
Contents

- New NHS contract
 - GPhC annual report
 - Recent market entry case
 - Minimum efficiency standards for premises
 - CBD Oil as food supplements – change on the way?
 - Pharmacy Show
-

New NHS contract

At the end of July 2019, the Department for Health and Social Care and the PSNC jointly announced a new 5-year NHS contract for community pharmacy in England. As well as dealing with the pounds, shillings and pence, the announcement contained several hints at regulatory reform.

Hub and spoke dispensing

What's the issue?

Current legislation does not allow hub and spoke dispensing between different legal entities – the hub and the spoke have to be owned by the same person or company. This acts as a barrier to smaller independents and, it is sometimes said, gives larger multiples a commercial advantage.

What's the solution?

On the face of it, it should be quite easy to change the legislation to remove this restriction, but all sorts of other legal (and political) obstacles got in the way last time the DHSC tried back in 2016. Let's see if it has more luck in 2020.

Better use of skills mix in pharmacies

What's the issue?

The new pharmacy contract aims to focus pharmacy income away from the dispensary and towards other services. If that's to happen, the Department believes it needs to look at who in the pharmacy team can supervise the supply, and is this different for different types of medicines.

What's the solution?

A tricky one, because the solution depends on the outcome you favour. Over to the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board – the Board that brought us the “decriminalisation” of dispensing errors, which has also been looking at what “supervision” could mean in the context of medicine supplies.

Merger regulations

What's the issue?

At the end of 2016 the market entry rules in England were changed to allow a pharmacy contractor to apply to NHS England to consolidate two contracts into one, and to obtain protection from another operator trying to open a new pharmacy by arguing that the closure had left a gap in service provision. This was meant to encourage pharmacy closures, but concerns have been raised that the protections in the rules are not sufficient and uptake has been low.



Articles

- [Regulatory reform in new pharmacy contract](#)
(Pharmacy Business)
 - [NICE guidance on cannabis unlikely to have immediate impact on pharmacies](#)
(Pharmacy Business)
 - [Caution, Serious Shortage Protocol ahead: Seven things you need to know](#)
(The Pharmacist)
 - [Get your IR35 rules right](#)
(Pharmacy Business)
-

What's the solution?

Expect the DHSC to set a specific time period for protection for consolidating pharmacies against competitor new contract applications.

Also, new rules may allow some flexibility for contractors who are merging a 100-hour contract and a 40-hour contract to enable them to reduce their opening hours, even if they are staying open at the 100-hour site.

GPhC annual report

The General Pharmaceutical Council has recently published its annual report into Fitness to Practise cases. Here are some of the headlines:

- The number of complaints against pharmacists continued to increase, reaching 2674 in the last year, up 345 on 2017/2018.
- The GPhC has introduced a new triage system with more “senior oversight”. This was one of the reasons why more cases (39% of all complaints) are now being closed at the triage stage.
- New threshold criteria for onward referral of concerns has led to an increase in the number of concerns being concluded without referral – 45% of concerns are now concluded at the investigation stage, up a massive 19% on the previous year.
- There has been a reduction in the number of concerns leading ultimately to removal, suspension or warning following a Fitness to Practise Committee hearing. There was a 50% fall in the number of cases ending in removal.

The 2018/2019 annual report suggests a lighter-touch approach to fitness to practise enforcement in the last year, but it remains to be seen whether this is a trend or a blip. The GPhC has said that it will continue to monitor the way in which it handles fitness to practise cases.

Recent market entry case

We recently acted for a pharmacist in objecting to a relocation application from a nearby pharmacy. The pharmacy wanted to leapfrog our client's two pharmacies and move from a busy town centre location into a health centre. After representing our client at the appeal hearing we successfully argued that the applicant had still not properly defined its patient groups. The applicant had already applied once (with the help of pharmacy consultants) and failed, and this was its second attempt (using different pharmacy consultants).

The applicant also failed to demonstrate that the move out of its current location into the health centre would not make the proposed pharmacy significantly less accessible, particularly for local shoppers.



 **Follow us on Twitter**

Follow Charles Russell Speechlys
[@CRS_Healthcare](https://twitter.com/CRS_Healthcare)

Minimum efficiency standards for premises

Minimum Energy Efficiency Standards (**MEES**) have been in operation for over a year and were brought in to improve energy efficiency in properties. MEES make it unlawful for landlords to grant new leases or renew existing leases of properties with energy performance certificate (EPC) ratings of F or G.

The responsibility for enforcement of MEES falls on local councils who can impose penalties of up to £150,000. National Trading Standards report that there have however been no fines to date for non-compliance.

From next year MEES will apply to existing residential leases and from 2023 they will apply to existing commercial property leases. This will make enforcement easier and therefore pharmacists need to be reviewing EPC ratings. Whether a pharmacist is a tenant under a lease, or a landlord looking to let property, MEES compliance may have an adverse financial impact, as the cost of making properties energy efficient may be high and require significant upfront outlay.

CBD Oil as food supplements – change on the way?

CBD-containing products are widely marketed in the UK as a food supplement but the EU has recently reclassified CBD as a novel food for the purposes of the EU Novel Food Catalogue. Whilst this does not have direct legal effect in the UK, the UK regulatory body which is responsible for food standards in the UK (the Food Standards Agency, or FSA) must have regard to the catalogue as part of its regulatory functions.

In light of the EU reclassification of CBD oil, in March 2019 the FSA issued a statement that “The FSA accepts the clarification from the EU that CBD extracts are considered novel foods. We are committed to finding a proportionate way forward by working with local authorities, businesses and consumers to clarify how to achieve compliance in the market place in a proportionate manner.”

It is understood that the FSA is currently working with CBD oil manufacturers and representative bodies. It is anticipated that new rules regarding the sale and manufacture of CBD products will be published in due course.

Pharmacy Show

After many years taking a stand at the Pharmacy Show and following feedback from clients and contacts we’ve decided to take a break from the Show this year; so we won’t see you on a stand, but will hopefully see you at another event soon!

Contact

Noel Wardle
Partner
+44 (0)20 7203 5395
noel.wardle@crsblaw.com
