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Employment in the life sciences sector: Q&A

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A Q&A guide to employment issues in the life sciences sector.

The Q&A gives a high-level overview of the issues affecting employment arrangements in the sector and the key considerations for employers and employees. It covers employee and consultant contracts; intellectual property rights; compensation and benefits; regulatory and compliance issues; working time and leave; international movement of workers and the likely impact of Brexit. The Q&A also provides a summary of recent employment case law affecting the life sciences sector.

Types of worker

1.a. Excluding generic employment issues, what are the key sector-specific issues that arise in relation to employment and other worker relationships in the life sciences sector?
The life sciences sector encompasses the application of biology and technology to health improvement, including biopharmaceuticals, medical technology, genomics, diagnostics and digital health. The UK has one of the most prominent and productive life sciences industries globally, generating turnover of approximately £20.7 billion in 2015. Employment in the life sciences sector is significant, with over 5,000 companies and 230,000 jobs recorded in 2016. A quarter of this employment involves highly skilled research roles, rendering it a highly remunerated sector in comparative terms.

Employment status

In the life sciences sector, while the bulk of individuals are engaged as employees or workers, many individuals are engaged as self-employed contractors or consultants. Determining employment status is a key issue in the life sciences sector, given the significant number of consultants and contractors engaged and the consequences of an incorrect classification. It is important to look at the reality of the situation to ensure that the documents accurately reflect the nature of an individual's engagement. Failure to do so could give rise to unforeseen legal consequences (given that employees have heightened statutory employment rights over consultants), and tax liabilities.

Under UK employment law, courts will consider the "substance" rather than the "form" of a contract when determining an individual's employment status. The labels used by the parties in the contract to describe the arrangement will only be the starting point. The matters to be taken into account and the weight to be given to them will vary depending on the circumstances.

Case law suggests that a key test is whether there is a "mutuality of obligations" between the employer and the employee. This means that the employer is obliged to provide and pay for work and the employee is obliged personally to carry out the work given to them.

Generally, an individual who is personally required to undertake work, with little or no control of how, what, when,

where and on what terms services are to be provided, is more likely to be employed. By contrast, someone who is genuinely self-employed would generally be said to be carrying on business on his or her own account. So, whereas the employer "buys" the individual, the customer "buys" the job.

Other factors which are taken into account by the courts include:

- Whether an individual is permitted to provide a substitute to perform services (which is more common for a genuine contractor) rather than being required to perform them personally.
- The extent to which an individual can provide services on his or her own terms (genuine contractors are more likely to be involved in bidding for work and negotiating over terms including price, rather than just accepting the terms presented to him or her on a "take it or leave it basis").
- The extent to which an individual is integrated within the organisation of a business (genuine contractors are less likely to be managing other employees or subject to the employment rules or policies of a business).
- The extent to which an individual takes a business risk (genuine contractors are more likely to take an investment risk by supplying their own capital or providing their own tools and equipment to perform the services).

Historically, the test was similar for tax and employment law purposes regardless of whether an individual was engaged by a business as an individual consultant or via a personal services company. However, new legislation came into force on 6 April 2014 (in the Finance Act 2014), which narrowed the test for self-employment for tax purposes in relation to individuals engaged via personal services companies. See *Practice note, IR35: Finance Act 2014 changes concerning the right of substitution*.

It should be noted that there will be the introduction of off payroll working rules for the private sector from April 2020. The likely effect will be a sharp reduction in the use of personal service companies, as clients/customers will face an income tax risk if they are used. See *Legal update Autumn 2018 Budget: key business tax announcements: Off-payroll working extended to private sector from April 2020*.

Currently, where an individual is engaged by a business via a personal services company the test of self-employment focuses primarily on whether any party within the chain has exercised, or has the right to exercise, supervision, direction or control. Accordingly, an individual will be treated as an employee of the personal services company for tax purposes where the contract between the personal services company and the business gives the business a right of control over the individual, even if that control is not exercised. This means many consultants (previously treated as self-employed for tax purposes) may now be treated as employees.

There has also been a shift in the burden of proof so that where an individual is engaged via a personal services company, the presumption will be that the individual is an employee and that income tax and national insurance contributions should be deduced by the personal services company. This provides an additional level of comfort to the end-user client. The IR 35 rules will only apply to small businesses after April 2020.

For more information on employment status, see *Practice note, Employment status (1): employee, worker or self-employed?*.

Agency workers

A significant proportion of the workforce in the life sciences sector are agency workers, supplied by employment agencies to work for temporary periods. Companies engaging agency workers should ensure there is a clear

division of responsibility between the company and the agency in terms of managing the agency worker. Companies should also consider putting in place contingent worker policies for agency workers to adhere to while providing services to the company, for example, regarding matters such as anti-harassment and dignity at work. They should also consider implementing guidelines on offering agency workers permanent roles (on the company's own headcount) at the end of temporary contracts, including addressing whether breaks in service are necessary to ensure that dates of commencement of continuous employment are clearly defined, and ensuring that each agency worker is made subject to all relevant employment terms, conditions and policies on starting a permanent role.

Hirers need to ensure that agency workers have pay parity with comparable permanent employees once they have reached 12 weeks' service. For more information, see *Practice note, The Agency Workers Regulations 2010: "Week 12" rights: the same basic working and employment conditions as direct recruits*.

For more information on agency workers, see *Practice note, Agency workers: overview of rights*.

Joint ventures

Companies within the life sciences sector often engage in joint ventures relating to particular products or innovations. This is likely to involve employees or contractors engaged by the respective companies working together for the joint venture, potentially for lengthy periods of time. Companies should ensure that there is clear line management and accountability in those circumstances, and that it is clear which rules and policies apply to the individuals while engaged on joint venture projects. Companies should consider whether temporary assignment documents should be issued to affected individuals to ensure that their rights, responsibilities and obligations are clear during the joint venture period.

Depending on the nature and duration of a joint venture, it may be that certain employees' employment will automatically transfer to the joint venture entity pursuant to the Transfer of Undertakings (Protection of Employment) Regulations 2006 (*SI 2006/246*) (TUPE). For further information, see *Practice note, TUPE: overview*.

The work of a production facility is prone to changing requirements (both big increases and big decreases). In relation to decreases, this might be caused by adverse regulatory decisions, generic or biosimilar entry, clinical failures, outsourcing decisions, facility sales and so on. As a result, wind downs, reallocations and redundancy programs are quite common.

In the world of outsourcing, the TUPE question does arise but normally there is a fairly lengthy period of wind down in which the end of the project is clearly visible and the workforce is minimised gradually. Significant service-related TUPE transfers are not common in outsourcing because, ultimately, it is normally a difficult and lengthy process to transfer a project. Where it might happen, there is a risk of brain drain and businesses should make sure their key staff are protected as far as possible.

Some businesses operate a full time equivalent (FTE) model, which involves temporarily allocating resources to a project on a full-time basis. The potential application and implications of TUPE should be considered carefully in this scenario.

Employee issues

A significant proportion of work in the life sciences sector is project-driven, particularly within research and development (R&D). Therefore, the requirement for workers or employees will be dependent on each specific project or task. Employers should consider this at the start of any engagement, and assess on what basis an individual should be engaged (that is, whether as an employee, contractor or otherwise), and whether on a permanent or fixed-term basis.

