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Life Sciences – Perspectives and Current Trends

Louise Skinner, Pulina Whitaker & Paul Ranson

1 October 2020

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Labor and Employment issues: Key Actions for Reopening Amid the Pandemic

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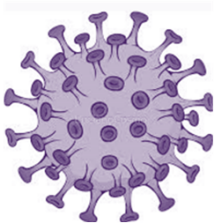
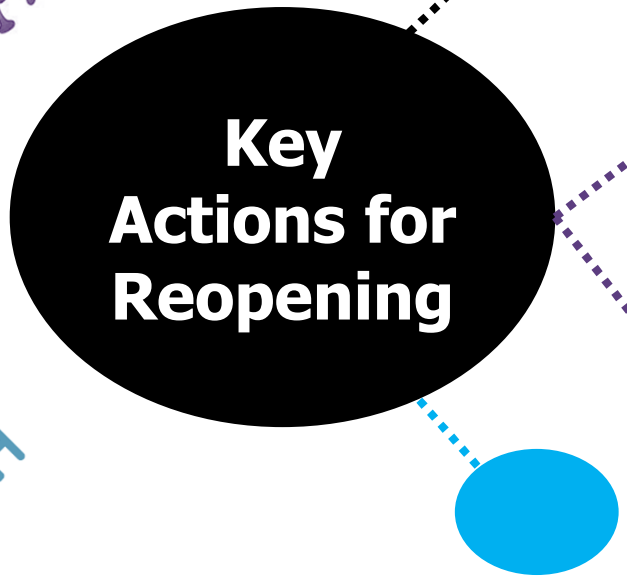
Key Actions for Reopening Amid the Pandemic





RISK ASSESSMENT

Conduct a COVID-19 risk assessment in consultation with workers (and unions if applicable).

IMPLEMENT

Implement the health and safety measures identified as necessary following the risk assessment. Consult staff (and unions if applicable) on the measures that are introduced.

POLICIES AND PROCEDURES

Review policies and procedures. Consider whether amendments will be necessary and whether new policies and procedures are required

EDUCATE

Staff will need educating on any new protocols. Managers will need specific training on how to enforce new measures and on supporting staff.

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Compliance with Government Directives and Industry-specific Requirements

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Compliance with Government Directives and Industry-Specific Requirements

UK Government Guidance
Industry-specific guidance was published on 11 May 2020 and has been updated regularly throughout the pandemic

Risk Assessment
Employers with more than 50 employees are expected to publish the results of their risk assessments on their website (all employers are expected to do so)

At-risk individuals
Clinically extremely vulnerable people can now return to work provided the workplace is COVID-secure but they should be offered the safest available on-site roles (remote working is encouraged for such individuals)

At-risk individuals
Your risk assessment should have particular regard to staff who are clinically vulnerable and clinically extremely vulnerable, and consider whether any measures can be put in place to mitigate the risk posed to such individuals

No one-sized fits all approach
Deciding which employees are essential to restart on-site activities will be difficult. Some may be very keen to return, others less so. Be flexible wherever possible.

Remote working
Potential backlash against continued remote working from those concerned they need to be physically present in the workplace to justify role / avoid redundancy

UK Government Guidance – recent updates

Update on social gatherings

- The UK Government has set a legal limit of 6 on socialising groups indoors and outdoors
- This limit does not apply to workplaces but employers should ensure that practices within the workplace reflect the Government's guidance on providing a COVID-secure workplace.

Update on the mandate for the collection of Test and Trace Data

- Employers should assist the NHS Test and Trace service by keeping a record of staff shift patterns where applicable for 21 days and assist NHS Test and Trace with requests for data where required.
- This is to assist with containing clusters and outbreaks.

Update on working from home guidance and self-isolation

- Office workers who can work from home **effectively** are advised to do so. Anyone else who is not able to work from home, should go to their place of work. However, the decision to return the workplace must be made in consultation with workers (this can include through trade unions or employee representatives where applicable).
- From 28 September, employers are legally obliged to not knowingly require or encourage an individual who is required to self-isolate to come to work.

