JAPAN

18th November 2021

Part 2: European Life Sciences Perspective: Current Trends and Brexit Implications – (Employment, Data Privacy, Regulatory)

Morgan Lewis

Presenters

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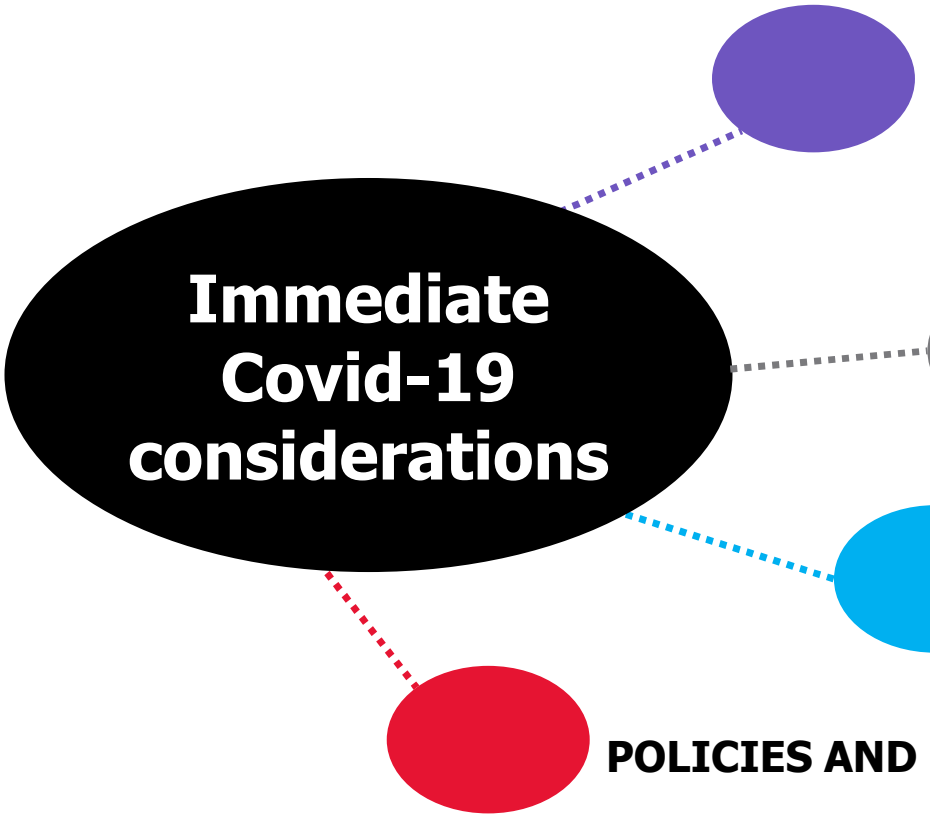
Morgan Lewis

Employment law – key considerations and trends

Morgan Lewis

What is the current picture for employers in Europe?



RISK ASSESSMENT

If not already done, conduct a COVID-19 risk assessment in consultation with workers (and unions if applicable) on return-to-work protocols or review existing risk assessments in light of the constantly changing rules.

VACCINATIONS

The rapid rollout of the UK's vaccine programme has triggered important practical and ethical considerations for employers.

EDUCATE

Staff will need to be informed of new protocols. Provide training to managers on how to enforce new measures and support staff.

