CharlesRussell Speechlys

Pharmacy Brief

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Contents

Can employers force employees to be vaccinated?

Now that the coronavirus vaccination programme is in full swing, attention is turning to the consequences of mass-vaccination, including whether people can be excluded from activities if they have not been vaccinated. There has been a particular focus on whether employers can prevent non-vaccinated employees from coming to work, or can refuse to employ people who have not been vaccinated.

This is an issue which is fraught with legal difficulties and whilst vaccination remains non mandatory, employers will have to look to other means to minimise the risk of staff members being exposed to the virus. There are clear religious and age discrimination issues to mandatory vaccinations but also concerns over lack of testing data for the vaccine on pregnant women for example and a growing number of conditions where vaccination is not being recommended.

One of the key problems is that those vaccinated are not exempt from self-isolation requirements and may still transmit the virus to others. The longevity of the protection offered is unclear and vaccines are not 100% effective. Private vaccinations are not readily available, and for many people, vaccination is not imminent. Therefore, our advice to clients is that existing Covid-secure arrangements must remain into the longer term and certainly this calendar year.

Our specialist employment team has been advising employers to carefully consider the legal risks against the benefits of a mandatory vaccination policy before even considering how to draft the related contract and policy documentation, or assessing how to comply with strict data protection obligations in relation to employees' vaccination records. They should stop short of mandatory vaccination policies, and instead facilitate and encourage vaccination whilst continuing with appropriate safety measures until much further down the line.

You can read more on this subject here.

Medicines and Medical Devices Act 2021

Much of the law in the UK relating to the marketing, licensing, distribution, prescribing and supply of medicinal products comes from EU legislation. The UK Government was required by EU law to implement and/or enforce EU law in the UK, and it usually implemented EU law (such as the EU Medicines Directive) by introducing secondary legislation (known as "regulations") without having to go through the process of creating a new Act of Parliament. Introducing secondary legislation is much quicker and more straightforward than introducing a new Act of Parliament.

This explains why most medicines law in the UK is contained within the Human Medicines Regulations rather than in an Act of Parliament: most of the law contained within the Human Medicines Regulations flowed from EU law.

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Articles

- Can pharmacy professionals be sued for COVID vax negligence? (Chemist and Druggist)
- Buyers and sellers beware (Pharmacy Business Magazine, page 50)

Now that UK has left the EU, it is no longer required to follow EU law in relation to medicines legislation (the position in Northern Ireland is more complicated because of the NI Protocol). Any changes to UK medicines law must now be made by, or in accordance with, a UK Act of Parliament rather than implementing new EU law.

To that end, in February 2021 The Medicines and Medical Devices Act 2021 received Royal Assent. The Act is an enabling piece of legislation: it contains very little detail in itself, but enables the Government to introduce changes to UK medicines law through secondary legislation.

The Act will therefore allow the Government to introduce regulations to make changes to the way in which medicinal products are handled.

One of the areas of change that the Government has suggested may be implemented sooner rather than later under the Act is in relation to hub and spoke dispensing.

At the moment the law on hub and spoke dispensing only allows it to be carried out by pharmacies owned by the same legal entity – so it is not permitted for Company A to assemble a medicinal product on behalf of Company B which supplies the product to the patient. That restriction is contained in the Medicines Act 1968 and so could previously only be changed by amending the Medicines Act itself, either through an amending Act or in accordance with EU law. Now that the Medicines and Medical Devices Act 2021 is in force, again it will be easier for the Government to change the restrictions on hub and spoke dispensing, for example to allow assembly to be carried out by Company A for supply to the patient by Company B.

New market entry rules for Wales

In October 2020, new market entry regulations were introduced in Wales, although the new rules will be implemented in two stages and won't come fully into force until October 2021.

The first stage of implementation is an obligation on all LHBs to publish PNAs by the end of September 2021. There are requirements for the contents of each PNA, for consultation and for publication.

Once all LHBs have published their PNAs, from 1st October 2021 new contract applications can only be granted if they meet a need identified in the PNA.

It remains to be seen, of course, whether the new PNAs will identify any unmet needs, or whether the changes will close Wales to new contract applications.

PNAs then have to be updated every 5 years (compared to every 3 years in England), although supplementary statements can be issued if there are significant changes which affect the provision of pharmaceutical services.

The rules for relocations will also change from 1st October 2021: a relocation will only be granted if it *"meets the need for pharmaceutical services, of pharmaceutical services of a specified type, identified in the relevant pharmaceutical needs assessment"*.

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It is not entirely clear what the consequences of these changes will be for pharmacy owners or applicants, but those thinking of applying for a new contract in Wales, or relocating an existing contract, might consider whether to apply before October 2021.

DHSC White Paper on NHS reform

On 11th February the DHSC published a White Paper on structural reform of the NHS in England, describing the proposals as incremental change rather than the top to bottom reorganisation that we had in 2012/2013.

The White Paper sets out some broad intentions and aims, but not the finer detail which will follow later this year, with the intention of having new legislation in place in 2022.

The Government says that purpose of change is to improve integration by, for example, enabling "Integrated Care Systems" (or ICS) to play a greater role and to remove much of the "transactional bureaucracy" which gets in the way of "sensible decision making".

Pharmacy isn't mentioned much in the White Paper (only once compared to 10 times for GPs and doctors). It refers to a statutory ICS NHS body having greater responsibility for commissioning pharmaceutical services, but no further detail is provided.

The White Paper also touches on a recurring theme from the Government – that it feels that there are too many healthcare regulators and these should be consolidated. This might not necessarily mean the end of the GPhC, but it might mean the GPhC and PSNI being merged, for example.

CRS Pharmacy Conference – March 2021 webinar

Sadly we have not been able to host our annual Pharmacy Conference in person this year. However, on 4th March we ran a webinar where we discussed some of the issues raised in this quarter's Pharmacy Brief in more detail, together with exploring more of the latest developments affecting the pharmacy sector and what to expect in 2021. Topics included:

- Recent trends in relation to GPhC enforcement
- Market entry update
- Recent developments in data protection law
- Forthcoming regulatory change, including in relation to hub and spoke dispensing.

We know that pharmacists and others involved in retail pharmacy businesses are very busy at the moment and a number of people weren't able to join the webinar. We have therefore prepared a recording of the webinar. If you would like a copy of the recording, please email events@crsblaw.com.

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