Compliance with Government Directives and Industry-specific Requirements

Key Legislative Changes and Government support

Annual Leave

The Government relaxed the restriction on carrying over the four weeks' leave derived from the Working Time Directive. Workers may carry-over untaken WTD leave where it was not reasonably practicable to take it in the leave year due to COVID-19 (e.g. increased demand due to COVID-19 meant the employee could not take holiday).

EVL may become more significant in the event of a second wave

Emergency Volunteer Leave

New form of statutory unpaid leave. Employees may volunteer for 2, 3 or 4 consecutive weeks in essential health and social care services if they obtain an "emergency volunteer certificate" and give 3+ days' notice. Employees are protected from detriment and dismissal in such circumstances.

Job Retention Scheme

The JRS ends at the end of October 2020 and was closed to new entrants from 30 June 2020. New Job Support Scheme introduced from 1 November, under which the Government will subsidise wages of employees working less than full-time. New legislation provides HMRC with powers to scutinise use of COVID-19 support schemes.

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Health and Safety, Whistleblowing and other Litigation Risks

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Health and Safety, Whistleblowing and other Litigation Risks

Health and Safety

Statutory Duty

Employers 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 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. Implement measures to minimise risks. Employers must take all reasonable practicable steps to minimise the risks.

Consult with employees (or elected representatives 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.

Common measures include:

- Regular cleaning of public places
- Allowing remote working
- Stationing employees two metres apart
- Splitting workforce into teams and/or staggering work times

Health and Safety, Whistleblowing and other Litigation Risks

Whistleblowing

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

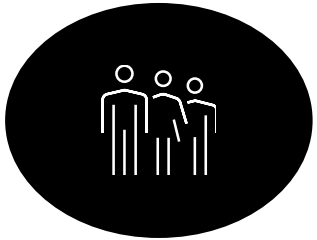
Concerns may qualify as protected disclosures. If so, individual is protected from detriment and dismissal

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

Employers who following government guidance are likely to have an adequate defence to allegations. **No financial cap** on compensation in whistleblowing claims

Health and Safety, Whistleblowing and other Litigation Risks

Other Litigation Risk



Employee Misconduct and Grievances

Potential for sexual harassment issues as employees return to the workplace or other harassment complaints where employees fail to respect personal space or comply with safety guidelines

Health and Safety Litigation

Complaints relying on sections 44 and 100 of Employment Rights Act 1996, which protect employees from detriment and dismissal in certain health and safety cases

Breach of contract, unfair dismissal, unlawful deduction of wages

Sudden impact of COVID-19 may have forced employers to make quick and important decisions to protect the business. Potential increase in claims relating to unlawful deduction of wages, unfair dismissal and/or breach of contract, among others

Discrimination

Direct and indirect discrimination risks – ensure decisions are applied consistently and are not based on protected characteristics

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Managing Continued Home-working in the Medium to Long Term

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Managing Continued Home Working in the Medium and Long Term

Managing Remote Working

Government Guidance

Employers are once again required to facilitate remote working wherever possible. Employers should assess business needs and consider whether physical presence in the workplace is required. The UK Government's most recent announcement states that in particular, office workers who are able to effectively work from home should do so over the winter period. Employers should also consider the needs of employees who are struggling with continued home-working.

Statutory Requests

All employees with 26 weeks' service are eligible to request flexible working. Employers may refuse the application but must handle the request in a reasonable manner.

Dealing with Increased Requests

Going forward, consider how to deal with requests and how to choose between them. Risk of direct/discrimination risk. In order received? Preference to those with statutory rights (e.g. disabilities)? Relevance of different reasons? Consistency? Appoint same person/team to oversee?

Workplace Assessments

Employers have the same health and safety responsibilities for home workers as for any other workers. Provide workers with advice on completing their own basic assessment at home.

Mental Health

Put procedures in place so you can keep in direct contact with home workers to recognise signs of stress as early as possible. Be approachable, available and encourage team members to talk if they are having problems.

Equipment

Employers should check that employees have the right equipment to work safely. Discuss equipment and technology with employees, agree what is needed and support employees in setting up new equipment or technology.

