McDermott Will & Emery

ISSUE 3 2018

IN
International News

FOCUS ON

Life Sciences

Risky Business: Due Diligence for Life Sciences Companies

Tracking Trends in Global Collaboration

Business as Usual: Drug Companies prepare for Brexit

McDermott Will & Emery

IN International News

EDITOR
Andrea Hamilton
Partner
Brussels
+32 2 282 35 15
ahamilton@mwe.com

PUBLICATION EDITORS
Aileen Devlin
Kate Hinze

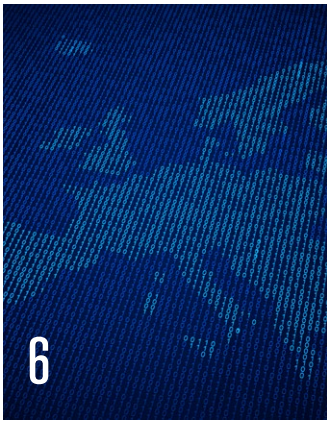
CREATIVE SERVICES
Jane Hanlon
Valerie Flemming

The life sciences industry has changed dramatically in recent years, keeping pace with developments in technology; for example, one can now sequence a gene in seconds rather than a year. The sector continues to evolve at a rapid pace, bringing with it exceptional opportunities for businesses to navigate the corresponding challenges. For investors interested in early stage companies, the defining challenge is to reduce risk, which can be achieved by thorough due diligence; and the same technology that is driving developments enables more competitive licensing opportunities and increased late-stage funding.

Similarly, opportunities are available to companies which recognise that enhanced data protection for customers can be a prompt for seizing control of their data-based relationships. Likewise, companies in China facing more frequent data inspections can take advantage of the preparation to ensure their risk mitigation strategies are up to date. Change is not always a bad thing.

Please contact me if you have any comments on our articles or would like to discuss any of the issues raised.

TABLE OF CONTENTS



FEATURES

FOCUS ON > LIFE SCIENCES

Data Inspections in China: Increased Supervision and Compliance

LEON LIU, CAROL SUN AND JACOB CLARK

Data protection inspections have become more frequent for companies with operations in China. Many companies are struggling for guidance on how to comply. CONTINUED >

In 2016, and as part of a global effort to update the law to address data and technology issues, China introduced the PRC Network Security Law (NSL), also known as the Cybersecurity Law. This was the first time China has implemented similar-themed legislation at the same time as European and other Western jurisdictions, allowing a clear comparison between China and the West's attempts to move towards more aggressive data regulation.

The NSL and its group of related laws and regulations creates "top-down" regulation of China's network security and data matters, and empowers several government agencies to supervise and conduct inspections on companies to ensure compliance with the law and its data and network protection requirements. These inspections are becoming more frequent, but companies are lacking guidance on how to handle them.

SUPPORT AT THE HIGHEST LEVELS

The NSL was implemented on 1 June 2017, and is aimed at protecting China's cyber/network security and digital economy. Compared to Western data laws, such as the EU General Data Protection Regulations (GDPR), the scope of the NSL is much broader. It includes strict requirements for the protection of personal information; determines which companies are subject to data regulation; and how these companies must store, protect, and transfer personal data and data related to national security, economic development, or the public interest.

The importance placed on the NSL and its top-down framework is demonstrated by China's President Xi Jinping declaring that "Cybersecurity is national security", and his emphasis on companies' responsibility to protect Chinese data and networks. This top-down approach seeks to create a framework of standards for companies charged with the protection of data and cybersecurity, as well as the creation by high-level agencies of a cyberspace or network security framework that is interpreted and implemented at lower levels.

The importance of data protection and cybersecurity to the government, coupled with the NSL's broad scope, has resulted in an increase in the frequency and breadth of inspections.

LEGAL BACKGROUND

Article 49 of the NSL provides the general legal basis for inspections of companies deemed to be "Network Operators" which, under the definition in the NSL, includes almost all companies. Article 49 states that such entities must implement a system of internal supervision and inspection, cooperate fully with any external inspections, and set up a complaint and reporting system to ensure the reporting of issues concerning network information security is accepted.

In addition to the NSL, there are other, related, laws and regulations from various government agencies that also empower authorities to conduct inspections.

Article 69 of the NSL obliges companies to comply with an inspection, stating that refusing or obstructing the relevant department from implementing a system of supervision and carrying out inspections, or refusing to support or assist Chinese public security agencies in its inspections, amounts to a violation of the NSL, which would likely result in a fine.

Although the fine amounts are small compared to fines under the GDPR, violations of the NSL carry additional penalties, such as a suspension of a company's business license, shutting down the company website, and social credit implications.

INSPECTION AUTHORITIES

There are three main agencies charged with conducting supervision and inspections:

- The Cyberspace Administration of China (CAC) is directly led by President Xi Jinping, and has oversight across all cybersecurity inspection and supervision work. In addition, the CAC is empowered to carry out its own audits and inspections, and to formulate its own policies. Its inspections cover the general breadth of data issues under the NSL. Given its broad scope and prominent leadership, the CAC is one of the most powerful administrative bodies involved in inspection work under the NSL.
- The Public Security Bureau (PSB) is China's police equivalent and can initiate criminal inspections for data breaches and network crimes. It is empowered to conduct inspection and supervision under the NSL, PRC Criminal Law, and other regulations. The PSB also has its

own regulations concerning network security supervision and inspection: the Public Security Bureau Regulations on Network Security Supervision and Inspection.

- The PRC Ministry of Industry and Information Technology (MIIT) is generally responsible for the regulation and development of the internet and other, related information technology. It is also empowered to conduct data inspections, supervisions, and audits under the NSL, but its inspection focus is on companies engaged in information technology-related industries.

The methods of inspection for all agencies are generally the same. At this stage, however, there are still several issues among the implementing agencies, including an unclear division of labour and jurisdictional authority, separate implementing regulations, and low efficiency when conducting inspections.

INSPECTIONS

In general, there are two types of network security inspections:

1. A general inspection
2. A post-crisis inspection

A post-crisis inspection is conducted by any of the agencies listed above after a "data crisis" has occurred. Its purpose is to resolve the questions of how the breach occurred, who was responsible, and how it can be rectified.

A general inspection can be a scheduled, responsive, or random inspection by any of the agencies listed above. They can take place at different times, by different agencies, all focusing on different inspection goals. General inspections seek to increase a company's compliance to ensure that the risk of data crises is mitigated.

Since the implementation of the NSL in June 2017, two main trends have emerged. The first is that inspections are seemingly random: taking place across various industries at various times.

