IN
INTERNATIONAL NEWS

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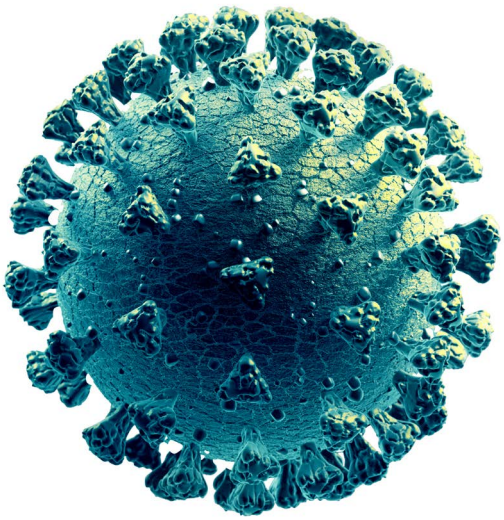
COVID-19 GLOBAL PANDEMIC



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These extraordinary times are prompting an exceptional response from every field of business across every sector. Lawyers often talk about constantly evolving regulatory and commercial landscapes, but there has never been a pace of change as rapid as this, with daily updates being made to what was previously considered immutable legislation. The European Commission has confirmed that the Coronavirus (COVID-19) crisis justifies derogation from normal conformity assessment procedures for certain items, the Medical Device Regulation has been postponed by a year, and EU antitrust and State aid rules have been relaxed.

Businesses are responding and adapting to the most immediate challenges, while also keeping an eye on longer term issues, such as data security when employees are working from home.

There is, however, light at the end of the tunnel and, of course, there are other developments that have nothing to do with the current health crisis but still need to be understood and acted upon.

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

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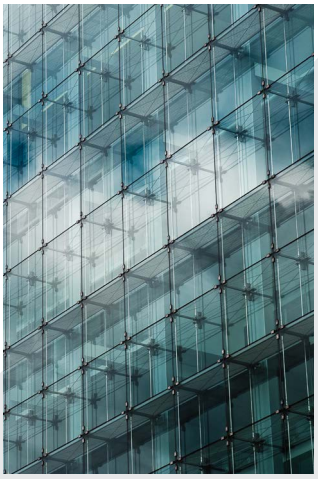

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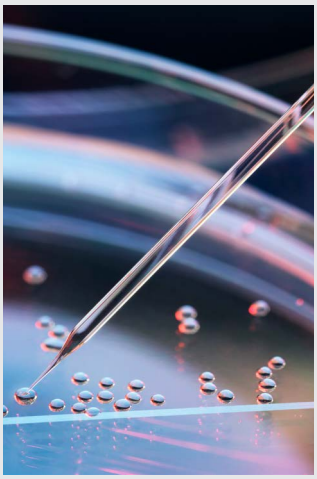

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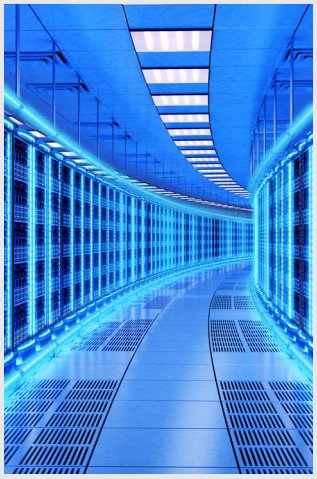

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THE LEGAL IMPACT IN EUROPE ON PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES

Sharon Lamb, Dr. Stephan Rau, Emmanuelle Trombe and Jana Grieb

The current crisis mode has triggered legal and commercial issues that affect the pharmaceutical and medical device industry across Europe.

CLINICAL TRIALS NOT RELATED TO COVID-19

The European Medicines Agency (EMA), together with the European Commission and the Heads of Medicines Agencies (HMA), on 20 March 2020 published an initial Guidance on the Management of Clinical Trials during the COVID-19 pandemic, followed on 25 March by additional points to consider. Sponsors should question whether or not they need to start a new clinical study or include new study participants in an ongoing study; consider whether the study could be temporarily suspended or its overall duration extended; and determine if the conduct of the study could be modified.

The French drugs agency, the Agence Nationale de Sécurité du Médicament (ANSM) has published a Q&A with recommendations for ongoing clinical trials being conducted in France. The ANSM invites sponsors to email specific questions to questions.clinicaltrials@ansm.sante.fr or ccs-pole-recherche@sante.gouv.fr.

The German Federal Institute for Drugs and Medical De-vices (BfArM) and the Paul-Ehrlich-Institut (PEI) are currently prioritising the processing of amendment notifications required by COVID-19. BfArM has summarised the relevant guidance on its website and set up a dedicated email address for inquiries about clinical trials in connection with COVID-19: CT-COVID@bfarm.de. On 26 March 2020, BfArM published supplementary recommendations to EMA's guidelines.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance on Managing clinical trials during Coronavirus (COVID-19). Parties are asked to submit applications for clinical trials relating to COVID-19 directly to the Clinical Trial Helpline (clintrialhelpline@mhra.gov.uk).

ACCELERATED MARKET ACCESS FOR DRUGS TO TREAT COVID-19

At EU level, the Priority Medicine (PRIME) system enables accelerated assessment and granting of conditional approval for priority medicines. The EMA offers free scientific advice for the benefit of companies developing vaccines or therapeutics against COVID-19 *via* 2019-ncov@ema.europa.eu.

The EMA's Guidance on the Management of Clinical Trials specifically addresses the launch of new clinical trials for treatments of COVID-19, and requests the use of large, multinational trial protocols in line with the call by the Committee for Medicinal Products for Human Use for robust trial methodology in clinical trials for potential COVID-19 treatments or vaccines.

In line with World Health Organisation requests, parties should ensure that the official acronym for the Coronavirus (COVID-19) is entered in the title field of the trial registration data set to facilitate finding and extracting clinical trials from public databases.

For products intended for use in emergency situations, reduced pharmaceutical and non-clinical data may be accepted. The EMA and national regulators will assess whether or not public health would benefit from immediate availability, and whether or not that benefit is greater than the risk posed by accepting less than the usually required evidence of safety and efficacy.