Managing Continued Home Working in the Medium and Long Term

Managing Remote Working

Set Clear Expectations

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

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.

Storing Information and Data Protection

Homeworkers may need specific training on their obligations in relation to data protection and confidentiality. Employers should also carry out a data privacy impact assessment of the data protection implications of employees working from home.

Childcare

Employers should be sensitive and flexible to staff with childcare responsibilities wherever possible. Consider whether a more flexible homeworking arrangement can be implemented (e.g. different hours and flexible deadlines).

Mortgages and Insurance

Employees will need to check there are no issues with them working from home with their mortgage provider/landlord, and their home insurer. Employers should check their insurance to make sure they are covered for remote workers using business equipment.

Place of Work

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 employment law and data protection issues.

How to Ensure Managers can Spot Issues and Mitigate Risk

Leading by Example

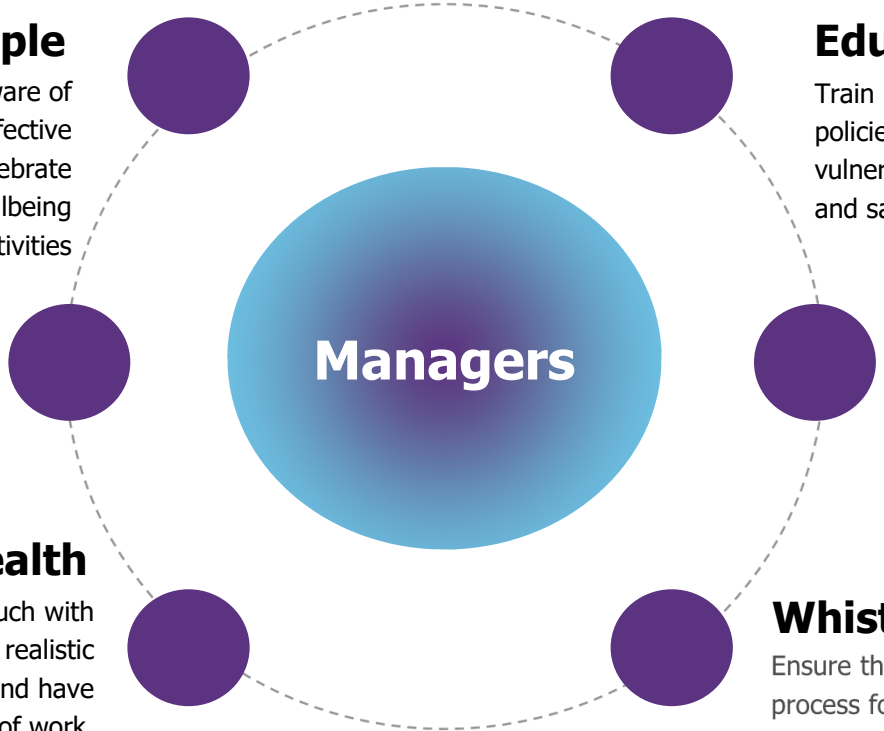
Ensure that managers are aware of their role and the need for effective leadership. Ask managers to celebrate success and to encourage wellbeing activities

Reminders

Managers may need refreshers on how to conduct difficult conversations and on resolving conflicts in the workplace

Mental Health

Managers should keep in touch with their team. They should set realistic deadlines and workloads, and have open discussions about hours of work.



Educate

Train managers on new COVID-19 protocols and policies e.g. on what staff will be classed as vulnerable and on how to enforce new health and safety measures

Resources

Ensure managers know where to locate Company resources so that they can inform themselves and point staff to such materials

Whistleblowing

Ensure that managers are clear about the process for dealing with concerns and can signpost it to employees.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Diversity and Inclusion

Focus on diversity and inclusion has been given renewed focus by recent events in the US, in particular the death of Floyd George.

Many companies are making public statements on the importance of diversity and inclusion, and showing renewed commitment to diversity initiatives in place or to be introduced.

Gender pay reporting in the UK has improved and widened the dialogue on gender equality, which has elevated to a board level issue and priority.

