SQUIRE PATTON BOGGS

Local Connections. Global Influence.

Life Sciences

We counsel many of the world's largest life sciences companies.

We count among our clients more than 500 companies engaged in the industry, including many of the top 20 life sciences companies worldwide. We provide exceptional legal, regulatory, legislative and strategic advice on a wide range of industry issues and related matters around the globe, helping our clients capitalize on opportunities and handle the challenges of a competitive and volatile business environment.

Why Choose Us

- We have deep expertise advising medical device manufacturers, pharmaceutical companies, biotech companies, CROs, public universities and others in a full range of legal matters, including corporate and commercial transactions, intellectual property, dispute resolution, regulatory compliance and clinical trials.
- Our focus on creativity, innovation and insight is balanced against a sound foundation of the law and a deep understanding of the life sciences industry and relevant regulatory issues.
- We stress the importance of collaboration across practices and disciplines, as well as among our many worldwide locations. This enables us to draw expertise from numerous backgrounds and specialties for the ultimate benefit of our clients.
- Our practice structure enables us to bring you seamless, coordinated legal advice and advocacy on a cost-effective basis wherever you may need it.
- We offer one of the most global legal platforms for serving our clients' needs, with more than 40 Offices across four continents.

Our Approach

We regularly handle matters that span the life sciences industry and involve products such as:

- Pharmaceuticals, including plasma-derived biopharmaceuticals, for a wide variety of indications
- Medical devices and systems
- Stem and regenerative cell therapy
- Home healthcare products
- Metabolic syndrome treatments
- Drug delivery systems
- Digital imaging products
- Therapeutics
- Drug and medical device manufacturing technology

Our Clients

We serve a broad range of clients, including:

- Manufacturers
  - Biotechnology
  - Medical devices
  - Pharmaceutical
- Distributors
- Healthcare organizations
- Start-up companies
- Joint ventures
- Academic medical centers
- Contract research organizations (CROs)
- Clinical and animal laboratories
- Health information companies
- Private equity, venture capital and hedge fund firms
- Investment banks
- Sovereign investment funds
- Family investment offices

Whether just starting up or continuing a long tradition, life sciences businesses seek our experienced counsel for such activities as developing and marketing their innovative products and services, conducting cross-border technology transfers, complying with regulatory authorities and getting their products to market quickly.

We represent clients in matters ranging from registering, protecting and defending patents to setting up joint ventures and providing general corporate counsel. In addition, given our substantial experience in working with the relevant committees in the US Congress and regulatory agencies, we help our clients understand how potential legislation or regulations might affect products they are thinking about bringing to market or already are in the market. Lawyers work closely with clients from an idea's conception through commercialization, including counsel on:

- Early stage product development and pre-market clinical trials
- Capital formation, including private equity and grant funding
- Execution of appropriate collaborations and agreements, including structuring strategic alliances and licensing relationships
- Compliance with ever-changing regulatory requirements throughout the global marketplace
- Protection of intellectual property in many countries, including trade secrets and patents
- Expedited processing to bring products to local and international markets
- Marketing and distribution

Clinical Trials

Our Healthcare and Life Sciences teams work closely with clients to support the timely, efficient and compliant launch of multinational clinical trials. These trials support marketing approval applications and meet post-marketing clinical investigation requirements around the world. We help pharmaceutical, biotechnology and medical device companies, hospitals, pharmacies, contract research organizations and academic research institutions conduct clinical trials in emerging jurisdictions of interest, including Russia, Poland, Hungary, China, Brazil, Argentina and Chile, as well as providing support in the US, Japan, the European Union, the Middle East and Africa. As part of our counsel to companies involved with clinical trials, we:

- Draft and negotiate clinical trial agreements between sponsors and CROs and other service providers
- Provide field-tested clinical trial agreement templates
- Help companies design and implement standard operating procedures (SOPs)
- Advise on regulatory and ethical issues associated with clinical trials
- Counsel on a wide variety of other issues, including sponsor liability, compensation to doctors and hospitals, compensation to participants in clinical trials and related data protection issues

Commercial Agreements

We are recognized leaders in assisting industry clients with a range of commercial transactions and related requirements.

