



# Hub and spoke dispensing: Submission from the General Pharmaceutical Council

8 June 2022

Department of Health and Social Care, by email.

## Introduction

We welcome the opportunity to respond to the consultation on proposals to enable all community pharmacies to access 'hub and spoke' dispensing. We have limited our response to those proposals that, if implemented, would have an impact on our role as the independent regulator of pharmacy professionals and registered pharmacies.

As the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in Great Britain, our role is to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmaceutical services in England, Scotland, and Wales.

We have a statutory role in relation to 'system' regulation (as we regulate registered pharmacies) as well as 'professional' regulation of individual pharmacists and pharmacy technicians. Our main work includes:

- setting standards for the education and training of pharmacists, pharmacy technicians and pharmacy support staff, and approving and accrediting their qualifications and training
- maintaining a register of pharmacists, pharmacy technicians and pharmacies
- setting the standards that pharmacy professionals must meet throughout their careers
- investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public or to uphold public confidence in pharmacy
- setting standards for registered pharmacies which require them to provide a safe and effective service to patients
- inspecting registered pharmacies to check if they are meeting our standards.

To help pharmacy owners meet our standards for registered pharmacies, we have produced guidance, including **guidance for registered pharmacies providing pharmacy services at a distance, including on the internet**. This guidance, updated in April 2022, covers the hub and spoke model and explains what pharmacy owners should consider before deciding whether any parts of their pharmacy service can be

provided safely and effectively at a distance (including on the internet), rather than in the traditional face-to face way.

## **Patient safety and accountability**

We acknowledge the potential benefits that enabling hub and spoke dispensing across separate businesses can bring if operated effectively, including freeing up pharmacy professionals' time and increased efficiency. However, it does raise issues of responsibility, accountability, liability, and the interconnectivity of IT systems.

With regards to patient safety, we believe the largest risk with hub and spoke arrangements is a lack of understanding around roles, responsibilities, and accountabilities. Managing individual registrants and staff across different sites and across different legal entities is complex and clear governance will be essential.

We therefore agree that legislation should clearly mandate the arrangements between the hub and spoke and legislation should require the hub and spoke to clearly set out the respective responsibilities and accountability of each of them. We welcome further clarity for pharmacy owners in the drafting on the anticipated governance arrangements expected to be in place between a hub and spoke which would satisfy this provision.

There should be clear arrangements between the hub and spoke setting out responsibilities, accountabilities, and liabilities for each step within the supply process. This clarity needs to cover both accuracy and clinical appropriateness, responsibilities, and accountabilities. This will be crucial to ensuring the arrangements work efficiently without any unintended consequences impacting upon access to medicines and patient safety. The details of the arrangements should be documented (either in writing or electronically) and be accessible for inspection by the relevant regulatory authorities.

Responsibility for monitoring the accuracy of systems that allow movement of data and ensure data protection across different legal entities, as well as the potential for system failures, should be included as part of the arrangements between hub and spoke.

## **Information to appear on the packaging**

Our understanding is that in cases where the hub and spoke are both registered pharmacies, the proposals allow the two organisations the flexibility to decide between themselves which name and address appears on the packaging. We are not clear whether the intention of this proposal is that the patient's relationship, in so far as matters relating to the supplied medication, will be solely with the registered pharmacy whose name and address appears on the packaging. If this is the intention, the implications (regarding accountability and responsibility) for the other pharmacy should be made clear.

People have the right to transparency when it comes to knowing who dispensed and supplied their medicines. Ideally, the label on the package of dispensed medicine should carry the name and address of both the hub and spoke. However, we understand that for some people, hub and spoke dispensing will be a complex concept and this may cause confusion, especially as to who they should contact if they have an issue with their prescription.

Therefore, we feel that the packaging of the dispensed medicine should have the contact details of the pharmacy that the person should contact should they have any questions about their prescription. This may differ depending on the arrangements between each hub and spoke. The agreed arrangement should be clearly documented and be accessible for inspection by the relevant regulatory authorities.

It will be important to consider patient and public views on practical issues such as labelling and displaying notices before an approach is finalised.

## Transparency and information for patients about dispensing models in operation

We agree that legislation should ensure that pharmacies utilising hub and spoke dispensing must display a prominent notice to inform patients that hub and spoke dispensing is being used, as well as the name and address of any hubs being used. Patient consent is fundamental, accepting that the consent process needs to be practicable and proportionate.

For pharmacies operating entirely at a distance, it should be made clear that the notice must be prominently displayed on the spoke pharmacy's website.

It is important to note the implications of failing to display such a notice will mean that the owner of the spoke pharmacy would not be lawfully conducting a retail pharmacy business for the purpose of section 69 of the Act. It is therefore essential that this requirement is clearly set out in legislation.

### Areas for clarification

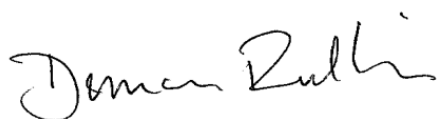
We would welcome clarification on the following:

- In the first hub and spoke model proposed, the hub prepares/assembles the medicines, but it is not clear whether the spoke can also directly supply medicines to the patient. It should be made possible for the spoke to supply medicines to the patient that the hub does not have in stock, or to supply any controlled drugs to the patient.
- The current proposals do not enable the spoke to supply medicines to the hub to fill a prescription. In situations where the hub does not have a particular medicine in stock or is unable to make a complete supply, we believe that the spoke should be able to send medicines to the hub. The MHRA allow the movement of small quantities of a medicine from one pharmacy to another to meet a patient's individual needs and that this is considered by MHRA to fall within the definition of provision of healthcare services.

We will continue to work with DHSC and other relevant stakeholders to ensure that our registration criteria for pharmacies accurately reflects any changes in the law and that we take account of proposals in our standards for registered pharmacies.

If you would like to discuss the points raised in this response, or any other aspects of the GPhC's work, please do not hesitate to contact us on the details below.

Yours sincerely,



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