It is particularly important for employers operating within the life sciences sector to protect their confidential information and intellectual property (IP), given the innovative techniques and products they frequently create and manage. Therefore, it is advisable for employers within the life sciences sector to require new employees to sign up to full IP, confidential information, and restrictive covenants, to protect the business' confidential information, and, in turn, protect its legitimate business interests.

As part of monitoring compliance and ensuring confidential information and IP is not used in an unauthorised manner, companies may need to monitor employee activities, including emails being sent externally, the downloading of files to USB drives and webpages visited by employees. Employers should include a provision within their employment contracts or a separate policy to enable them to conduct those monitoring activities throughout the employment relationship for the purposes of protecting the legitimate business interests of the company. For further detail on data privacy issues, see *9. Are there any sector-specific obligations or considerations in relation to the handling of employee data or the monitoring of employees in the workplace?*.

Companies operating in the life sciences sector require highly skilled workers, often with unique specialisms. As a result, the recruitment pool is often global and immigration issues are a concern, especially where employees need to be onboarded and deployed rapidly. For further information, see *12. What are the specific employment and immigration issues (if any) that have arisen as a result of Brexit in the life sciences sector?.*

On the factory floor, bad behaviour and incompetence can have dramatic consequences for the business. Consequently, the words "gross misconduct" (as a rationale for dismissal) are explored very carefully in relation to disciplinary proceedings and dismissals. There can also sometimes be an urgent business need to dismiss employees, and in this scenario there is some conflict with the US-style approaches involving immediate termination and possible severance payments.

It is common for disciplinary proceedings to arise out of or from an investigation into failures in a quality management system, or for the two procedures to run in parallel. The documents and outcome of the quality management system investigation are unlikely to attract privilege and sometimes the employee being disciplined will know the position of the quality management system investigation in detail. Therefore, it is important for the legal advisor to know the background to the quality management investigation. In the context of significant allegations that are likely to result in court proceedings, the advisor may need to consider running a privileged investigation in parallel to (or before) the quality management investigation.

Other worker relationships

Unionisation is not a prominent feature of the life sciences sector.

1.b. What are the key issues that arise in relation to self-employed relationships in the life sciences sector?

Life sciences companies frequently use consultancy arrangements. This is particularly beneficial where an individual's particular skills are required to carry out a defined function or for a defined period.

Who is the counterparty?

Where the counterparty is a personal services company, it is important to ensure that obligations placed on the personal services company (especially in relation to IP, confidentiality and restrictive covenants) are also enforceable against the individual(s) providing the services. The simplest way to achieve this is to either:

- Enter into a tripartite consultancy agreement (between the client company, the personal services company and the relevant individual), in which the individual agrees to abide by all obligations placed on the personal services company.
- Execute a bipartite agreement (between the client company and the personal services company) in which the personal services company agrees to restrain the individual and to procure that the individual signs a side letter agreeing to abide by relevant conditions.

Neither approach, however, offers a perfect solution. While a tripartite agreement may maximise the enforceability of contractual protections, it also extends a greater degree of control over the individual providing the consultancy services which may be indicative of personal service, thereby increasing the risk that the relationship could be recharacterised as an employment or worker relationship (see *Employment status*). A side letter between the personal services company and the relevant individual will not create the same risk, but it will be harder for the client company, as a third party, to enforce the terms of the side letter. While the client company could pursue the personal services company for the individual's breach of the side letter, depending on the nature of the personal services company, it might not have the resources to satisfy any judgment against it. The choice of approach may depend on the reason why the individual is hired and the importance of direct enforceability against the individual. For example, if the individual is only hired for a discrete project and will not be used on a repeat basis, the risk of recharacterisation may be sufficiently low that a tripartite approach would be appropriate. For more information, see Standard documents, *Consultancy agreement via a service company* and *Side letter to the consultancy agreement via a service company*.

IP

The default position for IP in an employment relationship is that IP generated in the course of work belongs to the employer. However, no such presumption exists for self-employed individuals (see *Practice note, Intellectual property issues relating to employees and consultants*). As a result, IP would automatically vest with a consultant, which is unlikely to be a client company's desired position, especially if the consultant has been engaged specifically to work on a project in which new inventions or confidential information are being generated. It is therefore important to include an express assignment of IP clause within any consultancy agreement, under which the consultant agrees to assist the client company to assign all IP rights to the client company, and if possible, sign a power of attorney to this effect. For further details on IP issues, see *4. Do any sector-specific considerations apply to the assignment of intellectual property rights in the life sciences sector?*.

Risk of relabelling the nature of relationship

Depending on the nature of the work required from a consultant, life sciences companies are likely to exert a comparatively high level of control over consultants, which risks the relationship being relabelled as one of employment (see *Employment status*). In particular, a key issue occurs where the consultant has sufficiently unique skills that even if a right of substitution exists, in practice it cannot be exercised, thereby increasing the risk of the relationship being deemed an employment relationship in reality.

A related issue is that as part of protecting confidentiality and IP, companies may wish to restrict consultants from working for multiple (and possibly rival) companies simultaneously or within quick succession. This will require negotiation with the consultant, who might wish to be free to work elsewhere. Additionally, as such a restriction will increase the level of control exerted over consultants, companies will need to consider whether this restriction may increase the likelihood of the relationship being relabelled as an employment relationship (especially if the factors of personal service and mutuality of obligations also exist).

Contracts of employment and consultancy agreements

2. Are there any sector-specific changes that you would make to a generic employment contract in the life sciences sector?

Qualifications

Life sciences employers may require employees to hold specific qualifications and to provide evidence of those qualifications (for example, a certificate or confirmation from the relevant institution) to the employer before the commencement date of the employment contract. This requirement is most likely to occur in agreements with highly skilled workers where their possession of a given qualification is essential to their work, or the employer wishes to have confidence that the individual is suitably qualified. If required, it would be prudent for an employer to make an offer of employment or engagement conditional on providing evidence that such a qualification has been obtained. The relevant provisions may also state that failure to provide sufficient evidence as required in the employer's reasonable opinion will result in the employment contract automatically terminating without liability on the employer's part. In certain scenarios, employment may be conditional on retaining a specific qualification or enhancing a specific qualification (which may require ongoing training or CPD points, for example). If this is the case, an employer may wish to include details of these requirements within the employment contract as a contractual condition for continued employment.

IP and confidentiality

Given the critical nature of know-how and IP to life sciences businesses, all employees exposed to know-how or IP (and back office functions where appropriate) should be required to adhere to enhanced confidentiality and IP provisions. Particular considerations include:

- Ensuring the definition of confidential information encompasses all sensitive information produced by the employer.
- Restricting the circumstances in which confidential information can be used or disclosed by the employee.
- Assigning all IP generated by the employee to the employer (and if possible, including a power of attorney, which would ideally be appended to the employment agreement). However, an employee might wish to carve out any IP they generated before the employment relationship starting or which is generated outside of work. This may be a point of negotiation, although, in relation to patents, the employee's statutory position cannot be diminished lawfully (see *Section 42, Patents Act 1977*).
- Giving the employer the right to claim any indirect job-related inventions created by an employee. See *Standard clause, Intellectual property clause for employment contract (long-form)*.