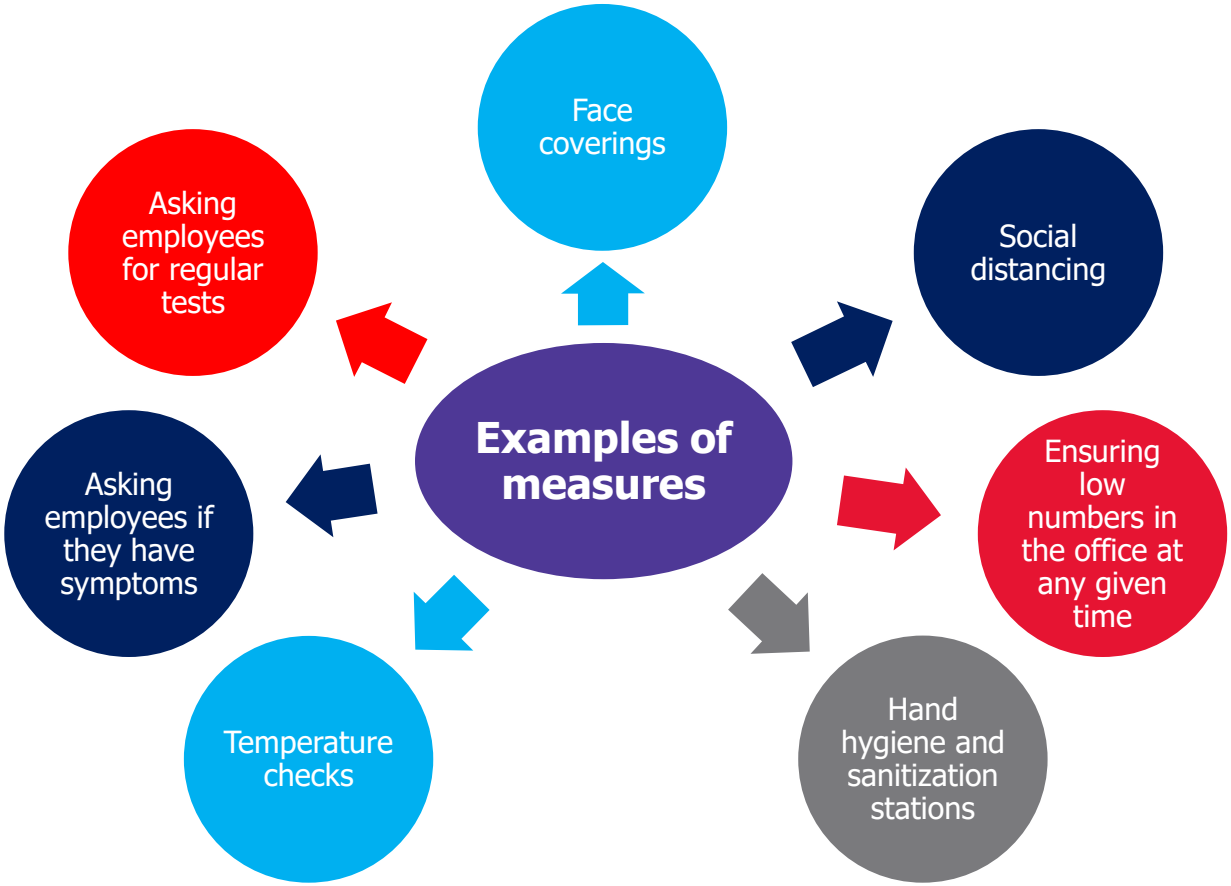
POLICIES AND PROCEDURES

Consider whether amendments will be necessary and whether new policies and procedures are required. For example, consider modifying office space, providing ventilation, and sanitizing high-contact areas more often.

What is the current picture for employers?

In many countries, some or all government restrictions have been lifted and few countries are instructing people to work from home.

However, continued nervousness among employers to maintain a safe and healthy work environment means many are still keeping some restrictions in place.



What are we seeing in the market?

Market Response

Employers are adopting different approaches - from a full return to office with vaccination mandate in place – to "soft vaccine mandates, with unvaccinated employees permitted to work remotely – to fully flexible policies on return to work and vaccination status.

Impact

Employers' flexible working policies may affect whether they remain or become an employer of choice. Flexibility will be an important recruitment and retention tool.

Employers' Approach

Employers will need to risk-assess, design and implement new policies and procedures, and educate their staff on the expectations and parameters of new working models.

Hybrid working is here to stay. For now.

Competitors are adapting, and adapting fast.

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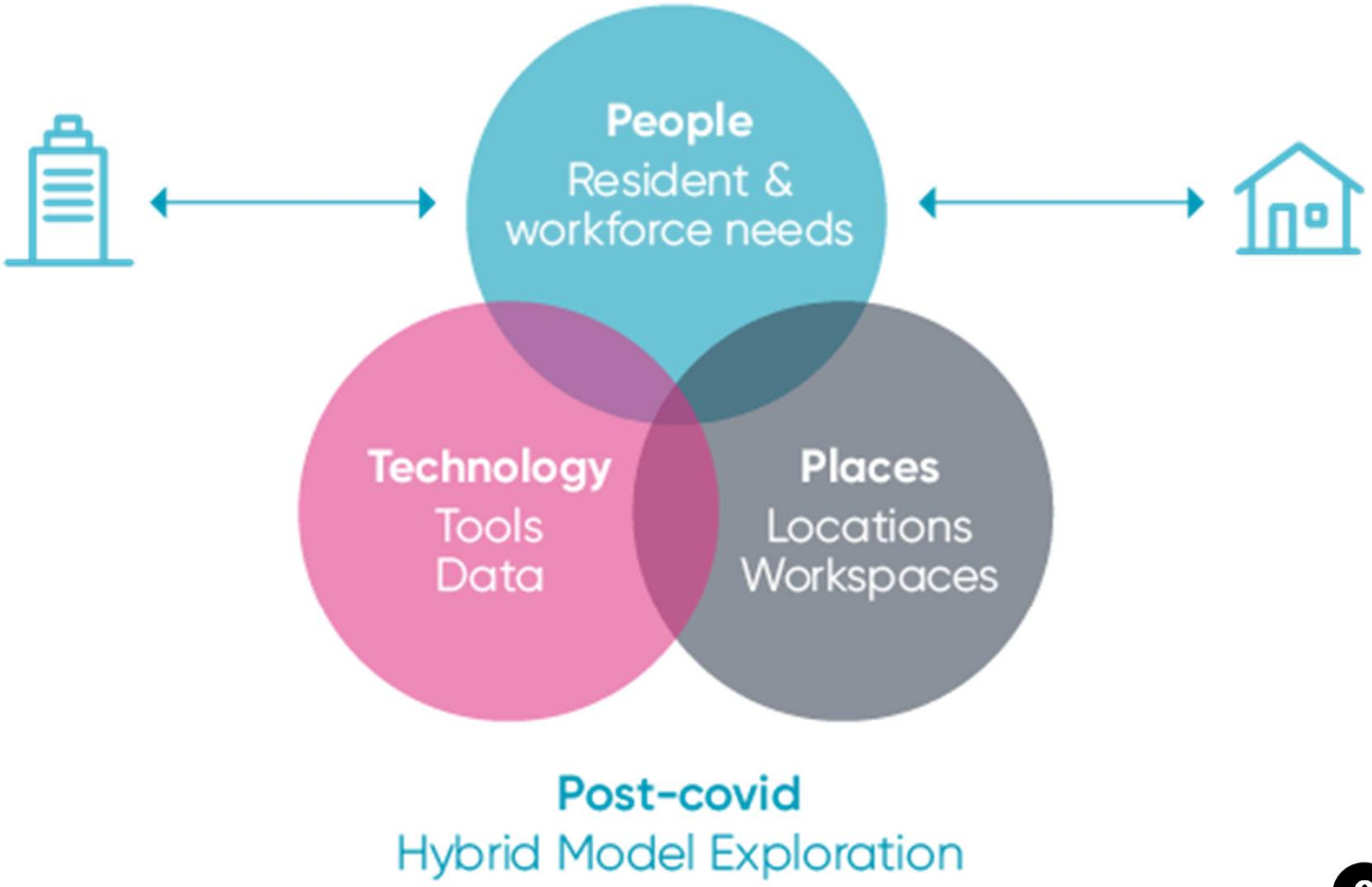
Hybrid working

A hybrid model combines remote and flexible working practices with office-based working.

Hybrid models should consider what work is done, where work is done, how work is done and who does the work.