- Distribution and licensing agreements for drugs, medical devices, mobile medical devices, home healthcare products, diagnostic products, and cosmetics and dietary supplements
- Supply agreements, including for drugs, medical devices, home healthcare products and diagnostic equipment
- Contract manufacturing agreements
- Outsourcing agreements, including agreements for satisfying pharmacovigilance obligations

Corporate and Transactional

Life sciences clients looking to invest or expand their operations benefit from our extensive expertise handling large corporate and financing transactions. We have handled these matters for more than 100 years and routinely advise clients engaged in every type of corporate transaction, offering legal advice on corporate mandates across the spectrum, ranging from smaller, more straightforward deals to complex multibillion-dollar and multidisciplinary transactions.

This includes mergers, acquisitions and divestitures, frequently involving multiple jurisdictions, as well as joint ventures, transfers of ownership, asset purchases and the integration of existing facilities and related businesses. We provide integrated management of the commercial, compliance and regulatory issues inherent in a wide variety of transactions. This involves providing the full range of legal services necessary to complete a particular transaction, in a cost-effective, timely manner based on an extensive resume of prior deals.

We also advise industry clients on the establishment and maintenance of corporate entities and have substantial experience in helping start-up companies to secure public and private financing through equity and debt arrangements, whether through private equity funds, venture capitalists, foreign direct investment or alternative sources such as grants or partnership agreements.

Data Privacy

Our team counsels clients on data breaches and data breach notification requirements, as well as compliance with national regulations such as HIPAA. We also help life sciences organizations to do business on a global scale, and other clients dealing with international healthcare-related issues, to achieve compliance with international cross-border data privacy rules such as the European Union Privacy Directive. We regularly assist life sciences clients in developing workable privacy compliance programs and provide counsel on specific privacy and data protection issues that arise in connection with activities involving the processing, transfer and storage of personal data, such as:

- Product development
- Employee relations
- New technologies
- Website management
- Data licensing arrangements

US Food and Drug Administration (FDA)

We represent clients in all FDA-regulated areas, including prescription drugs, biologics, over-the- counter drugs, nutritional supplements, food, medical devices and cosmetics. Our client work spans a wide spectrum of matters, including advising on effective strategies to obtain approval to market a new product, assisting in determining which regulatory pathway to follow, assessing regulatory and business risks associated with a particular strategy, responding to and defending enforcement matters, initiating and participating in rulemakings, and counseling on public policy issues, as well as cost-effective due diligence.

Intellectual Property

Our renowned Intellectual Property & Technology Practice actively protects and enforces the IP rights of life sciences companies of all sizes and defends them from charges of violating the IP rights of others. We assist in the review, drafting, analysis and revision of license agreements; acquisition of worldwide IP rights; IP protection strategies; and patent prosecution. Our lawyers guide patent applications through the approval process and obtaining broad, valuable patent protection, obtaining trademark protection, drafting and implementing licensing and distribution agreements, and litigating to enforce patent or trademark rights or to defend against the claims of others.

This work includes:

- License, development and commercialization agreements
- Joint R&D agreements
- Acquisition of IP rights globally
- IP protection strategies, including freedom to operate searches and analysis
- US patent applications and prosecution
- US-Japan Patent Prosecution Highway procedures
- University-private company joint development and license agreements
- Intellectual property-related disputes

