LATHAM & WATKINS LLP

European Healthcare & Life Sciences Market Update H1 2022

Foreword

Welcome to the first edition of our European Healthcare & Life Sciences Market Update, a new report summarising key emerging trends, opportunities, and challenges facing the market in 2022. During the last 12 months, the European healthcare and life sciences market has thrived while in the throes of the Brexit transition and the COVID-19 pandemic and vaccine rollout, showing remarkable growth in M&A and venture capital activity, attracting a fresh crop of global investors, and channeling increased funding into UK digital health.

As new investors approach the market — attracted by the booming biotech and life sciences sector, Europe's wave of innovation, public and private investment in digital health, and a growing pipeline of pharma carve-outs — dealmakers must stay alert to increasing global regulatory scrutiny. In this edition, amongst myriad regulatory changes faced by the European life sciences industry, we scrutinise the practical implications pharmaceutical companies in Europe and overseas should be aware of now that the EU Clinical Trials Regulation has finally come into effect.

If you have questions or wish to discuss any of the topics in this report in further detail, please contact any of the authors or the Latham lawyer with whom you normally consult.

▲ 53%
in deal activity in 2021

373 deals
worth $272bn

▲ 47%
in value

Source: PwC analysis

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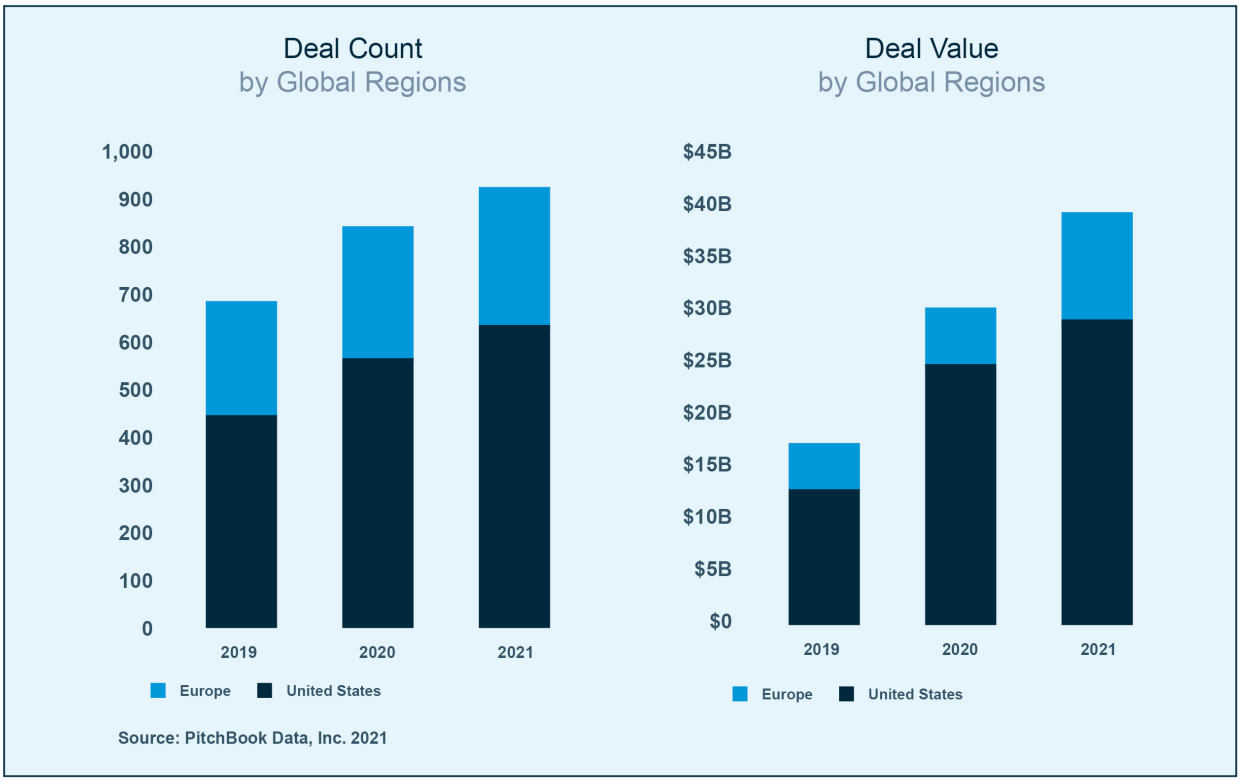
4 MAJOR INVESTMENT TRENDS TO WATCH

The European healthcare and life sciences sector is currently at the crest of a wave of innovation that has been gathering pace across the continent for a decade. The momentum of innovation the sector has accelerated in response to the COVID-19 pandemic and global regulatory changes. As life sciences and biotech innovation combine with advances in machine learning, Big Data, and next-generation computing, a growing number of investors have taken notice of the sector as an expanding opportunity. This article outlines four major investment trends in Europe's growing market: growth equity, corporate venture capital, strategic partnerships, and direct listings and special purpose acquisition companies (SPACs).

Growth Equity

Historically, venture capital has backed emerging companies in Europe, but as the startup scene matures, more traditional private equity (PE) investors and crossover investors are getting involved. Growth equity, a well-established asset class in the US, is now expanding in Europe, with investors taking minority positions in exchange for the prospect of greater returns.



Growth equity investors typically take a minority position at the top of a stack of existing institutional investors, meaning they are unable to exert the level of control usually seen in buyouts. One board seat and a limited set of reserved matters are likely to be the limits of their influence. Founders tend not to relinquish control to financial investors, and instead remain responsible for all key decisions (besides the usual exceptions to cover non-performing situations). PE investors thus cannot control an exit and typically need the support of others to exercise a drag, while lacking an IPO trigger.