Hybrid working models

Fully Remote

Cross-border Hybrid

Dynamic Hybrid

Fully in Office

Default Digital

Synchronised Hybrid

Flexible working requests

A number of countries have in place certain rights with respect to flexible working e.g. in the UK there is a right to request to work flexibly for all employees with at least 26 weeks' service, although employers are not *required* to grant requests.

There may be a greater emphasis for employers to carefully consider flexible working requests from employees, especially in light of the current climate and shift in remote and hybrid working patterns.

Employers will not only be expected to deal with these requests consistently to avoid discrimination claims, there may also be a greater onus placed on employers to consider whether other alternatives may be offered to the employee making the request.

BBC

Mother refused 5pm finish wins £185,000 payout

Alice Thompson wanted to work shorter hours to pick her daughter up from nursery, but ended up resigning. The former estate agent spent tens ...

Hybrid/flexible working: further considerations (1)

Set Clear Expectations

Build a healthy relationship of trust and confidence. Agree when employees should be available, how they will stay connected, how work-life balance will be managed and how performance will be measured.

Employees' preferences

As offices start to reopen, employers will need to consider how to coordinate differing preferences amongst employees.

From a practical perspective, it may be more difficult when *some* people are in the office than when *everyone* was at home.

Mental Health

Consider putting procedures in place so you can keep in direct contact with workers at home and those returning to the office to recognise signs of stress as early as possible.

Be approachable, encourage and facilitate good communication channels.

Hybrid/flexible working: further considerations (2)

Claims

Possibility of more harassment claims as people struggle to work together again, including a rise in sexual harassment claims.

Expenses

Employees may be entitled to claim a deduction against taxable income for certain household expenses and travel costs. These expenses must be incurred wholly, exclusively and necessarily in the performance of their employment duties.

Training

Employers should implement training / working groups to ease the transition back to in person working and to promote good culture.
Ensure channels for reporting concerns are clear and that managers know how to deal with complaints raised.
Flagging complaints procedures, grievance policies, whistleblowing policies/hotlines to managers so they are aware of how to deal with complaints.

Remote working and cross-border considerations

Key Considerations

Employers implementing full-time remote working will need to consider employees' contractual place of work. Employees may be keen to work internationally and fluidly, but this may give rise to various issues.

Employment Law

Local employment protections:

- minimum rates of pay
- paid annual holidays
- rights on termination

Regulatory

These can vary across sectors and may depend on the individual circumstances of each case (e.g. the nature and seniority of the role being performed)

Data

Does the employee's role involve processing personal data?

Consider data protection issues

Tax

Consider the following risks:

- income tax liability
- social security liability
- the employer is regarded as having created a "permanent establishment" there for corporation tax purposes.

Health and safety, whistleblowing and other litigation risks

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Health and safety, whistleblowing and other litigation risks (1)

Health and Safety

Statutory Duty

Employers in many European countries have a statutory duty to provide a safe place of work and general legal duties of care towards anyone who may be accessing or using their place of business.

Employees may also have independent statutory duties to take reasonable care for their own health and safety, and that of other persons, and to co-operate with you to ensure that your rules are complied with.

Required Action

Carry out suitable and sufficient risk assessments to identify risks (including home-working environments). Implement measures to minimise risks. Employers must take all reasonably practicable steps to minimise the risks.

Consult with employees (or elected representatives / works councils or unions, as applicable) about measures introduced that affect their health and safety. Train employees on new risks COVID-19 poses to their health and safety.

What health and safety measures should be introduced?

See the UK Government's Working Safely Guidelines for examples (or equivalent in other European countries).

Common measures include:

- Regular cleaning of public places
- Good ventilation (including air conditioning)

Health and safety, whistleblowing and other litigation risks (2)

Whistleblowing

Employers may receive complaints regarding failures to abide by health and safety guidance or to properly assess and address risk.

Concerns may qualify as protected disclosures. If so, the individual is protected from detriment and dismissal.

Ensure workers are **trained** on how to respond to whistleblowing complaints. **Review your whistleblowing policy** and ensure it is accessible to all staff.

Employers who follow government guidance are likely to have an adequate defence to allegations. Note that there is **no financial cap** on compensation in whistleblowing claims.

Impact of Brexit on Employment & Immigration

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Impact of Brexit on Employment and Immigration

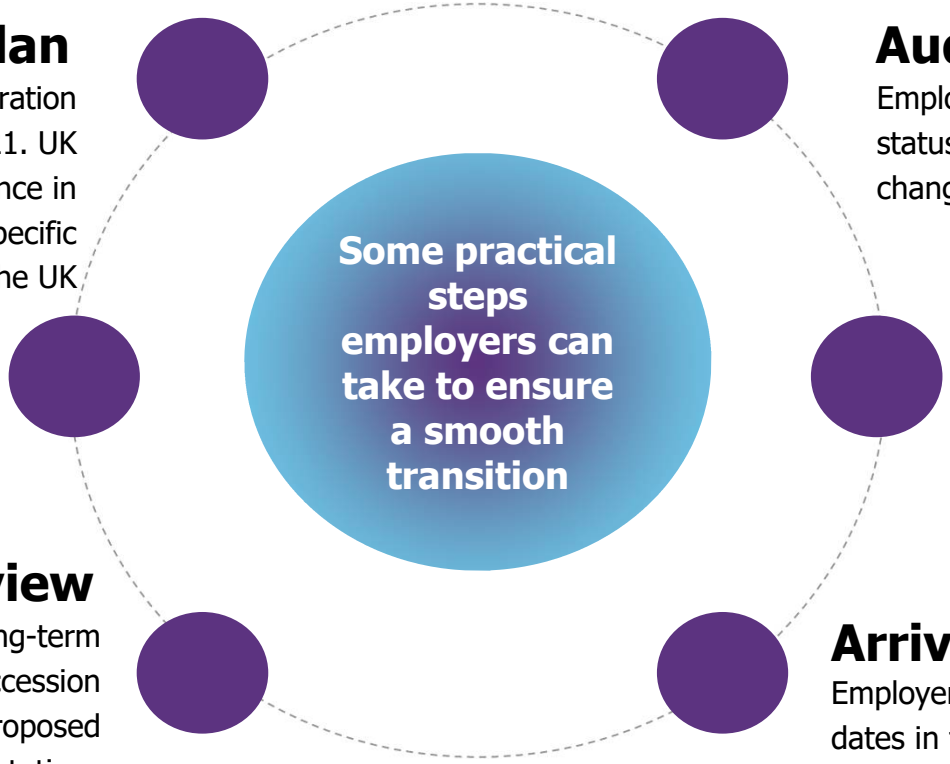
Relatively little expected to change in the short term from an employment law perspective, although certain aspects of retained case law likely to change direction over time e.g. holiday pay and carry-over.