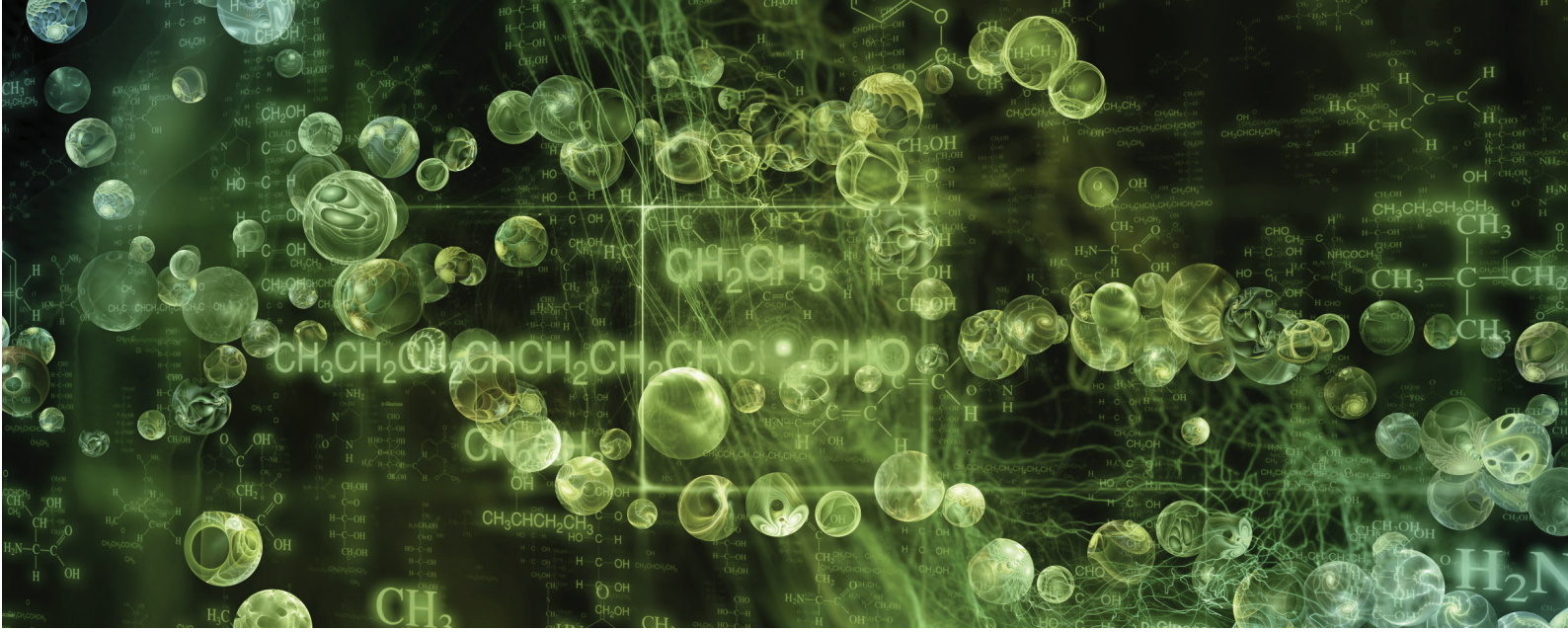
International Dispute Resolution

Life sciences businesses working across borders need sophisticated counsel when conflicts arise. This is the case in business transactions and contract disputes or disputes related to foreign patients. We are one of only a small number of legal practices able to serve the needs of clients on a truly global basis, with long-established practice groups throughout the Americas, Europe and Asia Pacific. We have extensive experience handling arbitration matters before the International Chamber of Commerce (ICC) and other similar organizations involving matters including breach of contract, IP rights violation, product liability and derivative lawsuits.

Legislative Advocacy and Regulatory Policy

Nationally recognized for our advocacy and regulatory knowledge, we have strong ties to leading policymakers and an impressive track record of success. We have four former house members on our team, Republican and Democrat, three of whom served on committees with jurisdiction over the healthcare and life sciences sectors. Part of our reputation can be attributed to our long-standing working relationships with members of Congress and senior staff on each of the House and Senate health-related committees, as well as congressional leadership. These valuable relationships often enable us to achieve clients' desired changes with either statutory changes or committee report language. Members of our team often participate in the development of legislation on issues of concern to our clients and are frequently consulted as a resource for policy analysis. Given this depth of experience, we help our clients understand how potential legislation or regulations might affect products they are thinking about bringing to market or already are in the market.

Our practice also has a history of building and managing large coalitions of like-minded companies in the healthcare sector, as well as those from across different industries that face the same threats. Our deep understanding of legislative and regulatory processes, coupled with our ability to manage the coalition format, has enabled us to help large coalitions achieve impressive victories time and again.