One explanation for this is that the government is trying to ensure initial compliance with the law, gauge the reaction of companies to the inspection system and new regulations, and learn from the inspections to be able to develop a more consistent general inspection system for future implementation. The other explanation is that the agencies are using the inspections to attempt to more clearly define their own jurisdictional authority and as a means to experiment and further develop inspection procedures.

> "Companies should prepare for various frequencies and timing of inspections."

These explanations are likely to be the driving force behind the second trend: the agencies are continuously developing and releasing new implementation measures, guidelines, and notices concerning inspection actions. Examples include a notice detailing specific inspection work and methods by the MIIT in August 2018; a September 2018 notice mentioning a summit convened by the PSB, MIIT, CAC, and others to discuss developments in data inspection work; and the November 2018 regulations on inspection released by the PSB.

HOW TO PREPARE

The constant regulatory development combined with a lack of clarity between agencies means that companies should be prepared for sudden changes in compliance requirements and inspections at any time on a wide range of content.

Because any agency can conduct an inspection at any time, companies should prepare for various frequencies and timing of inspections. They should, however, not panic if they receive an inspection request, as it is very possibly a routine inspection.

Methods of inspection include

- Self-inspection
- Entrusting a third party to conduct an inspection or audit
- Remote inspections
- On-site inspections that include document review, employee interviews, on-site verifications, and tool and infrastructure testing.

When facing an inspection, companies should prepare for key employees to be interviewed, such as the general manager, IT managers, the legal representative, and legal personnel.

All companies should prepare a communication and engagement strategy to a government request for inspection, which can be challenging in a fast-changing regulatory environment. Global inspection response guidelines, or a policy drafted by a company's headquarters, may not be sufficient for an inspection by Chinese authorities.

Companies therefore need inspection response guidelines or a policy tailored for China, and must continually monitor inspection trends and regulatory developments surrounding data protection. Having a China-specific plan in place to respond to inspections will allow a company to avoid risks and operate smoothly in the Chinese marketplace.

Leon Liu
Partner, MWE China Law
Shanghai
lliu@mwechinalaw.com

Leon focuses on white-collar crime, government and internal investigations, data security and data privacy, corporate governance, anti-corruption and antitrust, export control, and regulatory compliance.

Carol Sun
Counsel, MWE China Law
Shanghai
csun@mwechinalaw.com

Carol focuses on regulatory compliance, white-collar crime, government investigation, data security and data privacy, and dispute resolution.

Jacob Clark
Foreign Counsel, MWE China Law
Shanghai
jxclark@mwechinalaw.com

Jacob focuses on white collar crime and securities defense.

Joint Controllers: Constraint or Opportunity?

ROMAIN PERRAY AND GUILLAUME BÉAL

On the surface, the similarities between Facebook and Jehovah's Witnesses are not obvious. The European Court of Justice (ECJ) has, however found one: they are both "joint controllers" of processing activities on personal data.

The most pressing issue in data protection is no longer the right to be forgotten, which in reality doesn't exist in a digital world. The issue on everyone's mind now is who is liable and, more specifically, how far their liability extends, with regards to compliance with data protection requirements.

Companies, public authorities and associations are considered as "joint controllers" when jointly determining both the purposes and the means of any personal data processing. The Article 29 Working Party, which comprises representatives of all EU data protection authorities, the European Data Protection Supervisor, and a representative of the EU Commission, has attempted to pin down exactly what constitutes a data controller, acting either independently or jointly. In both cases, this is determined by the answer to two questions: why and how data processing takes place.

LEGAL, FINANCIAL AND STRATEGIC IMPACT

In two significant decisions rendered since the implementation of the General Data Protection Regulation (GDPR) in May 2018, the ECJ has ruled on who and what constitutes joint controllers. Until now, this had only been raised incidentally in a case involving Google in Spain.

The ECJ's decisions will affect the overwhelming majority of EU Member States' domestic legislation on data protection. Other than in a small handful of instances, most Member States' national data protection authorities have never addressed, and some of them, including France, still do not provide for, express joint controllership of data, despite the GDPR specifically requiring them to have provisions in place.

Interestingly, the ECJ ruled that it is not "the mere fact of making use of a social network", or being a member of a religious community, that makes an individual a joint controller who is partly responsible for the data processing carried out by that network or community.

Social networks become a joint controller, according to the ECJ's June 2018 decision in *GDPA v Wirtschaftsakademie,* when an entity creates a fan page, which allows the social network to access *via* cookies the personal data of any visitor to that fan page, whether or not that visitor has an account with the social network.

> "The entire online ecosystem is going to be affected."

For religious associations, according to the ECJ's July 2018 decision in *Tietosuojavaltuutettu / Jehovan todistajat Uskonnollinen*, their operating procedures or even their relationships with their members, particularly when organising services, make themselves and the entity a joint controller, regardless of the existence of written instructions.

The determining factor is simple: a religious association or social network becomes a joint controller with a member or user when that member or user creates, for commercial or charitable purposes, an online public space that, in parallel, enables the association or network to collect third party data.

This is not entirely new information. In 2003, the ECJ ruled in *Bodil Lindqvist v Åklagarkammaren i Jönköping* that any online reference made by a religious association to their members' private lives, in particular to their health, constituted the processing of personal data and was, therefore, subject to EU data protection requirements. Religious associations may have thought they are exempt from secular law, but they are not.

WIDER IMPACT

For technical service providers, the impact of the ECJ decisions is even greater. Their usual qualification as data controllers has been seriously challenged. By developing any tool, in particular one that is integrated and used on behalf of both their customers and themselves, they determine, or at the very least participate in, the purposes and means of data processing, even if they only intended to improve their services. In this situation, they will now be regarded as joint controllers, especially if they benefit from a wider audience thanks to the traffic generated to them from customers using their tools.

It's clear that the opportunity to receive more traffic is the prerequisite for being defined as a joint controller. It is not the ability to access personal data, which the ECJ expressly rejected in *Unabhängiges Landeszentrum für Datenschutz Schleswig-Holstein v Wirtschaftsakademie Schleswig-Holstein GmbH*. It does not matter whether the data is processed as statistics, or even anonymously; it is enough that the aggregated data is transmitted between the service provider and the "customer."

The entire online ecosystem is going to be affected, from cloud computing to fintech, biotech, medtech and intermediation platforms to targeted-advertising businesses. This shift is being confirmed by recent decisions of EU Member States' domestic authorities. For example, the French Supreme Administrative Court ruled in June 2018 that online publishers that install cookies on their visitors' terminals on behalf of advertisers are joint controllers. In July, the French Data Protection Authority, the CNIL, issued two formal notices requiring start-up companies, in their capacities of data controllers, to stop using further geolocation data for their own purposes without prior consent.