On deal terms, growth equity sees venture capital and PE continuing to converge. While venture capital investors typically expect a non-participating liquidation preference (i.e., the option to have their money back in priority to the ordinary share return, or to participate pro rata in the ordinary share return), PE sponsors are going one step further to protect themselves in a downside scenario by requesting a participating preference (i.e., the option to have their money back in priority, as well as pro rata participation in the ordinary share return) or coupon accruing on the preference return.

PE sponsors are also increasingly exploring a right to freely sell their shares in the market or to have their shares redeemed, or if an exit has not occurred by a certain date, to provide the exit certainty that they lack in the venture scenario.

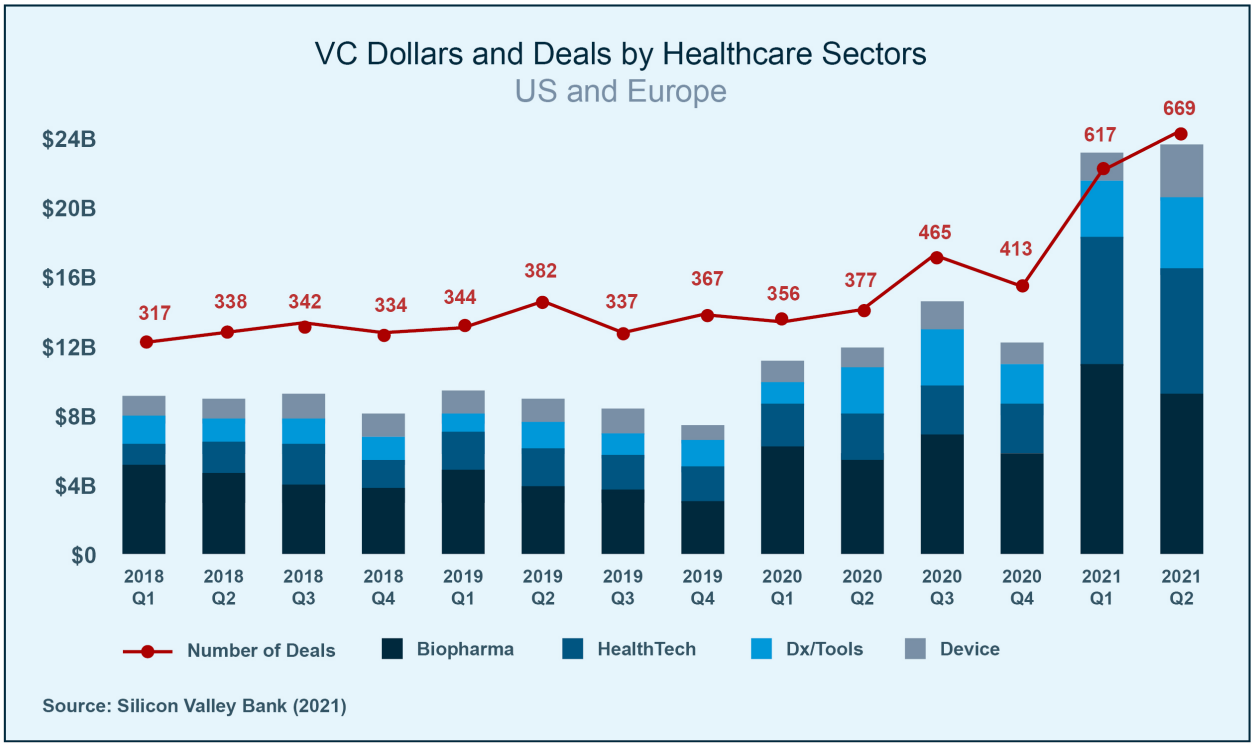
When it comes to governance, PE investors favour more robust governance rights and structures. In some instances, they have sought the right to remove founders if their conduct brings the company into disrepute.

PE sponsors might also require more robust compliance to fulfil their internal requirements and prepare for an IPO. While founders can be reticent about additional time and cost, often they welcome the assistance of a sponsor in this area.

Cross-border equity investors should deal with foreign investment control regimes at an early stage, as many Member States, such as Germany, have tightened their foreign investment control regimes in some areas of the healthcare sector.

Corporate Venture Capital

With so much appetite for healthcare and life sciences investments, large corporations have been setting up dedicated initiatives to invest directly in emerging companies at an early stage. In corporate venture capital, a company acts as a PE or venture investor, taking a minority stake in a fast-growing business.



This model benefits corporates as a means to develop new technologies and business models and gain competitive advantage, as corporates typically focus on investments in companies that offer complementary products or services to their own. Meanwhile, for young companies, such financing can provide access to technological knowhow, distribution channels, production facilities, and cooperation partners, in addition to funding.

There is a growing appetite among corporate venture funds for supporting early rounds of fundraising so as to more actively participate in product development processes. This helps funds avoid costly mistakes, not least because as early-stage investors they can take more control, release money in smaller tranches, and minimise their exposure to expensive later-stage risks such as regulatory problems and commercialisation challenges.

Corporate venture investors are also able to leverage their own expertise when offering support to the drug approval process, including sharing best-practice insights to enhance interactions with regulators. In doing so, these investors can add significant value to companies and drive much better returns from their early-stage investments.

Strategic Partnerships

In life sciences, emerging companies typically rely upon strategic partners to progress products through development and commercialization. These partners are usually well-established pharmaceutical corporates and often also include technology companies, government agencies, and universities. Strategic partnerships are highly tailored arrangements in which the parties carefully allocate responsibility between themselves for specific product-related efforts, including the design, set up, and management of clinical studies; conduct of regulatory activities; management of supply chains and distribution channels; and identification of new product opportunities. Sales and distribution partnerships are a particularly notable development, with co-marketing or shared sales forces. Financial success for life sciences companies depends on researching and developing a range of products and technologies, so arrangements that share risks and responsibilities for particular products allow each partner to diversify its own portfolio and gain a financial stake in the success of the partnered products.