No additional employment

Life sciences employers are unlikely to want to allow employees to be able to work for other employers simultaneously, as this may increase the risk of IP or confidential information being shared outside the company. This restriction should be dealt with clearly in the employment contract in a "no outside employment" clause. However, there might be occasions where it is appropriate for employees to undertake roles for other entities (for example, as a school governor or charity volunteer). This can be dealt with by requiring employees to disclose any existing outside roles they undertake and asking for the employer's written consent before undertaking any new roles.

Post-termination restrictive covenants

Post-termination restrictive covenants are appropriate to protect the legitimate business interests of a company (see *Practice note, Restrictive covenants in employment contracts*). Broadly, the rights that a court will allow to be protected fall into the following categories:

- Trade connections (with customers, clients or suppliers) and, more generally, goodwill.
- Trade secrets and confidential information.
- Stability of the workforce.

Given that certain life sciences companies often operate in distinct markets where several rivals are competing for the same customers, suppliers and employees, it is important to introduce restrictive covenants where these are necessary to protect the legitimate business interests of the company. Post-termination restrictive covenants should go no further than is reasonably necessary to protect the applicable legitimate business interests of the company, otherwise they are likely to be deemed to be void by a court as a restraint of trade. The employer must tailor the restrictive covenants to the specific individual entering into them, considering their seniority, and the amount of confidential information to which they are privy.

To be enforceable the employer would have to be able to show, having regard to the employee's seniority and scope of influence, that the restrictive periods last no longer than is necessary to protect the employer's legitimate interests and do not act as a restraint of trade. The most likely legitimate interests in the life sciences sector will be protecting the employer's confidential information and commercial know-how, which is often critical to their business. In narrow markets, suppliers and clients could be limited and therefore an employee interfering with or poaching these could also be damaging. The same is true of poaching other company employees, especially those with unique skills.

Assessing the reasonableness of restrictive covenants will include examining the geographical scope, duration and breadth of the activities prohibited. Life sciences companies are often global in nature. Therefore, it might be reasonable for covenants to prevent employees undertaking certain activities anywhere where the employer conducts business or, potentially, globally. To ensure geographically wide covenants are enforceable, the duration might have to be reduced or, the restricted activity definition narrowed. Given many life sciences companies are in niche markets, narrow prohibitions are feasible and could even be achieved by listing named competitors for whom the employee cannot work for a time (although this might not be feasible if it still effectively acts as a restraint of trade on an employee with a similarly narrow skillset).

Ideally, covenants should always be tailored for each employee dependent on the level of confidential information available to the employee. Additionally, an employee's role may change over time, so it is important to consider whether existing restrictive covenants are still suitable where a change in role is implemented. In particular, as

employees are promoted and have greater opportunities to potentially harm the company should they leave its employment, it is important to assess whether covenants should be lengthened in duration or widened in scope.

3. Are there any sector-specific changes that you would make to a generic consultancy agreement in the life sciences sector?

IP and confidentiality

Given the critical nature of know-how and IP to life sciences businesses, all consultants exposed to know-how and IP should be required to adhere to enhanced confidentiality and IP provisions. See *Standard clause, Intellectual property clause in a consultancy agreement with an individual or service company*. Particular considerations include:

- Ensuring the definition of confidential information encompasses all sensitive information produced by the consultant.
- Restricting the circumstances in which confidential information can be used or disclosed by the consultant.
- While the default position for IP in an employment or worker relationship is that IP generated in the course of work belongs to the employer, no such presumption exists for self-employed individuals. As a result, IP would automatically vest with a consultant, which is unlikely to be a client company's desired position, especially if the consultant has been engaged specifically to generate IP. It is therefore important to introduce express provisions of assignment of IP to the client company (and if possible, including a power of attorney, which would ideally be appended to the consultancy agreement). However, a consultant might wish to carve out any IP they generated before the consultancy relationship starting or which is generated outside of work. This may be a point of negotiation.
- If a consultant is allowed to retain IP ownership over some or all of their product, this needs to be dealt with carefully and consequential issues need to be assessed. For example, could the client company ultimately require a licence from the consultant to use the work product produced by the consultant?

Restrictive covenants

Restrictive covenants and exclusive service clauses are not frequently used in consultancy agreements, in part due to the heightened level of control this imposes on the consultant and because this is likely to suggest an employment relationship in reality (see *Employment status*). However, there are circumstances where those restrictions (and especially non-compete covenants) may be appropriate within a life sciences sector context, given the highly confidential and sensitive nature of the products and information they may deal with (see *Post-termination restrictive covenants*).

4. Do any sector-specific considerations apply to the assignment of intellectual property rights in the life sciences sector?

Patents are the most important intellectual property rights in the life sciences sector and they are commonly used to protect the key pharmaceutical and biotechnological inventions relating to a product. A patent can be applied to an invention if (among other grounds) it is capable of industrial application (*Article 52(1), European Patent Convention* (EPC); *section 1(1)(c), Patents Act 1977* (PA 1977)). Certain inventions are excluded from patentability. This includes, but is not limited to, the treatment of the human or animal body by surgery or therapy

and the diagnostic methods practised on the human or animal body. These exclusions will not apply to products, particularly substances and compositions, for use in the methods. In the life sciences context, there are also specific types of inventions that are not patentable due to being considered contrary to “ordre public” or morality.

The rights-holder of a patent covering an invention relating to a medicinal product cannot exploit the product in the European Economic Area (EEA) until they have market authorisation (MA) to place this product on the market in the relevant territory. However, the MA process may be lengthy, which means the normal length of a patent would offer a significantly diminished reward to the pioneering business responsible for the invention. Therefore, the Supplementary Protection Certificate Regulation (*Regulation 469/2009*) (SPC Regulation) provides for an additional period of protection if the MA is not granted until more than 4.5 years after a patent is filed. In this circumstance, the SPC begins on the expiry of the patent. The SPC duration is calculated by reference to the period of time between the filing of the patent and the first MA to place the product on the market in the EEA, less five years and subject to a maximum duration of five years, expiring 15 years after grant of the MA or five years after the expiry of the patent, whichever is earlier (*Article 13, SPC Regulation*).

Trade marks are a significant feature of the life sciences sector, particularly in the context of marketing and sale of healthcare products. The repackaging and parallel importation of branded drugs is particularly important and contentious. Importers will buy drugs in EU member states where they are inexpensive and resell them in countries more expensively. In these circumstances, the original manufacturers are often unable (particularly where the activity is all within the EU) to respond by asserting their rights relating to trade marks. Those rights are said to have been exhausted. See *Practice note, Parallel trade in pharmaceuticals: EU Internal Market rules on the use of IP rights*.

Inventions are a large part of the life sciences sector and they, along with the rights to exploit them, are frequently protected by the provisions covering confidential information and IP in an employment or consultancy agreement. Whether the inventions are patentable or not, these provisions are important in securing key business assets. Also, for other types of business asset, such as pre-clinical test results and clinical trials data, these types of contractual provision are critical to secure and protect them.

The default position for IP in an employment relationship is that IP generated in the course of work belongs to the employer. For other relationships, it is important to ensure that the person creating the IP agrees to an appropriate assignment.

For further information on IP in the life sciences sector, see *Practice note, Overview of IP issues in the health and life sciences*.

