells.com

David Winter
Co-leader, Fund Formation Practice, Washington, D.C.
T+1 202 637 6511
david.winter@hoganlovells.com

Listen on-demand:

- *Talking the Cure* podcast series
- Impacts of the U.S. election for the life sciences and health care industry
- "Buy American" panel discussion: How will the Executive Order impact drug and device companies, and what should you do about it?
- How landmark OTC drug reform legislation will affect your business
- Paths for medical device companies to partner with the federal government
- The Defense Production Act and the PREP Act: Key tools in the fight against COVID-19

Global supply chain

The COVID-19 pandemic has disrupted supply chains, created delays and disruption, and caused businesses worldwide to consider invoking force majeure. The magnitude and complexity of supply chain problems created in the wake of COVID-19 are unprecedented in the modern era. To navigate this crisis, businesses need to assess risk, consider pragmatic and tailored solutions, and act promptly to mitigate damage and safeguard vital business functions.

Asia

- Chinese regulators announce new requirements for exports of medical supplies and nonmedical masks

Europe

- Combating COVID-19: Government powers for safeguarding supply of critical products and potential conversion of production

Germany

- Facility-based mandatory vaccination applies from March 16, 2022
- Proposed measures in Germany for safeguarding supply of critical goods in the combat against COVID-19

India

- COVID-19 - Implications for the Indo-German supply chain

Italy

- Converting your production to make masks and disinfectants? Our legal guide for Italy

United Kingdom

- Blockchain – the vaccine to pharma's supply chain issue

United States

- FDA explains when medical device makers must notify of an interruption in manufacturing
- USTR opens process for possible reinstatement of product exclusions from China Section 301 tariffs
- FDA leads global work on continuous manufacturing approaches to up quality, supply chain resilience
- FSIS Issues Notice on Measures to Protect Inspection Program Personnel from COVID-19 Infection
- Biden Administration releases First 100-day review, spurring immediate actions for U.S. supply chains
- FDA expands mutual reliance and harmonization with foreign regulators for inspectional oversight
- FDA issues guidance on conducting remote interactive evaluations during the COVID-19 pandemic
- New FDA inspection program released for "streamlined approach" for combination product cGMP
- Increased use of virtual tools, optimized inspectional activities, & enhanced supply chain oversight
- FDA advises drug manufacturers on best practices for restarting operations during COVID-19 pandemic
- FDA updates industry on what drug & biologic inspections will occur during COVID-19 pandemic
- Five key takeaways from the Senate hearing on FDA oversight of foreign drug manufacturing
- USTR invites comments on potential Section 301 exclusions in response to the coronavirus
- DOJ Antitrust Division and FBI to investigate collusion stemming from supply chain disruptions
- The Department of Defense's report on Securing Defense-Critical Supply Chains

Key contacts

Mike Heyl
Partner, Washington, D.C.
T +1 202 637 5456
mike.heyl@hoganlovells.com

Ajay Kuntamukkala
Partner, Washington, D.C.
T +1 202 637 5552
ajay.kuntamukkala@hoganlovells.com

Jane Summerfield
Partner, London
T +44 20 7296 2000
jane.summerfield@hoganlovells.com

Listen on-demand:

- Managing supply chain risks effectively in time of crisis
- COVID-19-Challenges for supply chains in international business relationships: An Indo-German perspective
- Managing supply chain disruption in the life sciences and health care industry
- COVID-19 and the supply chain – contracts and force majeure

Virtual health

As the world responds to the COVID-19 pandemic, physicians and patients are increasingly turning to virtual health solutions, including telehealth and remote monitoring, as a central facet of health care delivery. Providers are reaching across state and national borders using technology to provide medical services via email, interactive video, and apps that facilitate diagnosis, consultation, treatment, monitoring, and even medical research.

