COVINGTON

COVINGTON & BURLING LLP

E-ALERT | Employment Law Briefing

June 15, 2011

AGENCY WORKERS REGULATIONS: ISSUES FOR LIFE SCIENCES COMPANIES

The U.K. Department for Business, Innovation and Skills (BIS) has recently issued the final version of its guidance on the Agency Workers Regulations 2010, which implement Directive 2008/104/EC.

The Regulations come into force on 1 October 2011, and will entitle agency workers (or "temps") to the same basic pay and working conditions as the hirer's own employees; and access to the hirer's facilities and information on job vacancies. Pay for the purposes of the Regulations is essentially the reward employees receive for work done, and includes basic salary, holiday pay, commission and bonus (where the bonus rewards the amount or quality of the individual's work); it does not include severance payments, or "additional extras" such as long-term incentive schemes, loans or pension payments. This E-alert concentrates on those issues that we have identified in discussion with clients and industry groups as being of particular relevance to life sciences companies. It also takes into account the Government's guidance, re-issued this month.

1. WHO IS WITHIN SCOPE? OUTSOURCED THIRD PARTY SERVICE PROVIDERS?

Life sciences companies tend to outsource business and regulatory functions to a greater extent than companies in most other sectors. It is already common, for example, for pharmaceutical companies to rely on third party organisations to conduct clinical trials on their behalf, or to engage a contract sales or marketing forces to promote their products. Increasingly, pharmaceutical companies are outsourcing other regulatory functions, such as pharmacovigilance, medical information or regulatory affairs.

Organisations offering such services to life sciences companies generally do not think of themselves as suppliers of agency workers, but the Regulations potentially have that effect. An agency worker is defined as anyone:

- employed under a contract with the "temporary work agency",
- who is supplied temporarily to a hirer; and
- who is subject to the hirer's supervision and direction.

The Regulations define a temporary work agency as a person in the business, whether operating for profit or not, of supplying agency workers. The BIS guidance makes it clear that agency workers will be in scope even when they are supplied by an intermediary umbrella company, or where the contract between the worker and the temporary work agency is a contract "for services" (rather than an employment relationship), involving an intermediary service company. The BIS guidance suggests that "managed service contracts" are outside the scope of the Regulations, but offers no firm definition or explanation as to what a managed service contract is.

For life sciences companies with a workforce that includes many atypical workers - contractors, service providers, agency workers - it will be extremely challenging to determine which groups may assert rights under the Regulations. Employers may in some cases have to analyse the individual's circumstances closely in order to understand the potential legal exposure. The following examples illustrate the point:

Example (i)

Company A has a sales force comprised of both employees and contract sales workers provided by a third party. Guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) indicates that Company A, as marketing authorisation holder, has primary responsibility for ensuring that its products are marketed and sold in accordance with the Medicines (Advertising) Regulations 1994, while the Code of Practice of the Association of the British Pharmaceutical Industry (ABPI Code) requires Company A to ensure that both employed and contract representatives comply with all aspects of the ABPI Code. Liability for any failure to comply rests with Company A. As a result, quality assurance or compliance staff and/or sales managers ensure all relevant sales staff receive the same training, and are monitored regularly and consistently for both compliance and performance metrics. Bonus targets are consistent for all workers.

Are the contract sales workers in scope? Two of the three tests provided in the Regulations would seem to be satisfied - namely, that workers are employed by a third party, and work under the supervision and direction of the hirer. What is less clear is whether the supply to the hirer is "temporary", and the BIS guidance unfortunately provides no answers on that point.

Example (ii)

Company B sponsors clinical trials across Europe but, in accordance with the ICH guidelines on Good Clinical Practice, the trials will be overseen by a Clinical Research Organisation (CRO). While, as sponsor, Company B will remain legally responsible for ensuring trials are conducted in accordance with local and European regulation, it will have no day-to-day involvement in the process; instead, the trials will be managed and the trial sites will be monitored by the CRO.

Are the third party's staff in scope? This arrangement is unlikely to be caught by the Regulations, since Company B will not supervise or direct the employees conducting the clinical trials.

Example (iii)

A law firm seconds two trainees to a biotechnology client to oversee pharmacovigilance contracting programmes. The trainee lawyers will be subject to the client's rules and regulations during their secondment, which is expected to last six to nine months.

Are the trainee lawyers in scope? The BIS guidance suggests not - because the law firm's main activity is not the supply of workers to clients. However, the Regulations do not state that the supply of workers must be the temporary work agency's primary business, so some doubt remains.

2. DO WE HAVE TO PAY AGENCY WORKERS A BONUS?

BIS guidance confirms that the Regulations include within the definition of "pay" bonuses or commission payments directly attributable to the amount or quality of the work done by the individual. This might include commission linked to sales or production targets and payments related to quality of personal performance. The problem is that many employers attribute bonus partly on the basis of personal performance and partly to reflect the performance of a product, the division in which the employee works, or of the wider business. In those circumstances, unless the amount attributable to personal performance can be distinguished from the company-wide (or product performance) element of the bonus, then the whole bonus may fall within the definition of "pay".

A first step for employers is therefore to determine whether their bonus schemes fall within the scope of the Regulations, or not. If they are in scope, should the company apportion part of the bonus clearly to company performance, so excluding agency worker participation in that element of the bonus?

If bonus (or a portion of it) is attributable to the "amount or quality" of the work done by an agency worker, then the agency worker is entitled to the bonus that he or she would have received if employed directly by the hirer. In order to make a fair determination, companies may have to integrate contract sales workers (for example) into the annual employee appraisal process - something that is rarely, if ever, done currently. Such integration and assessment may of course increase the risk of an agency worker claiming employee status, so careful thought will need to be given to the design of any new processes.

3. HOW DO WE MAKE A MEANINGFUL COMPARISON?

The Regulations require temporary work agencies to ensure that agency workers are given the same pay as relevant comparators, being those employed directly by the hirer to perform the same or similar roles. But what is unclear currently is whether agency workers can cite a hypothetical comparator in support of their claims, or whether they need to name a current employee, or employees. We know that some pharmaceutical companies may completely outsource pharmacovigilance (for example) and therefore have no employees against whom to compare terms and conditions. Perhaps that will provide those employers with a defence to claims. BIS guidance suggests hypothetical employees are permissible, but that interpretation does not sit comfortably with the wording of the Regulations, and may not be practicable in the circumstances described above.

Those interested in a more detailed discussion concerning the Regulations should contact any of the following:

Robin Blaney	+44.(0)20.7067.2120	rblaney@cov.com
Chris Bracebridge	+44.(0)20.7067.2063	cbracebridge@cov.com
Grant Castle	+44.(0)20.7067.2006	gcastle@cov.com
Christopher Walter	+44.(0)20.7067.2061	cwalter@cov.com