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2019 Pharmacy Conference

We held our annual Pharmacy Law Conference (#CRSPharmaConf) on 28 March 2019 at the Wellcome Collection. Over a hundred delegates attended and we were delighted to have such positive feedback: 100% of delegates said that they would recommend the conference to a colleague – so we hope to see you, and your colleagues, in 2020!

Online pharmacies

We have seen a surge in interest over recent months from clients – both existing pharmacy operators and new entrants to the market – enquiring about setting up online pharmacies. Typically the business model includes an online prescribing function as well as the supply of medicines.

The legal issues surrounding a move to an online platform are complex. For those looking to enter the online pharmacy space, particularly where there is also an online prescribing element, key issues include:

- Website layout, to avoid breaching rules on the advertising and promotion of medicinal products
- Who will be carrying out the prescribing activity – a UK-registered doctor, an EU-registered doctor or an alternative prescriber such as a pharmacist?
- Will the business require registration with the Care Quality Commission because it is carrying out a registrable activity such as the treatment of disease, disorder or injury?
- Who is supplying the medicine and who will have to apply for the EU common logo registration which applies to online medicines suppliers?
- How will the business comply with the recent guidance from the General Pharmaceutical Council which appears to impose significant restrictions on pharmacies which supply medicines online, either through their own websites or through third party websites?
- Do you have appropriate legal documentation in place, for example to cover the website terms and conditions, privacy notice and any agreements with third parties?
- What products will the website supply and how will that affect the proposed business model?
- Will the business supply only to patients in the UK or will it also supply to patients living outside the UK, either in the EU or elsewhere?

Our specialist team has guided several clients through the process of setting up new online pharmacy businesses and can guide you through the pitfalls.



Articles

- [Judge suggests pharmacists won't be prosecuted under shortage powers](#)
(Chemist & Druggist)
 - [The GPhC is not quite Big Brother with its new surveillance powers](#)
(Chemist & Druggist)
-

Medicines shortages – serious shortage protocols (SSPs)

On 9 February, the law requiring POMs to be supplied only in accordance with a prescription was relaxed in the case of serious shortages. We have covered the detail of the change in a previous edition of the Pharmacy Brief. However, the new law was subject to legal challenge by the Good Law Project. GLP's application for judicial review was refused and its appeal against that decision has also just been refused.

It remains to be seen if, and how often, SSPs are actually used.

What does “significant change” mean in market entry cases?

We recently opposed an unforeseen benefits application in a rural North Somerset location. Our client operated a pharmacy in a village which had no doctors' surgery. The nearest surgery was located in a village about 3 miles away and was a dispensing practice.

The dispensing doctors formed a limited company and made an application for a new pharmacy within their surgery. The doctors said that they would give up their dispensing rights if the new pharmacy application was granted.

On behalf of our client, we opposed the new contract application on the basis that:

- Granting the application would not confer significant benefits in the Health and Wellbeing Board's area. In particular, there was already a dispensing service for eligible patients in the village where the surgery was located from the GP and there was a network of pharmacies in surrounding towns and villages
- Granting the application would prejudice the proper provision of pharmaceutical services because it would force our client's pharmacy to close, leading to a loss of service provision in our client's village
- Granting the application would result in a significant change in arrangements in place for the provision of pharmaceutical services in the HWB's area

Following an oral hearing, NHS Resolution determined the appeal and refused the application, agreeing with us on all three arguments. In relation to whether granting the application would result in a significant change in arrangements, NHS Resolution accepted our client's submission that his pharmacy would close if the new contract were to be granted and that the closure would result in a loss of service provision in our client's village. That loss of service provision would result in a significant change in arrangements.

Our client was delighted with the outcome, not least because, since the surgery is located in a controlled locality, it will not be possible for the doctors to reapply for another 5 years.

Property issues in pharmacy sales

At the Pharmacy Conference in March, the Real Estate team spoke about property matters that can delay or prevent a pharmacy sale. Some of the key points for a seller are ensuring that:

- The property is owned by the correct entity – usually the pharmacy company being sold
- All title deeds for the property are held and any landlord's consent obtained for any alterations, underlettings, change of use etc.
- Any lease has not expired
- Asbestos surveys, fire risk assessments, air-conditioning reports and energy performance certificates have been produced
- All parties are aware of existing guarantees and whether guarantees will be required as part of the sale
- All planning permissions and building regulation documents are held
- All rent reviews have been completed and evidenced
- Where there is a residential unit above the pharmacy, all relevant laws have been complied with. We have recently been instructed by a pharmacist who lets out a number of houses and is currently under investigation by a local authority which alleges that he was operating a House of Multiple Occupancy without the relevant licence

Age-restricted sales

Pharmacies sometimes sell products which cannot be supplied to people under 18, such as certain razor blades. It is important that owners have in place a procedure for dealing with age-restricted sales and that staff are appropriately trained. Local authorities routinely carry out test purchases using under-age "customers" and if an age-related product is sold, the owner may face prosecution.

IR35

The off-payroll working rules – commonly referred to as IR35 – are intended to ensure that individuals who work like employees pay broadly the same employment taxes as employees, regardless of the structure within which they work. As highlighted at this year's Pharmacy Conference, the 2018 Autumn Budget announced the extension of rules from the public to the private sector to increase compliance with IR35 with effect from April 2020. The government's consultation on the proposed changes closed on 28 May and we can expect a summary of responses to be published later this year. If your pharmacy engages locums via their own company, watch this space for further updates and contact Becky Lawton in our Employment team on becky.lawton@crsblaw.com if you have any queries.

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