The ANSM has implemented accelerated procedures for the initial assessment of authorisation requests for clinical trials related to COVID-19. The ANSM recommends that trial managers submit an authorisation request as soon as possible and contact the French Ministry of Health (the DGOS) before the finalisation of the initial authorisation procedure.

BfArM and PEI currently give priority to projects that relate to the diagnosis and/or treatment of COVID-19. BfArM and PEI accept successive submission of marketing authorisation application documents in order to speed up the review of the application. The consultation fee in relation to COVID-19 treatment can be reduced to a quarter of the statutory fees.

The MHRA said on 23 March 2020 that it is working closely with the Department of Health and Social Care and other healthcare partners on COVID-19, and is prioritising certain fields, including the development of vaccines and the launch of clinical trials for new medicines, and managing the supply of medicines and healthcare products. MHRA's Guidance can be found here.

MARKET ENTRY FACILITATION

The market entry of personal protective equipment (PPE) usually requires a—sometimes lengthy—conformity assessment and Conformité Européene (CE) marking.

On 3 April, the Commission issued Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the COVID-19 context, confirming that the public health crisis associated with the COVID-19 outbreak justifies derogation from the normal conformity assessment procedures for PPE and certain medical devices. There is, however, still a need to be attentive to falsified certificates and counterfeit devices and Member States should take appropriate market surveillance measures.

The Commission has also published several guidelines to assist companies in the legal and regulatory assessment of PPE, hand sanitisers, 3D printers and products made by 3D printers. The European Committee for Standardization and the European Committee for Electrotechnical Standardization have also provided a large number of free relevant standards, which are available on the websites of the respective member associations at the Member State level.

EXPORT AND IMPORT OF PPE AND SELECTED MEDICAL DEVICES

The Commission, in Regulation (EU) 2020/402 of 14 March 2020, temporarily made the export of certain products, including protective goggles and visors, face shields, oral and nasal protective equipment, and protective clothing and gloves, subject to authorisation until 26 April 2020. During that period, an export license would only be issued in special, individual cases.

These new export restrictions are problematic for companies whose products fall within the scope of the Regulation but are contractually obliged to supply these products to third countries. Companies will have to assess whether an export license can be considered and, if not, what legal and other options exist to deal with the export ban.

On 3 April 2020, the European Commission agreed to temporarily waive customs duties and VAT on the import of medical devices, and protective equipment, from third countries.

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HOARDING OF AND PROFITEERING FROM RESTRICTED MEDICINES AND PRODUCTS

To prevent hoarding and profiteering, European Governments have taken some extraordinary steps. The situation is as follows at the date of publication.

An order adopted on 23 March 2020 limited the sale of non-prescription paracetamol, ibuprofen and acetylsalicylic acid (aspirin) until 11 May 2020. Online sale of such products has been suspended until further notice.

By a Decree dated 23 March 2020, the French Government can requisition until 31 May 2020 existing masks, and those in production between 14 March and the date on which the health emergency ends. The same Decree allows for stocks of imported masks above a threshold of five million units per quarter per company to be entirely or partially requisitioned by order of the Minister for Health.

Pharmaceutical companies should keep an eye on production networks and supply chains.

The French government further tackled the increase in selling prices (profiteering) of hydro-alcoholic gels caused by the COVID-19 outbreak by capping both wholesale and retail prices until 31 May 2020.

The website www.stopcovid19.fr allows manufacturers and distributors of essential products and equipment to distribute those items to health professionals and public institutions.

On 20 March 2020, BfArM published an allocation order requesting that pharmaceutical companies and wholesalers not supply drugs beyond the usual demand in order to counteract stockpiling that leads to an unequal distribution of drugs in the market.

The order applies to "supply-relevant drugs", which include prescription drugs with an active ingredient that is particularly relevant to public health. Pharmaceutical companies should examine to what extent their drugs are affected by the allocation order.

On 20 March 2020, the UK Government expanded the list of medicines that cannot be parallel exported from the United Kingdom or hoarded, which now includes adrenaline, insulin, paracetamol and morphine.

Companies can continue to withhold medicines to maintain Brexit stockpiles and as part of stock management arrangements agreed with marketing authorisation holders.

IMPENDING SUPPLY BOTTLENECKS

For several weeks now, attention has been turning anxiously to China, which supplies raw ingredients to other countries. In addition, the Indian Government has recently limited the export of 26 pharmaceutical ingredients, including paracetamol, certain antibiotics, progesterone, and vitamins B12, B1 and B6.

Pharmaceutical companies should keep an eye on production networks and supply chains relevant to them and, where possible, ensure that they do not depend exclusively on individual suppliers. If there is a risk of a supply bottleneck, pharmaceutical companies should review their rights under the respective contracts in order to at least limit adverse commercial effects.

MORATORIUM FOR THE MDR REGULATION

The Medical Devices Regulation (MDR), which was supposed to come into effect on 26 May 2020 for one year, was postponed on 17 April 2020 until 26 May 2021; notified bodies remain assigned under the current law, the Medical Devices Directive (MDD), until then. The transition period for medical devices with MDD certificates will remain unchanged and expire on 26 May 2024.

For the most up to date information on this rapidly evolving situation, click here for France, here for Germany and here for the United Kingdom.

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EU ANTITRUST AND STATE AID RULES RELAXED TO HELP BUSINESSES

Andrea Hamilton, Sabine Naugès and Christian Krohs

The European Commission and European Competition Network (ECN) have taken unprecedented action to try and relieve the pressure on businesses and consumers.

EU ANTITRUST RULES RELAXED FOR CERTAIN COLLABORATIONS

On 8 April 2020, the European Commission issued a Temporary Framework Communication, providing guidance and criteria regarding competitor collaboration projects in response to the economic shocks caused by the Coronavirus (COVID-19) crisis. The focus is on collaboration projects aimed at mitigating or eliminating shortages of "essential scarce products and services"—especially critical medicines—even if such collaboration may otherwise risk infringing competition laws.

While companies remain responsible for assessing their own proposed conduct, the European Commission will provide informal, oral guidance to businesses or—exceptionally—a "comfort letter" to allow projects to be implemented quickly. At the same time, businesses are cautioned that opportunistic anticompetitive conduct, such as limiting supply or abusing a dominant position by charging excessive prices, will be targeted for enforcement.