Compensation and benefits

5. Do any sector-specific considerations apply to compensation in the life sciences sector? What about benefits?

In the life sciences sector, individuals may be employed in the research and development of new drugs and other pharmaceutical advancements. This often results in inventions which the employer can patent and directly commercialise, benefiting from the exclusivity the patent allows, or which contribute to the development of a marketable product. As such, employee inventors may be entitled to compensation from their invention. This may be a point of negotiation between the employee and employing company.

For an employee to be compensated for their invention, it must be of an “outstanding benefit to the employer” and

the compensation must be "just" in the circumstances (*section 40, PA 1977*). If that "outstanding benefit" can be demonstrated, then the employee shall be entitled to "a fair share (having regard to all the circumstances)" of the benefit the employer has or may reasonably be expected to derive from the invention or the patent for the invention, including from its assignment or licence (*section 41, PA 1977*).

Difficulty can arise in establishing what an "outstanding benefit" and "a fair share" is. In *Duncan and another v GE Healthcare Ltd [2009] EWHC 181 (Pat)*, "outstanding" was held to mean "something special" or "out of the ordinary"; more than merely "substantial", "significant" or "good". The "benefit" has to be something more than one would normally expect to arise from the duties for which the employee was paid. For further details, see *Practice note, Intellectual property issues relating to employees and consultants*.

In addition to compensation for inventions, employees in the life sciences sector are likely to benefit from a competitive salary. To recruit the best talent, there is constant pressure on employers to provide their employees with competitive wages and benefits. Employees can therefore expect to receive health insurance, dental insurance, a pension contribution, performance-related bonuses, share schemes and flexible working hours. To retain employees, many life sciences employers offer employees retention bonuses. The bonuses work by offering the employee a bonus for the successful completion of a certain milestone. For instance, 25% of the bonus is paid in the first year, 25% is paid in the second year, with the remaining 50% paid at the end of the third year.

Regulatory landscape

6. Are there any statutory or regulatory considerations that have a particular impact on employees, workers or the self-employed in the life sciences sector?
The life sciences sector is heavily regulated in the UK. Through a combination of statute and regulations, the UK imposes significant controls on the production, distribution, sale and advertising of medicinal products and devices. The key statutes and regulations are:

- The Human Medicines Regulations 2012 (*SI 2012/1916*), which regulate (among other matters) the manufacturing, dealing in, marketing and advertising of human medicines.
- The Medical Device Regulations 2002 (*SI 2002/618*), which regulate the marketing of medical devices generally.
- The Medicines Act 1968, which, although largely superseded by the Human Medicines Regulations 2012, continues to be relevant to certain parts of the life sciences sector (such as pharmacies).
- The Medicines for Human Use (Clinical Trials) Regulations 2004 (*SI 2004/1031*), which regulate clinical trials of medicines for human use.
- The Animals (Scientific Procedures) Act 1986, which controls animal research.
- The Good Laboratory Practice Regulations 1999 (*SI 1999/3106*), which require that all non-clinical studies be carried out in accordance with good laboratory practice.

A breach of many of the provisions in the above statutes and regulations by any person is a criminal offence, typically punishable by fine or imprisonment for up to two years. A breach (whether by an employee, agent, or body corporate) can also jeopardise the grant, award or continuing holding of any mandatory licences, authorisations, certifications or registrations necessary to lawfully manufacture, deal in, market or advertise medicinal products and devices. The Human Medicines Regulations 2012 also make clear that, in relation to certain offences under the regulations, where the offence is committed by an employee or agent, the relevant employer or principal is also guilty of the same offence and may be prosecuted accordingly.

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK's regulator of medicines and medical devices. It is an executive agency, sponsored by the Department of Health and Social Care. It is responsible for (among other matters) enforcing the Human Medicines Regulations 2012 and the Medical Device Regulations 2002.

In addition to the above framework of statute and regulation, many companies in the UK life sciences sector are members of industry associations which operate their own additional systems of self-regulation. Two prominent associations are the *Association of the British Pharmaceutical Industry* (ABPI), which represents research-based pharmaceutical companies and the *Association of British HealthTech Industries* (ABHI), which represents companies within the healthtech industry.

Members of the ABPI are required to comply with the ABPI's Code of Practice for the Pharmaceutical Industry (ABPI Code) which sets standards for the promotion of prescription-only medicines to health professionals and other relevant decision makers in the UK. The ABPI Code is enforced by the Prescription Medicines Code of Practice Authority (PMCPA) (a self-regulatory body). Sanctions for a breach of the ABPI Code include the publishing of a detailed case report, a public reprimand, a mandatory audit, and suspension or expulsion from the ABPI.

The ABHI similarly operates a Code of Ethical Business Practice (ABHI Code) with which members are required to comply. The ABHI Code sets minimum standards appropriate to the various types of activities carried out by its members, including guidelines on interactions with, and promotions to, healthcare professionals and healthcare organisations.

Employees and workers

In view of the importance of compliance with the various regulatory and self-regulatory frameworks, companies in the life sciences sector often provide extensive, ongoing compliance training for their employees tailored to their relevant roles.

Employers may also include contractual provisions in their employment contracts requiring employees to comply with particular statutes, regulations or industry codes of practice applicable to their role, and separately specify in their disciplinary policies that a breach of those may be treated as an act of misconduct (which may, if serious, result in dismissal).

Self-employed

Companies may include contractual provisions in their terms of engagement with self-employed persons that require their compliance with particular statutes, regulations or industry codes of practice relevant to their role, and to attest to, and commit to, their own personal compliance knowledge and ongoing learning.

Policies and procedures

7. What, if any, sector-specific policies, procedures and considerations apply to staff handbooks in the life sciences sector?
Staff handbooks in the life sciences sector are likely to include information on the following:

- Employee screening procedures.
- Health and safety regulations.
- IP and patents.
- Confidentiality.
- Non-disclosure agreements.

For further information, see *Checklist, Policies, procedures and forms to include in a staff handbook*.

8. Are there sector-specific anti-bribery, modern slavery and other compliance and enforcement issues in the life sciences sector?

Anti-bribery and corruption

As many healthcare professionals, organisational staff and buyers in the UK healthcare sector are officials, employees or contractors of the government, companies in the life sciences sector should be aware of, and take measures to implement the requirements of, the Bribery Act 2010. This should include having an anti-corruption and bribery policy tailored to the nature of the company's activities (see *Standard document, Anti-corruption and bribery policy (long form)*).

In addition to the Bribery Act 2010, the Human Medicines Regulations 2012 broadly prohibit the offering of unlawful inducements (including free samples and hospitality) to those qualified to prescribe or supply medicinal products (see *regulations 298 and 300*). A breach of the regulations is a criminal offence punishable by fine and imprisonment.

Industry-specific codes of practice may set additional self-regulating standards in relation to interactions between life sciences companies and healthcare professionals. The ABPI Code, for example, includes a general prohibition that, save in certain limited circumstances, no gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Modern slavery

The Modern Slavery Act 2015 (MSA 2015) creates three types of criminal offence:

- Slavery or servitude.
- Forced or compulsory labour.
- Human trafficking.

Larger employers in the life sciences sector will typically have an anti-slavery and human trafficking policy, giving guidance to employees, workers, self-employed contractors and business partners on slavery and human trafficking and the measures taken by the employer to tackle slavery and human trafficking in its business and supply chains. The policy will be tailored to the nature of the employer's business and supply chains. (For a template policy, see *Standard document, Anti-slavery and human trafficking policy*.)