It is hoped that ethnicity pay reporting will have the same impact for racial equality, when the regime is finally implemented.

Life sciences firms are placing greater emphasis on auditing pay practices and diversity and inclusion initiatives and taking active steps to improve diversity and inclusion, and attract and retain the best talent.

Diversity and Inclusion

- Appreciate the importance of pay equity reviews
- Provide diversity and inclusion training
- Conduct a privileged pay equity audit and/or culture audit
- Analyze workplace demographics, applicant pools, and promotion patterns
- Consider developing aspirational goals
- Create a diversity and inclusion council and/or employee resource groups
- Develop talent recruitment and retention strategies

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Impact of Brexit on Employment & Immigration

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Impact of Brexit on Employment and Immigration

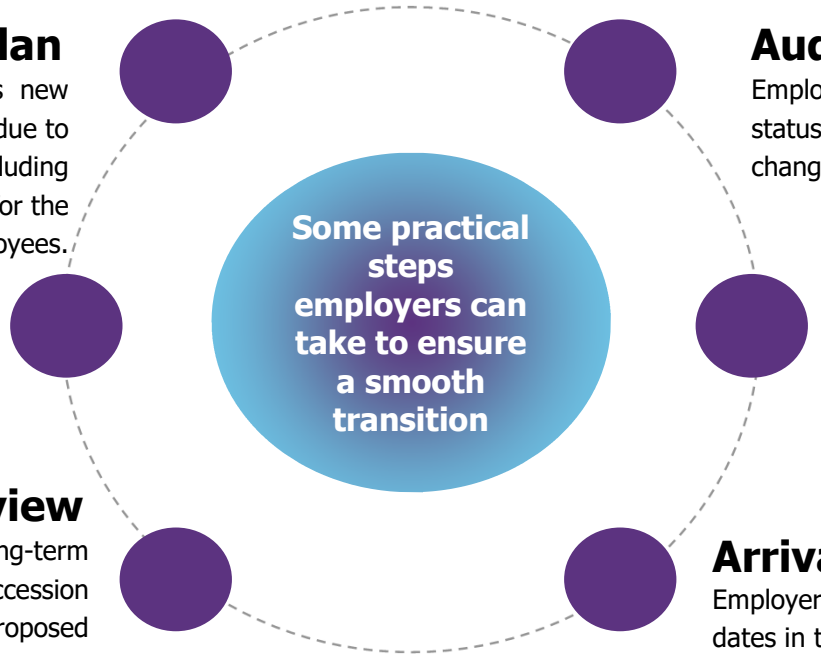
Relatively little expected to change in the short term from an employment law perspective, although certain aspects of retained case law likely to change direction over time e.g. holiday pay and carry-over.

Brexit will create 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 already been taking 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

Employers should plan for the UK's new points-based immigration system that is due to come into effect on 1 January 2021, including applying for a Tier 2 sponsor licence for the relevant employees.

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 should identify EEA and Swiss Nationals working in the UK

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 or abroad to determine eligibility to apply for settled status

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GDPR: Transfers, Brexit, Enforcement

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Our Discussion

- GDPR continues to be a hot topic and a ripe area for enforcement
- Data transfer – how to do it
- Brexit remains an unknown from a privacy perspective – will the UK obtain an adequacy decision
- Schrems II – consequences for data transfers
- Collective actions for privacy breaches