This follows an unprecedented "joint statement" by the European Competition Network with a similar message that its members will not actively intervene against "necessary and temporary" measures, including cooperation among competitors, in order to avoid a "shortage of supply" of critical products. In the days preceding and following the joint statement, several national competition authorities and governments went further, authorising temporary waivers, amending competition legislation or otherwise indicating flexibility in their approach to competition law enforcement in critical industries.

Principles of Competitor Collaboration

The key takeaway of these developments is that the competition rules still apply, but are sufficiently

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flexible to allow limited critical industry adjustments to address severe economic shocks. Businesses should carefully assess any proposed collaboration project to ensure compatibility with applicable competition laws, and should seek guidance from relevant regulators where appropriate or necessary.

Low-Risk Conduct

Collaborations between companies that do not compete in the relevant field, and which do not involve competitively sensitive information (such as prices, capacity or customers) are generally considered lower-risk. For example, the sharing of best practices to mitigate the impact of COVID-19 on the workforce is unlikely to raise concerns, as long as participation in the discussions and implementation of any recommendations is voluntary.

Similarly, companies active nationally may seek to co-ordinate their purchasing with other businesses in an effort to ensure continued comprehensive supply of necessary consumer products. EU competition law has precedent for such co-operations in the form of the pan-European supermarket purchasing alliances that competition authorities have previously accepted under certain conditions.

High-Risk Conduct

Certain types of conduct have a particularly high risk of being considered objectively anticompetitive and not justifiable, regardless of the circumstance. Such conduct would expose companies to significant fines and includes

- Price fixing or coordinating price fixing
- Limiting or coordinating capacity
- Agreeing to or refusing to deal with a particular customer(s) or suppliers(s)
- Exchanging competitively sensitive information among competitors, in particular pricing strategies, or an agreement to exchange information.

In addition, companies that hold significant market power or have a “dominant” position may face antitrust risk under Article 102 of the Treaty on the Functioning of the European Union (TFEU) or even stricter national rules if they unilaterally impose excessive prices, refuse to supply certain customers or discriminate between customers without justification.

Conduct that May Be Permitted but Still Requires Careful Consideration

Recent developments show that certain conduct, including collaborations, may be permitted if it is necessary, limited in time and scope, and benefits consumers by preventing the scarcity of essential goods and services. Businesses should, however, carefully assess any proposed collaboration project, implement appropriate safeguards and, where needed, seek guidance from relevant regulators where appropriate or necessary. Examples of potentially permissible collaborations include

- Joint purchasing or production
- Stock management and distribution of critical products
- Shared use of assets or staff
- Exchange of information on, for example, stock levels, distribution patterns or stock shortfall (not prices)
- Standardising COVID-19 research and development (R&D) projects
- Co-operation between suppliers at different levels of the distribution chain to enable wholesale sales to end customers.

While these examples of temporary co-operation appear feasible in light of current enforcement statements and the extraordinary circumstances, they are still not without risk and should be undertaken only after careful consideration and, possibly, notification to the relevant authorities.

COMMISSION PERMITS CERTAIN STATE AID

On 19 March 2020, the European Commission adopted a temporary framework that allows Member States to grant certain State aid to businesses to help them face the economic and financial consequences of the health crisis. The temporary framework is based on Article 107(3)(b) TFEU, which allows for State aid "to remedy a serious disturbance in the economy of a Member State."

Companies active nationally may seek to co-ordinate their purchasing with other businesses.

The Commission expanded the temporary framework on 3 April 2020 to include measures aiming to accelerate the R&D of Coronavirus relevant products, to protect jobs and to further support the economy. On 9 April 2020, the Commission sent out to Member States, for consultation, a proposal to extend the scope of the framework to recapitalisation measures.

The temporary framework currently in place provides for several types of aid:

1. Direct grants, selective tax advantages and advance payments of up to €800,000
2. State guarantees for loans taken by companies from banks
3. Subsidised public loans to companies
4. Safeguards for banks that channel State aid to the real economy. The temporary framework makes clear that such aid is considered as direct aid to the banks' customers, not to the banks themselves
5. Short-term export credit insurance
6. Support for Coronavirus-related R&D
7. Support for the construction and upscaling of testing facilities
8. Support for the production of products relevant to tackle the Coronavirus outbreak
9. Tax payment deferrals and/or suspensions of social security contributions
10. Wage subsidies for employees.

The Council of the European Union also endorsed, on 23 March 2020, the activation, for the first time, of the general escape clause of the Stability and Growth Pact, which enables Member States to depart from their normal budget requirements in a coordinated and orderly manner.

The European Commission has authorised dozens of aid schemes, most of them in a record time of 48 hours upon notification and in accordance with Article 107(3)(b) TFEU and the temporary framework.

For example, only two days after the adoption of the temporary framework, the Commission authorised three separate French support schemes expected to mobilise more than €300 billion of liquidity: two schemes enabling Bpifrance to provide State guarantees on commercial loans and credit lines for enterprises with up to 5,000 employees; and a scheme to provide State guarantees to banks on portfolios of new loans for all types of companies.

Since then, the Commission has authorised schemes including:

- A €.2 billion French Solidarity Fund scheme for small enterprises
- A €10 billion French guarantee scheme to support the domestic credit insurance market
- A German aid scheme allowing for direct grants, repayable advances tax or payment advantages, loans, guarantees and equity
- Loan schemes allowing the German State-owned Kreditanstalt für Wiederaufbau and other regional authorities and promotional banks to provide subsidised loans.

More information on these topics can be found here and here.

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WORKING (CYBER) SAFELY FROM HOME DURING COVID-19

Laura Jehl, Paul Ferrillo, Mark Schreiber and Kari Prochaska

Amid the Coronavirus (COVID-19) pandemic, more people than ever before are working remotely from home. This raises new cyber security challenges for businesses but there are ways to mitigate the risk.

This sudden shift to working from home significantly increases cyber risks to businesses. The United States Department of Homeland Security and Cybersecurity and Infrastructure Security Agency, together with the United Kingdom's National Cyber Security Centre, issued a joint alert on how COVID-19 is being exploited by malicious cyber actors. The French National Information Security Agency, the ANSSI, has also noted an increase in fraud related to the public health emergency and attempts to exploit COVID-19 for phishing or scams. There are, however, steps individuals and organisations can take to help reduce cybersecurity risks.