Early stage research and development (R&D)-focused strategic partnerships are not without risk, but often provide the only route for organizations to get ahead of competitors. Depending on the nature of the partnership, life sciences companies can benefit from upfront payments, milestone payments, and, eventually, a royalty based on a percentage of the product's net sales or a share of product profits, while the R&D costs and the risks associated with the investment of time, money, and other resources are also shared. This arrangement can allow

companies to pursue more ambitious and potentially more valuable R&D programs for their products, while the pooling of resources allows members of R&D partnerships to produce results faster together than they could alone.

The most successful partnerships clearly define the parties' rights and obligations with respect to these aspects of product development and commercialization, while also paying close attention to EU competition law. R&D agreements are generally not considered harmful for competition, but they should be carefully assessed because the European Commission does not exempt all of them from competition law requirements.

Direct Listings and SPACs

Traditional IPOs have become less common for mid-tier healthcare companies due to market uncertainty and volatile valuations. Instead, direct listings and SPACs have been emerging as alternatives.

Emerging companies enjoy ever-expanding opportunities to raise significant equity at good conditions pre-IPO, meaning many startups are well-funded and do not need to raise new capital to go public. However, instead of a traditional IPO, startups can list their existing shares on a stock exchange via a direct listing, without the involvement of an underwriter and without issuing any new shares.

Direct listings can be a cheaper alternative to IPOs, as the process is more flexible because there is no bookbuilding procedure. With no new shares issued, the shareholdings of founders and existing shareholders are not diluted.

Going public through a business combination with a SPAC can be a faster alternative to a traditional IPO and it facilitates cross-border listings that are becoming increasingly relevant, especially in the European biotech sector. SPACs allow operating companies to list on a (foreign) public market through a reverse merger.

Because a SPAC has already gone through an IPO prior to seeking a merger counterparty, SPAC mergers avoid market timing issues and the risk of a deal falling down due to volatile conditions. For portfolio companies seeking growth capital, SPAC sales can be particularly advantageous by allowing them to raise funds via a private investment in public equity (PIPE), in addition to the cash available from the SPAC's trust account. However, given the recent high level of redemptions seen prior to the closing of de-SPAC deals, the amount of new capital being raised cannot be significantly smaller than expected, and we would expect corresponding reduction in the costs of the transaction.

There has been increasing interest in European SPACs, in particular as a result of the increasingly receptive regulatory environment. However, European SPACs are beginning to suffer from the same challenges seen in the US, with many first time SPAC projects put on hold or being postponed. For more information on SPACs challenges, see **European Regulatory Outlook and Impact**.

ARE CARVE-OUTS A NEW OPPORTUNITY FOR BIG PHARMA?

A frenzy of deal activity in pharma carve-outs has taken place in recent years, as large, global pharmaceutical companies reach a point in the life cycle of their products when they are ready to divest such legacy or mature products. This article summarises what deal teams should know about these complex transactions that are expected to remain popular throughout 2022 and beyond.

Carve-outs are attractive because they can enable rapid, substantial cash generation and offer the opportunity to realign portfolios and redeploy resources, including human capital, to new areas of focus. Very often the products concerned are beyond patent and dossier protection, and generic competitors are already on the market. This means the companies face falling revenues and potentially lower profits. As such, product owners question the future of these assets in their portfolios, which often results in a process to exit and free up resources for investment in new pipeline drugs and growth platforms.

Profit margins on new blockbuster drugs are often 80% or higher, but as generic alternatives emerge and pricing comes under pressure, that margin can drop to 40%, depending on brand strength and promotion expenditures. The manufacture and marketing of these legacy products also absorbs resources that can be better allocated to future innovations. The result leaves companies with the option of outsourcing activities such as manufacturing, distribution, and promotion to a third party, or downscaling promotion activities. When those options are not sufficiently lucrative, companies may turn to divesting such products, which is becoming increasingly common.

Interested buyers typically include rival big pharma companies that see a strategic or geographic fit for the product within their portfolios. However, a cohort of asset-light companies has emerged in recent years to create a strong market for sales of mature pharma products. These businesses typically outsource capital-intensive elements like manufacturing, storage, and logistics, and rarely support their own R&D capabilities, but instead acquire established products with strong brand recognition to keep those products in the market.

These buyers are motivated by building portfolios of products with stable characteristics that are proven and well established and may be responsive to an increase in promotional activities. They will often seek to streamline processes and increase profitability for as long as possible, but their business models can accept profit margins that are no longer attractive to the sellers. As more and more buyers enter the market with such an approach, the pipeline of pharma carve-outs continues to grow, essentially creating a new industry that extends the lifespan of products that might otherwise have faded from the market.

Deal Challenges

Pharma carve-outs are complex transactions to execute, because acquirers are not taking over whole businesses. Rather, they must extract key assets and separate them from the seller's operations. The buyer takes over marketing authorisations, which requires a regulatory process that varies from jurisdiction to jurisdiction. The transfer of trademarks is usually less complex but it is a key element, because the acquired products typically have strong brand recognition.

The biggest challenges usually arise in connection with the supply chain, which can often be outsourced to one or more third parties. Such outsourcing requires the purchaser to establish a replica of the existing supply chain to ensure a smooth transition of the business. This process may involve a decision to take over all existing contractual arrangements, which, in principle, requires third parties' consent unless the respective contracts provide for a right to freely assign the contract to an acquirer of the product. Sellers may offer an interim arrangement for a transition period, but acquirers need to be mindful of the length of the transition period as they have to transfer all third-party relationships into their own networks.