Key contacts

William Ferreira
Partner, Washington, D.C.
T +1 202 637 5596
william.ferreira@hoganlovells.com

Brooke Bumpers
Counsel, Washington, D.C.
T +1 202 637 5800
brooke.bumpers@hoganlovells.com

- Health care trends in a post-pandemic economy
- Reforms to software-based medical devices take effect
- EU Member States agree on interoperability specifications for national COVID-19 tracing apps
- Virtual Health: What's on the horizon for telehealth and remote monitoring
- Deciphering International Telemedicine Regulations
- Expanded access to telehealth services during the COVID-19 pandemic
- The False Claims Act Guide: 2021 and the road ahead

Talking the Cure podcast series:

- Discussing the current surge of digital health innovations in Europe
- Discussing the rise of telehealth in the life sciences and health care industry

Listen on-demand:

- What's on the horizon for telehealth and remote monitoring

EU regulatory

To help combat the threat posed by the COVID-19 outbreak, the European Commission announced the publication of new guidance aimed at assisting manufacturers to increase production of essential medical equipment.

Europe

- Proposal for a new Regulation on Substances of Human Origin (SoHO Regulation)
- IoT in the EU: Lessons from COVID-19, and next steps for liability and regulation
- Remote QMS audits under the MDR are finally allowed by the European Commission
- The European Commission proposes a new Pharmaceutical Strategy for the EU
- EC working group provides guidance concerning COVID-19 product claims on cosmetic products
- Towards a revision of current tissue, blood, and cells legislation in the European Union
- EMA publishes list of COVID-19 treatments that have been the subject of the Agency's guidance
- Regulation of COVID-19 Tests in the EU: when do you need to involve a Notified Body?
- COVID-19: Summary of National Payment Moratoria Measures in Europe
- European Commission issues guidance on lawful placing on the market of PPE and medical devices
- EMA recommends expanding remdesivir compassionate use to non-ventilated COVID-19 patients
- MDCG issues guidance for ventilators and related accessories
- The European Commission extends export restrictions on Personal Protective Equipment
- EMA publishes guidance providing regulatory adaptations for MAHs in the context of COVID-19
- European Commission issues guidelines for COVID-19 in vitro diagnostic tests and their performance

Belgium

- The AFMPS issues third version of the Alternative Test Protocol for surgical face masks
- The AFMPS further extends measures to combat shortages of medicinal products by another month
- AFMPS recalls the risks associated with the use of chloroquine and hydroxychloroquine
- AFMPS announces continued use of medications believed to aggravate COVID-19 after EMA's confirmation

Germany

- Chambers Life Sciences 2022 Guide – Germany Trends and Developments
- Paid leave for corona vaccinations?
- New Rules: German government passes far-reaching expansion of foreign investment control
- Overview of EU, German federal and German states' financing measures for companies responding to COVID-19

Italy

- National Recovery and Resilience Plan (PNRR): "Mission Culture"
- Impact of coronavirus on loans in Italy
- Italy – COVID-19 pandemic: new measures issued by the Italian Government

Poland

- Lifting the state of epidemic - effects on economic entities
- New COVID-19-related rules impacting the pharmaceutical industry in Poland

Hungary

- Hungary lifts FDI veto after pressure from EU Commission – all's well that ends well?

Russia

- The Supreme Court of Russia to Clarify Certain COVID-19 Related Legal Issues
- Russian regulatory trends in the pharma industry in light of the outbreak of COVID-19

Spain

- New reform of the Foreign Direct Investment regime in Spain
- Spain's AEMPS clarifies position on hydroxychloroquine, echoing statements of EMA and Lancet
- The Spanish insurance sector in the light of the COVID-19 pandemic
- Impact of Spanish government's COVID-19 measures on life sciences companies operating in Spain

United Kingdom

- The UK's new health data strategy
- The Legacy of Lockdown: Making law and policy post COVID-19
- As you were - implications for employers of the "Living with COVID" plan
- Keep a lid on it - reducing respiratory infections in the workplace

Netherlands

- Medicines shortages: Dutch Ministry publishes Policy Rule; EMA calls for MAHs to register contact

Key contacts

Hein Van den Bos
Partner, Amsterdam
T +31 20 55 33 675
hein.vandenbos@hoganlovells.com

Fabien Roy
Partner, Brussels
T +32 2 505 0970
fabien.roy@hoganlovells.com

Dr. Jörg Schickert
Partner, Munich
T +49 89 290 12 198
joerg.schickert@hoganlovells.com

Listen on-demand:

- Making law and policy post COVID-19: changing machinery of government
- Making law and policy post COVID-19: regional fragmentation

Additional resources

You can access all of the firm's latest publications, webinars, and useful tools on the Hogan Lovells COVID-19 Topic Center.