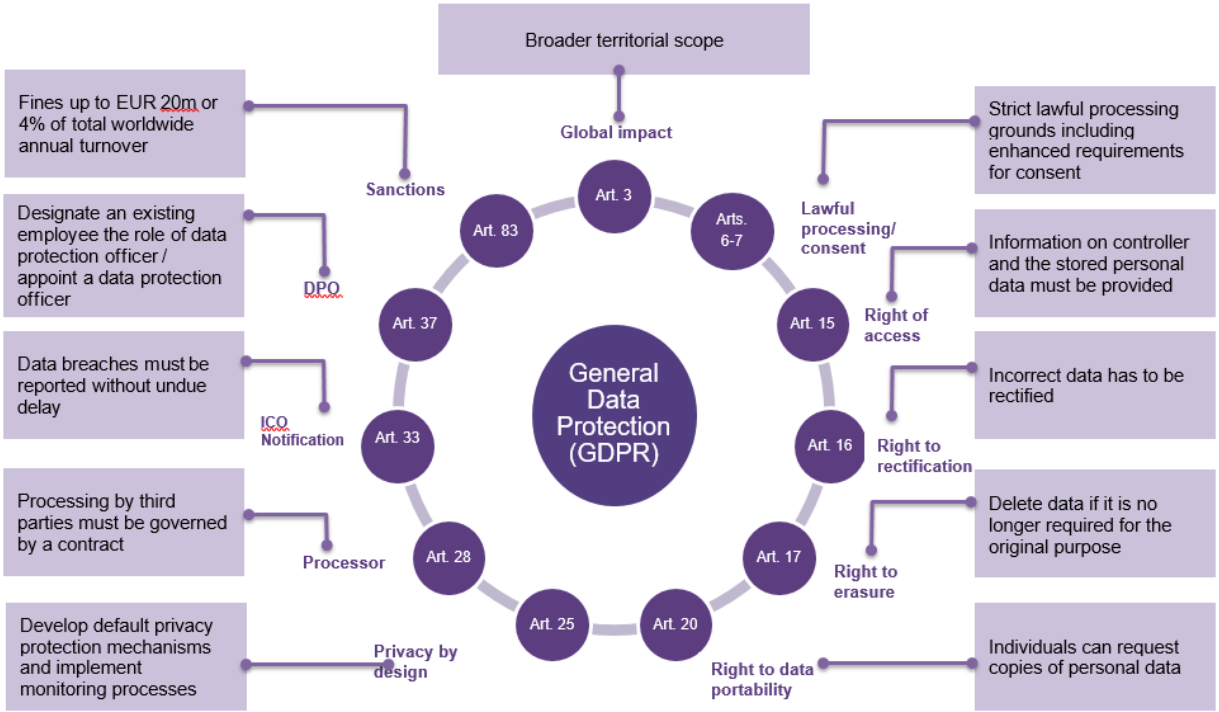
The EU General Data Protection Regulation

- EU GDPR came into effect on 25 May 2018
- Local EU and UK data protection laws supplement the GDPR
- The GDPR applies to controllers and processors having an EU-based establishment where personal data are processed in the context of the activities of this establishment
- The GDPR also applies to controllers and processors based outside the EU territory where the processing of personal data regarding EU data subjects relates to:
    - the offering of goods or services (regardless of payment)
    - the monitoring of data subjects' behavior within the EU
- "Personal Data" means any information relating to an identified or identifiable natural person ("data subject"); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that person
- Personal data has to be processed fairly and lawfully – transparency is key e.g. privacy notices

The EU General Data Protection Regulation, cont'd

- Data Protection Officer: for controllers/processors processing substantial sensitive personal data or who have core activity of monitoring individuals on a large scale or public body
- Right to request to be forgotten, have data rectified or deleted
- Privacy by design: privacy safeguarding technology built-in from the start
- Actively factor privacy considerations into the design and upgrade of all systems, policies, settings which process personal data
- Privacy by default: privacy-friendly default settings until user chooses otherwise
- Data protection impact assessment: prior to processing if high risk for individuals
- Controllers must notify data breach to DPA without undue delay/within 72 hours and to individuals without undue delay if there is likely to be high risk to individuals
- Penalties for breach of GDPR – up to higher of 4% global turnover or €20,000,000
- Controllers and processors are both directly liable under GDPR

Overview of the GDPR



Data Transfers under GDPR

- General restriction on transferring personal data outside EEA to a "third country"
- Adequate countries: Andorra, Argentina, Canada, the Faroe Islands, Guernsey, Isle of Man, Israel, Japan, Jersey, New Zealand, Switzerland and Uruguay
- GDPR permitted data transfer options (safeguards):
  - Binding Corporate Rules
  - Standard contractual clauses: importer controller/processors based in the third country; exporter controller must be based in Europe
  - Importer subject to an approved Code of Conduct
  - Importer subject to an approved certification mechanism
  - No longer the Privacy Shield after Schrems II
- 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