When third-party manufacturers are incumbent, those manufacturers often want to renegotiate pricing with the purchaser. However, establishing a new manufacturing arrangement with an alternative manufacturer can take years and requires regulatory approval, so the buyer has little room to manoeuvre in any negotiations. Further, a purchaser is typically not permitted to initiate or hold discussions with the current manufacturer prior to the completion of the divestment, resulting in uncertainties at signing of the divestment as to the ability to take over the current manufacturing arrangements. Consequently, the purchaser is acquiring the product based on certain historic cost calculations that may shift quite considerably.

Ensuring supply chain resilience and business continuity is paramount in these transactions, but the risk of being locked out of the market as a result of a failure to replicate elements of existing processes is significant. The same considerations apply when the divested product is manufactured by the seller for a transition period only. In these scenarios, the purchaser has to set up a new manufacturing source.

For sellers, the sophistication of any potential acquirer can be a key consideration in an auction process. Many of these asset-light companies are now well-established buyers with streamlined processes, doing several of these deals in a year. For smaller players transacting at lower volumes, allocating the necessary internal resource to execution can be difficult. Sellers are therefore interested in not only maximising the purchase price but also divesting the product with minimum disruption, namely shorter and more reliable transition periods and lower reputational risks resulting from potential out-of-stock occurrences. This consideration can lead sellers to accept a lower price in favour of a more experienced buyer.

Outlook

The increasing focus on growth areas and digital models that can help improve patient outcomes has caused global pharmaceutical companies to turn the spotlight on their portfolios and seek to sharpen their strategies. Corporate carve-outs and spin-outs are widely expected to remain bullish across the M&A markets in 2022 and beyond, and we expect the pharma sector to continue to be particularly lively.

The growth and success of the new contingent of asset-light market participants in the pharmaceutical and healthcare space is creating a further impetus for transactional activity. As these businesses go from strength to strength, they create new opportunities for big pharma to divest mature assets that may no longer benefit from patent, regulatory, or other protections, allowing them to free up valuable resource to commit to the high-cost, high-risk process of new product development.

EUROPEAN REGULATORY OUTLOOK AND IMPACT

M&A and venture capital activity in 2021 was phenomenal, with the UK biotech and life sciences sector raising over £3 billion in the first three quarters, compared to £2.8 billion raised in the whole of 2020. This article explores anticipated regulatory developments and examines how deal teams should respond.

The resolution of Brexit, a new US administration, and the widespread rollout of COVID-19 vaccines delivered an unprecedented year for healthcare and life sciences deals. Now, as regulators introduce and enhance a wide range of rules impacting healthcare and life sciences, dealmakers must prepare for regulatory change ahead.

Key Anticipated Changes

CMA Will Be More Prominent in Global Deals

Amid the many changes to UK regulations post-Brexit, acquirers now face parallel EU and UK competition investigations. As a result, the UK's Competition and Markets Authority (CMA) is taking a more prominent role in reviewing global M&A deals.

Dealmakers must be alert to the increasingly interventionist approach of the CMA, including in transactions with a limited UK nexus. This is likely to increase the regulatory burden on acquirers, including for non-problematic cases, since the CMA has no equivalent to the EU's "short form" procedure, which allows for a less burdensome notification in simple cases.

The CMA is also taking an expansive approach to jurisdiction and market share, and to reviews of commercial business practices, particularly in the healthcare sector.

Economic Nationalism Will Drive More FDI Screening

Growing economic nationalism is threatening to impact M&A across Europe, with multiple jurisdictions actively enforcing foreign direct investment (FDI) screening regimes and intervening in the acquisition of strategically important companies.

The UK's long-awaited National Security and Investment Act came into force on 4 January 2022, and has retrospective review powers over certain investments. The act includes powers to void, prohibit, or unwind transactions; mandatory notification and preclearance for investments relating to 17 broadly defined sectors; and voluntary notification for other sectors.

Healthcare and life sciences companies should consider if in-scope sectors such as suppliers to emergency services, synthetic biology, advanced robotics, or artificial intelligence are applicable, as the scale of the proposed changes means the act is likely to catch a significant number of transactions.

Pensions Regulators Will Be Increasingly Assertive

With multiple employers deferring deficit recovery contributions in 2020 and growing holes in defined benefit pension plans, dealmakers should anticipate increased scrutiny of deals that involve a defined benefit pension plan — especially as the UK Pensions Regulator gained enhanced powers in October 2021.

The UK Pension Schemes Act 2021 expands the circumstances in which the Pensions Regulator can exercise existing moral hazard powers. It also creates new moral hazard powers that can be exercised against any person and includes penalties that include criminal sanctions.

Regulators Will Increase Enforcement Globally

Last year brought a general step-up in enforcement worldwide, as regulators increasingly coordinated efforts, shared learnings, and sought to take action on a growing range of issues.

Given the wide geographical presence of many healthcare and life sciences companies, the high volume of personal data held on patients and clinical trial participants, the highly regulated nature of the industry, and the need for third-party tie-ups to secure distribution channels, the sector is particularly exposed to the risk of short-term corporate decisions having long-term financial and reputational consequences. Large and well-publicised fines, including for bribery, cyber and data breaches, and cartel behaviours, highlight the risks that dealmakers must take into consideration.

How Should Dealmakers Respond?