SECURE AND HARDEN VIRTUAL PRIVATE NETWORKS

The virtual private network (VPN) must now support an entire workforce working from home, around the clock, and on sensitive matters. VPNs need to be able to scale expected and excess or "overflow" traffic. Scalability can be handled *via* a software or appliance solution. Certain solutions require user companies to maintain software licenses, which can generally be purchased on an individual basis.

Multi-factor authentication (MFA) should be used for all VPN access. If MFA is already deployed, businesses should expand it to additional staff and endpoints. Although an MFA rollout is potentially disruptive, requiring MFA for VPN access is an important step in warding off unauthorised access.

Servers running VPNs should be updated and vulnerabilities patched promptly. Vulnerabilities should be prioritised according to severity and the likelihood that they will be exploited.

Administrative access to a network should be restricted and "least privileged access", the concept of restricting

access rights to only those who absolutely need it, should be practised religiously. An attacker who obtains those credentials could access the VPN and move laterally through company systems.

Of course, default and administrative passwords should be changed regularly and made more complex. Now is the time to consider changing a password policy to require lengthier and more complex passwords.

Companies should prevent employees from disabling security features and remote access precautions, or creating security workarounds.

VPNs need to be able to scale not only expected traffic, but also excess or "overflow" traffic.

"Bring Your Own Device" (BYOD) rules and standards should be updated to securely manage employee devices using mobile device management (MDM) software in order to allow secure access to internal resources. Endpoints with VPN access must be equipped with adequate endpoint security software and meet system security configuration guidelines, including items such as Split Tunneling, least privilege and host-based firewalls. Employee devices with access to internal applications should be managed by MDM software in order to ensure compliance with security requirements.

To ensure the implementation of new or strengthened security measures, there should be executive- and chief information security officer (CISO)-level oversight of any change management, including to the network baseline or devices.

STRENGTHEN EMAIL AND PHISHING ATTACK PRECAUTIONS

It is worth reminding employees to stay vigilant and follow cybersecurity best practices, as they may be less alert to corporate policies when working from home. As a precaution, companies should set up or strengthen email filters to guard against phishing and spoofing attacks.

Email filters generally work by blocking potential spam email or malicious content, or through specifically configured rules-based approaches, which may be bolstered by machine learning. A comprehensive email solution protects against all threats, including phishing, impersonation and spam. Employee training regarding phishing techniques and frequent updates on common COVID-19 spam email campaigns can help keep a network safe. The following are broad but useful tips to send to employees:

- Treat emails that appear to come from health authorities, such as the World Health Organization (WHO), with caution as threat actors are impersonating high profile organisations.
- Trust only well-known sources for information on COVID-19. Fake donation websites and email addresses are being used to steal passwords and financial information.
- Exercise caution when opening attachments or clicking links from unfamiliar senders or websites.
- Be wary of attempts by threat actors to reach out by telephone (vishing) or text (smishing).
- Stay alert for indications of an attack, *e.g.,* a false sense of urgency or pressure to ignore security procedures.
- Ensure the Wi-Fi router and all devices are protected by a strong password and the latest encryptions.
- Promptly install updates.
- Don't let family members use work equipment.
- Prohibit "shoulder surfing", photographs and "snapshots", and otherwise secure physical locations at home.
- Notify the helpdesk or information security team immediately when you receive suspicious communications.

The following helpful resources address these threats:

- Coronavirus Fraud Schemes Surge, as FBI, HHS OIG Advise Cyber Hygiene
- Defending Against COVID-19 Cyber Scams
- COVID-19 Complication: Ransomware Keeps Hitting Healthcare
- SANS' Working From Home factsheet and guidance on Creating a Cyber Secure Home
- The European Union Agency for Cybersecurity's Tips for cybersecurity when working from home.

STAY ON TOP OF PATCHING AND BACKUPS

Organisations should ensure they continue to deploy security patches for infrastructure and software. Bad actors may take advantage of lax patching practices, so it is important to be mindful of the availability of patches to address vulnerabilities.

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Backups ensure that data can be recovered in the event of data security incidents, such as ransomware, system failures and other data integrity issues. Having a reliable, recent backup that has been tested can help a business avoid paying a ransom to malicious actors. In addition, enhanced logging enables the identification of errors and course correcting.

ENSURE IT AND SECURITY STAFF RESILIENCY

The exceptionally wide reach of COVID-19 may necessitate cross-training, teaming and collaboration between IT and information security in the event that a number of key employees are affected at the same time.

At the very least, organisations should appoint a backup CISO who takes the helm when the CISO is traveling or out sick, and the incident response plan should designate a backup to the backup leader, in case personnel are unavailable.

REVIEW THE INCIDENT RESPONSE PLAN

In addition to being required by certain regulators, a good incident response plan (IRP) is like the coach's playbook for an entire game. It should tell the incident response team how to respond to an cyberattack, such as credential harvesting attacks, ransomware attacks or a network intrusion. All organisations should review their existing IRPs to ensure they account for a remote workforce scenario and comply with the following:

- Key personnel should have access to the latest version of the IRP from home.
- The IRP must be accessible if company systems are encrypted in a ransomware attack or otherwise disabled.
- There must be a hard copy of the IRP, easily located in a secure home workspace.
    - Ideally, all critical team members should have hard copies.
- The IRP should include updated cellphone contact information and alternate email addresses for all incident response team members, and a plan for offline or out-of-band communications, in the event that connectivity is disabled or the threat actor is inside the network.

MANAGED SECURITY SERVICE PROVIDERS

When healthcare organisations are inundated with seriously ill patients, they can't afford downtime caused by data security incidents. When security teams are shorthanded or personally affected by the virus, oversight of IT systems may be impaired. Both situations make organisations extremely vulnerable to cyber criminals.

Organisations should consider engaging a trusted cybersecurity firm to provide managed security services. They can help the in-house security team augment managed detection and response in order to identify threats early and reduce the consequences of a breach. A Security Operations Center can provide remote monitoring of IT systems to detect intrusions and anomalous activity. Implementing 24/7 managed detection and response can allow internal teams to focus on building resilience.

Bad actors may take advantage of lax patching practices.

A longer version of this article can be found here.