Additionally, under section 54 of the MSA 2015, all large commercial organisations (irrespective of industry) that carry on business in the UK and have a total turnover of £36 million or more must produce an annual slavery and human trafficking statement. The statement must set out the steps that the organisation has taken to ensure that its business and supply chains are slavery-free or, if no such steps have been taken, a statement to that effect. The topics that should ordinarily be covered in the statement are:

- The structure of the organisation (including its business and supply chains).
- Its policies on slavery and human trafficking.
- Its due diligence processes in relation to slavery and human trafficking in its business and supply chains.
- The parts of the business and supply chains where there is an identified risk of slavery and human trafficking.
- Key performance indicators, to assess how effectively the organisation is ensuring that there is no slavery in its business or supply chain.
- The training that is available to staff regarding slavery and human trafficking.

Employers in the life sciences sector may have complex and extensive supply chains. To help mitigate the risk of modern slavery practices arising in the supply chain, employers should ensure that appropriate risk-based due diligence is conducted in relation to the operations of suppliers and that suppliers are (where possible) engaged on contractual terms that reinforce the employer's commitment to anti-slavery and human trafficking. Terms may include:

- The designation by the supplier of a particular individual within the supplier's organisation who is responsible for the supplier's compliance with anti-slavery and human trafficking requirements.
- An obligation to adhere to the standards required by the employer.
- An obligation on the supplier to ensure it complies with local anti-slavery and human trafficking laws in each country in which it operates.

Employers should also consider regular supplier audits in areas such as labour and integrity.

Other compliance issues

The life sciences sector is heavily regulated in the UK. Through a combination of statute and regulations, the UK imposes significant controls on the production, distribution, sale and advertising of medicinal products and devices. Breaches of the relevant statutes and regulations (whether by an individual or body corporate) are typically criminal offences punishable by a fine or imprisonment for up to two years (or both). A breach may also jeopardise the grant, award or continuing holding of any mandatory licences, authorisations, certifications or registrations necessary to lawfully manufacture, deal in, market or advertise medicinal products and devices.

While the relevant statutes and regulations address many matters, life sciences companies should note, in relation specifically to personnel, the following under the Human Medicines Regulations 2012:

- Manufacturers are required to ensure that a "qualified person" is available at all times who is responsible for carrying out, in relation to medicinal products manufactured, assembled or imported under licence, certain duties stated in the regulations. Qualified persons have their own professional rules and may incur personal liability for failures in the course of their role. This may mean that companies give director-like indemnities to the employee and have special insurance or the employee has a personal insurance policy that is paid for

by the company. Either way, this is likely to be covered in the employment contract.

- Wholesale dealers must ensure that a "responsible person" is available at all times who has knowledge of the activities to be carried out and of the procedures to be performed under licence which is adequate to ensure that the conditions of the licence are being met and that the quality of medicinal products handled by the wholesale dealer comply with the regulations.
- Holders of a UK marketing authorisation, traditional herbal registration, or Article 126a authorisation in relation to a medicinal product must operate a pharmacovigilance system. This includes having available at all times an appropriately "qualified person" responsible for pharmacovigilance who resides and operates in the EU and is responsible for the establishment and maintenance of the pharmacovigilance system.
- Holders of a UK marketing authorisation or certificate of registration for a medicinal product must ensure that any medical sales representatives who promote the product are given sufficient training, and have sufficient scientific knowledge, to enable the representative to provide information about the product that is as precise and complete as possible.

Some of these requirements, including any residence requirement relating to the EU, will likely be affected by Brexit (particularly in a no-deal scenario).

9. Are there any sector-specific obligations or considerations in relation to the handling of employee data or the monitoring of employees in the workplace?

The Data Protection Act 2018 (DPA 2018) governs the processing of personal data in the UK and implements the General Data Protection Regulation (*(EU) 2016/679*) (GDPR). The DPA 2018 impacts many aspects of the life sciences sector, including the handling of employee data in the workplace. Given that life sciences companies are often global in nature, the transfer of data is particularly important.

Employees working in the life sciences sector will often be handling "special categories of personal data". This could include information such as a patient's age, sex, ethnicity, medical history and status. Often, patient's initials or assigned ID, as well as their date of birth, are used for clinical trials. Employers should undertake measures where practicable to carry out pseudonymisation. Pseudonymisation of data enhances privacy by the "processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information" (*Article 4, GDPR*). Employees will have to handle this data with a higher level of care, as special categories of data are given a higher level of protection within the DPA 2018. Additionally, access controls should be implemented to enhance data security. For example, for genome projects, specific permissions have to be signed for researchers or data analysts to be able to access the patient data. A list of people who are granted permission to look at the data is kept on file and must be updated by signing an addendum if more employees need to be added.

Given the highly confidential and sensitive nature of the data that employers in life sciences often handle, employers may need to consider if it is appropriate to monitor employees more vigilantly than an average employer. Due to the need to understand and monitor the details of the production process (so that thorough investigations can be done), it is becoming standard practice to have CCTV monitoring staff during production activities. There might also be monitoring of electronic communications in the workplace to mitigate against the risk that confidential or sensitive information is not being accessed, shared or sent on to any person or company other than those necessary. Employers should ensure they have legitimate grounds under the GDPR, the Employment Practices Code and employment laws, to be able to monitor employees at their workplace.

Employers should create a clear and strict internal policy for any potential monitoring of employees, especially if it

is done by electronic means that employees may not readily be aware of. Technological developments to monitor this activity can include data loss prevention (DLP) tools, which can monitor outgoing communications to detect any potential data breaches. Employers must ensure they are using any such applications with proportionality and should consider undertaking a data protection impact assessment (DPIA) (one of the specific data transfer processes mandated under the GDPR) before the introduction of any monitoring technology. An employer should also include a notice in their employment contracts which states that employees may be monitored for this purpose. This is particularly important after *Barbulescu v Romania (Application no 61496/08) [2017] ECHR 742*, where the Romanian state authorities were found to have failed to ensure the respect of the right to privacy when an employee was dismissed on disciplinary grounds for having used the internet for personal purposes during his working hours (see *Legal update, Monitoring of personal messages on work-related internet messaging account did not breach right to privacy (ECtHR)*). Employees should be made aware of the nature and extent of any monitoring and told by employers when significant changes are introduced.

Data processing should be proportionate to the risks faced by the employer. Employees will be handling special categories of personal data and therefore must ensure there are appropriate technical and organisational measures in place to protect the rights of the data subject. It is important to ensure there is data minimisation where possible. Whenever data such as medical research, clinical trials or medical reports are no longer being used, each employer should have a process in place for how this information should either be archived or deleted, as well as a data retention period after which the data should be deleted.

For more information, see *Practice note, The GDPR and Data Protection Act 2018: employer obligations* and *Practice note, Monitoring employees*.

10. Are there any sector-specific challenges in relation to working time, leave entitlements or holiday pay in the life sciences sector?

Working time

The life sciences sector is a demanding and fast-paced working environment. Employees will occasionally find the work stressful and time consuming, especially in the lead up to the launch of a new product or technological application. During these busy periods, employees will likely work in excess of their contractual working hours. In the UK, it is usual to require an employee to sign an opt-out to the maximum average 48-hour week under the Working Time Regulations 1998 (*SI 1998/1833*). This is usually included as an appendix to an employment contract or otherwise contained within the employment agreement. Senior employees, who have autonomous decision-making powers, have control over the hours they work, and whose time is not monitored or determined by their employer, are exempt from this 48-hour limit to the average working week. However, even if an individual is an autonomous decision-maker, a company may still require them to sign up to the 48-hour opt-out for clarity.