Litigation

We offer clients an exceptional combination of litigation and life sciences capabilities to resolve multifaceted legal matters with a deep understanding of the healthcare business. We are ideally positioned to handle all types of litigation life science companies might encounter around the world, including civil, commercial and intellectual property litigation. Our lawyers counsel and defend clients faced with pending and threatened litigation and governmental investigations stemming from sweeping regulatory reform and significant advancements in science and technologies focused on patient care and services. We represent clients in state and federal courts through jury and bench trials, in administrative procedures and hearings, and through the appellate process. These cases include a wide variety of lawsuits, including complex, bet-the-company litigation. We advise clients on liability and risk mitigation options related to corporate agreements, such as mergers, acquisitions and affiliations of all kinds, and on precedent-setting issues and rules shaping the industry. We also counsel and defend clients against allegations of fraud and abuse and antitrust price-fixing, and assist clients as they navigate healthcare regulatory and licensure challenges at both the federal and state levels.

Products Liability

Our team is known for its expertise in the field of pharmaceutical and medical products liability. We often represent companies in complex litigation involving bodily injury, property damage or economic loss allegedly caused by defective products, pharmaceuticals, cardiac devices or exposure to toxic substances.

We serve as trial, appellate and national coordinating counsel in high-visibility product liability cases, defending claims against manufacturers and sellers of prescription medications, over-the-counter products and medical devices such as:

- Trasylol®
- ACTOS®
- Baycol®
- PPA-containing products
- VIOXX®
- Factor VIII blood clotting products
- OxyContin®
- Spinal implants
- Omniscan®

Regulatory Counsel

Tougher international, federal and state regulations challenge healthcare and life sciences industry players every day. Lawyers in all our offices around the world regularly handle the regulatory issues inherent in bringing life sciences products to market. Our lawyers are familiar with all relevant regulations and can help with compliance issues and in negotiations with regulators and investigators around the world. We advise on every facet of regulatory compliance from new product inception to international distribution.

We develop and execute clients' offensive and defensive regulatory strategies by engaging the Centers for Medicare and Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Health & Human Services – Office of Inspector General (HHS-OIG), the National Institutes of Health (NIH), the Food & Drug Administration (FDA), the Federal Trade Commission (FTC) and the Department of Defense (DOD), among other federal agencies, as well as similar agencies outside the US.

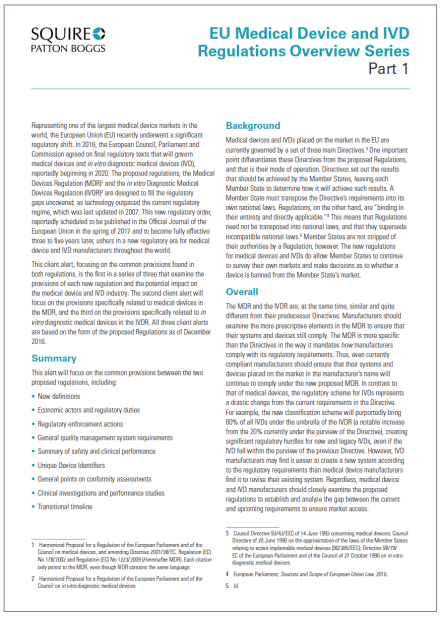
In Europe, our lawyers monitor EU regulations and assess their likely impact on specific clients. We regularly coordinate with the European Medicines Agency, the European Commission and national regulatory authorities to stay abreast of regulatory developments and guide clients and their products through the myriad details surrounding the regulatory compliance process.

Our experience extends across a wide range of issues and regulations, including:

- 510(k) premarket clearances
- Advertising and promotion
- Agency enforcement
- Anti-bribery and anticorruption
- Clinical best practices
- Cosmetic approvals and cosmetic labeling issues
- Dietary supplements
- Drugs and biologics
- Food and drug regulation
- Food safety
- Foreign market entry
- Good Manufacturing Practice (GMP) and Quality System Regulation (QSR)
- Government procurement issues
- Import/export issues
- Internal investigations
- Medicare, Medicaid and children's health insurance program coverage and reimbursement
- Mergers, acquisitions and divestitures
- National and state healthcare regulations
- Off-label uses for drugs and medical devices
- Pharmaceutical, biologic and medical device approvals – pre-clinical, clinical and post-marketing
- Pharmacovigilance regulations
- Product recalls and market withdrawals
- Reimbursement issues
- Responding to subpoenas