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ISSUING AND RESPONDING TO *FORCE MAJEURE* NOTICES

Lisa Richman, Tom Ryan, Terrence Dee and Andrew Savage

Some companies may be viewing *force majeure* provisions as a tool to respond to loss of revenue caused by the Coronavirus (COVID-19) pandemic. It is therefore crucial that businesses are aware of their contractual rights, potential exposures and legal remedies.

As recent news articles have made clear, the enforceability of contracts is coming into question owing to the pandemic. This uncertainty is partly caused by the various lock down orders that can prevent actual performance of the contract; plus companies may be invoking *force majeure* or similar provisions to either delay or avoid monetary expenditures. At a minimum, force majeure provisions are being used to renegotiate certain contracts.

It is crucial, given these developments, that businesses are aware of their contractual rights, potential exposures and legal remedies.

The extent to which a disruption that impacts performance under the contract and is outside the parties' control constitutes a qualifying *force majeure* event is highly fact-specific and depends on, amongst other things, the terms of the contract, the specific facts, governing law, and how courts in the relevant jurisdiction(s) interpret *force majeure* provisions. In most instances, in order to excuse a party's performance in whole or in part, it will be required to provide written notice of a *force majeure* event.

Parties should always take care before asserting *force majeure* to avoid a premature claim for breach of contract or anticipatory repudiation. The counterparty may also seek to terminate the contract or avoid its own performance after receiving a notice of a *force majeure* event. If a legitimate *force majeure* defence is asserted, the party asserting force majeure will not be liable for breach of contract.

BEST PRACTICE FOR PROVIDING NOTICE OF FORCE MAJEURE

The following points are some best practices when providing notice of *force majeure* for businesses that are unable to fulfil their contracts.

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First, review the contract carefully to determine whether or not it includes a *force majeure* provision, and note

- The specific events and circumstances that qualify for *force majeure* treatment.
- Other relevant terms and conditions in the contract, including its governing law, events of default, termination and cancellation terms, materially adverse change clause, dispute resolution, *etc*.
- Whether or not the performance of any of the parties' obligations under the contract will be impracticable or impossible, or if the purpose of the contract is frustrated because of the direct or indirect consequences of a *force majeure* event, or for a different reason.

Second, it is vital to investigate and document the facts and circumstances leading to the conclusion that there has been a *force majeure* event.

Third, the notice requirements in the contract or under the applicable law(s) must be followed. Some contracts contain detailed procedures and timelines for giving notice. Some jurisdictions require strict compliance with the notice provision in the contract when providing notice of *force majeure*. The connection between the specific *force majeure* event and the business's inability to perform the contract in whole or in part must be explained in detail.

If the *force majeure* provision is silent concerning notice, it may nevertheless be possible to provide preliminary notice of the possibility of *force majeure* once it becomes evident that performance may be delayed or rendered impossible. The notice can always be amended or supplemented as additional details become available.

Fourth, all steps necessary must be taken to mitigate or reduce the effects of the *force majeure* event (including its downstream effects and consequences) on the business's ability to perform under the relevant contract, including providing notifications. These steps must be documented thoroughly.

Some jurisdictions require strict compliance with the notice provision in the contract.

Fifth, it is possible that business interruption insurance or an event-specific insurance policy may cover the current crisis. Businesses should read therefore read their policies thoroughly.

Finally, the potential consequences or downstream impacts of the counterparty potentially suspending its own performance under the contract if notified of a *force majeure* event should be considered. Where

possible, businesses should work collaboratively to mitigate the effects, to ensure there is a market for its goods or services in the future.

BEST PRACTICE WHEN RECEIVING NOTICE OF FORCE MAJEURE

Of course, for every business giving notice of a failure to fulfil its contract, another business is hugely disrupted.

Parties receiving a *force majeure* notice should review carefully any notice they receive to determine whether or not it falls within the scope of the *force majeure* provision or applicable law, and if the form and timing of the notice was proper; and to identify the availability and impact of applicable laws and facts, including whether or not the party claiming *force majeure* has fulfilled its other obligations under the contract.

The business will also need to determine when and how to respond, which will include assessing whether or not

- Performance or payment is excused
- To terminate the contract in response to the notice
- The need to take other actions, such as mitigating damages, notifying third parties, or making a claim under an insurance policy, *etc.*

Businesses should consult with counsel as early as possible to ensure parties are appropriately complying with their obligations and protecting their rights.

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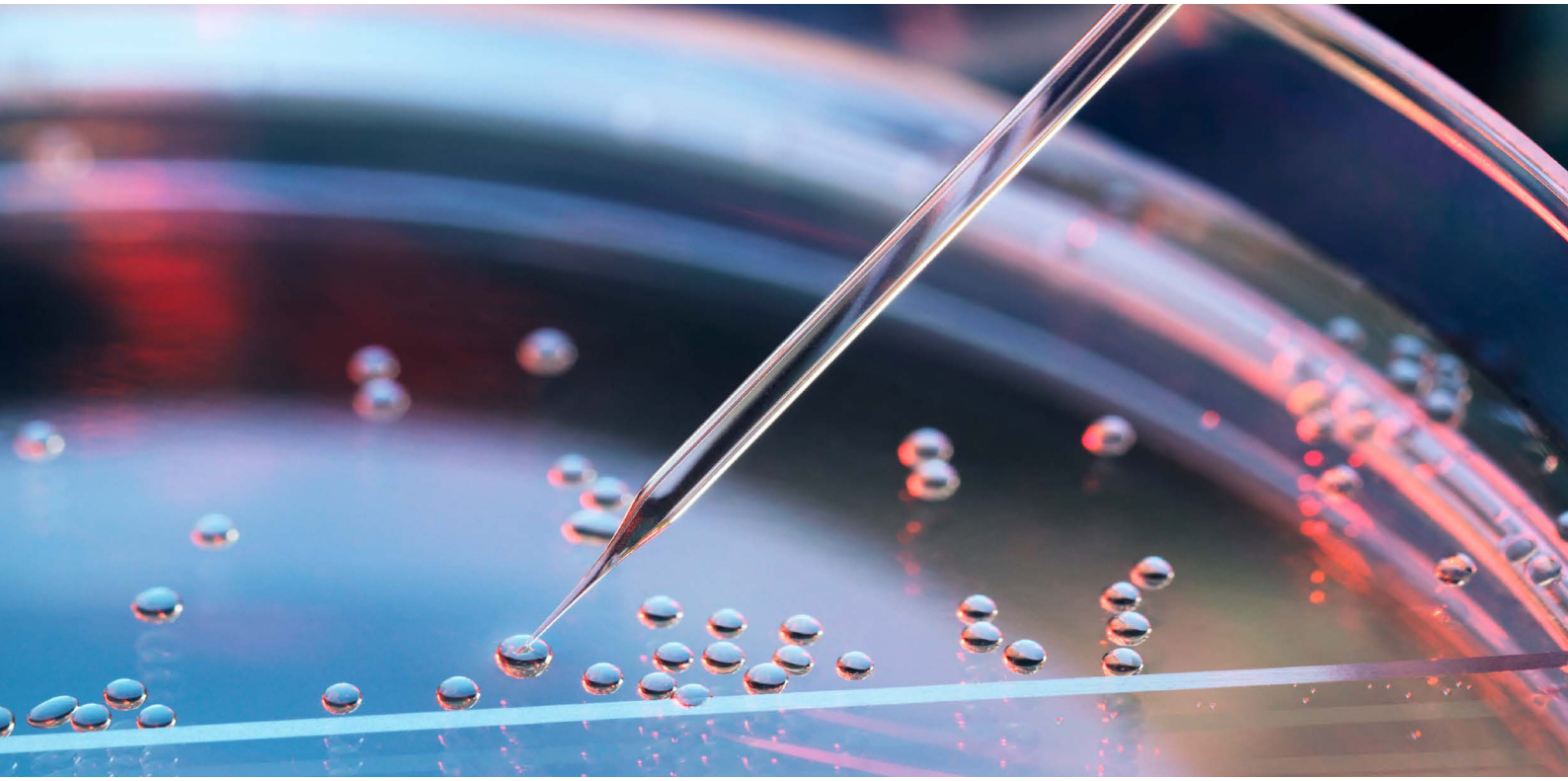
FERTILE OPPORTUNITIES