For more information, see *Practice note, Working Time Regulations: 48-hour weekly limit*.

Leave entitlements

During particularly busy periods, it may not be feasible to allow employees to take annual leave. It would be prudent for employers to include a contractual provision which will require employees to provide their employer with a specific amount of notice (which is often a month), before taking their holiday. Employers are also likely to want to include a provision enabling the employer to require the employee to take holiday at certain times of the

year (for example, to factor in busy and quieter periods and ensure that the workload is covered throughout the year).

For more information, see *Practice note, Holidays*.

11. Are there any sector-specific considerations or procedures relating to whistleblowing that commonly occur in the life sciences sector?

The life sciences industry is a sector in which the highest ethical standards are expected. Pharmaceutical, biotechnology and medical device companies have an ability to impact directly on public health through their products and services. Therefore, the life sciences sector has a clear and compelling ethical obligation to uncover wrongdoing within their organisations. The failure to do so could have serious consequences for the individuals put at risk, and the organisations more widely. Consequently, whistleblowing mechanisms are a critical tool for ensuring that life sciences companies comply with their ethical obligations, by uncovering and addressing concerns.

There are many legal requirements on a pharmaceutical business which, if breached, can give rise to whistleblowing, as well as any ethical issues, concerns about products, environmental and health and safety issues. Additionally, there is the possibility that employees might go directly to regulators about these issues, if they think their employer is falsifying records or cutting corners on health and safety, for example.

The UK whistleblowing regime

The Public Interest Disclosure Act 1998 (PIDA) provides two levels of protection for whistleblowers. The dismissal of an employee or employee shareholder will be automatically unfair if the reason, or principal reason, for their dismissal is that they have made a "protected disclosure". PIDA also provides protection to the wider class of "workers" from being subjected to any detriment on the ground that they have made a protected disclosure.

Whether a whistleblower qualifies for protection depends on satisfying the following tests.

Have they made a qualifying disclosure?

First, there must be a disclosure of information. In *Cavendish Munro Professional Risks Management Ltd v Geduld [2010] IRLR 38*, the EAT held that a disclosure must involve information, and not simply voice a concern or raise an allegation. For further information, see *Legal update, Court of Appeal considers relationship between information and allegations in whistleblowing claims*.

The second and third requirements are that the disclosure must be a disclosure of information which, in the **reasonable belief** of the worker making it tends to show that one or more of the **six specified types of malpractice** has taken place, is taking place or is likely to take place (*section 43B(1), Employment Rights Act 1996* (ERA 1996)).

The categories of wrongdoing covered by the legislation are:

- Criminal offences (*section 43B(1)(a), ERA 1996*).
- Breach of any legal obligation (*section 43B(1)(b)*).
- Miscarriages of justice (*section 43B(1)(c)*).

- Danger to the health and safety of any individual (*section 43B(1)(d)*).
- Damage to the environment (*section 43B(1)(e)*).
- The deliberate concealing of information about any of the above (*section 43B(1)(f)*).

With respect to the requirement of a reasonable belief, the worker does not have to prove that the facts or allegations disclosed are true, or that they are capable in law of amounting to one of the specified wrongdoings. As long as the worker subjectively believes that the relevant failure has occurred or is likely to occur and their belief is, in the tribunal's view, objectively reasonable, it does not matter that the belief subsequently turns out to be wrong, or that the facts alleged would not amount in law to the relevant failure. For further information, see *Toolkit, Whistleblowing.* Given the nature and breadth of activity in the life sciences sector, disclosures could fall within virtually any of the above categories, and often a combination of them.

Finally, section 17 of the Enterprise and Regulatory Reform Act 2013 (ERRA 2013) amended ERA 1996 so that a disclosure made after 25 June 2013 is only a qualifying disclosure if the worker reasonably believes that the disclosure is "in the public interest". In most cases where the disclosure relates to a breach of the worker's own contract of employment (or some other personal matter), the disclosure is unlikely to be in the public interest. It is likely that employees blowing the whistle in the life sciences industry will be able to point to a clear public interest when alleging misconduct in the organisation, given the inherent public interest in ensuring life sciences companies meet ethical standards and the potential consequences should they fail to do so.

Is it also a protected disclosure?

For a qualifying disclosure to be protected, it must be made to one of the categories of people listed in sections 43C to 43H of ERA 1996. These include:

- The worker's employer (*section 43C(1)(a)*).
- The person responsible for the relevant failure (*section 43C(1)(b)*).
- Legal advisers (*section 43D*).
- Government ministers (*section 43E*).
- A prescribed person (*section 43F*).
- Other persons subject to certain conditions (*section 43G*).

PIDA encourages the disclosure of information to the employer in the first instance. There are rigorous conditions for wider disclosure outside the list above. For more information, see *Practice note, Whistleblower protection: wider disclosure*.

There is no financial cap on compensation in whistleblowing claims, and no required minimum period of service.

For more information on whistleblowing generally, see *Practice note, Whistleblower protection*.

Procedural and policy considerations

Internal whistleblowing procedures act as a vital check and balance to ensure ethical conduct within an organisation. This is particularly important in the life sciences sector, given the potential repercussions that wrongdoing could ultimately have on the health of individuals. Therefore, having a robust whistleblowing policy

and procedure is an essential tool to ensure the integrity and long-term viability of a life sciences company.

A whistleblowing policy and procedure should:

- Convey the seriousness and importance the employer attaches to identifying and remedying wrongdoing within the organisation.
- Encourage workers to raise concerns internally as soon as possible.
- Remind workers of the standard of conduct expected of them.
- Specify a reporting line to ensure that workers know whom to contact with a concern.
- Outline the procedures for investigating disclosures and what steps may be taken if wrongdoing is uncovered.
- Clarify what will happen to colleagues who victimise genuine whistleblowers, or those who abuse the system by making malicious allegations.
- Provide access to further sources of advice and guidance on whistleblowing.

For a standard-form whistleblowing policy, see *Standard document, Whistleblowing policy (long form)*.

Protection for whistleblowers in the life sciences sector

Ensuring the safety of their products and services is a core objective of any life sciences business. It is therefore important that employees in the life sciences sector feel comfortable reporting suspected misconduct, breaches of health and safety, or threats to public health to their employer or regulator.

A comprehensive whistleblowing policy is an important step in encouraging employees to make disclosures. Likewise, the treatment of whistleblowers following a disclosure is important not only from a legal compliance perspective, but also in the interests of creating an open and honest environment where employees feel comfortable raising concerns.

In accordance with section 47B(1) of ERA 1996, workers have the right not to be subjected to any detriment on the ground that they have made a "protected disclosure". Detriment is interpreted consistently with the meaning established by discrimination law, namely that the worker is disadvantaged. For further information, see *Practice note, Direct discrimination: Detriment*. The Whistleblowing Commission Code of Practice sets out several examples of disadvantages that could amount to a detriment.