Brexit has created significant changes for how the pharmaceutical and life sciences industry in the UK manage mobility of their employees between the UK and the rest of Europe.

Many employers in the life sciences sector who have a large EU workforce have taken steps to reassure employees and retain and recruit talent in the period of uncertainty which has followed from the Brexit vote in June 2016.

Practical Steps for Employers

- There are many practical steps that employers in the life sciences sector can take now to ensure a smooth transition post-Brexit.



Plan

The UK's new points-based immigration system came into effect on 1 January 2021. UK employers must hold a sponsor licence in order to engage overseas workers for specific skilled roles in the UK

Audit

Employers should audit the immigration status of their workforce to help plan for change

Employee applications

Employers should decide how to support employee applications and how much to invest in the process

EEA and Swiss Nationals

Employers will be required to obtain additional right to work documentation for any EEA or Swiss commencing employment from 1 July 2021

Review

Employers should review long-term recruitment and succession planning and proposed secondments and rotations

Arrival dates

Employers should check employee arrival dates in the UK to determine whether they require sponsorship under the new points-based system or if they already hold status under the EU Settlement Scheme

Data Protection

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Our Discussion

- UK GDPR vs. EU GDPR
- Territorial application
- International data transfers & ICO consultation
- Data privacy breaches and collective action
- Training
- Cookies

UK GDPR vs. EU GDPR

UK GDPR

- The EU GDPR is retained in UK law as the UK GDPR with very similar terms to the original EU GDPR
- The UK has independence to keep the framework under review
- The UK GDPR sits alongside the UK's Data Protection Act 2018

EU GDPR

- EU GDPR may still apply in the UK by virtue of its extra-territorial effect
- Organisations with pan-European operations are likely to have to comply with two separate (but similar) legislative regimes with risk of dual enforcement action

Territorial Application

UK GDPR

- UK GDPR applies to processing of personal data in the context of activities of an establishment of a controller or a processor in the UK, regardless of whether the processing takes place in the UK or not
- **Establishment**: Establishment implies the effective and real exercise of activity through stable arrangements, although the legal form of such arrangements, whether through a branch or a subsidiary with a legal personality, is not the determining factor
- **No establishment**: Where no UK establishment exists, the application of the UK GDPR is determined by the location of the data subjects. UK GDPR applies where use of personal data by an organisation relates to:
  - the offering of goods or services to individuals in the UK, irrespective of whether a payment is required; and
  - the monitoring of those individuals' behaviour in the UK
    - therefore → tracking individuals on the internet to analyse or predict their personal preferences will trigger the application of UK law. Almost every website which uses tracking cookies or mobile application which retrieves usage information will be subject to the UK GDPR

Territorial Application

EU GDPR

- EU GDPR applies where:
  - **Establishment**: Data processing activities are conducted by organisations established in the EU
  - **Targeting**: Data processing activities relate to:
    - offering of goods or services (even for free) to data subjects situated in the EU (not just EU citizens); or
    - monitoring of the behaviour of such data subjects as far as their behaviour takes place within the EU

International data transfers

Restricted transfers

UK GDPR continues EU GDPR policies of restricted personal data transfers outside of the UK. Such transfers are subject to data transfer rules

Adequacy Decisions

UK may designate other countries as providing an adequate level of protection from personal data transferred from the UK

An adequacy decision exists between the EU and the UK

Appropriate Safeguards

In the absence of adequacy regulations, personal data can be transferred outside the UK on the basis of "appropriate safeguards", and on the condition that enforceable data subject rights and effective legal remedies for data subjects are available (UK GDPR, Articles 46(2)(a)-(f))

Binding Corporate Rules

Used by multinational corporate groups, groups of undertakings or a group of enterprises engaged in a joint economic activity such as franchises, joint ventures or professional partnerships. EU BCRs are no longer an appropriate safeguard for data transfers from the UK to outside the UK.

Standard Contractual Clauses

Original EU SCCs remain valid post-transition period for data transfers outside the UK. Changes can be made to the EU SCCs so they make sense in a UK context provided there is no change the legal meaning of the SCCs. New EU SCCs were published in June 2021. These must be used from **27 September 2021** where personal data is transferred outside of the EU to a country where no adequacy decision exists.

Privacy Shield

The adequacy decision between the EU and the US is referred to as the "Privacy Shield". Decision in ***Schrems II*** (July 2020) found that the Privacy Shield was invalid.

UK organisations transferring personal data to the US should use other alternative data transfer mechanisms

International data transfers (cont.)

WhatsApp: €255m fine for GDPR breaches in Sep 2021. One of the key points arising from the decision is that specific adequacy decisions relied on for overseas safeguards should be listed out

- Adequate countries: Andorra, Argentina, Canada, the Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Switzerland, the UK and Uruguay
- Other "appropriate safeguards"
  - A legally binding and enforceable instrument between public authorities
  - An approved code of conduct
  - An approved certification mechanism
- GDPR permitted derogations:
  - Explicit consent
  - Transfer is "necessary" for performance of contract; to establish, exercise or defend legal claims; from a public register
  - Where the transfer is not repetitive, concerns a limited number of data subjects, is necessary for compelling legitimate interests of controller (not overridden by data subject rights) and safeguards in place to protect the data

International data transfers - which data transfer option?