Global

- How to get vaccine passports right
- Key data protection challenges for 2021
- Looking ahead to 2021: AI – A brave in world?
- A global Privacy and Cybersecurity guide
- COVID-19: A global guide

Antitrust

- COVID-19 and cooperation: Changes in competitive law?
- President Biden issues sweeping Executive Order to promote competition
- Post-pandemic antitrust - what to expect and what to do
- Reducing antitrust risk of collaborations during the COVID-19 pandemic

Asia

- Changes in insurance regulation: Mainland China / Hong Kong / Singapore / Indonesia / Vietnam
- Outsourcing, technology transformation and cloud in Asia: the legal and regulatory essentials 2021
- Asia Pacific data protection and cybersecurity guide 2021
- Southeast Asia – looking ahead into 2021
- Hong Kong government announces long-awaited corporate rescue regime
- A review of MAC Clauses in a COVID-19 Climate in Japan
- A closer look - opportunities for foreign investors in China insolvency
- China takes a pragmatic approach to relaxing regulation of the life sciences sector during COVID-19

Corporate Governance

- Second extension of the temporary measures allowing for virtual meetings of corporate bodies
- Is Your Board Ready? 10 tips for boards facing an emerging crisis

Employment

- Playing the COVID card: COVID-related force majeure litigation in U.S. courts
- D.C. issues new mandatory COVID-19 leave poster
- Fair to dismiss unvaccinated care home worker
- Supreme Court blocks OSHA vaccine-or-test mandate; allows enforcement of CMS healthcare mandate
- OSHA "vaccination-or-test" ETS stay lifted – how should covered employers respond?
- NYC issues employer vaccine mandate
- D.C. requires paid COVID-19 vaccination leave, extends DCFMLA leave for COVID-19-related reasons
- Federal vaccine mandates enjoined nationwide: Should employers pause mandatory vaccination efforts?
- Navigating OSHA ETS Uncertainty – What Happens Next
- Second Circuit lifts injunction on NY health care vaccine mandate
- OSHA ETS finally issued: large employers must mandate vaccination or weekly testing by January 4
- Task Force provides some flexibility for federal contractors regarding vaccine mandate requirements
- Mandatory health pass (Green Pass) in Italy to enter workplaces - Work & Safety against COVID-19

- New COVID-19 executive order expands requirements for U.S. government contractors
- COVID-19 designated as an "airborne infectious disease"; NY Hero Act plans must be implemented
- COVID-19: Global employee vaccination and testing guide
- Considerations for crafting a post-pandemic return-to-office policy in Colorado
- Washington and Oregon join California in mandating vaccination for health care workers
- CDC flip-flops on mask guidance for fully vaccinated individuals; what should U.S. employers do?
- COVID-19 considerations: vacation and PTO
- COVID-19 and vaccinations – employment and data privacy considerations
- CDC Issues Testing Strategy for COVID-19 in High-Density Critical Infrastructure Workplaces
- COVID-19: The country is opening up – what does this mean to your business?

Finance

- Carried interest schemes for asset managers
- EU Version of DIP Financing – discussion in light of the US Framework
- COVID-19: Measures taken by financial supervisory authorities in certain jurisdictions
- COVID-19: Overview of EU and Spain's financing measures to protect companies
- COVID-19: Tracker for SEC and related developments for U.S. public companies

Insurance

- The COVID-19 experience: Insurance in a post-pandemic world
- The UK Supreme Court decides on COVID-19 business interruption coverage

Litigation Landscape podcast series:

- An ethical return to the workplace
- Preparing yourself for virtual hearings
- Key considerations for employers
- Market abuse: in the regulatory spotlight

Listen on-demand:

- Navigating the return from lockdown in the UK
- U.S. employment considerations
- COVID-19 webinar series – Insurance

How we can help

The COVID-19 pandemic requires quick-turn, out-of-the-box approaches to mitigating a global health crisis that changes daily. We are helping our clients navigate the minefield of regulations around the world and work with the relevant government agencies to develop creative approaches that respond to the immediate needs and potentially alter the long-term implications of this disease.