A detriment may be both an act and a deliberate failure to act. Whether detriment is "on the ground" that a worker has made a protected disclosure is assessed on the same basis as that used in direct discrimination cases, except that there is no statutory requirement for a comparator. For more information, see *Practice note: overview, Discrimination in employment: overview: Direct discrimination*.

On 25 June 2013, section 19 of the ERRA 2013 introduced the concept of vicarious liability, making employers liable for detriment caused by employees and workers. Section 19 also imposed personal liability on workers who victimise whistleblower colleagues.

On 24 April 2018, the European Commission published new draft legislation to strengthen whistleblower protection across the EU, the *Proposal for a Directive on the Protection of Persons Reporting on Breaches of Union Law*. This is designed to protect persons who report any breaches of EU legislation which they have

observed during work-related activities. This is an important development for those working in the life sciences sector as there are many EU laws which apply to sectors such as pharmaceuticals and medical devices. The new legislation will apply to all organisations with at least 50 employees or with an annual turnover of at least EUR10 million. It is unclear at the time of writing whether the UK would be subject to this law after Brexit.

Brexit and immigration

12. What are the specific employment and immigration issues (if any) that have arisen as a result of Brexit in the life sciences sector?
There will be significant immigration issues resulting from Brexit. For more information, see *Practice notes, The EU Settlement Scheme* and *Employing EU nationals*.

What this means for employers in the life sciences sector

Brexit will create significant changes for how the pharmaceutical and life sciences industry in the UK manages the mobility of their employees between the UK and the rest of Europe. As an industry which is already experiencing talent shortages, employers in the life sciences sector should take time to engage with their workforce in preparation for Brexit. Many employers in the life sciences sector who have a large EU workforce have already been taking steps to reassure employees and retain talent in the period of uncertainty which has followed from the Brexit vote in June 2016.

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

- Audit immigration status of workforce to help plan for change.
- Identify EEA and Swiss nationals working in the UK.
- Identify UK nationals working elsewhere in the EEA.
- Check employee arrival dates in the UK or abroad (to determine eligibility to apply for permanent residence).
- Review long-term recruitment and succession planning and proposed secondments and rotations.
- Decide how to support employee applications and how much to invest in the process.
- Plan employee communications and provide information to employees on current application processes and proposed changes.
- Communicate key application actions and deadlines to employees.
- Encourage employees to obtain confirmation of rights by applying for registration certificates or permanent residence.
- Provide practical advice to those not yet eligible to apply for permanent residence and steps they can be taking now.
- Plan for possible alternative measures post-exit, such as Tier 2 applications.
- Review current right-to-work procedure to ensure that employees are prepared for the implications of the widening of the right-to-work regime.

Post-Brexit EU-UK migration in the life sciences sector

After the UK leaves the EU and after the proposed transition period, the UK government has indicated that free movement will end. The UK government commissioned the Migration Advisory Committee (MAC) to advise on the "economic and social impacts of the UK's exit from the EU and also on how the UK's immigration system should be aligned with a modern industrial strategy". The MAC published a report in September 2018 and recommended that EU nationals should fall within the existing immigration rules for non-EU nationals, such as Tier 2 of the points-based system. The recommendations are still under consideration. See *Legal update, Migration Advisory Committee (MAC) publishes recommendations for the UK's post-Brexit work immigration system*

If the recommendations are accepted in full, the cost of recruiting talent into the life sciences sector in the UK will increase dramatically. Currently under Tier 2, employers must pay an Immigration Skills Charge (ISC) of £1,000 per person per year and an immigration health surcharge of £400 per person per year. The cost of relocating an employee and their family members can therefore be in the region of £10,200 for a family of four in Home Office fees alone, which are non-refundable if the employee leaves the UK before the end of their visa. In addition, it can take between ten to 12 weeks to obtain a Tier 2 visa and once granted, the visa will only enable the employee to undertake the role for which they have been sponsored. This may result in a potential reduction in labour mobility and companies may look to relocate employees to countries where the immigration rules allow for a quicker and less costly relocation of employees. Therefore, in the life sciences sector, where there is significant international movement of talent, advanced planning as well as investment in the training and development of the local labour force will become more crucial to ensure that employers have the resources required at the requisite time.

In addition, if the proposals are accepted in full and EU nationals are required to obtain Tier 2 visas in the future, employers in the life sciences sectors should be aware that there are both salary and skill thresholds under Tier 2. Any employers wishing to recruit for low-skilled roles would be required to recruit from the local labour force in the UK. In the light of these proposed developments, employers in the life sciences sector will need to engage their workforce to ensure that the UK remains an attractive location for employees.

For more information on Tier 2 sponsorship and on Immigration generally, see the *Immigration collection page*.

Due to Brexit, there is likely to be some movement of company qualified persons from the UK to an EU member state so that products can be released into the single market by those qualified persons.

13. What are the main anti-discrimination issues and diversity initiatives in the life sciences sector?

The life sciences sector has been criticised for its lack of diversity, particularly regarding the lack of recruitment of women in the field. It has been reported that, generally, female junior faculty are still paid less than men and are less likely to attain tenure than their male colleagues. Furthermore, a study has shown that women are less likely than men to apply for assistant professorships but would have a better chance of success than men if they actually tried to apply.

Progress has nevertheless been made in the life sciences sector to take active steps to improve gender diversity. A report by EY conducted in late 2015 found that 20% of organisations have a structured, formal programme to develop women's careers in leadership and a further 4% will bring in these programmes in the near future.

However, there is still a significant gender imbalance in the life sciences sector, particularly in senior and management roles. In 2016, a report by Korn Ferry Hay showed that the life sciences sector had one of the largest pay gaps in the UK industry. Since 2017, gender pay gap reporting obligations have been introduced, in which companies with 250 or more employees are required to publish their reports, which may assist in accelerating salary changes for women in the sector. For further information, see *Practice note, Gender pay gap*

reporting obligations.

Diversity initiatives through policy interventions are expected to benefit the progression of women in the life sciences sector. Recommendations have been put forward by the group "Cell Stem Cell", which have identified policy interventions such as flexible family care spending, having gender-balanced review and speaker selection committees, incorporating implicit bias statements and focusing on education as a tool to encourage more women to work in the sector. A survey showed that 30% of respondents thought their companies could improve the identification of female leaders in the future. There is a greater focus on promoting sciences and mathematics to girls at school level to create a lasting change in the sector in the future.

An ethnicity pay gap consultation is underway by the Department for Business, Energy and Industrial Strategy to evaluate ways in which organisations could be obliged to report their ethnic diversity statistics, in a similar initiative to gender pay gap reporting obligations, in the near future (see *Legal update, Government launches consultation on mandatory ethnicity pay reporting*.). The consultation focuses on questions to employers regarding the main benefits for employers and whether it will lead to meaningful change and action. If this strategy goes ahead the approach may encourage employers, including in the life sciences sector, to promote ethnic diversity in the workplace. It is estimated in one report that equal participation and progression across ethnicities could add an additional £24 billion to the UK's economy per year. Organisations in the life sciences sector are increasingly aware of diversity in the workplace and as such are making efforts to reduce unconscious bias with the hope this will improve talent recruitment processes and retention of talent, as a result.