- Privacy Shield – no longer valid for EU to US transfers – DoC says to continue to abide by commitments as do some European supervisory authorities; no grace period so invalid from July 2020; no point renewing!
- Standard contractual clauses – easy to execute; not so easy to implement
  - Need to consider legal framework in importer's country;
  - Consider additional safeguards e.g. encryption in transit and at rest;
  - Importer to notify exporter if it cannot comply with SCC obligations
  - Exporter or supervisory authority can suspend data flow pending EDPB approval of the transfers continuing
- BCRs – time and expense to get approval
  - EU supervisory authorities take several years to approve
  - UK approved BCRs need to be approved by an EU supervisory authority before end of Brexit transitional period (31 December 2020)
- Consent – GDPR standard of explicit consent
- Code of conduct and approved certification mechanisms – usually drawn up by trade associations to develop sector-specific guidelines to help with compliance with the UK GDPR. Codes must be approved by the ICO
- Give notice to data subjects of the transfers

International data transfers – ICO consultation

ICO Consultation	Public consultation on the international transfer regime under the UK GDPR launched on 11 August 2021 and closed on 7 October 2021. ICO has sought input on the extra-territorial effect of the UK GDPR and the principles of international data transfers
International transfer risk assessment	Organisations relying on appropriate safeguards under Article 46 of the UK GDPR remain obliged to conduct an assessment as to the destination country's laws and practices. ICO has produced draft guidance and a draft tool to help organisations conduct these assessments
International data transfer agreement (IDTA)	ICO has published two proposals for data transfer agreements: (1) model international data transfer agreement; and (2) short form addendum incorporating clauses of model data transfer agreements issued in other jurisdictions. If adopted, this would constitute the "UK SCCs"
How to prepare	Exact timelines are subject to change. IDTA requires parliamentary approval. Suggested preparatory steps include: (1) ensure visibility over UK GDPR transfers; (2) confirm which transfer tool is the most appropriate transfer mechanism; (3) conduct and evaluate transfer risk assessments

Data Breaches & Collective Action

High Profile UK Examples

- **British Airways (October 2020):** £183 million, reduced to £20 million. Airline processed large amounts of personal data without adequate security measures, leading to a cyber attack which was only discovered 2 months later (reduction in fine due in part to impact of Covid-19)
- **Marriott (October 2020):** £99 million, reduced to €20 million. Lack of appropriate technical or organisational measures (reduction in fine due in part to impact of Covid-19 on business)
- **Ticketmaster (November 2020):** £1.25 million. Failure to implement appropriate security measures to prevent a cyber attack. It took Marriott four months to notify the ICO

Common themes

- All three involved infringements of Article 5(1)(f) and 32 GDPR (i.e. security of processing)
- Negligence in respect of the breaches (e.g. the BA insecurities could have been largely resolved by Microsoft standard updates)
- To some extent, all three involved vulnerabilities created by third parties (**security is only as good as the weakest link**)

Class actions? GLOs vs. Representative Actions (opt-in vs. opt-out)

- **Morrisons:** 5,500 employees filed a claim under a Group Litigation Order (GLO)
- **British Airways**: Reportedly settled a UK class action lawsuit relating to the same data breach. Allegedly involved 16,000 claimants. Largest class action personal data claim in the UK (so far)
- **EasyJet**: GLO currently being sought against Easyjet following reports in 2020 of a cyber-attack involving 9 million customers' personal data
- **Lloyd v Google:** On 10 November 2021, the Supreme Court gave its much-anticipated judgment in this case, rejecting the attempt to bring an opt-out representative action claim against Google relating to the unauthorised tracking of iPhone users. The Supreme Court's decision shows an unwillingness to group individuals and award a "uniform sum" for damages without properly inspecting the circumstances of their claims and requiring those circumstances to be proven
- **TikTok:** Representative action filed in UK High Court alleging breaches of data protection legislation. The Claim was stayed pending *Lloyd v Google* but will reportedly proceed as planned. We may therefore still see some representative actions for data privacy claims going ahead

Data Protection Training

Staff training and awareness is a key element of data protection compliance efforts.

If there has been a data breach, regulators will ask to see details of staff training

Tailored training for staff with more involvement in handling personal data

Retain records of staff training in support of the company's accountability obligations

Mermaids Decision July 2021

Training must be adequate and effective

Penalty notice: "*all Mermaids staff and volunteers received mandatory data protection training in December 2018, which is updated annually, however, the ongoing contraventions were not identified by anyone at Mermaids during the period of operation of the insecure email system, which demonstrates that the training was inadequate and/or ineffective*"

Training alone is therefore not sufficient

Cookies

Amazon $886.6m fine in 2021 reportedly due to cookie consent

1

What are they?

- Text files containing small amounts of information which a provider of an online service can implant on the equipment of a user's device when the user visits a website, thereby creating a unique ID

2

Privacy and Electronic Communications Regulations 2003 (PECR)

- Provide "clear and comprehensive" information
- Consent of website users or subscribers (**N.B.** consent mechanism should not emphasise "agree" or "allow" over "reject" or "block"). **However**, there is momentum behind proposals to relax cookie consent requirements

3

Categories of cookies

- Distinguish in information notice between (1) strictly necessary cookies; (2) analytical or performance cookies; (3) functionality cookies; (4) targeting cookies; and (5) social media cookies

September 2021: ICO calls on G7 leaders to tackle cookie challenges

4

Enforcement

- Up to £17,500,000 or 4% of total worldwide annual turnover (whichever is higher). Up to £500,000 for breaching PECR
- Enforcement has historically been low but increasing scrutiny is expected (particularly in the AdTech space)

Overview of EU Regulatory Framework and Brexit Implications

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Agenda

- Overview of EU Pharmaceutical and Medical Device Regulations
- Current live regulatory topics
- Implications of Brexit

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OVERVIEWS

Overview of EU Pharmaceutical Regulation

- Directive 2001/83
  - What is a medicinal product?
  - All medicinal products must have a marketing authorisation
  - Abbreviated routes and exemptions
- Regulation 726/2004
  - Centralised medicines regime
  - European Medicines Agency
- Clinical Trials 2001/20
  - To be replaced by a new Regulation in January 2022
  - New hub and database

Overview of EU Pharmaceutical Regulation (cont)

- Paediatric use
  - PIP
  - Exclusivity
- Orphan Medicines
  - Exclusivity
- Advanced therapy medicinal products
  - Cell products
- Pricing and Reimbursement
  - National competence
- Law and guidance – Notice to Applicants
  - E.g. pharmacovigilance

Medical Devices and IVDs - Definitions

- What is a medical device?
  - an article, material etc, together with any software, intended by the manufacturer for use in relation to a disease/the anatomy/ physiological process, or control of conception with a principal intended action other than by pharmacological, immunological or metabolic means.