> "The opportunity to receive more traffic is a major element for being defined as a joint controller."

But, where there is disruption, there is opportunity.

OPPORTUNITIES

Although it's not immediately obvious, joint controllership situations may also create several interesting opportunities.

Companies, public authorities, and associations should start to consider themselves not as data processors, but as joint controllers, and adjust their compliance to fit the requirements of this role. This will first strengthen the approach initiated by the GDPR, which focuses on the receipt and use of data and, accordingly, determine what role is undertaken by each party involved in this flow of data. It will also mean that entities have better control of risk by avoiding crisis-based requalification and sanctions that are not been adequately anticipated. All room for confusion and danger of non-compliance can therefore be removed from the outset.

Under the GDPR, the times of the data controller being the sole offender are now over. The status of "data processor" is no longer a guarantee for service providers; they can now face fines and/or damages. Under these circumstances, acting as a joint controller can provide significant protection, especially since situations involving joint controllers rarely cover all processing activities. Far more often they apply only to a few aspects, such as the common use of a database, with the parties being independent data controllers for any further use of the data for their own purposes.

Joint controllership situations do not, according to the *Wirtschaftsakademie* decision, "Necessarily imply equal responsibility for the various operators involved in the processing of personal data," but instead imply that "Operators may be involved at different stages of that processing of personal data, and to different degrees." Joint responsibility can therefore be variable and modulated accordingly, more or less dependent on the management of the tool, but not necessarily on subsequent reuses of data, as each operator can remain independent data controllers for their respective processing.

The most significant opportunity is financial. Unlike the status of data processor, the status of joint controller allows service providers to reuse on their own behalf the personal data that is processed through their tools, without having to obtain the unilateral approval of their clients or users.

Romain Perray
Partner
Paris
rperray@mwe.com

Romain has extensive experience in data privacy and data protection law.

Guillaume Béal
Associate
Paris
gbeal@mwe.com

Guillaume focuses his practice on high end corporate transactions, with particular strength in the energy and TMT sectors.

How "Dieselgate" Expanded Into An Antitrust Investigation, and What This Means For You

STEFAN MEISNER, LISA RICHMAN, PAUL THOMPSON AND CARINA KANT

The European Commission's dieselgate investigation shows that one problem can easily become another. To prepare for shifts in focus, companies must know when to disclose wrongdoing or seek leniency.

Compared to the massive fines US regulators imposed on Volkswagen and other companies involved in the dieselgate scandal, the European Union and its Member States have responded less aggressively. Recently, however, the Commission has found a new enforcement angle: turn falsifying emissions tests into an antitrust violation.

In September 2018, the Commission opened a formal investigation into discussions between the "circle of five" –BMW, Daimler, Volkswagen, Audi and Porsche–over whether or not they colluded to impede the development of technologies to reduce car exhaust emissions. This is not a traditional antitrust probe because it does not focus on price fixing or market sharing. According to Competition Commissioner Margrethe Vestager, however, "Having a cartel is much more than just agreeing on prices."

The Commissions' investigation has its roots in the summer of 2016, when Germany's antitrust watchdog raided Volkswagen, Daimler, BMW and others, on suspicion that they colluded in setting steel purchase prices. It was by accident that the German watchdog found evidence suggesting that German carmakers participated in a broader effort to collude.

In 2017, Daimler and, reportedly, Volkswagen, sought leniency by revealing more than a thousand meetings between the German car makers covering a range of technical topics, including emission technology. The Commission subsequently conducted dawn raids at BMW, Audi, and Daimler as part of the probe into whether or not the German carmakers violated antitrust laws.

SHARING FINDINGS BETWEEN EU COMPETITION AUTHORITIES

In accordance with procedural law for EU antitrust investigations, the German watchdog forwarded to the Commission the documents that it discovered during the raid into the alleged steel cartel. Under EU procedural law, the Commission and EU Member State competition authorities can share documents obtained during investigations, even documents discovered "by accident." Even though most EU Member States and the Commission cannot use those documents as "evidence" to prove a violation, they may use them to open a new investigation or expand an existing one.

HOW CAN COMPANIES RESPOND?

Volkswagen and Daimler decided to apply for leniency. Before taking this step, however, a company should investigate the relevant facts and consult an antitrust lawyer. When a company learns that its employees may have violated the antitrust or other criminal laws, it has several options available to it.

Putting Down a Marker

A marker allows the company to preserve and protect its place in a leniency queue for a defined period while it investigates further. Putting down a marker may provide a considerable advantage, because only the first applicant that meets the requirements for leniency can get immunity from fines. Subsequent successful applicants may still benefit from a reduction of fines, but they do not get complete immunity.

If a company does not provide enough information, the Commission will reject its application, and the company will need to reapply, opening the way for another applicant to qualify for immunity.

The EU marker system caters to the needs of those applicants who, for legitimate reasons, are not in a position to submit all necessary evidence and information immediately, but are able to perfect their leniency application within a certain specific time. Such a situation may arise, for example, when new management learns of cartel activity, or when an employee reports such activity

after an internal compliance training or through a hotline. The system therefore encourages a race between potential cartellists by enabling applicants to gather the necessary information and evidence required to complete their immunity application.

Companies may also submit "verbal" markers, but should wait until they have investigated and clarified the relevant facts and circumstances before doing so.

In the United States, a company that becomes aware of possible criminal antitrust violations, but is not yet certain that a violation occurred, can also apply for a marker to hold its place in line. The Antitrust Division of the US Department of Justice (DOJ) administers this leniency program.

In most instances, the first company to apply gets full leniency in terms of fines and criminal culpability. In contrast, any subsequent leniency applicants do not receive a reduction of fines, although DOJ may weigh the co-operation of those who are second or later in line when deciding whether to reduce penalties.

Applying for Leniency

As soon as the company has gathered the required information, it may apply for leniency, even if it hasn't put down a marker. The EU Member States' national leniency programmes are similar to the EU programme. Under the EU leniency programme, in order to be granted immunity from fines, the company has to

- Co-operate fully and continuously with the Commission
- Submit all evidence
- Terminate its participation in the cartel
- Not destroy or suppress any evidence
- Reveal its request and content of the leniency application
- Not force other companies to participate in the cartel

There is a higher hurdle if the Commission already had knowledge about an infringement at the time of the application. Even if a company fails to fulfil all requirements, a reduction of fines is still possible under the EU leniency system.