Thought Leadership

Always in tune with developments in the healthcare and life sciences industry, we respond to breaking news events through briefings and publications emailed to our clients or posted on our website or our *Triage Health Law* blog. Typical developments may include new legislation, impending laws and court rulings that have potential impact on the organizations we represent. These swiftly executed communications give clients an overview of the event and analysis of its possible effects on their business. Our lawyers are frequent speakers and panelists at major industry conferences and webinars, authors of white papers and articles for industry publications, as well as sought-after commentators by the media on evolving industry topics and issues.



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EU Medical Device and IVD Regulations Overview Series
Part 1

Representing one of the largest medical device markets in the world, the European Union (EU) recently underwent a significant regulatory shift. In 2016, the European Council, Parliament and Commission agreed on final regulatory texts that will govern medical devices and *in vitro* diagnostic medical devices (IVD), reportedly beginning in 2020. The proposed regulations, the Medical Devices Regulation (MDR)[1] and the *in vitro* Diagnostic Medical Devices Regulation (IVDR)[2] are designed to fill the regulatory gaps uncovered, as technology outpaced the current regulatory regime, which was last updated in 2007. This new regulatory order, reportedly scheduled to be published in the Official Journal of the European Union in the spring of 2017 and to become fully effective three to five years later, ushers in a new regulatory era for medical device and IVD manufacturers throughout the world.

This client alert, focusing on the common provisions found in both regulations, is the first in a series of three that examine the provisions of each new regulation and the potential impact on the medical device and IVD industry. The second client alert will focus on the provisions specifically related to medical devices in the MDR, and the third on the provisions specifically related to *in vitro* diagnostic medical devices in the IVDR. All three client alerts are based on the form of the proposed Regulations as of December 2016.

Summary

This alert will focus on the common provisions between the two proposed regulations, including:

- New definitions
- Economic actors and regulatory duties
- Regulatory enforcement actions
- General quality management system requirements
- Summary of safety and clinical performance
- Unique Device Identifiers
- General points on conformity assessments
- Clinical investigations and performance studies
- Transitional timeline

1 Harmonized Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/38/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (Hereinafter MDR). Each citation only points to the MDR, even though IVDR contains the same language.

2 Harmonized Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices.

Background

Medical devices and IVDs placed on the market in the EU are currently governed by a set of three main Directives.[3] One important point differentiates these Directives from the proposed Regulations, and that is their mode of operation. Directives set out the results that should be achieved by the Member States, leaving each Member State to determine how it will achieve such results. A Member State must transpose the Directive's requirements into its own national laws. Regulations, on the other hand, are "binding in their entirety and directly applicable."[4] This means that Regulations need not be transposed into national laws, and that they supersede incompatible national laws.[5] Member States are not stripped of their authorities by a Regulation, however. The new regulations for medical devices and IVDs do allow Member States to continue to survey their own markets and make decisions as to whether a device is banned from the Member State's market.

Overall

The MDR and the IVDR are, at the same time, similar and quite different from their predecessor Directives. Manufacturers should examine the more prescriptive elements in the MDR to ensure that their systems and devices still comply. The MDR is more specific than the Directives in the way it mandates how manufacturers comply with its regulatory requirements. Thus, even currently compliant manufacturers should ensure that their systems and devices placed on the market in the manufacturer's name will continue to comply under the new proposed MDR. In contrast to that of medical devices, the regulatory scheme for IVDs represents a drastic change from the current requirements in the Directive. For example, the new classification scheme will purportedly bring 80% of all IVDs under the umbrella of the IVDR (a notable increase from the 20% currently under the purview of the Directive), creating significant regulatory hurdles for new and legacy IVDs, even if the IVD fell within the purview of the previous Directive. However, IVD manufacturers may find it easier to create a new system according to the regulatory requirements than medical device manufacturers find it to revise their existing system. Regardless, medical device and IVD manufacturers should closely examine the proposed regulations to establish and analyze the gap between the current and upcoming requirements to ensure market access.