- What is an IVD Device?
  - a reagent, kit, instrument, etc intended by the manufacturer to be used *in vitro* for the examination of human specimens, including blood and tissue for the purpose of providing information on a physiological or pathological state, a congenital abnormality, the compatibility of donations, or to monitor therapeutic measures.

Overview of Old EU Medical Device Directives

- Previous legislation – Medical Device Directive 93/42/EC
  - to ensure the free movement of goods, while providing a high level of protection and ensuring devices perform as stated by the manufacturer.
  - sets out the essential requirements and outlines the conformity assessment procedures.
  - need for a Notified Body (NB) depends on the Class (I, IIa, IIb or III) of the device.
  - NBs - private organisations entrusted by regulatory authorities to award/police CE marks.
  - no NB for Class I - the manufacturer performs and documents the conformity assessment.
- New legislation - May 2021 – Medical Devices Regulation (EU) 2017/745 (MDR).

New Medical Device Regulation

- New regulations on vigilance and post-market surveillance
- New EU EUDRA database (May 2022).
- Economic operators –distributors, importers, suppliers, Authorized Representatives.
- Software requirements must be evaluated to determine potential classifications.
- Stricter NB requirements with new MDR designation required.
- UDIs to be introduced for traceability.
- Stricter rules on clinical, performance evaluation, and clinical investigations.
- Safety and Performance Requirements replace Essential Requirements.

Overview of EU IVD Regulation

- Delay proposal?
- Move from list-based approach to risk-based approach
- Four risk categories: A (low risk) to D (high risk)
- Conformity amended to reflect the new classification rules
- More manufacturers need to use a Notified Body - 80/20 > 20/80
- New requirement to provide a body of clinical evidence
  - Scientific validity, analytical performance, clinical performance
- Process of performance evaluation to be required throughout the lifetime of the device
- Requirement for post-market surveillance (PMS) and PMS plan
- Summary of Safety and Performance for Class C & D
- Unique Device Identifier (UDI)

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SOME LIVE EU REGULATORY ISSUES

Health technology Assessment/Reimbursement

- 100+ regional/national HTA bodies consider medicines and other health technologies
- Cost effectiveness and cost utility analysis is often represented as an incremental cost-effectiveness ratio (ICER) in Euros per Quality Adjusted Life Year (QALY)
- Considered against an upper limit of what the payer will pay for a QALY
- National autonomy subject to EU Transparency Directive 89/105
- European Network for Health Technology Assessment (EUnetHTA)
- Draft Regulation on Health Technology Assessment
  - Scoping, joint clinical assessments, Joint scientific consultations of EMA products
- Centralised JCA will focus on the relative efficacy not economic parameters.
- Consideration and assessment prior to CHMP opinion
- Process moving toward mandatory MS cooperation from 2026 following a transition period

Clinical Trial Regulation

- Clinical Trial Directive 2001/20 – to harmonize clinical trials administration and apply GCP but hampered by variations in local implementation/requirements
- Clinical Trial Regulation EU No 536/2014 to come into effect in January 2022.
  - Directives and regulations
  - EU Portal
  - EU Clinical Trials Register

Orphan Medicines

- Orphan medicines – Regulation 141/2000
  - Procedure for orphan medicine designation
  - Incentives for the development and placing onto the market of orphan medicines
  - Includes 10 years' market exclusivity (+2 years for paediatric orphan medicines) against from similar medicines with similar indications
- Revision of the EU's legislation on orphan and paediatric' medicines - 141/2000 and 1901/2006 on paediatric use ')
  - It is proposed to revise both regulations to address unmet needs through more tailored incentives medicines addressing the specific needs of children and patients with rare diseases are developed.
  - Impact assessment ended on 6 January 2021. 12-week public consultation.

Promotion and Transparency

- EU legislation– Directive 2001/83. National enforcement
- Detailed and further provisions through EFPIA/national codes
- No POM advertising to the public except approved vaccination campaigns
- No 'excessive and ill-considered' promotion on public health
- To encourage rational use and not exaggerate properties
- Primacy of the medical profession
- Protecting healthcare budgets
- Inducements and hospitality
- Sunshine law equivalents on HCP benefits – some laws (France etc), codes.

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BREXIT IMPLICATIONS

UK Legislation and Guidance

- Aim to replicate the current arrangements so far as possible
- MHRA will be a 'stand-alone' agency
- 50 Guidance Notes
- Divergence or alignment?
- Extra work for UK companies
  - Clinical trials
  - Batch release
  - Pharmacovigilance

Immediate Logistic Consequences - Pharma

- EMA was headquartered in London till 1 March 2019 - now Amsterdam
- Massive extra work due to Brexit
  - Move of Centralised Procedure MAHs
  - New Centralised Procedure owners
  - New RMS for DCP/MRP MAs
- UK MHRA provides >30% of EMA's scientific expertise and conducted 25% of EMA's inspections
- EMA needed to assign this work to other Member State Competent Authorities

