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Legal and ethical implications of hub & spoke dispensing
Pharmacy Law & Ethics Association
Wed 4th May 2022
Richard Hough

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A long time ago
in a galaxy far, far away....

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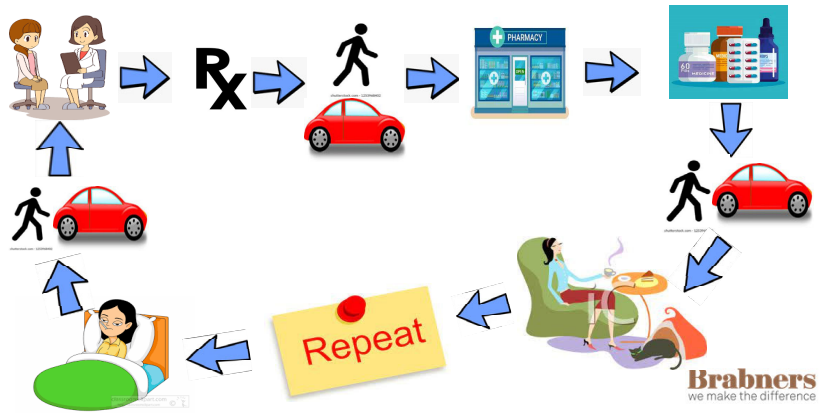
Traditional access to medicines – a model of inefficiency…..



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The enabling legislation for split-site dispensing

- Dispensing covers a number of different processes, including the receipt of a prescription, undertaking clinical and accuracy checks and the sourcing, preparation, assembly and supply of medicines.
- Traditionally, all aspects of dispensing were undertaken in a single pharmacy.
- In a hub and spoke dispensing model, however, some of these processes can be undertaken in another pharmacy.
- **Section 10(1)(b)(i) Medicines Act 1968** states (in respect of assembly of a medicinal product):

"*it shall be in a registered pharmacy at which the business in medicinal products carried on is restricted to retail sale or to supply in circumstances corresponding to retail sale and the assembling is done with a view to such sale or supply either at that registered pharmacy* ***or at any other such registered pharmacy forming part of the same retail pharmacy business***"

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Dispensing robots - a game changer for hub and spoke

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DHSC definition of **hub and spoke dispensing**:

"arrangements where a retail pharmacy, notionally at the end of a spoke, receives prescriptions, and sends them electronically to a remotely located hub, which in turn takes in prescriptions from multiple spokes. At the hub, medicines are selected, packaged and labelled and then transported back to the spoke to be checked by the pharmacist and collected by the patient"

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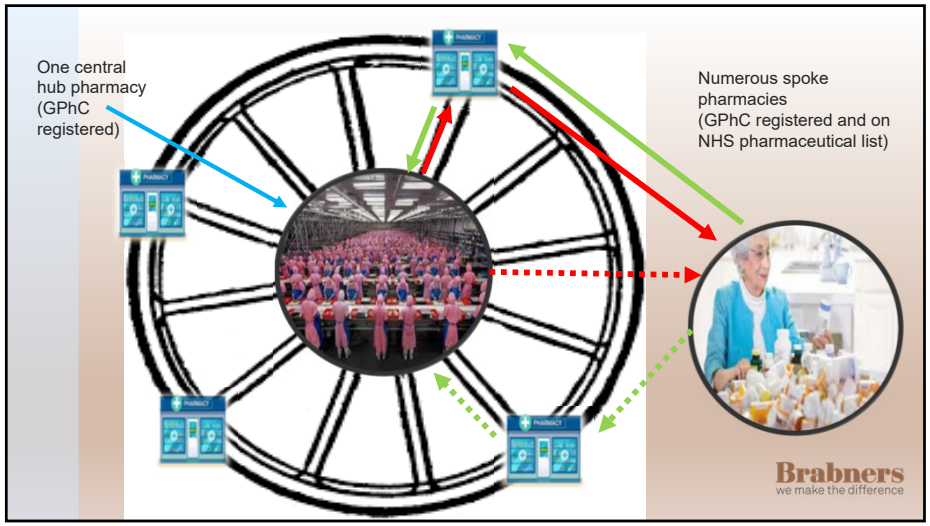

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Hub and spoke – the current position

- Only available to pharmacies where the "hub" and the "spokes" are ***both part of the same retail pharmacy business***.
- A method of centralised dispensing whereby dispensing volumes are consolidated from several pharmacies within the same business where one pharmacy (the hub) centrally assembles prescriptions on behalf of other pharmacies within the group (the spokes).
- Potential to make the dispensing process more efficient, safer, lower operating costs and free up pharmacists' time at the spokes to spend more time with patients.
- Cost advantages to be exploited by expanding the scale of assembly and preparation, which makes centralised automation more viable, *notwithstanding significant capital costs*.
- Allows the spoke pharmacies to consider operating from smaller premises, as the demand to store stock at the spoke pharmacies is reduced (leading to lower storage costs, reduced overheads and, potentially, less employment costs).
- Spoke pharmacies act as collection points for prescriptions where additional enhanced and locally commissioned services may also be provided, *subject to availability of adequate funding*.

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The introduction of inter-company hub and spoke – haven't we been here before?

- Yes, the Government originally intended to introduce legislative change in 2016
- Consultation paper '*Amendments to the Human Medicines Regulations 2012: 'Hub and spoke' dispensing, prices of medicines on dispensing labels, labelling requirements and pharmacists' exemption*'
- Consultation paper was met with vehement backlash within the sector – concerns around patient safety
- Government decided to extend the consultation period (i.e. the proposal was kicked into the long grass)
- Eventually published its response in November 2021

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So what's new?