3 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC); Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

4 European Parliament, *Sources and Scope of European Union Law*, (2016).

5 *Id.*

Seminars and Workshops

Throughout the year, we offer you the opportunity to meet with members of our Healthcare and Life Sciences teams and other industry professionals at firm-hosted seminars and workshops that provide insight into current issues and hot topics within the industry. Our professionals also participate in major global events related to the industry. Details about all of our previous and upcoming events can be found on our website.

Contacts

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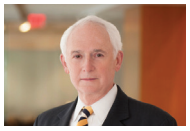

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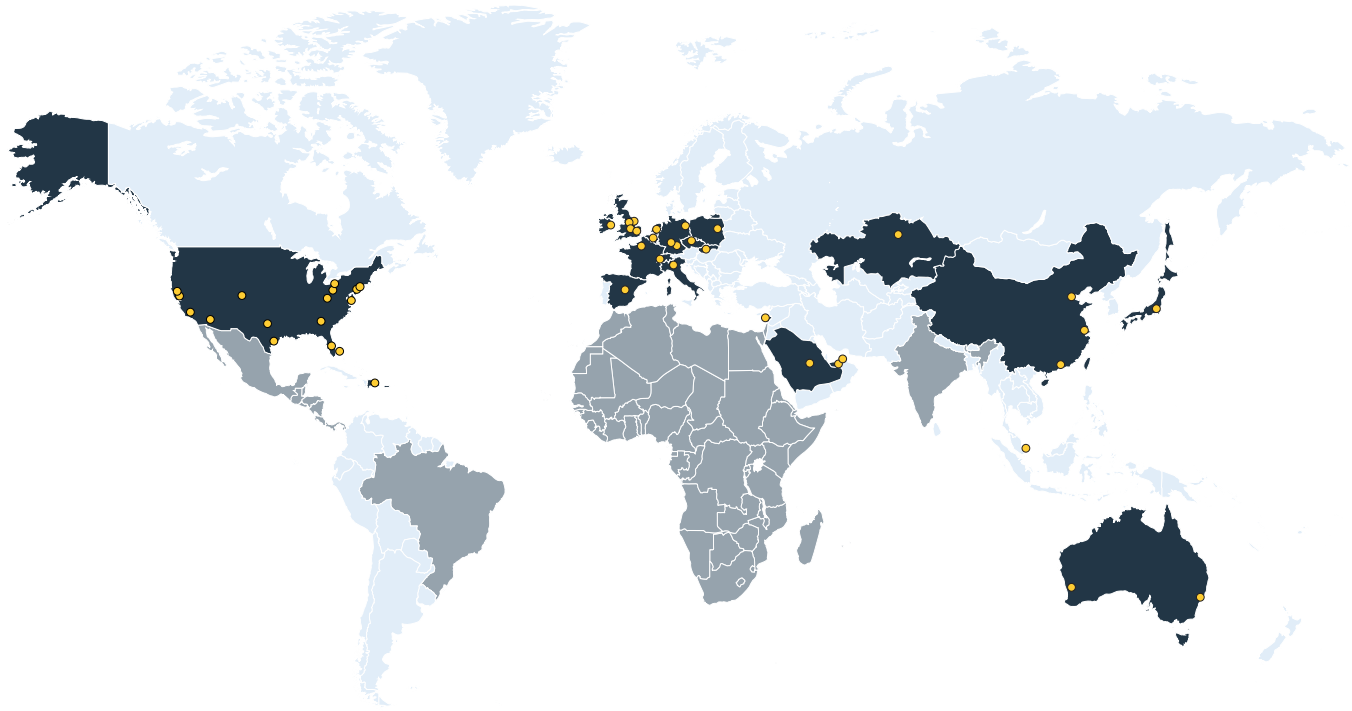
We Are Where You Are

More Than 40 Offices Across Four Continents



Squire Patton Boggs Locations

Regional Desks and Strategic Alliances

Our Locations

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