As with the EU system, the United States provides leniency to the first successful applicant who reports cartel activity and fully co-operates with DOJ about the nature of the illegal conduct. DOJ looks at many of the same factors as the European Union in deciding whether or not to grant an application for leniency. It has also published a useful guide to the programme, which is mandatory reading for anyone considering making an application

Whether in the European Union or the United States, one thing that all leniency applicants must remember is that, even if the company gets full immunity, that immunity is only from prosecution by the government. The risk of damage claims made by individuals or companies that suffered economic disadvantages because of the cartel still exists.

US Self-Disclosure Process

In the United States at least, there are avenues that are open to companies that uncover evidence of criminal violations, outside of antitrust violations. For the past several years, for example, DOJ has had a self-disclosure policy in place for companies that uncover evidence of Foreign Corrupt Practices Act violations.

In March 2018, DOJ expanded that self-disclosure policy to all violations of US criminal laws. Under the policy, a company that voluntarily self-discloses misconduct, fully co-operates with DOJ, remediates the problem, and disgorges its profits from the misconduct gets "A presumption that the company will receive a declination absent aggravating circumstances…" What is true in the antitrust space is also true for other criminal violations in the United States: timely and full disclosure of the problem can avoid a criminal prosecution for the company.

OUTLOOK

German carmakers are facing significant fines from the Commission, and many of them have already been fined in the United States. In the face of these risks, all companies need to pay close attention to the advantages and disadvantages of leniency applications, including the status of prior applications by other companies, before deciding how to proceed when faced with a potential violation of antitrust laws.

In those instances when a company uncovers evidence of other criminalwrongdoing, it must consider all its options under US law, including self-disclosure to DOJ.

Stefan Meisner
Partner
Washington, DC
smeisner@mwe.com

Stefan advises clients on antitrust matters, including global cartel investigations and collateral investigations.

Lisa Richman
Partner
Washington, DC
lrichman@mwe.com

Lisa focuses her practice on international dispute resolution matters. She also has experience conducting internal investigations around the world.

Paul Thompson
Partner
Washington, DC
pthompson@mwe.com

Paul advises clients on global white-collar compliance, internal investigations, and enforcement actions, with a particular emphasis on matters involving DOJ.

Carina Kant
Associate
Düsseldorf
ckant@mwe.com

Carina advises clients on antitrust and competition law, including antitrust litigation and compliance matters.

Cost v Care in the UK NHS

SHARON LAMB

A recent judgement raises significant questions about the regulation of medicines and the role of national bodies, and fuels the debate on budget constraints being taken into account when offering treatment.

In September 2018, Bayer Plc and Novartis Pharmaceuticals UK Ltd lost a landmark case against NHS commissioners who had adopted a policy that Avastin be used off-label for ophthalmic use.

Avastin is licensed for cancer treatments, not for ophthalmology treatments, although trials have shown it is safe and effective for ophthalmic use. The NHS policy was estimated to save £100 million per year, as Avastin is significantly cheaper (£28 per injection) than the licenced available alternatives, Bayer's Eylea at £816 per injection and Novartis' Lucentis at £551 per injection.

This was not the first time that a policy to prescribe Avastin had been challenged. In 2011, a similar NHS policy was challenged but, in that case, the policy was changed before the matter was heard by a court.

In the most recent case, Bayer and Novartis argued that the policy was unlawful on four grounds, including that, because Avastin doesn't have a marketing authorisation for ophthalmic use, its prescription for this purpose would undermine the role of the regulatory bodies.

The court dismissed all four arguments. As well as finding that doctors could take cost into account when making prescribing decisions, it determined that the European Medical Agency did not have exclusive competence to decide if a drug was effective. The court instead found that national bodies were also able to assess clinical effectiveness and safety.

The judge held that, if national bodies were unable to make this assessment, this would give "unbounded power to pharmaceutical companies to decide which medicines to make available for which purposes" and "would be seriously detrimental to the wider public interest in maintaining a cost-effective public health system."

Whilst the Royal College of Ophthalmologists welcomed the decision, which will save NHS bodies an estimated £100 million per year, Bayer and Novartis are reported to have sought permission to launch an appeal. Bayer stated the decision was a setback for public health, and sets a worrying precedent that denies patients the protection afforded by the regulatory process.

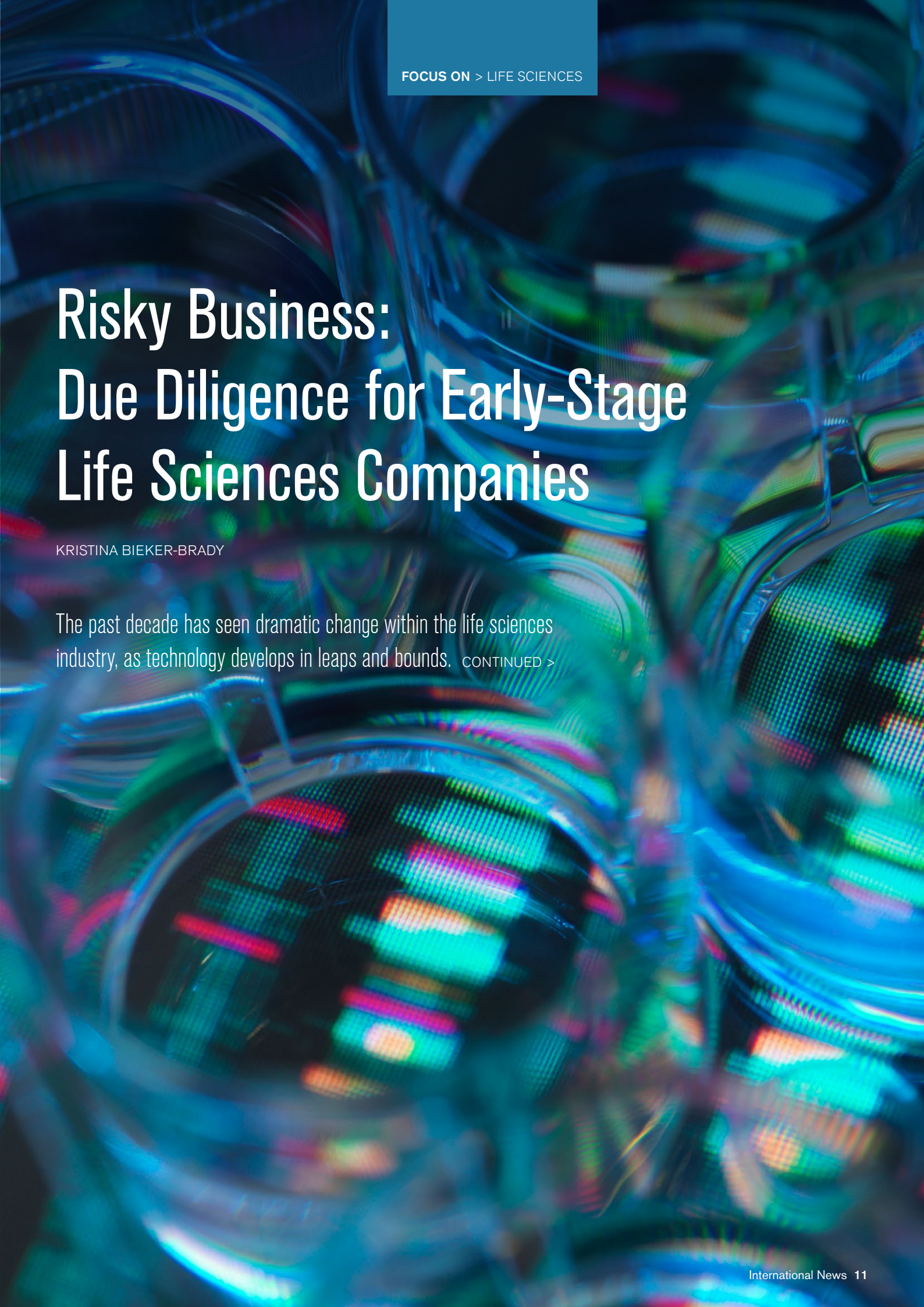
The case follows an unsuccessful challenge in 2017 by the Association of British Pharmaceutical Industries to NHS cost-limiting measures that mean treatments which are expected to cost the NHS more than £20 million per year in the first three years will not receive additional funding, and are subject to additional negotiation.