Assess the Opportunity

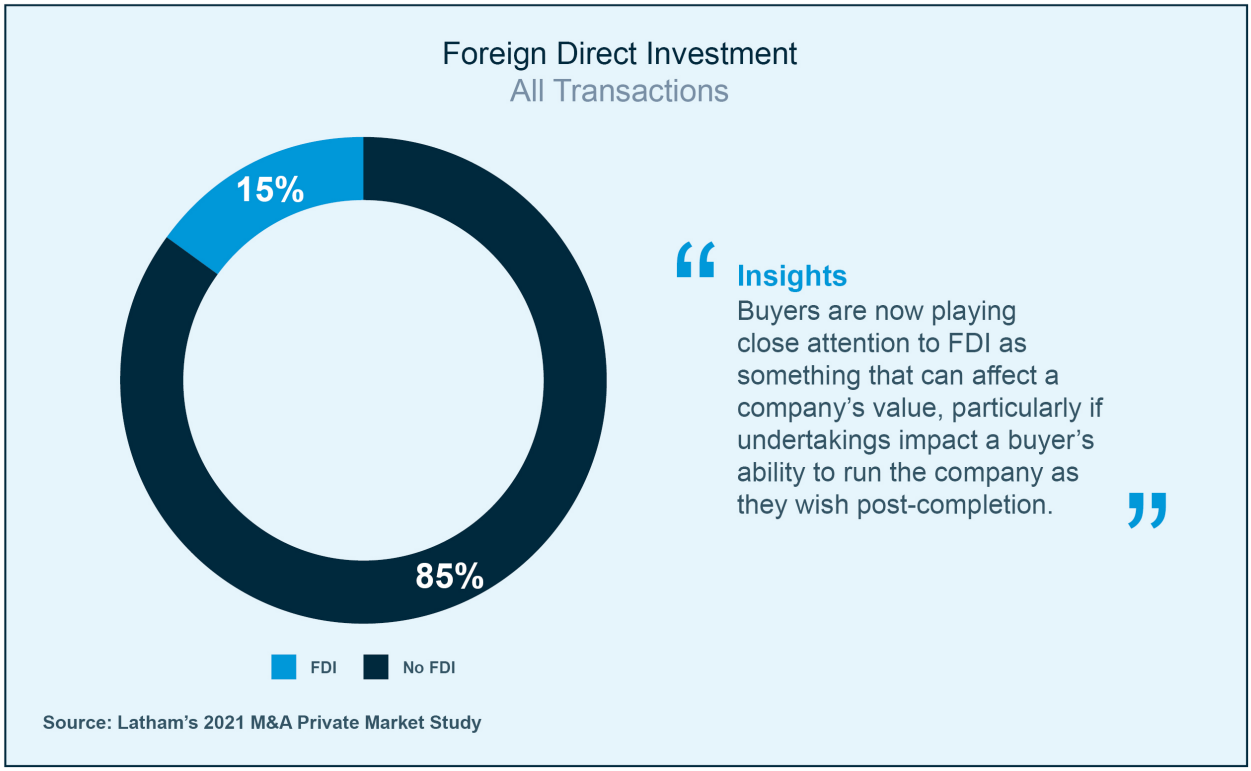
The market will place a greater emphasis on deal planning and critical assessment of regulatory risks, calling for strategic regulatory clearance plans to manage filings, clearances, and other hurdles. If a transaction falls within scope of a particular regime then screening processes might involve extensive disclosures, in turn impacting deal timetables and creating barriers to closing.

More clients are undertaking a merger control-style analysis of FDI approval issues, including analysing their own shareholder base and that of other investors in the deal. Deal teams should consider opening a dialogue with regulators to allay concerns and consider potentially acceptable remedies or undertakings that could impact deal value.

Balancing the requirements of different regulators requires agility. The Committee on Foreign Investment in the United States, for example, may accept undertakings as a condition of clearance, including prohibiting or limiting the transfer of certain intellectual property, trade secrets, or know-how. The UK has also accepted undertakings, but differences between the CMA and other antitrust regulators could create challenges in ensuring that remedy offers effectively straddle the EU and UK systems.

Allocate Risk and Uncertainty

Latham's 2021 Private M&A Market Study — which examined more than 320 European deals — found that the prevalence of FDI approval conditions grew last year. They featured on 15% of deals in 2021, compared to 10% in 2019.



Deals with an FDI condition were most common in healthcare and life sciences, which represented 26% of deals, and the UK, France, and Germany were the most commonly cited FDI regimes.

While the prevalence of FDI conditions is significantly less than that of merger control conditions (included in 52% of deals analysed in 2021), this will likely shift moving forward, particularly in regulated industries. Dealmakers should consider the scope of FDI conditions and the efforts parties must take to satisfy them, in addition to the implications for deal timetables and certainty.

Further, compressed deal timetables and a seller's market in recent years have contributed to a downward trend for liability caps on warranty claims — 63% of sellers in Latham's 2021 Private M&A Market Study limited their commercial warranty liability to less than 20% of equity value, compared to 41% in the 2014 edition.

While buyers may have sought additional warranties, indemnities, and post-closing price adjustments to mitigate recent uncertainties, the M&A market remains competitive and acquirers often accept less-than-perfect deal protections. This emphasises the importance of detailed regulatory diligence and the potential need for risk-based post-closing audits or remedial processes.