Hamid Yunis and Bella North



Investors in search of a healthy return are increasingly investing in the fertility services sector, as demonstrated by reports that the global market is expected to reach US$36.2 billion by 2026, representing a compound annual growth rate of 10.2%.

Investments in the healthcare sectors have historically proven themselves to be extremely resilient, regardless of the economic cycle, which is why investors have the confidence to pursue further opportunities in the wider health and social care sectors. This includes the in vitro fertilisation (IVF) sector and less well-known assisted reproductive technologies (ART), such as intracytoplasmic sperm injection. The ART sector is in part considered to be recession-proof and this has led to ART being considered as a potentially appealing sub-sector for investment.

The healthy growth of this sector is driven by a number of factors, which include advancements in treatments, better success rates and a global social and cultural shift in attitudes to the use of ART. In addition, the rapid expansion of middle-class economies across Asia, the Middle East and North Africa in particular, has contributed to a rise in global per capita disposable income. This combination of available liquidity and a greater acceptance of ART has helped to expand global access and a demand for services that continually outstrips supply.

In the mature ART markets, such as Europe and North America, the combined offering of fertility preservation (such as egg freezing) and new techniques (such as

embryonic genetic testing) are creating real paradigm shifts. Fertility treatments are no longer only targeted at individuals who are infertile but also to those who have chosen to start a family later in life due to lifestyle and social reasons.

In particular, a trend for delaying childbearing beyond the age of 35 is reported to have greatly increased in recent decades, resulting in a greater need for fertility preservation services. As a direct result, employers are recognising the benefits of offering fertility treatments as part of healthcare benefits packages in an attempt to attract the best talent and as a way of demonstrating the importance of staff well-being. For example, global tech companies are reported to have extended health benefits to include egg freezing for all female employees.

Such technological developments in fertility preservation are fuelling demand, accessibility, and competitive pricing for products and services that increase fertility choices for the full range of potential parents.

Globally, demand is also driving a desire for cross-jurisdictional standardisation in treatment as economies of scale are realised through collaboration, a more comprehensive healthcare offering and potential outsourcing of clinical support services that supplement ART.

With this boom comes an opportunity for investors, in particular, private equity funds and family offices, to move away from more traditional investments. Instead, it is worth looking at a broader spectrum of asset structures such as medtech, diagnostics and women's health services, that seek to complement ART and benefit from the increase in demand for fertility treatment and preservation services.

OUTSOURCING EQUIPMENT

In addition to a highly skilled and expensive labour force, success in ART relies on high-value equipment. This cannot be avoided but, to maximise their return on investment in equipment, providers are increasingly looking at how technology can contribute to further revenue growth rather than simply aiding treatment success rates.

The option to lease high-value equipment at scale, such as cryogenic storage facilities and outsource testing and clinical support services to third parties, enables new entrants in the market, or those looking to expand, to minimise upfront capital expenditure and subsequent capital depreciation costs. This provides a further opportunity for investors to support and access the benefits of the booming fertility market whilst diversifying its portfolio.

WOMEN'S HEALTH

Investments that focus on wider women's health treatments and are targeted, bolt-on products and services that run in conjunction with ART providers, and which possibly complement and aid the success of ART, are gaining popularity.

Providers of ART are recognising the potential of offering support for the psychological needs of consumers and integrating these services within routine fertility care. For example, high-end clinics are increasingly offering diet supplements and alternative therapies as part of a wider range of wellbeing consumer packages to support fertility treatments, which are no longer confined to "recognised" medical procedures.

Investors are showing confidence to pursue opportunities in ART and wider healthcare sectors.

The trend for private fertility clinics to offer add-on or supplementary treatments has occasionally been met with some negative coverage, with some providers accused of offering medically-unproven extras, such as vitamin drips and acupuncture, alongside traditional IVF. These additional treatments can potentially increase the total cost by thousands of pounds.

This criticism does not, however, appear to be deflecting the global trend of expansion in this field. Investment in diligently researched goods and services that complement fertility treatments is therefore still a potential way to enter the market and benefit from the boom.

More generally, the offering of add-on products and services highlights the demand for integrated care that aims to improve the co-ordination of services across all healthcare markets. This healthcare model continues to grow across the sector.