Data Transfers - SCCs

- Standard contractual clauses (to processors or controllers) are a very common method of transferring data outside the EU
- The European Commission has consistently emphasised the need for data transfers to be possible for economic purposes
- In Schrems II, the processor SCCs were validated
- The ECJ made clear that the laws of the importer were relevant to assess if the importer can meet its obligations under the SCCs
- If there is a risk that the importer has legal obligations that could undermine the SCCs obligations, the transfer may need to be suspended unless additional safeguards can mitigate against these risks – we await EDPB guidance on additional safeguards
- Encryption; restrict access; consider if transfers are necessary; localise?
- Transfers to the US will not, necessarily, invalidate the SCCs for importers in the US – a risk assessment may be needed
- If the importer cannot comply, the transfer must be suspended or terminated – notify the supervisory authority

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
- Other new options: Code of Conduct, privacy seals – details awaited from supervisory authorities
- Give notice to data subjects of the transfers

UK Data Protection Act 2018

- UK Data Protection Act 2018 – in force on 25 May 2018
- Implements local law permitted provisions of GDPR:
  - children's consent at 13 years;
  - processing for criminal records;
  - exemptions from restrictions for processing special categories of interest e.g. public interest exemptions;
  - exemptions from subject access rights
- Includes law enforcement processing and intelligence services processing provisions
- Sets out powers of enforcement of ICO

Brexit and UK Data Privacy

- UK has left the EU – transitional period until 31 December 2020
- UK GDPR will be implemented to give direct effect to GDPR
- Until we receive an adequacy decision, the UK will be a third country (like the US) – data exports from the EEA will be restricted – SCCs etc will be needed
- Other data privacy laws already incorporated in UK law e.g. ePrivacy Regulations give effect to Electronic Communications Directive
- ICO has approved current EU SCCs for data transfers from the UK – likely to be replaced in future with UK versions; EU will also release replacements to the current SCCs for GDPR purposes (long awaited)

Key Takeaways

- Schrems II – consider risks and measures to mitigate against the risk: is there an alternative to the proposed transfer if you need to suspend?
- Brexit – the UK will be a "third country" with restrictions on data exports from the EEA unless we receive an adequacy decision by the end of 2020
- Collective actions are on the rise for privacy breaches

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Regulation

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Topics

- Coronavirus
- Medical Devices Regulation
- Clinical Trials Regulation
- Pediatric and Orphan Medicines
- Brexit

Coronavirus I – COVID-19-related medical devices and medicines: Relaxations

- 2001/83/EC Article – Article 5 relaxation for 'special needs';
- Specific measures aimed at alleviating the regulatory requirements
- National rather that EU initiatives but EU afforded national authorities broader discretion in applying existing derogations and exemptions
- Expediting timeframes
- Derogations and exemptions from usual regulatory requirements for a limited period
- Providing guidance on the navigation of existing regulatory pathways
- Indemnities (confidential) including in respect of product liability issues
- Encouragement of non-specialist manufacturers (e.g. ventilators)

Coronavirus II – Pharma Industry Strategy Roadmap Consultation

- EU concerns
  - Dependence on ex-EU API
  - Shortages
  - Affordability
  - Innovation ecosystem
  - Innovation/public health misalignment
- Possible Solutions
  - Encourage and support EU manufacturing
  - HTA cooperation through non-legislative means
  - Innovation incentives and transparency
  - 'Sound functioning' of the biosimilar and generic markets

Medical Devices/IVDR Regulations I

- Due to come into effect 26 May 2020
- Delay driven by:
  - Delay in guideline production
  - Notified body readiness
  - EUDAMED delay
  - COVID 19
- Now 26 May 2021
- IVDR prognosis
  - 2022 timeline therefore less attention
  - 80/20 reversal on Notified Body involvement

Medical Devices Regulation II

- Stricter pre-market control of high-risk devices at an EU level;
- The inclusion of certain aesthetic products;
- A new risk classification system for diagnostic medical devices;
- Improved transparency through the EU database of medical devices (Eudamed);
- Device traceability through the supply chain ‘economic operators’;
- A requirement for an 'implant card' for patients with implanted medical devices;
- Stricter rules on clinical data and clinical studies on devices;
- Manufacturers to collect data about the real-life use of their devices;
- Improved coordination between EU Member States.