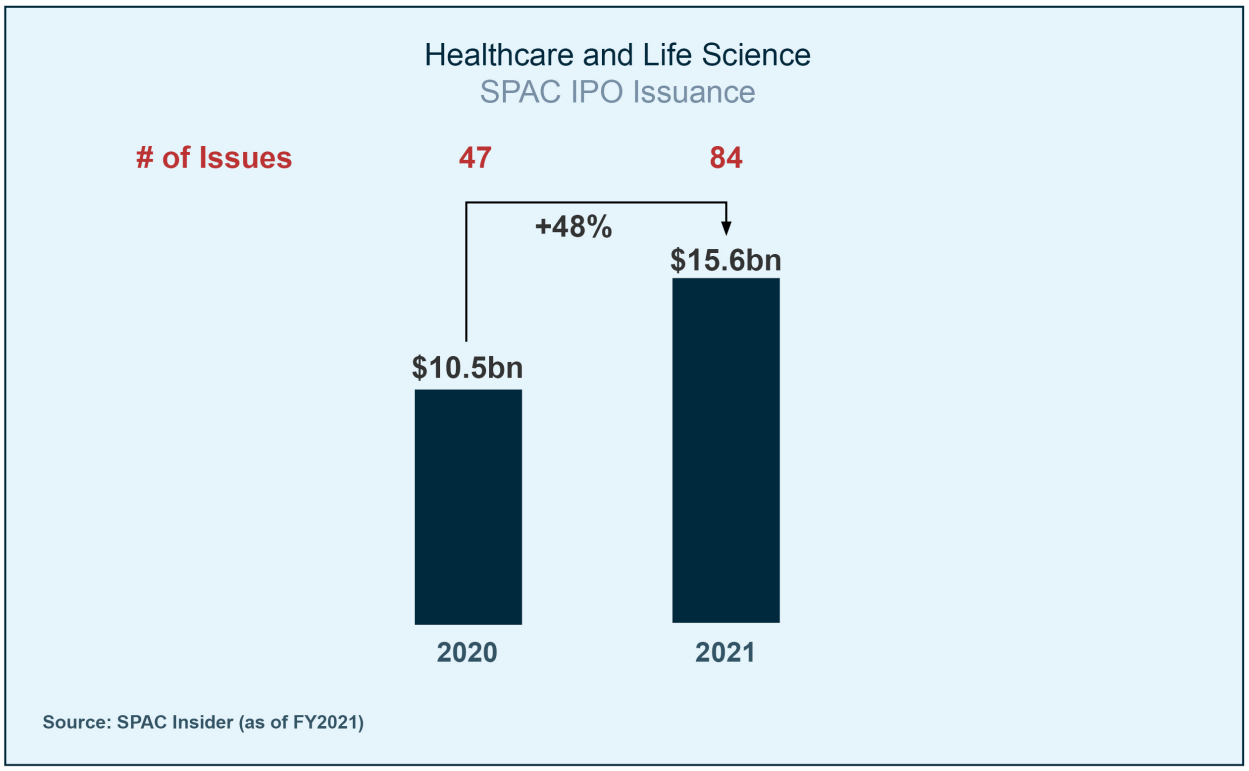
Mind the Gap

Gap covenants governing the conduct of the target business between signing and closing came under heightened scrutiny in 2020 and 2021, as dealmakers debated what type of business conduct counted as "ordinary course" in extraordinary times.

In an increasingly regulated M&A environment, deal teams should expect a greater focus on these covenants, particularly given lengthening timelines between signing and closing. Buyers need sufficient control of and confidence in the operation of the business by the seller — but without having full control through equity ownership, buyers must also be cognisant of gun-jumping rules.

New Deals, New Challenges

SPACs took off in the US in 2020 and 2021, with SPAC sponsors launching shell companies to take private companies public via merger. SPACs proved especially popular in healthcare and life sciences, particularly in digital health, with 84 healthcare and life sciences IPOs in 2021 raising a combined total of US$15.6 billion, according to SPAC Insider.



This trend has not gone unnoticed by regulators. The US Securities and Exchange Commission (SEC) noted in April 2021 that it was looking carefully at filings and disclosures by SPACs and their private targets, and warned that warrants as part of SPAC IPOs should, in certain circumstances, be listed as liabilities rather than equities.

The launch of European-style SPACs; the growing number of triple-track deal processes with an auction sale, IPO, and SPAC sale as possible outcomes; and heightened regularly scrutiny and increasing instances of distressed M&A all present new challenges. Agile legal advisers will need to be able to navigate these complexities if they are to give dealmakers the competitive edge.

8 KEY QUESTIONS ON THE EU'S CLINICAL TRIALS REGULATION

After years in the making, the EU's clinical trials regulation came into force on 31 January 2022. Eveline Van Keymeulen, a partner in Latham & Watkins' Brussels and Paris offices, outlines what companies need to know.

What Is Happening With the EU Clinical Trials Regulation?

The regulation was passed into EU law in April 2014, but could not become applicable until the EU clinical trials portal and database were fully functional. Following a period of delay caused by technical difficulties, the European Commission confirmed in July 2021 that the portal and database are up and running, in line with the specifications agreed between the European Medicines Agency, the Commission, and the EU Member States.

The regulation, applicable from 31 January 2022, replaces the Clinical Trials Directive that currently governs the application for, and conduct of, clinical trials in the 27 EU Member States.

What Is the Significance of the Portal and the Database?

The portal is one of the major novelties that the regulation introduced and will serve as a single communication platform for stakeholders through which trial sponsors and competent authorities can exchange relevant information. The database will act as a repository of all data and information about clinical trials in the EU and, with limited exceptions, will be fully searchable by the public.

Together, the portal and the database will facilitate easier cooperation between Member State authorities on clinical trials, enable better communication between trial sponsors and Member States, and allow stakeholders to search for specific clinical trial details. The portal and database will also allow citizens across the EU to access clinical information about medicines.

How Will the Regulation Change the EU Clinical Trials Regime?

The regulation introduces significant changes to the conduct of clinical trials in the EU.

First, it creates a single framework for the submission of clinical trial applications and related data and information. While the directive requires separate clinical trial applications in each Member State, the regulation introduces a centralised process for the submission of a single application to all Member States concerned.