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POTENTIAL CHALLENGES

With opportunities come challenges and there are some significant issues for investors, in particular, private equity funds, to consider, including the following:

- Identifying sizable businesses with talented, clinician-led, management teams
- Finding profitable investment opportunities in providers
- Maintaining a strong brand with a reputation for high success rates and clinical leadership
- Understanding, navigating and ensuring compliance with the various regulatory and employment legislation across multiple jurisdictions. Although there are strong barriers to entry, these may be viewed favourably by a sophisticated investor
- Ensuring medium term and long term transparency for state reimbursement
- Ensuring that adequate business insurance coverage is in place
- Establishing and maintaining effective and professional cross-functional governance structures
- Managing third party performance, especially if the business relies on external suppliers for key equipment, clinical services, and IT software
- Effective handling of data and privacy issues, particularly the personal information of prior and existing patients
- Locating appropriate infrastructure/clinics, and co-operating with landlords.
- Developing a robust exit strategy.

Focusing on sectors that support ART is a way to enter the market and benefit from the boom.

There is also likely to be a shift in the profile of the typical investor in this sector. For example, a sovereign wealth fund may have the potential to facilitate deeper partnerships with public bodies; and private family offices may want to hold an investment for a longer period than typically permitted within a customary private equity fund structure.

A version of this article was published in Healthcare Markets International in October 2019.

The ongoing management of the global impact of Coronavirus (COVID-19) has potentially created a false dip in the fertility market. Investors should consider these opportunities and challenges on a medium or long-term basis on the assumption that the pandemic will end and that the market will stabilise within a short period.

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IMPORTING AND EXPORTING ALCOHOL BEVERAGES

Alva Mather and Beth Hatef

Clients considering importing or exporting alcohol beverages to or from the United States must first understand the key US regulatory requirements.

In recent years, there has been a great deal of growth in alcohol beverage imports and exports between the United States and overseas markets. Alcohol producers on both sides of the Atlantic may be thinking about ways to maximise the opportunities provided by their brewery, winery, or distillery capacity. Companies that are not currently involved in the alcohol industry may be interested in breaking into the sector through the establishment of an importation or exportation business.

To import or export alcohol beverages to or from the United States, a company must comply with the many US government requirements. Several US federal agencies regulate the importation and exportation of alcohol beverages in the United States, including the Alcohol and Tobacco Tax and Trade Bureau (TTB), which is the federal agency responsible for regulating the production and distribution of alcohol beverages; Customs and Border Protection (CBP); and the Department of Commerce.

PRIMARY US IMPORTATION REQUIREMENTS FOR ALCOHOL BEVERAGES

All producers of food and beverages, whether located in the United States or another country, must register with the US Food and Drug Administration (FDA). The Bioterrorism Act of 2002 also requires importers to provide advance notice to FDA of the importation and food and beverage products.

A company seeking to import alcohol beverages into the United States needs to obtain certain licences. Most importantly, the company will need to obtain an Importer's Basic Permit from TTB. To be eligible for a basic permit, the company must maintain and staff an office in the United States. If the company plans to sell other brands of alcohol beverages at wholesale in addition to the brands it will import, the company will also need to obtain a federal Wholesaler's Basic Permit from TTB.

In addition to federal licensing, state licence(s) may be required to import or export alcohol beverages, particularly in the state where the company's operations will be located, and even if the beverages are only moving between US states and not countries.

Once the company is properly licensed as an importer, it will then need to make sure that it is legally able to import the particular products it plans to import. TTB requires product-specific approvals for all imported

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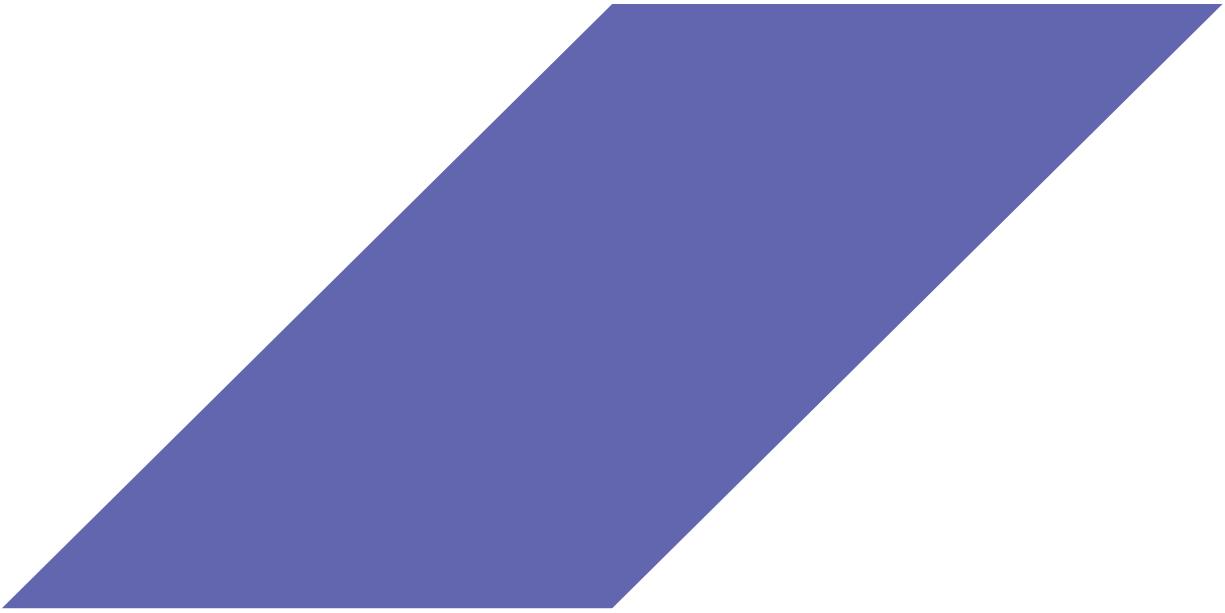

alcohol beverages and an importer must obtain a certificate of label approval (COLA) for each alcohol beverage product it plans to import into the United States. In addition to the COLA requirement that applies to all alcohol beverages (with limited exception for certain beverages not regulated by TTB), certain alcohol beverages also require formula approval from TTB.

All alcohol beverages to be imported into the United States must arrive at the importer's place of business or at a Customs bonded warehouse that the importer designates. Alcohol beverage shipments must include a COLA, or a COLA waiver, issued by TTB to the importer in order for the products to be cleared by CBP for removal from Customs custody. CBP also requires prior notice of all alcohol beverage shipments into the United States.