This case comes at an important time for the UK pharmaceutical industry when the impact of Brexit is not yet clear and the voluntary pharmaceutical pricing scheme is being negotiated.

The decision also comes amidst wider discussions in the NHS about the extent to which cost and budget constraints should be taken into account in decisions over what treatments and drugs should be offered to patients.

Sharon Lamb
Partner
London
slamb@mwe.com

Sharon is highly experienced in transformative health care transactions and projects, and provides comprehensive health care regulatory advice.



Risky Business: Due Diligence for Early-Stage Life Sciences Companies

KRISTINA BIEKER-BRADY

The past decade has seen dramatic change within the life sciences industry, as technology develops in leaps and bounds. CONTINUED >

The life sciences industry has changed dramatically over the last 10 years: cancer treatments using a patient's own immune system to selectively kill cancer cells and gene therapies that treat deadly childhood diseases are just two treatment areas that were previously out of reach. Incredible advances are happening at warp speed. Where it once took an entire year to sequence a single gene, it now takes mere seconds.

These rapid advances in medicine are extraordinary, but they are stressing systems less adaptable to change. The long-held standards underlying patenting, drug approval and pricing, as well as public/private investment models, are being challenged and changed. Nearly all players in the life sciences industry – academic institutions, large pharma, investors, startups, and others – are quickly learning that they need to be adept and adapt. Indeed, in order to navigate the rapid evolution of medical innovation, organizations must also proactively find new paths through the legal, regulatory, and financial health care landscapes.

TO BE OR TO BUY: CRITICAL COMPONENTS OF CREATING A HEALTHY LIFE SCIENCE COMPANY

Whether you are a company with a breakthrough technology or an investor, there are ways to increase the likelihood of success. Early on, companies need to identify the specific barriers to exclusivity, regulatory approval and pricing and begin to customize the paths to market for their product. The earliest stages of a company's life cycle provide some of the most crucial opportunities to spend intellect, though not necessarily excessive capital, in order to create new strategies for success.

KNOW THYSELF: DEFINING THE FIRST STEP FOR EARLY-STAGE COMPANIES AND INVESTORS

Reducing risk is synonymous with increasing valuation. From the outset, companies must develop strategies that reduce risk, but they often do not need to immediately execute these strategies. Determining both what to do and when to do it is critical to increasing value while preserving capital. The first valuation increase often results from obtaining key experimental data, platform intellectual property, or forming critical collaborations. The ideal investor is one who has the money, timeframe, and risk tolerance to get the company over this first valuation hurdle.

> "Reducing risk is synonymous with increasing valuation."

UNDERSTAND THE DESTINATION AS WELL AS THE ROUTE

Achieving success goes beyond crafting a company model that is attractive to early investors. It means also having long-term strategies that anticipate the company's eventual exit, whether in the form of an initial public offering (IPO), acquisition, or continued growth into a commercial therapeutic company.

Finding the route requires identifying and planning for present and future risks, and thinking through strategies to eventually mitigate them. While working to actually reduce risk can be expensive, it is a high value undertaking if done at the right time. Ultimately, prioritising advancing the technology, developing key partnerships, assessing third-party patent risks, obtaining a layered patent/exclusivity portfolio and gaining regulatory approvals are all part of a path to success.

When it comes to risk, the importance of timing is often underestimated. Knowing when to expend resources to reduce risk – not too early or too late – is as critical as knowing how to control risk.

HOW TO PRIORITISE: UNDERSTANDING THE RISKS AND WHEN TO TACKLE THEM

Within the life sciences industry, different specialty areas – be they drug therapies, devices, patient diagnostics – all face similar issues, though with different solutions. To make matters more complicated, the paths to success vary greatly within a single field. The following are critical elements to consider in order to spot potential hurdles, develop strategic approaches, and position a company for success:

Assess and Adjust Management

Having experienced management is an initial indication of a well-positioned company, though not always a guarantee. A company that has an executive who knows the target field and/or understands clinical trials, or is a serial entrepreneur are all good places to start. A board with top-notch investors and industry leaders is also a good indicator. The critical denominator is management that can engage in informed decision-making in the rapidly evolving life sciences industry. Indeed, building a strong management team is one of the best forms of general risk mitigation for an early-stage company. For investors, the strength of management can be an excellent gauge of a company's future in an unpredictable environment for growth.

Market Exclusivity

There are multiple avenues for achieving market exclusivity, including

- Patents: Obtaining critical patents can be a valuable and early milestone. A plan for strategic staging for lifecycle management can also deliver high value at little cost early on.
- Patent-term extension (PTE): PTE extends the life of a patent for a novel therapy beyond normal expiration as compensation for regulatory delays. Critical to PTE is obtaining the right patent before clinical trials begin.
- Regulatory exclusivity for new drugs: A drug that is a new chemical entity (NCE) approved by the US Federal Drug Administration (FDA) may qualify for five years of exclusivity. Critically, this exclusivity is not tied to having a patent.
- Orphan designation: Drugs that treat small patient populations may qualify for "Orphan" designation. Like NCE exclusivity, Orphan status is not tied to a patent. Unlike PTE, which is only available upon drug approval, Orphan status can be obtained years in advance as an early risk mitigation strategy.
- Market dominance through sales: Treatments for small patient populations, therapeutics having high manufacturing costs, or products with obsolescence, *i.e.*, certain medical devices, can sometimes achieve long-term exclusivity through early market dominance. Even a relatively short period of patent or regulatory exclusivity can create the window needed to economically block competitors.