EU-UK Trade and Cooperation Agreement - Pharma

About		
• Agreement on 24 December 2020. Not 'once and for all'. Establishment of Working Group • Mutual recognition of GMP inspections of facilities for medicinal products and GMP documents		
What the Agreement Entails		
• Each party may conduct its own inspection on reasoned notice and any material change not considered adequate by the other party, allows it to terminate the cooperation	• No provision for the mutual acceptance of batch testing certificates but UK will accept EEA batch testing and Qualified Person certification until 1 January 2023	• Nothing on mutual recognition of regulatory regimes. Products will be regulated in the UK separately from the EU, and companies will need to comply with both sets of requirements
• No customs on medicinal products originating in an EU member state (or Turkey) or the UK	• Each party may determine its own position in relation to exhaustion of intellectual property rights	• Each party shall provide a period of additional patent protection (an SPC)
• Each party to protect CCI submitted to obtain an MA against unfair commercial use		

UK Response

- 'Grandfathering' rights:
  - Centrally authorised products will automatically be given UK MAs
  - Can opt out but if not converted cannot market in UK after 31 October 2019
- Various transitional periods
- New orphan regime
- Expedited MA applications for MHRA including:
  - A 67-day assessment of new applications for products containing new APIs or biosimilars which have received an EMA CHMP positive opinion
  - A full accelerated, 150-day, assessment for new active substances

Medical Devices – Immediate Consequences

- Medical Devices – 3 Directives (e.g. 93/42/EEC), MD Regulation 2017/745 –
  - CE-marking
  - NBs – free circulation
- 45% of all Medical Devices CE marked in Europe use UK NBs
- 70% of Non-EU Based Manufacturers use UK NB services
- Where UK Notified Body used - EU position is that UK Notified Bodies will lose their status as EU Notified Bodies from 31 October 2019
- BSI has formally applied for designation as a Notified Body in the Netherlands and achieved ISO 13485 Accreditation
- LRQA - LR seeking to replicate the appointments LR holds in the UK with majority of these new appointments to be in the Netherlands

Medical Devices – Longer term considerations

- UK still under the Directives
- Will UK mirror the new EU device regulation 2017/745? - Consultation on new devices regime
- UK transitional periods not reciprocated by the EU
- UK will accept EU NB approved medical devices till June 2023
- UK CA marks
- All devices will need to be registered with the MHRA.

Parallel Trade

- UK has decided to continue Parallel Trading
  - UK will unilaterally align to the EU/EEA exhaustion regime from Brexit day
  - Long term options will be reviewed and subject to consultation
- EU has made no comparable commitments

What Changes and What will Happen in the UK?

- The pharma sector is the UK's 3rd largest in the UK adding $19bn to economy
- The industry has relied for 40 years on harmonized procedures and free movement in EU
- To replace access to Horizon 2020, etc UK pledged R&D investment >2.4% GDP by 2027
- No mutual regulatory recognition. Hence UK effectively now a third country for the EU.
- MHRA joined the Access Consortium (with Australia, Canada, Singapore and Switzerland).
- Difficulty of Northern Ireland Protocol – transition till 1 January 2022. Then what?

Upcoming Session – Life Sciences Growth Series
次回のセッション

Patenting digital therapies – crossroad of life science and technology
デジタル治療薬の特許化– ライフサイエンスと技術の交差点

Tuesday, November 30, 2021
8:00 pm EST / 5:00 pm PST
2021年11月30日（火曜日）
8:00 pm 東部標準時 / 5:00 pm 太平洋標準時

Wednesday, December 1, 2021
10:00 am JST / 9:00 am CST
2021年12月1日（水曜日）
10:00 am 日本標準時/ 9:00 am 中国標準時


Janice H. Logan


Brett A. Lovejoy

Morgan Lewis

Other Upcoming Sessions – Life Sciences Growth Series
来月以降セッション – Life Sciences Growth Series

December
12月

Date / Time　日時	Title　タイトル	Speaker(s)　講師
Wednesday, December 8, 2021 9:00 pm EST / 6:00 pm PST 2021年12月8日（水曜日） 9:00 pm 東部標準時 / 6:00 pm 太平洋標準時 Thursday, December 9, 2021 11:00 am JST / 10:00 am CST 2021年12月9日（水曜日） 11:00 am 日本標準時/ 10:00 am 中国標準時	Governance constructs considerations in Japan-US cross-border strategic alliances and collaborations 日米間の戦略的提携とコラボレーションに関連するガバナンス構造についての検討	Suzanne L. Filippi スザンヌ L. フィリピ
Tuesday, December 14, 2021 8:00 pm EST / 5:00 pm PST 2021年12月8日（水曜日） 8:00 pm 東部標準時 / 5:00 pm 太平洋標準時 Wednesday, December 15, 2021 10:00 am JST / 9:00 am CST 2021年12月14日（火曜日） 10:00 am 日本標準時/ 9:00 am 中国標準時	Using AI in Pharma R&D and Clinical Testing—Regulatory and Legal Issues for the US landscape 製薬研究開発および臨床試験におけるAIの利用－米国における規制および法的問題	Kathleen Sanzo, Jacqueline R. Berman, Nancy Yamaguchi, Jitsuro Morishita キャスリーン・サンゾ、ジャクリーン・バーマン、ナンシー山口、森下実郎

Coronavirus COVID-19 Resources

We have formed a multidisciplinary **Coronavirus/COVID-19 Task Force** to help guide clients through the broad scope of legal issues brought on by this public health challenge.

