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#### **GPhC reminds online pharmacies about patient safety issues**

Since the GPhC issued specific guidance about the provision of online pharmacy services in April 2019 we have acted for a number of pharmacists who have been the subject of a fitness to practise investigation following concerns raised by the Inspectors regarding the safety of online services. This has included cases involving the imposition of conditions or suspension on pharmacy premises and fitness to practise allegations against individual pharmacists.

The GPhC has recently issued a reminder to pharmacists to make sure that they read and follow its guidance to ensure that online services are provided safely and effectively ([Patient safety concerns relating to online prescribing services | General Pharmaceutical Council \(pharmacyregulation.org\)](#))

This is a key area of focus for the Council at the moment in our experience. The requirements are complex and unwary pharmacists risk enforcement action. We can advise on the requirements, and assist any pharmacists who are facing regulatory action.

#### **DHSC and PSNC announce new funding deal (the small print)**

On 23rd August 2021, the DHSC and PSNC jointly announced a funding deal for community pharmacy for the coming year. Understandably it is the flat total funding envelope that grabs the headlines, but deeper into the announcement there were a couple of snippets that hint at regulatory reform.

The first is something that we have covered in recent Pharmacy Briefs: changes to medicines legislation to allow the wider use of hub and spoke dispensing models, including allowing hubs and spokes to be owned by separate legal entities. The announcement promises regulatory change (as soon as practicable), and we understand from sources that work continues on a consultation document which we expect to be published shortly.

The second statement is a little more cryptic – “*We have agreed to continue further conversations regarding the regulation of dispensing and supply of medicines taking into account novel ways of undertaking these activities, while, at the same time, ensuring the integrity of the market entry system, based on Pharmaceutical Needs Assessments.*”

We anticipate that this is in reference to the ongoing debate about changes to the law on supervision, and the extent to which a pharmacist must be physically present in the pharmacy and “in a position to intervene” when medicines are handed over to a patient. Again, expect further discussion on this over the coming months.

#### **MHRA consultation on innovative medicines at the point of care**

On 12th August, the MHRA started a consultation on proposed regulatory reform for Point of Care manufacturing of innovative medicines.

The consultation provides that “POC manufacturing refers to the manufacture of personalised medicines made for the patient either within or very close to where they are receiving care, for example, an operating theatre, ambulance or a military hospital. Many POC products have a short shelf life – some need to be



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## Articles

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- [Compliance aid basics](#)  
(P3 Pharmacy)
  - [Looking for better lease terms?](#)  
(P3 Pharmacy)
  - [What does the new Health and Care Bill mean for community pharmacy?](#)  
(Chemist and Druggist)
- 

used within minutes - so they cannot be manufactured in advance or supplied from a distance.”

The consultation will run for 6 weeks, and can be found here - [Regulator seeks views on innovative medicines manufacture at point of care - GOV.UK \(www.gov.uk\)](#)

### **Not another regulator for community pharmacy?**

On 6th July, the Government began the process of enacting a new Health and Care Bill, which aims to reform some aspects of NHS care in England.

It is likely to take some months for the Bill to pass through its various stages and become law, but the current draft establishes a new body, the HSSIB, which has the function of investigating incidents that occur in England during the provision of health care services and have, or may have, implications for the safety of patients. The purpose of an investigation would be to identify risks to the safety of patients and address those risks by facilitating the improvement of systems or practices in the provision of NHS services.

There is detail in the Bill about how the HSSIB can commence an investigation and its powers to investigate and gather information, but these are wide-ranging, with criminal sanctions for anyone who deliberately obstructs an investigation. Given the role of the HSSIB, it would be surprising if it does not, at some point, come to investigate incidents that relate to pharmaceutical services.

### **Pharmacy market entry in Wales**

A reminder that new market entry rules will come into full force in Wales in October 2021. There are a number of changes being brought in, and these have been summarised in a previous Pharmacy Brief. One of the biggest changes is to focus new contract applications on Pharmaceutical Needs Assessments which must be published by each Local Health Board, so it will be worth contractors reading their local PNA once it has been published to see if it identifies any unmet needs.

### **It's a deal**

Our Pharmacy Transactions team has seen high levels of market activity over the last few months with recent completions including:

- Sale of Dartford based Station Road Pharmacy Ltd to Medsfirst Ltd (brokered by Hutchings Consultants Ltd)
- Sale of Yorkshire based pharmacy operator Steeton Healthcare Ltd to Steeton Pharma Ltd (brokered by Hutchings Consultants Ltd)
- Purchase of Yorkshire based pharmacy operator Alex Crewe Ltd for Avicenna Retail Ltd
- Sale of Gloucestershire based pharmacy operator AD Byers Ltd to Pharmplus2 Ltd (brokered by Christie & Co)
- Purchase of Doncaster based pharmacy operator Kians Ltd for HI Weldrick Ltd (brokered by Alliance Valuers)

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### Message from Noel Wardle

Noel Wardle left Charles Russell Speechlys on 31st August 2021 after over 16 years with the firm.

Following his departure, Charles Russell Speechlys will no longer be carrying out core contentious work for pharmacy clients which includes, for example, market entry (NHS contract) applications, GPhC fitness to practise cases and NHS England and MHRA investigations and disputes.

Noel can continue to assist pharmacists with regulatory matters at his new firm (Temple Bright) and can be contacted at [noel.wardle@templebright.com](mailto:noel.wardle@templebright.com).

The firm's pharmacy team is now led by Tim Jenkins and will continue to provide other legal services for pharmacy clients in the same way as before (including commercial advice, pharmacy transactions (buying and selling pharmacies), real estate, employment, insolvency and commercial disputes).

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