Whether you are managing disruptions in your supply chain or clinical trials, are looking to increase access to digital tools, or are exploring pathways to expedite regulatory approvals for critical medical products such as tests, therapies, vaccines, and personal protective wear, our team is at the ready to help.

Led by our world-renowned Global Regulatory practice, we have a dedicated team of lawyers and regulatory specialists who have long-standing relationships and experience with key U.S. and EU regulatory agencies, as well as in-depth knowledge of health care policies and legislation, privacy and cybersecurity requirements and threats, and new developments in international trade and government contracts.

Our Global Regulatory team is supported by lawyers from our Corporate, Litigation, and Employment practices who are advising on contracting issues, crisis leadership, liability and risk management, and employment considerations.

A selection of our experience

- Advocating to FDA on behalf of multiple clients regarding regulatory issues related to recent FDA guidance on alcohol-based hand sanitizers during the COVID-19 emergency.
- Assisting multiple clients with regards to Emergency Use Authorization (EUA) submissions for COVID-19 diagnostic tests, treatments, and surgical masks.
- Assisting manufacturers regarding the application of PREP Act liability immunity in connection with large scale manufacture and supply of medical devices and drugs needed for the COVID-19 response.
- Advising manufacturers in connection with orders of medical devices and drugs by FEMA and HHS for the Strategic National Stockpile, including rated orders issued under the Defense Production Act.
- Advising clients on the impact of COVID-19 on clinical trials, such as patient travel to clinical sites and potential force majeure claims from clinical trial vendors.
- Advising clients on the use of telehealth and other digital health applications to monitor COVID-19 patients in their homes.
- Advising clients on drug shortage and supply chain disruption due to export bans of certain medicinal products.
- Advising clients in drafting COVID-19 policies, including employee communications, privacy requirements, travel policies, etc.
- Advising clients on the regulatory pathway and expanded coverage for home infusions for immunocompromised patients.
- Advising non-traditional life sciences and device companies on the requirements and logistics of producing critical need supplies.
- Assisting new-market entrants on the procurement of supplies from overseas and helping them navigate the FDA and CBP requirements to import these products.
- Advised **Vayu Global Health Innovations** in obtaining an EUA from FDA that allowed its bubble CPAP (bCPAP) device to be immediately distributed to hospitals to help alleviate the ventilator shortage associated with COVID-19.
- Teamed up with regulatory consultant Wanda Henry Co**.** to advise **Sansure Biotech, Inc.** in its FDA EUA for a molecular diagnostic test kit for COVID-19.

- Advising **Ford Motor Company** in its collaboration with GE Healthcare to help reinforce the Strategic National Stockpile and to support the treatment of coronavirus patients.
- Advised the **Kraft Group/New England Patriots** to obtain the necessary government approvals to pick up 1.3 million N95 masks from Shenzhen, China, and deliver them to the Commonwealth of Massachusetts.
- Advised **Valneva** on its partnership with the UK Government for its inactivated adjuvanted COVID-19 vaccine, VLA2001.
- Advised **Lucira Health** on obtaining the first FDA Emergency Use Authorization for an at-home COVID-19 testing kit.

Alicante
Amsterdam
Baltimore
Beijing
Birmingham
Boston
Brussels
Budapest*
Colorado Springs
Denver
Dubai
Dusseldorf
Frankfurt
Hamburg
Hanoi
Ho Chi Minh City
Hong Kong
Houston
Jakarta *
Johannesburg
London
Los Angeles
Louisville
Luxembourg
Madrid
Mexico City
Miami
Milan
Minneapolis
Monterrey
Moscow**
Munich
New York
Northern Virginia
Paris
Perth
Philadelphia
Riyadh*
Rome
San Francisco
São Paulo
Shanghai
Shanghai FTZ*
Silicon Valley
Singapore
Sydney
Tokyo
Ulaanbaatar*
Warsaw
Washington, D.C.

*Our associated offices
Legal Services Centre: Berlin
*** Progressing with a wind down of operations in Moscow

For additional information, visit:

www.hoganlovells.com/life-sciences

@HLLifeSciences

Hogan Lovells Life Sciences and Health Care