Clinical Trials Regulation

- General EU move to transparency and public access to trial data in recent years. Accelerated by CTR
- Regulation became law in 2014 but still not yet fully in force due to various delays
  - Not to implemented until EU Portal and Database in place – delays due to Brexit and technical issues
- Changes
  - Streamlining the process for clinical trial application across the EU
  - Assessing and authorizing clinical trials by removing duplication and reducing delays in the process
  - Introducing a lighter regulatory regime for trials conducted with medicines that are already authorized and which pose minimal risk compared to normal clinical practice
  - Simplifying reporting requirements, sparing researchers from submitting largely identical information on the trial process to various bodies
  - Recognizing co-sponsorship, which acknowledges that a trial can be led by more than one organization
  - Introducing the concept of a single decision on a clinical trial, which will replace the previous separate approvals given by the National Competent Authorities and Ethics Committees

Paediatric and Orphan Medicines Review

- July 2020 Commission evaluation - Orphan and Paediatric Regulations
- Conclusions - the Regulations
  - not suited to encourage investment in, the development of medicinal products in areas with unmet medical needs and no or very low profitability
  - did not ensure patient accessibility (availability or affordability) to authorized orphan and pediatric medicinal products.
- Could lead to:
  - the adoption of a new regulation to support the development and availability of products for unmet medical needs
  - a revision of the Orphan Regulation (in particular market exclusivity" should no longer be a one size-fits-all incentive, but tailored to the product profitability, investment, or type of application
  - amendments to the Paediatric Regulation, or the adoption of new regulation on unmet medical rather than a revision of the Paediatric Regulation itself.
- Next steps and timing of new legislation

Brexit I - Overview

- Deal or No Deal?
- If there is a no-deal Brexit the UK will be considered a third country
- 1 September 2020 suite of documents
- Medicines
  - Clinical trial registration
  - 1 January 2021 - all CAP MAs will become UK MAs
  - Options for pending MA applications
  - Batch authorisation
  - EU establishment requirements
- Medical Devices
  - Registration of MDs with the MHRA within 4, 8 or 12 months
  - MDR and IVDR will "not automatically apply in Great Britain," as after transition period expires – new regime promised
  - EU CE Marking recognized till June 30, 2023 and thereafter the UKCA required
  - Need for UK Responsible Person
  - Need in EU for authorised representative and options for UK notified bodies

Brexit II –Recent Guidance

- Conditional Marketing Authorisations, exceptional circumstances Marketing Authorisations and national scientific advice
- Registering new packaging information for medicines
- Guidance on the handling of applications for Centrally Authorised Products (CAPs) pending on 1 January 2021
- How Marketing Authorisation Applications referred under Article 29 will be handled from 1 January 2021
- Converting Parallel Distribution Notices (PDNs) to UK Parallel Import Licences (PILs) from 1 January 2021
- Handling of Active Substance Master Files and Certificates of Suitability from 1 January 2021
- Reference Medicinal Products (RMPs) from 1 January 2021
- Converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs),
- Guidance on licensing biosimilars, ATMPs and PMFs from 1 January 2021
- Comparator products in Bioequivalence/Therapeutic Equivalence studies from 1 January 2021

Biography

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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 extensive experience in advising life sciences clients, including many of the world's leading pharmaceutical companies, on the full ambit of employment legal issues, including ethical and regulatory concerns.

Biography

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Pulina Whitaker's practice encompasses data privacy and cybersecurity as well as employment . She is a co-Head of our global Privacy & Cybersecurity practice. She manages employment and data privacy issues in sales and acquisitions, commercial outsourcings and restructurings. Pulina provides day-to-day advisory support for multinationals on the full spectrum of data privacy issues, including data breaches, data protection compliance issues and data sharing and data transfer arrangements. Pulina has deep experience managing international employee misconduct investigations as well as cross-border data breach investigations. She has been appointed as a Compliance Monitor for the UN and for USAID. She is also a Trustee of Hostage International.