Offshore and cross-border

14. Is there much international movement of employees and workers in the life sciences sector?
The global life sciences industry is experiencing rapid change and faces persistent talent shortages. As a result, companies must often look across borders to hire the right people and there are high levels of global mobility within the sector. Limited availability of good candidates has led to a "war for talent" between companies who must offer highly competitive salaries (including generous incentives and relocation packages for employees and their family) to find and attract the right employees. Increasingly, employers recognise that assisting with relocation provides them with a strategic advantage, especially when motivating professionals to move abroad for long-term assignments. Most large companies will cover the cost of travel, moving and a relocation agency to help employees settle in. They may also provide tax advice and assist with the visa and work permit requirements. For individuals in more senior roles with children, some companies will pay for private schooling.

The global mobility environment is changing rapidly. Businesses and their employees working internationally are faced with complex regulations and laws. Wider political agendas and reforms have the potential to create new complexities and to increase mobility costs. The life sciences industry needs to be proactive in addressing trends to make sure that they are deploying their people effectively and cost efficiently.

The UK is the top destination for life sciences professionals moving from Eastern Europe, and second only to Switzerland for migrants from Western Europe. The pharmaceutical and life sciences industries directly employ approximately 233,000 people in the UK, 7% of whom are non-British EU citizens. Should the UK withdraw from the EU, free movement of people would end and new Immigration Rules would apply to EU citizens relocating to the UK. This will create significant changes for how the pharmaceutical and life sciences industry in the UK manages the mobility of their employees between the UK and the rest of Europe.

While the Tier 2 (Intra-Company Transfer) route lends itself well to facilitating both short and long-term assignments into the UK, it could become extremely costly for UK employers if all talent had to be moved into the

UK via this route. These proposed changes could cause a short-term decline in productivity, with a longer-term question over the UK's attractiveness for investment. Currently, UK companies are required to pay an ISC for each foreign worker that they employ. The cost of this is currently £1,000 for each year that the individual is employed in the UK. In addition, there is a mandatory immigration health surcharge of £400 per year associated with many UK immigration applications. Dependant family members will usually need to pay the same amount as the main applicant. For more information, see the *Immigration collection page*.

15. Is there much engagement of contractors and consultants in overseas jurisdictions in the life sciences sector?

As a result of persistent talent shortages in the global life sciences industry, companies often look across borders to engage contractors and consultants and there are high levels of global mobility within the sector. Increasingly, employers recognise that assisting with relocation provides them with a strategic advantage, especially when motivating contractors and consultants to move abroad for long-term assignments. The global mobility environment is changing rapidly. Businesses and their employees working internationally are faced with complex regulations and laws which differ from country to country. Wider political agendas and reforms have the potential to create new complexities and to increase mobility costs and time frames. Therefore, visa and work permit requirements will differ from country to country and employers in the life sciences sector need to be proactive in addressing the requirements for each country to determine whether a visa or work permit is required well in advance of the target start date for the contractor or consultant.

16. Are there any international employment law issues that arise in relation to the life sciences sector?

Tax

International tax issues typically arise in the context of international secondments or permanent transfers of employees between different countries. International life sciences companies with highly skilled employees often consider relocating employees to enhance and develop their businesses, but also as opportunities for employees to develop their own skills and talents.

Tax laws differ on a country-by-country basis, and often by reference to the country of residence of the individual involved. Specialist tax advice should be sought in relation to proposed international secondment or transfer arrangements. In particular, advice should be sought on:

- The length of the secondment or transfer and its impact on the individual's tax and residency status.
- Whether double taxation relief is available.
- The structuring of the individual's remuneration package, taking into account (for example) possible currency fluctuations, whether dual employment contracts would be beneficial, and how each element of compensation will be taxed. For international secondments, employers will also often consider including a tax equalisation clause in the secondment agreement in which the employer agrees to provide support to the individual being seconded and to help fund some of the taxes that the individual may incur during the secondment.
- Which country's social security system the individual will need to contribute to and how.
- Which entity should employ or engage the individual, which often involves consideration of corporate and taxation issues more generally rather than simply employee-specific tax concerns.
- The impact of the international secondment or transfer on the individual's other tax arrangements unrelated to their employment, for example, on the individual's other sources of income.

Anti-bribery

International life sciences companies are exposed to bribery and corruption risks through their global business operations. In some markets, the government structure and rule of law is less developed and this bears on bribery and corruption risk exposure. In addition to the global nature of the business of international life sciences companies, the healthcare sector also maintains close relationships with government bodies, is highly competitive, and subject to regulation globally, each of which increases the instances in which a company is exposed to activities and interactions with bribery and corruption risk. Failing to address these risks can lead to governmental investigations, regulatory action and civil and criminal liability.

In an effort to mitigate the above risks, international life sciences companies will typically:

- Have a global anti-bribery and corruption programme (with stakeholder engagement at all levels of the business).
- Have in place a global anti-bribery and corruption policy addressing commercial and other practices that give rise to risks of anti-bribery and corruption.
- Provide mandatory periodic training to employees, workers, self-employed contractors and third parties in accordance with their roles, responsibilities and risks that they face.

Due diligence on employment implications of business transactions and closures

Depending on the nature of the transaction, the following matters are likely be key in any employment-related due diligence on business transactions in the life sciences sector:

- **Identification of key employees.** This includes not only identifying the business's leadership team, but also identifying key individuals or employee populations with knowledge of or access to commercially sensitive and valuable information or most likely to be involved in the creation of IP (for example, as part of medical research). It will be especially important that employees in these groups are subject to comprehensive confidentiality and IP obligations and, to the extent any employee would present a risk to the business of the target company in the event their employment terminated, that they are also bound (where lawful) by post-termination restrictive covenants.
- **IP and confidentiality.** IP is generally one the most valuable assets in a life sciences transaction. It is therefore important that the rights of a target company to the IP, and the confidentiality of that IP, are appropriately investigated in any due diligence exercise. Part of that investigation will involve checking that individuals involved in the creation of any IP (whether employees, workers, or self-employed contractors) are bound by effective assignment agreements under which the relevant IP is assigned to the target company as the sole owner and also by comprehensive obligations of confidentiality.
- **Post-termination restrictive covenants.** Key employees of the target company may, depending on the nature of their role and knowledge, represent a significant risk to the ongoing business of the target following the termination of their employment. It is important for these employees to check whether the terms of their employment with the target company include post-termination restrictive covenants and, if they do, whether they are likely to be enforceable under local law.
- **Anti-bribery and corruption.** As a heavily regulated sector with often close links to government, the life sciences sector is exposed to the risk of bribery and corruption. It is important to:
    - check that any incentive arrangements operated by the target company (in particular, any incentive arrangements for its sales teams (whether in-house or outsourced)) are lawful in accordance with local law;

- check that the target has reasonable and appropriate policies and procedures in place regarding anti-bribery and corruption, including appropriate training programmes for personnel; and
- review any recent or ongoing governmental, regulatory or other investigations or claims involving the conduct of the target's employees.

Global codes of conduct and work policies

Global codes of conduct set out the ethical and behavioural framework underpinning the organisation's international operations and reflecting their values from a macro perspective. Companies with a global presence, such as those operating in the life sciences industry, will also be required to implement local policies, handbooks and checklist procedures which adhere to local law requirements.

Staff handbooks in the life sciences sector are likely to include information on the following:

- Employee screening procedures.
- Health and safety regulations.
- IP and patents.
- Confidentiality.
- Non-disclosure obligations.

For more information, see *Checklist, Policies, procedures and forms to include in a staff handbook*.

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