RETHINKING THE REGULATORY PATHWAY

Once a company makes it past proof-of-principle, the greatest risk of failure comes during the regulatory approval phase. This has always been true, but with the development of treatments that work by entirely new mechanisms, the uncertainty can become even higher. And yet there are also opportunities to achieve better outcomes.

By using novel combinations of drug therapies (biomarkers and big data, for example), some clinical trials are becoming faster, more definitive, and more predicative of the ideal patient population. New combinations of new technologies create a synergy that can allow refined endpoints for otherwise complex disease phenotypes. New regulatory trial paradigms are leading to better outcomes for all stakeholders, including the most critical: patients themselves. In short, novel therapeutics and allied technical advances are changing the routes to regulatory success.

PUBLIC OR PRIVATE

A game changer in the current market has been the ability of companies to raise money by going public through an IPO. Some company IPOs now occur before a single company drug has even become approved for a clinical trial. While a public offering can be attractive as an early exit and major fundraising strategy, it comes with risk: public markets bring increased transparency. So while a misstep in a clinical trial may be no surprise to private investors, it can translate into precipitous stock drops in the public markets.

In the Life Sciences industry, we are seeing more groundbreaking and life-changing treatments for patients than ever before. Getting these therapies to the market can be as challenging as the human health issues they solve. Success requires innovative thinking to overcome new hurdles, and having strong advisors with a track record of success at each step in the process is critical. And while reward does not come without risk, efficient and creative risk management clearly pays off.

Kristina Bieker-Brady, PhD
Partner
Boston
kbieker@mwe.com

Kristina focuses her practice on strategic patent portfolio development for early stage companies and the handling of intellectual property matters for companies and investors.

Tracking Trends in Global Collaboration and Licensing Agreements

EMMANUELLE TROMBE

For decades, partnering was the lifeblood of large pharma and small biotech alike. Today, small biotechs increasingly have the upper hand as technology enables more competitive products and rich capital markets decrease the deal imperative.

Today's open markets offer ever growing licensing opportunities and increased late-stage funding for biotechs. New players in the field offer a wider array of potential partnerships.

These factors afford biotechs greatly increased choice in how to fund their products, as well as enhanced leverage in selecting a partner and negotiating the details of a contract. As a result, transformational global collaborations throughout the industry are displaying new levels of creativity and flexibility. Companies are considering nonexclusive deals, shared territories and molecules, co-development and co-promotion rights, fast closings and other innovative structures.

CLINICAL COLLABORATIONS

Many emerging co-development partnerships centre on clinical trial collaboration. Changes in the regulatory environment have made it possible to combine two novel agents in a clinical trial, opening up new flexibility in clinical partnerships. These collaborations can take a variety of forms, such as sharing costs with the goal of also sharing clinical data, or providing a drug for a partner's clinical trial in a combination setting.

Drug development, particularly in oncology, is moving at a rapid pace, and these clinical collaborations allow organisations to explore more possibilities, faster. By forming a partnership for Phase 1 research, parties can work together on an exploratory basis without the contractual burden of a long-term commercial agreement or exclusivity terms.

INDICATION-SPECIFIC PARTNERSHIPS

If a successful product has the potential to be used across multiple indications, biotechs may look to a partnership to maximise the value of their brand for indications that they lack the resources, time or expertise to develop. Partnership with a large pharmaceutical company, for example, can allow a biotech to extract additional value from its successful product. However these types of transactions are still relatively rare and can pose significant difficulties, such as antitrust concerns in the European Union and China. Careful negotiation is therefore key, and partnerships should be meticulously structured to avoid any overlap.

PARTNERSHIPS IN ASIA

In recent years, China has become a major driver of global licensing deals, and a potential partner's development capabilities in China and other Asian markets is often an area of keen interest for biotechs. China offers immense potential for reaching large numbers of patients in a short timeframe, thanks to rapidly growing investment interest in life sciences products. For example, a midsize biotech with operations in the United States and Europe recently partnered with a Chinese organisation to develop a drug for treatment of ovarian cancer. Within one year of signing the contract, the Chinese organisation was able to start pivotal clinical trials. It is expected that the final product will be available not only in China, but in other Asian markets as well, within another year.

Joint development partnerships, rather than geographic splits, are increasingly common in China and in other Asian markets. Pharmaceutical companies are working to develop multiregional global trials that enroll patients in China, the United States and Europe. While such trials facilitate approvals in multiple jurisdictions, they also raise complexities regarding allocation of responsibilities, costs, and rights to data and intellectual property.

Indeed, these issues soon may become even more pressing. The China Food and Drug Administration (CFDA) recently ruled that China will begin conducting clinical trials in accordance with International

Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines. This means that data from clinical trials conducted in China might be applicable for international regulatory filings in the future. Uncertainty remains, however, about how Chinese clinical trials would factor into multinational entities' global clinical registration programs. The CFDA would need to release additional guidance regarding cross-border movement of tissue samples and certain types of data, as these currently are prohibited from being transferred outside of China.

It should be noted that Japan remains a very different regulatory environment from other Asian markets, and requires separate partnerships to leverage expertise specific to Japan's development pathways.

TIPS FOR SUCCESSFUL PARTNERSHIPS

When coming to the negotiation table, biotechs are wise to seek forward-looking contract considerations in the event of a successful product. Big pharma is engaging in licensing deals earlier than ever, not only in the pre-clinical stages, but sometimes even before pre-clinical assets are available. An increasingly important question for biotechs, therefore, is how to structure a contract to avoid giving away too much of the company's value too soon.

Another key factor in ensuring a successful partnership, beyond financials and market capabilities, is cultural fit. For example, a small biotech may benefit from a partnership with another smaller organisation that is equally nimble and energised, and committed to similar goals and values.

