From the Chief Medical Officer Professor Sir Michael McBride



HSS(MD)34/2025

FOR ACTION

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Chief Operating Officer, SPPG
GP Medical Advisers, SPPG
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Our Ref: HSS(MD)34/2025 Date: 3 October 2025

PLEASE SEE ATTACHED FULL CIRCULATION LIST

Dear Colleague

THE HUMAN MEDICINES (AMENDMENTS RELATING TO HUB AND SPOKE DISPENSING ETC.) REGULATIONS 2025

I wish to inform you that amendments to the Medicines Act 1968 and the Human Medicines Regulations 2012 (HMRs) in relation to Hub & Spoke Dispensing were made in June 2025 under The Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) Regulations 2025 and have now come into operation in Northern Ireland from the 1st October 2025.

Background

Hub and spoke dispensing is a pharmacy model whereby some routine parts of the dispensing process, like assembling prescriptions, are done in a central 'hub' pharmacy, while patient interactions and final supply occurs at 'spoke' pharmacies, allowing staff within those pharmacies to focus on delivery of patient centred services.

Following a UK wide public consultation <u>Hub and spoke dispensing - GOV.UK</u> in 2022 it was agreed by both the UK Government and NI Assembly that new legislative amendments should be taken forward to the Medicines Act 1968 and HMRs that will enable pharmacies belonging to different legal entities to set up hub and spoke arrangements provided medicines are returned to the spoke for final supply and also make it possible for dispensing doctors to act as a spoke, giving them access to the knowledge provided by pharmacists in the hub. Prior to these legislative amendments, a medicine dispensed in one pharmacy could only be sold or supplied by that pharmacy, or another within the same legal entity.

Information on the new legislative amendments

The amendments referred to above will enable the use of hub and spoke arrangements between hub pharmacies and spokes that are either pharmacies owned by different businesses or by dispensing doctors, provided the medicines are returned to the spoke for final supply. This use of these new hub and spoke arrangements are also subject to certain other conditions and requirements being met. These being as follows –

- Written arrangements must be in place between the hub and the spoke which give a comprehensive statement detailing the responsibilities of the hub and the spoke.
- The spoke must sell, supply, or dispense the medicine to the patient, the hub having assembled or part assembled it under these arrangements and returned to the spoke for final supply.
- The dispensed medicine must be labelled with the spoke's name and address, plus the date on which the hub assembled or part assembled the medicine (as well as standard information required on any dispensing label).
- The sharing of patient data between the hub and spoke (without the explicit consent of a patient) is permitted through an information gateway. This gateway requires the spoke to display an appropriate notice to patients and staff at the spoke and the hub to maintain the confidentiality of the patient data.
- The spoke is required to display a notice, both on their premises and/or their internet presence, aiming to provide full transparency to patients.

Hub and spoke arrangements will not be mandatory. In addition to the legislative amendments introduced by the Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) Regulations 2025, each UK administration is also now giving due consideration to any additional requirements that may be required locally to underpin this dispensing model within NHS arrangements when it comes into operation on 1st October 2025. The Department is keeping this matter under review and will work with Community Pharmacy NI to progress any potential changes that may be required to the Pharmaceutical Services Regulations (Northern Ireland) 1997.

Enabling all pharmacies to avail of hub and spoke dispensing arrangements, should they choose to do so, aligns with a strategic priority in the Department's 'Community Pharmacy Strategic Plan 2030' to modernise systems for the safe and reliable supply of medicines and professional advice from community pharmacies. These legislative changes, along with other changes such as previous amendments to the HMRs which provided flexibilities to pharmacists for dispensing of medicines in their original pack, will help community pharmacies to streamline how they manage dispensing workload and release capacity in pharmacy teams to undertake more patient centred services that align with HSC priorities.

Further Information

Further information can be accessed on the legislation.gov.uk website with the following link <u>The Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.)</u> Regulations 2025

Yours sincerely

PROFESSOR SIR MICHAEL MCBRIDE Chief Medical Officer

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PROFESSOR CATHY HARRISON Chief Pharmaceutical Officer

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This letter is available on the Department of Health website at

https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-