- **Medicines and Medical Devices Act 2021**
  - introduced post-Brexit in February 2021
  - includes provision for regulations to be introduced, which would permit hub and spoke dispensing ***between different retail businesses***
  - replaces powers that were available through the (now repealed) European Communities Act 1972
- Tide of opinion amongst some (not all) pharmacy representative groups appears to have softened in favour of inter-company hub and spoke
- PSNC briefing in June 2021 – "*hub and spoke dispensing available to all*"

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Opportunities and benefits

- Multiples - increased utilisation of their existing infrastructure to offer a chargeable outsourced dispensing service to independent pharmacies
- Independents in a locality could set up their own JV co-operative model
- Facilitation of the expanding role of community pharmacists (CPFC) – clinical skills
- Increased revenue / improved patient safety / operational cost savings

Threats and detriments

- Increased risk
- Data sharing / information governance / interoperability of IT systems
- Lack of evidence of cost savings
- Accountability
- New entrants to the market

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What still needs to be done?

- New legislation that will amend MA 1968 and HMR 2012 (to allow for assembly, labelling and supply between different legal entities)
- Alignment of regulation in respect of supervision, RPs and SIs
- Good Distribution Practice – provisions re the transfer of assembled or part-dispensed medicines
- Agreement as to which H&S model(s) will allow fair access for the whole sector
- Greater use of OP dispensing – changes needed to HMR 2012 and NHS Regs
- New legislation to allow for better use of pharmacy skill mix
- Changes to funding and fee structures

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Hub and Spoke Consultation 2022* - overview

- Published on 16th March 2022 & closes on 8th June 2022
- Seeking views from pharmacy stakeholders on proposals to enable all community pharmacies to access hub and spoke dispensing
- Two different proposed models for H&S:
  - **Model 1 (hub to spoke)** – where the dispensed medicines are returned assembled from the hub to the spoke pharmacy for onward supply from the spoke to the patient
  - **Model 2 (hub to patient)** – where the hub pharmacy, after assembly, supplies the dispensed medicines directly from the hub to the patient
- Proposals to enable dispensing doctors also to access hub pharmacies (as a spoke)
- Publication of draft legislation:
  - Proposed amendments to MA 1968 (Regs 2-7) and HMR 2012 (Regs 8-17)

* https://www.gov.uk/government/consultations/hub-and-spoke-dispensing/hub-and-spoke-dispensing

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Hub and Spoke Consultation – key themes

- "*Levelling the playing field*" between large chain and smaller pharmacies
- Freeing up pharmacy professionals' time (at the spokes) for ↑ additional services
- ↑ dispensing efficiency through placing ↑ reliance on automation
- ↑ Hub set-up costs & investment in automation (prohibitively expensive)
- Proposals to allow pharmacies to make ↑ use of OPs → ↑ use of automation
- ↑ Patient safety – expected ↓ in dispensing error rates (but NB automation errors!!)
- Participation not mandatory - pharmacies can choose to access H&S
- Not all medicines are suitable for hub and spoke dispensing (e.g. acute care & CDs)
- ↑ Training of staff
- ↑ face to face contact with patients at the spoke → ↑ health outcomes → ↓ pressure on other areas of NHS. **But availability of additional revenue for services at spoke?**
- Hubs to purchase the medicines (↑ purchasing power) – ↓ purchasing autonomy (spoke); anti-competitive?; ↑ rather than ↓ NHS spend?; ↓ spoke profit?

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Hub and Spoke Consultation – key themes cont'd

- Hubs to be registered pharmacies – part of the same regulatory framework as spokes
- Dispensing doctors can access hubs (as a spoke) but cannot act as a hub
- No limit on the number of hubs a spoke pharmacy can contract with
- Changes also needed to NHS Regs (especially if model 2 is adopted)?
- Flow of medicines from **spoke to hub** (e.g. if hub has stock shortage, spoke supplies balance)

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Draft legislation – main provisions

- Removal of "*forming part of the same retail pharmacy business*" - section 10 MA 1968
- Notification of H&S arrangements to patients at spoke pharmacy via RP notice
- Distribution of product by wholesale dealing – exclusion for Reg 222A retail sales
- **Reg 222A HMR** establishes that (under model 1):
  - Rx is submitted to a spoke
  - An arrangement must be in place between hub and spoke
  - A "**retail sale**" occurs between the hub and the spoke (as well as the retail supply from spoke to patient)
  - Hub must be a reg pharmacy & spoke must be a reg pharmacy or dispensing doctor
- **Reg 222B HMR** establishes that (under model 2):
  - As above, except that the **hub supplies directly to patient**
  - A retail sale is **deemed to take place** between spoke and patient (as well as the retail sale supply that takes place between hub and patient)

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"Arrangements" between the hub and the spoke?

Over-arching considerations

- Do nothing – allows complete freedom between hub and spoke
- Requirements determined by legislation
- Division of responsibility and accountability between themselves, by agreeing who is to be responsible and accountable for each step in the dispensing process, including the accuracy and clinical checks, and having this clearly documented between them – **the proposed option** (albeit "*whether or not legally binding*")

Ancillary considerations

- Name and address of **either** hub **or** spoke to appear on the dispensing label – flexibility?
- Sharing of patient information/data

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Summary of proposals:

- Both the hub and the spoke are part of the retail sale.
- The hub must be a registered pharmacy.
- The spoke must be either a registered pharmacy or a dispensing doctor.
- There must be an agreement between the hub and the spoke, which determines who is accountable for each step of the dispensing process.
- Requirement for conspicuously displayed notice at spoke
- Information to appear on the packaging – either hub or spoke

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Thank you.
Any questions?

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