> "Having a champion on each side of the partnership to handle the flow of information and manage day-to-day tasks is therefore vital"

Even after the contract is agreed, challenges still can and do arise in the operational aspects of a collaboration. Having a single strategic point of contact within each partner organisation can help smooth the process. This individual should have the organisational know-how to identify employees responsible for key tasks and obtain necessary information or data, and thus facilitate the collaboration's administrative aspects. The individual should also serve as a gate-keeper for information and resource requests, particularly in the case of a small biotech partnering with a large pharmaceutical company. The latter may have hundreds of employees on its teams and committees while the biotech might has only a dozen. Having a champion on each side of the partnership to handle the flow of information and manage day-to-day tasks is therefore vital.

Even in the best of partnerships, industry or corporate changes can throw a collaboration off course. Currently, almost 90 per cent of all licensing collaborations ultimately fail. Reasons for early termination can include loss of interest, change in corporate strategy or priorities, or lack of financial resources. Parties to a life sciences partnership should therefore conduct thorough due diligence on issues such as manufacturing practices, development capability, scientific understanding and regulatory requirements, and include in the contract clearly defined goals that are both firm and reasonable. Seasoned legal counsel with multijurisdictional experience can offer valuable assistance in navigating these various challenges, from pre-contract due diligence to licensing negotiations and beyond.

Emmanuelle Trombe
Partner
Paris
etrombe@mwe.com

Emmanuelle represents pharmaceutical, medical device and bio-pharmaceutical companies globally in transactional matters in complex transactions, large scale projects and key regulatory matters.

Pathways to Approval: Recent Developments in EU Pharma and Medical Device Regulation

JANA GRIEB

The contrast between the United States and European Union is no more apparent than when we consider the approach to centralized oversight of pharma and medical device regulation.

REGULATORY BACKGROUND

In the United States, the US Food and Drug Administration (FDA) provides centralized oversight of pharmaceuticals, medical devices, food and cosmetics. The European Union has no equivalent centralized body. Instead, multiple authorities govern different product categories and jurisdictions:

- The European Medicines Agency (EMA) governs drugs at the EU level.
- National authorities, *e.g.*, the UK Medicines and Healthcare Products Regulatory Agency, Germany's Federal Institute for Drugs and Medical Devices, and the Spanish Agency of Medicines and Medical Devices, oversee pharmaceuticals and medical devices at the state level but do not authorise medical devices.
- State or regional authorities within EU Member States supervise drug and medical device manufacturing, and inspect manufacturing facilities.
- Notified bodies are private entities assigned to conduct certain regulatory functions, including certifying medical devices.

EU legal instruments include regulations, which apply directly to EU Member States, and directives, which must be implemented into each Member State's national law in order to become applicable.

EU APPROVAL PATHWAYS FOR PHARMACEUTICALS

As in the United States, pharmaceutical products generally must undergo clinical trials in order to obtain marketing authorisation, and each clinical trial must receive authorisation before it may commence. EU pre-marketing clinical trials include three phases, each with an increasing number of patients involved.

Unlike the United States, however, there are four different marketing authorisation procedures for drugs in the European Union:

- The **national procedure** provides marketing authorisation for a drug in a single EU Member State and is conducted solely by that Member State's national authority.
- To obtain authorisation in more than one Member State, a drug manufacturer may use either the **mutual recognition procedure** or the **decentralised procedure**. If the drug in question has already secured approval in one Member State, the mutual recognition procedure applies. If no marketing authorisation currently exists in any Member State, the decentralised procedure is used. Under both procedures, one Member State is selected that has the function of reporting: the Reporting Member State (RMS). The other Member States where seeking approval are the Concerned Member States (CMS). The RMS conducts an assessment of the drug on behalf of all involved Member States. The CMS can comment and under certain conditions, *veto* the assessment. If the CMS agree with the assessment of the RMS, the drug receives marketing authorisation in all CMS.
- Finally, the **centralised procedure** is conducted by the EMA and grants authorisation in all EU Member States. The centralised procedure is mandatory for many innovative drugs, including monoclonal antibodies, advanced therapeutic medicine products, orphan drugs, and drugs for certain severe indications, such as cancer and autoimmune diseases. Applicants also may voluntarily select the centralised procedure for drugs that contain new active ingredients or that represent significant innovation. EU-wide authorisation under the centralised procedure is granted by the European Commission.

EU law offers two paths for expedited drug review and approval: the priority medicines system (PRIME) and conditional approval. To be eligible for PRIME, a drug must demonstrate a major therapeutic advantage or applicability to patients that currently have no treatment alternatives. PRIME-eligible drugs receive accelerated EMA review, *i.e.*, 150 days instead of 210.

Conditional approval is another option for significantly accelerated market entry. Eligible products include drugs indicated for severe diseases, tests to be used in emergency situations and orphan drugs. Applicants for conditional approval must demonstrate that the public benefit of

releasing the drug immediately—with incomplete clinical data—outweighs any risk involved in doing so.

Conditional approval may be granted for drugs still in phase I or II clinical trials, and is valid for one year. Upon completion of the clinical trials, including phase III, conditional approval may be converted to standard approval.

RECENT DEVELOPMENTS

The Clinical Trials Regulation (EU) No. 536/2014 (CTR) is expected to enter into force by the end of 2019 upon completion of a new EU clinical trial database. This regulation represents a significant step towards harmonisation and will facilitate multicentre clinical trials in EU Member States. A new EU portal will allow drug manufacturers to submit a single clinical trial application and receive authorisation for all clinical trial sites in the European Union. The CTR also includes strict timing requirements to accelerate the granting of any authorisation.

> "The Clinical Trials Regulation is expected to enter into force by the end of 2019"

Another key initiative, the EU-US mutual recognition agreement on good manufacturing practice (GMP) inspections, is slated to be fully implemented by July 2019. Under this agreement, US and EU authorities will recognise facility inspections conducted by one another and no longer separately conduct overseas inspections. The FDA presently recognises GMP inspections conducted in 14 EU Member States. For drug manufacturers, full implementation of the MRA will result in less inspections and thereby save time and money.

EU APPROVAL PATHWAYS FOR MEDICAL DEVICES

The European Union categorises medical devices into four risk classes:

- **Class I** – lowest risk
- **Classes IIa** and **IIb** – medium risk
- **Class III** – highest risk

As in the United States, medical devices with predicates notification may be authorised more easily, without the need for a clinical trial.

The EU authorisation procedure for medical devices diverges significantly from FDA protocols. As noted, no centralised EU authority exists for medical device approvals. Medical device manufacturers instead are responsible for self-certification, which includes preparation of technical documentation and a declaration of conformity. Manufacturers of risk class I devices may complete the self-certification process independently, but for devices in classes IIa, IIb and III, a notified body must be involved in the conformity assessment procedure. in particular to conduct a review of the manufacturer's quality management system.