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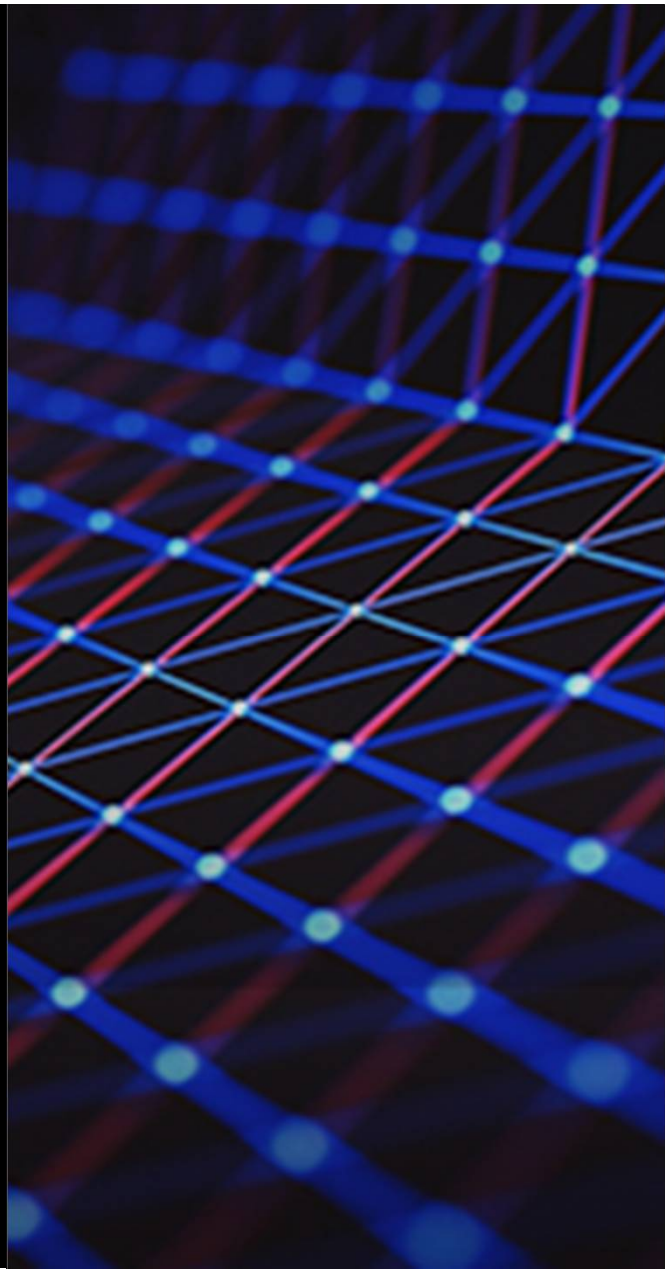
To help keep you on top of developments as they unfold, we also have launched a resource page on our website at **www.morganlewis.com/topics/coronavirus-covid-19**

If you would like to receive a daily digest of all new updates to the page, please visit the resource page to **subscribe** using the purple "Stay Up to Date" button.



Biography

Motonori Araki
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Motonori Araki primarily advises on mergers and acquisitions (M&A), commercial transactions, intellectual property licensing, and international dispute resolution. Moto has worked with clients across all industries with a focus on life sciences and technology, representing major US and Japanese companies in cross-border transactions and regulatory matters. His M&A work includes representing buyers and sellers on cross-border transactions and covers structuring, documenting, and negotiating transactions. Moto serves as the office managing partner of the firm's Tokyo office as well as the leader of the firm's Tokyo corporate and business transactions practice.

主な取扱業務分野は、M&A、商取引全般、知的財産権のライセンス及び国際紛争解決です。幅 広い業界のクライアントを支援しており、とりわけライフサイエンス分野、及びテクノロジー 分野の日米の企業を代理しクロスボーダー取引及び規制関 連案件を手掛けております。M&A 案件では、クロスボーダー取引において買主側または売主側を代理し、取引スキームの立案か ら、交渉及び契約文書の作成までの各段階における実務に豊富な経験を有しています。また、 東京オフィスのマネージング・パートナーであり、東京オフィスのコーポレート及びビジネス 取引関連業務のリーダーでもあります。

Biography

Louise Skinner
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Louise Skinner provides sophisticated, strategic advice on all aspects of employment law, with particular focus on regulatory employment matters. Described as "truly exceptional and insightful" by clients in The Legal 500 UK guide, Louise advises on issues including investigations, contractual disputes, whistleblowing, discrimination and restraint of trade. Louise has a particular focus on the financial services, life sciences, sports, media, and entertainment industries.

Biography

Lee Harding
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Lee Harding has a broad and versatile practice that goes beyond the provision of traditional legal services. Lee's practice is focused on the myriad legal implications arising out of a rapidly changing workplace: flexible working, five generations in the workplace, giving workers a voice, and the crossover between employment and the regulatory environment, to name but a few. The nontraditional legal services that Lee offers require a proactive approach to managing workplace issues before they escalate. He engages with a wide range of stakeholders to deliver sophisticated and actionable solutions that resonate across the entire business.

Biography

Paul Ranson
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Paul Ranson is a consultant who focuses on the regulatory and commercial needs of the pharmaceutical, biotechnology, and medical devices sectors. Paul's regulatory experience covers both marketing authorization-related matters and market access, pricing, and reimbursement issues. His commercial work is concentrated on transactions with a high degree of industry specificity including collaborations and outsourcing transactions.

As a result of his experience, Paul is a frequent speaker at conferences on a variety of topics including licensing, health technology assessment and various regulatory topics including during 2015 the Informa EU Pharmaceutical Law Forum in Europe and BIO and ISPOR in the United States. He has written some 10 reports on pharmaceutical and medical device regulatory issues and has authored/co-authored numerous journal articles.

ポール・ランソンは、製薬、バイオテクノロジー、医療機器分野に関する規制及び商業上のニーズに焦点を当てて助言するコンサルタントです。医薬品及び医療機器の販売承認に関連する案件に加え、市場アクセス、価格設定と医療機関への償還金に係る案件の両面を対象として規制関連のアドバイスを提供してきました。共同研究や委託業務等、ライフサイエンス業界の特殊性が高い取引を中心として執務しています。

豊富な経験を背景に、欧州に於けるインフォマEU薬事法フォーラム（Informa EU Pharmaceutical Law Forum）、米国に於けるバイオテクノロジー革新推進機構（BIO）及び国際医薬経済・アウトカム研究学会（ISPOR）等の会議で、ライセンス、医療技術評価、様々な規制関連のトピックについて講演しています。また、これまでに医薬品及び医療機器規制の問題に関する約10の報告書、数多くの論文を執筆/共同執筆しています。

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