The new regime also introduces a harmonised procedure for the assessment of clinical trial applications, with a joint assessment by all Member States concerned, and a separate assessment by each Member State involved with respect to specific requirements (including ethics rules) in its own territory. The regulation allows sponsors to make a single submission to both the competent authority and an ethics committee in each Member State at once, leading to a single decision per Member State. Each Member State's decision will be communicated to the sponsor via the portal.

The regulation shortens the timeframes for the assessment of clinical trial applications to ensure the EU remains an attractive place for sponsors to conduct trials. By subsuming ethics committee assessment in each Member State within the overall timeframe, the new process will increase transparency and predictability for sponsors.

Other changes include a new streamlined process for reporting adverse reactions through the portal, a more systematic notification system to report milestone events, and specific provisions on co-sponsorship. We will also see a new, lighter regime for "low-interventional" clinical trials, which are conducted using authorised medicinal products and pose minimal additional risk to the safety of trial subjects compared to normal clinical practice.

What Are the Regulation's New Transparency Provisions?

Sponsors should be aware of the heightened transparency regime, which is designed to foster public trust in the clinical trial system and introduces increased reporting requirements. While only limited information on clinical trials is publicly accessible under the current regime, the regulation requires sponsors to publish a broad set of data in the EU database.

For example, the sponsor must submit a summary of the results of a clinical trial to the database within a year of its completion, regardless of the trial outcome. That summary must include any adverse event information, modifications, interruptions, restarts, and limitations. The sponsor must also publish a further summary for laypersons containing the description and frequency of adverse reactions that data subjects suffered, the overall results of the trial, and comments on the outcome.

Are There Any Situations in Which Clinical Trial Data Will Not Be Publicly Accessible?

Yes. Transparency is a key feature of the new clinical trials landscape, but absent an overriding public interest in disclosure, confidentiality will be justified when needed to protect personal data under EU data protection law, or to protect commercially confidential information. In that regard, sponsors will be able to set deferrals to the public disclosure of specific documents in light of key trial milestones, depending on the category of the specific trial.

In addition, data will not be made public for the purposes of protecting confidential communication between Member States in relation to the preparation of the assessment report, or if necessary to ensure effective supervision of the conduct of a clinical trial.

Will the Regulation Apply in all 27 Member States?

Yes, it is directly applicable in all EU Member States without the need for further national implementing acts, although it will rely on some national laws and decision-making powers.

Member States will still be able to set the rules for ethics committee reviews in their countries, and will be responsible for assessing the clinical trial application under the second stage of the application process. They will also be able to decide whether to require a legal representative to be established in their territories when the sponsor is not established there. National laws will govern the systems put in place for ensuring compensation is available to trial subjects in the event that they suffer any damage from participating. Notably, the regulation mandates that Member States ensure such a system is in place.

Stakeholders should be aware that Member States are responsible for their own systems of enforcement and penalties for infringements of the regulation, which must be effective, proportionate, and dissuasive.

What Transitional Arrangements Are in Place?

The regulation foresees a three-year transition period. For clinical trials whose request for authorisation was made under the directive, before 31 January 2022, the directive will continue to apply on a transitional basis for three years. Requests can also continue to be submitted under the directive for the first 12 months of the regulation and, if authorised, those requests will be governed by the directive until 31 January 2025. By that date, all ongoing trials will become subject to the provisions of the regulation.

What Is Brexit's Impact on the Regulation?

The UK is now considered a third country for the purposes of EU law, and so the regulation will not be applicable to clinical trials conducted there.

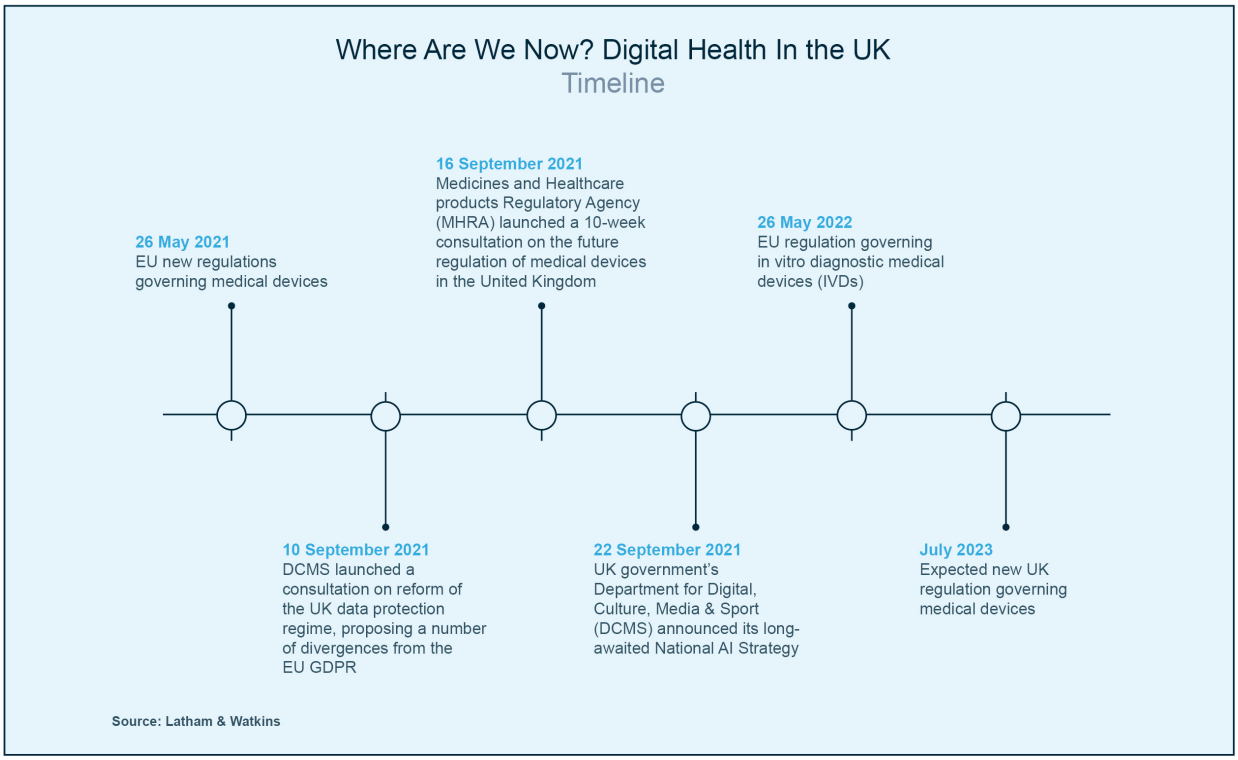
In practice, UK sponsors conducting trials in the EU will need to have an EU or EEA-based legal representative or sponsor. Conversely, EU or EEA-based sponsors are currently able to conduct clinical trials in the UK without the need for a local representative.