In addition to these initial requirements, importers must comply with a number of other regulatory requirements in the United States on an ongoing basis. As an example, importers must comply with applicable tax and duty requirements.

CBP collects excise taxes and duties on imported alcohol beverages. Excise taxes are due on imported alcohol beverages at the time the products are removed from Customs custody. CBP uses the Harmonized Tariff System to determine duty rates for all imported items. Companies that are unsure about the applicable duty to a particular product can request a ruling from CBP.

Importers must also comply with TTB's recordkeeping requirements. Specifically, importers must maintain daily records of their physical receipts and disposals of alcohol beverages, including the type and quantity of the released products, the name and address of the recipient of the beverages from Customs custody, and the date of the release.

Finally, importers must maintain ongoing compliance with all applicable laws and regulations. These include TTB regulations, such as its regulations relating to basic permit requirements (27 Code of Federal Regulations (C.F.R.) Part 1) and importation requirements (Part 27). Imported alcohol beverages can only be released from Customs custody in accordance with the Federal Alcohol Administration Act and its implementing regulations, such as regulations concerning labelling and advertising. Importers must also comply with TTB's regulations requiring basic permit holders to report changes in ownership, name, and address.

PRIMARY US EXPORT REQUIREMENTS FOR ALCOHOL BEVERAGES

In general, exporters of alcohol beverages from the United States must obtain TTB approval, either as a producer of alcohol, *e.g.,* a brewery or distillery, or as an export warehouse. The exact US export requirements that apply to alcohol beverages vary based on several factors, including the commodity at issue, *e.g.,* beer, wine, or distilled spirits; whether the exporter is also the producer of the product; and whether the product will be exported with or without taxpayment.

Alcohol beverages may be exported without payment of federal alcohol excise taxes if they are exported to another country, used as supplies on vessels or aircraft, shipped to a foreign trade zone, or shipped to the US armed forces for use overseas. To export spirits without taxpayment, the exporter must file form TTB F 5100.11 with TTB. Upon application, TTB can also can grant approval for an alternative procedure that allows the exporter to maintain its export documentation at its premises, and submit only monthly summary reports to TTB.

Each container or case of nontaxpaid alcohol beverages must be marked with the word "Export" before removing the products from bond. The exporter must also maintain and submit to TTB proof of actual exportation, *e.g.,* a customs certificate of lading and clearance.

Alcohol beverages may also be taxpaid and then exported. To export taxpaid alcohol beverages, the exporter must obtain a Wholesaler's Basic Permit from TTB (in order to take title of taxpaid alcohol beverages) and otherwise comply with TTB's export regulations (27 C.F.R. Part 28). Taxpaid alcohol beverages intended for export must be marked in the same way as alcohol beverages removed from bond for sale or use in the United States.

If a wholesaler is selling alcohol beverages for export, it must notify the producer that the products will be exported and provide certain paperwork to the producer upon removal for exportation. The producer then must file the paperwork with TTB to execute a claim for "drawback", which is a refund of the federal excise taxes paid on alcohol beverages that are then exported. The producer seeking drawback must provide proof of actual exportation.

TTB requires product-specific approvals for all imported alcohol beverages.

OTHER JURISDICTIONS' REQUIREMENTS

Of course, aside from the United States' export requirements, companies considering exporting alcohol beverages from the United States should also understand the requirements of the countries to which they will send the products.

TTB has established an Export Certificate Program to facilitate exporters' ability to comply with these requirements, which allows exporters to request a certificate from TTB certifying the authenticity of an exported alcohol beverage. TTB has certain specific requirements relating to Export Certificate requests, for example, requests must be submitted on company letterhead. It accepts such requests by email, and its goal is to process them within seven business days.

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IP AND DATA PROTECTION AFTER BREXIT

Ashley Winton and Sophie Wood

The initial UK and EU negotiating positions have now been revealed. Unless a COVID-19-related extension is negotiated, businesses should prepare for a "No Deal" Brexit to occur on 31 December 2020.

INTELLECTUAL PROPERTY RIGHTS

As of the end of the Brexit transition period, EU Trade Marks and UK Registered Community Designs will no longer include the United Kingdom. The UK Intellectual Property Office will grant additional UK trademarks and designs, but any agreement or licence that refers to these intellectual property rights should be reviewed.

The rules relating to the international exhaustion of trademarks when products are first put into the market will also change. A business that sells products in both the United Kingdom and the European Union should consider the effect this could have on its distribution strategy and pricing.

Patents are less affected as they are national in character. However, the much-anticipated Unitary Patent is now very unlikely to cover the United Kingdom. This means that UK patents should be obtained as part of any European or global patent strategy. Any infringement claims should also consider the United Kingdom as an additional jurisdiction.

With hard Brexit more likely, agreements dealing with intellectual property will need review.

At the, moment, big data is protected in the European Union by the Database Directive. At the end of the transition period there will be no reciprocal protection of UK and EU database rights. Many companies are considering licensing structures to better protect the intangible asset value of their big data databases.

DATA PROTECTION

The General Data Protection Regulation (GDPR) will be reflected into the United Kingdom as the UK GDPR. There are two immediate consequences: First, a UK-

based business that has retail customers in the United Kingdom and across the European Union will need to comply with the GDPR in respect of personal data received prior to 31 December 2020, the UK GDPR in respect of UK personal data, and the GDPR in respect of the personal data of its customers in Europe.

The laws protecting personal data are likely to become complex.

Second, data transfers out of the United Kingdom will be permitted as before, but personal data transferred in to the United Kingdom from Europe will be treated as if the United Kingdom does not have adequate data protection laws.

It is important, therefore, that each transfer of personal data from the Europe is mapped and brought into compliance with the GDPR. In most cases this will simply mean the execution of Standard Contractual Clauses, but this will not work in every case so other mechanisms, such as Binding Corporate Rules, should be considered.

OTHER MATTERS

The UK Information Commissioner's Office (ICO) is not part of the "lead authority mechanism". In the event of a data breach, for example, companies should therefore amend their incident response plans so that they report to both the UK ICO and an appropriate EU data protection authority.

Finally, UK and EU companies may need to appoint a Data Protection Representative in each other's territories.

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