Biography

Paul Ranson, Consultant
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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.

Paul spent the early part of his career in in-house roles with Smith Kline, Merck Sharp, and Dohme, and has subsequently maintained this industry focus.

Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

Abu Dhabi
Almaty
Beijing*
Boston
Brussels
Century City
Chicago
Dallas
Dubai
Frankfurt
Hartford
Hong Kong*
Houston
London
Los Angeles
Miami
Moscow
New York
Nur-Sultan
Orange County
Paris
Philadelphia
Pittsburgh
Princeton
San Francisco
Shanghai*
Silicon Valley
Singapore*
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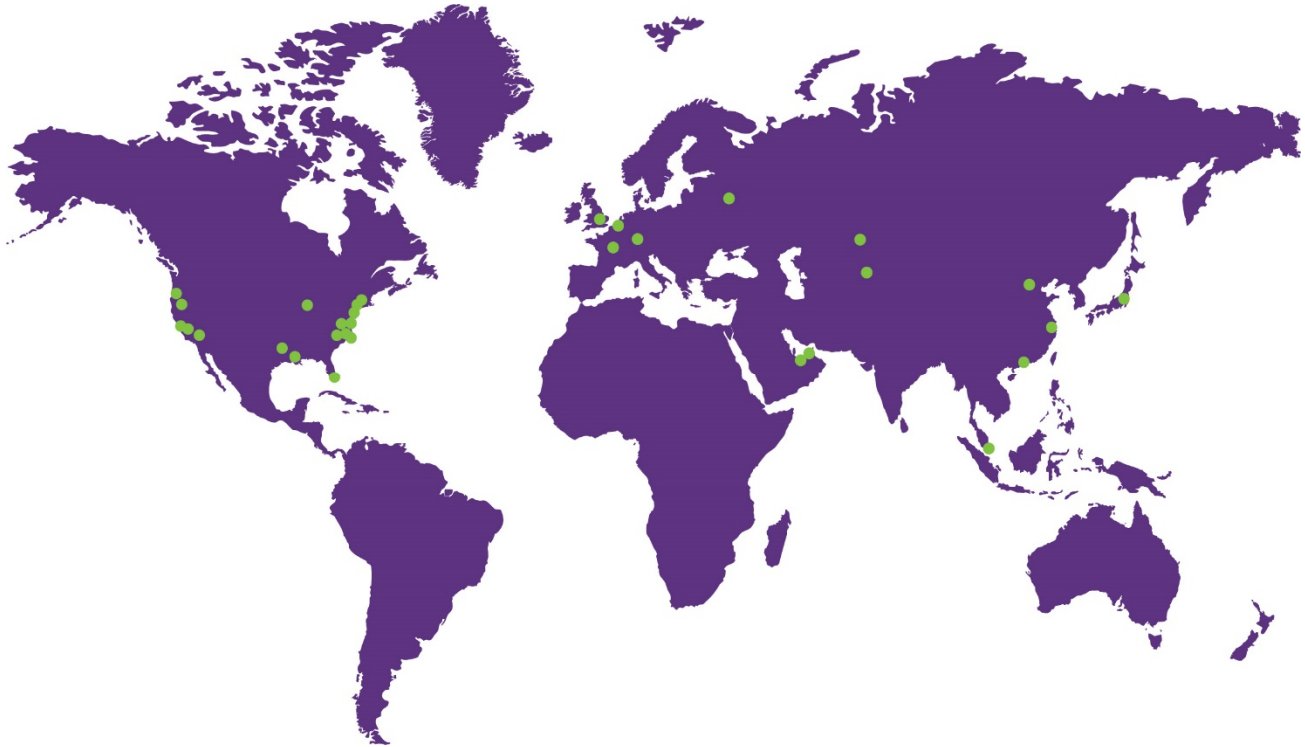

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