On 17 January 2022, the UK Medicines and Healthcare products Regulatory Agency (MHRA) launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closes on 14 March 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The consultation's outcome will be closely watched and will determine whether the UK chooses to align with the regulation or diverge from it to maintain regulatory flexibility.

UK DIGITAL HEALTH: TRENDS AND REGULATORY UPDATES

The UK has an active digital health market comprising both the private and public sectors. Venture capital funding in the digital health sector has increased significantly in recent years, with the majority of investment appearing to come from private investment firms, but also via increased public financing from IPOs. This article discusses the growing investment, how COVID-19 has affected digital health solutions, and the different legal regimes governing the digital health sector.

The COVID-19 pandemic has further heightened the positive and dynamic investment climate for digital health technologies in the UK. In particular, the pandemic has highlighted the need for resilience in healthcare systems, including through digital health solutions. As a result, the pandemic has significantly accelerated uptake of digital health solutions in the UK and related investment opportunities, as well as challenging structural barriers that had previously slowed investment in digital health innovations. Currently, digital health in the UK is governed by a patchwork of different legal regimes, rather than bespoke legislation, while various regulatory and enforcement bodies have jurisdiction over the digital health sector.



Medical Devices

On 26 May 2021, the EU overhauled its regulatory framework of medical devices with the introduction of a new regulation governing medical devices. A further EU regulation governing in vitro diagnostics (IVDs) is due to come into force on 26 May 2022 (with specific transitional periods depending on the type of IVD). These two new regulations do not form part of UK law following Brexit.

On 16 September 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) launched a 10-week consultation on the future regulation of medical in the UK, with the aim of creating a "bold new regulatory regime" effective from July 2023. The consultation, which closed on 25 November 2021, aims to amend the Medical Devices Regulations 2002 with a view to creating new access pathways to support innovation, creating an innovative framework for regulating software and artificial intelligence (AI) as medical devices, reforming IVD regulation, and fostering sustainability through the reuse and re-manufacture of medical devices. The consultation covers 15 key areas, including the scope of the regulations, classification of medical devices, economic operators, registration and unique device identifiers, conformity assessment, clinical studies, IVDs, software, and routes to market. For the most part, the proposed changes in many of these areas align with the new EU regime, although there are some notable divergences, in particular with respect to routes to market.

Software and Artificial Intelligence

In parallel with the consultation on future regulation of medical devices, the MHRA has published a set of 11 work packages detailing the UK's proposals to provide a regulatory framework for software and AI medical devices. The MHRA plans to deliver key elements of each work package from autumn 2021 until summer 2023. These proposed reforms, most importantly regarding software and AI as a medical device, will be of particular interest for companies offering digital health solutions in the UK.

Separately, on 22 September 2021, the UK government's Department for Digital, Culture, Media & Sport (DCMS) announced its long-awaited National AI Strategy, which sets out the government's 10-year plan to make the UK a "global AI superpower". The strategy focuses on three core pillars: (i) investing in the long-term needs of the AI ecosystem, (ii) ensuring that AI benefits all sectors and regions of the UK, and (iii) governing AI effectively.

Data Privacy

Digital health offerings will usually process data concerning health, genetic data, or biometric data, which are among a list of "special categories of personal data" under the UK General Data Protection Regulation. Such data can only be processed if one of a limited number of conditions is met, which are exhaustively set out in law.

Companies engaged in the digital health space should bear in mind the concepts of "privacy by design" and "privacy by default", which are built into the UK data protection regime and also the Information Commissioner's Office (ICO's) stated priority on records management in the healthcare space. In practical terms, this means implementing technical and organisational measures that secure data and ensure that data is processed in a manner commensurate to the purposes for its processing.

In 2020 and 2021, we saw a continuation of the trend of ransomware and other cybersecurity attacks targeting companies with large amounts of electronic health records or profiles. Defending against and responding to a ransomware incident, particularly one with multi-jurisdictional impact, is complex and requires consideration of a number of regulatory areas, including data protection, cybersecurity, law enforcement, industry-specific regulation, and sanctions (in relation to ransom payments).

On 10 September 2021, DCMS launched a consultation on reform of the UK data protection regime, proposing a number of divergences from the EU GDPR, including reducing compliance burdens, reducing barriers to data flows, and reducing barriers to innovation by making it easier to use, share, and reuse data for research and development purposes.

Looking Forward

This year will likely bring more clarity as the nascent regulatory framework for digital health continues to develop. Companies and investors in the digital health sector will need to keep pace with the fast-moving regulations and guidance, particularly in the area of AI, as well as potential further divergences between the UK and the EU.

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