RECENT DEVELOPMENTS

The Medical Device Regulation (EU) 2017/745 (MDR), published in 2017, is slated to become fully applicable in May 2020. It will apply directly in all Member States and aims at further harmonisation and enhanced product safety. For example, the MDR expands the scope of medical device law to include certain cosmetic products, such as non-corrective contact lenses, subcutaneous filling material and liposuction equipment. These products will in future have to meet the same regulatory requirements as medical devices.

Furthermore, the MDR will subject certain categories of products to higher risk classification. This applies, for instance, to software. Many software applications are expected to fall into higher risk categories than they currently do. Such applications include software used for diagnostic and therapeutic decision making and software intended to monitor physiological processes.

Currently, medical device manufacturers often launch products in the European Union before the United States, because the EU approval process is considered simpler than the FDA's. The MDR may change this, as requirements in the conformity assessment procedure will increase for many products.

THE IMPLICATIONS OF BREXIT FOR APPROVAL PATHWAYS

Fast-approaching Brexit carries significant ramifications for both pharmaceutical and medical device regulatory approvals in the European Union. Negotiations are ongoing, and it is hoped that the final withdrawal agreement will include a transitional period extending the application of EU law through 31 December 2020, as is provided for in the current draft. If no such agreement is reached, however, EU law will cease to apply to the United Kingdom on 30 March 2019.

The regulatory consequences are significant. The EMA has already begun relocating from London to Amsterdam, and it is expected that marketing authorisation for drugs will see severe delays during the period of relocation.

Similarly, many notified bodies for certification of medical devices are currently located in the United Kingdom. Even if some of these bodies relocate to the European Union, they will not have the capacity to perform all of the work that UK bodies currently perform. The MDR will compound this shortage of notified bodies by requiring reassignment and putting more products into higher risk classes that require involvement of a notified body. Medical device manufacturers therefore should consider seeking new certifications as soon as possible. For many products, there is the option of a soft transition: until May 2020, certificates may be issued under the current law (MDD) and remain valid until 2024.

Jana Grieb
Counsel
Munich
jgrieb@mwe.com

Jana focuses her practice on health care, life sciences and medical technology. She has advised numerous pharmaceutical and medical devices companies in a variety of transactions and contractual matters across the European Union.

Business as Unusual: Drug Companies Prepare for a Post-Brexit Health Care System

GARY HOWES

The status of the United Kingdom post-Brexit and how the life sciences industry might be affected is still up for debate.

When predicting what the United Kingdom's pending European Union departure will look like, and how it might affect the life sciences industry, the straightforward answer is that no one knows for sure. However, the European Medicines Agency (EMA) – the regulator and monitor for medicines in the EU – has been consistent in its message: upon departure, the United Kingdom will be treated as a "third country" with no special access to the EU market.

Currently, the United Kingdom plays a critical role in the EU drug approval process, with the EMA headquartered in London since its establishment in 1995. But in March 2019, presuming Brexit officially occurs, the EMA will move to Amsterdam, along with more than 900 jobs. This will be a major loss for the United Kingdom, and a challenge for the EMA in terms of resource planning, staffing and administration, as 30 per cent the current EMA workforce may be lost during transition.

Questions about post-Brexit supply disruptions also abound, with the EMA warning of potential access problems for 39 medicines as of September 2018. Although an improvement compared to July, when it was above 100, it's unlikely the number will reach zero by March 2019. Some actions being taken, such as stockpiling UK product in the European Union, and vice versa, might help prevent disruption immediately after Brexit. But longer-term planning requires certainty of what the post-Brexit landscape looks like.

Britain's domestic regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), has stated: "What is needed to ensure the supply of medicines to British patients is an agreement between the [UK] and the EU27 to allow the free flow of medicines and their components." While this might seem the best outcome for patients and the industry, it's important to remind

ourselves of the deal the UK government is trying to negotiate, namely one that's acceptable to its own and supporting Members of Parliament, the voting public, and the European Union.

While questions remain, there are some post-Brexit implications of which we are reasonably sure.

> One License May Not Fit All

Over the last decade, a large proportion of drugs have been approved via the "Centralised Procedure". Here, the applying pharmaceutical company is granted a single European Union approval, permitting EU-wide product sales. Brexit will change that. Firstly, if the entity that originally applied for and was granted the centralised approval is UK-based, that authorization will need to be transferred to an EU-based entity, since EU-wide approval must be held by an entity established in the European Union. Secondly, if the United Kingdom is no longer part of the European Union, the centralised approval cannot, as far as we know today, be applicable. Although UK approval could possibly be divisible from the centralised approval process, fundamentally two approvals will be needed: one for the United Kingdom and one for the European Union.

> Qualified Persons Must Be in the Right Place

Before drugs can be sold in the European Union, their compliance with quality standards for release into the market must be legally certified by a Qualified Person (QP): an individual qualified to assess that quality compliance. To release product into the European Union, the QP must actually live there. Post-Brexit, companies with QPs residing in the United Kingdom will need to either relocate them to EU countries or replace them with individuals residing in the European Union.

> Prepare for Import/Export Shifts

UK drug companies will need to prepare for a different approach to how products and components enter and leave the country, particularly items crossing several borders within the supply chain. For instance, an active pharmaceutical ingredient (API) might be produced in Germany, but the finished product is manufactured in the United Kingdom. This would require a protocol for importing that API into the United Kingdom. This is doable, as many APIs are currently manufactured outside the European Union and imported for incorporation into finished products. But those imports are based on existing regulations accounting for this, with the EMA approving the non-EU facilities. So to achieve this, there must be certainty about what regulations govern imports into the United Kingdom, and what is acceptable to the European Union for re-exporting finished products.

In the end, though the United Kingdom may be able to replicate every EU protocol, procedure and process for approving, manufacturing and delivering product, this doesn't mean the European Union needs to accept those products. It all depends on the deal. Ideally, the MHRA wants the United Kingdom to remain part of the European medicines regulatory environment, or for a mutual agreement to be agreed to quickly. But with a potential "hard" or no-deal Brexit on the horizon, the United Kingdom must hope for the best but plan for the worst.

Article created prior to our most recent Update on Brexit. Please check out our blog for additional Brexit news.

Gary Howes
Counsel
London
ghowes@mwe.com

Gary has nearly 25 years of experience advising clients in the life sciences sector on the myriad legal issues that affect this key industry.

Learn More

Visit **www.mwe.com/experience** to learn more about our Firm's capabilities.

To subscribe or update personal email subscriptions from McDermott, visit **www.mwe.com/subscribe**.

Our publications are all accessible from **www.mwe.com.**

McDermott
Will & Emery

www.mwe.com/international/