

Hub and Spoke Dispensing

Royal Pharmaceutical Society Response

1. **Do you agree or disagree that we should remove the impediment in medicines legislation that prevents the operation of hub and spoke dispensing models across different legal entities?**
 - Strongly agree
 - **Agree**
 - Neither agree nor disagree
 - Disagree
 - Strongly disagree
2. **Do you agree or disagree that the 2 proposed models, hub-to-spoke and hub-to-patient, that will be enabled through the Human Medicines Regulations 2012 provide sufficient flexibility?**
 - Strongly agree
 - Agree
 - **Neither agree nor disagree**
 - Disagree
 - Strongly disagree
3. **Are there any further hub and spoke models which should be considered?**

No, but consideration could be given to the use of hospital robots to be used to dispense primary care prescriptions overnight / during the day depending on their capacity, across a neighbourhood / system
4. **Do you agree or disagree that the Human Medicines Regulations 2012 should mandate arrangements that are in between the hub and the spoke to ensure accountability?**
 - Strongly agree
 - **Agree**
 - Neither agree nor disagree
 - Disagree
5. **Do you have any comments on the proposed requirement for arrangements between the hub and the spoke?**
 - There should be national guidance as to what should be included in these arrangements, a type of checklist so that all areas are considered and discussed

- They must enable spoke pharmacies to be able to return medicines to the hub within a specified time period if the patient doesn't pick them up
- The hub must comply with Good Distribution Practice and be responsible for this until the medicine reaches the spoke / patient home
- All hubs must be based in the UK
- They must clearly define responsibility and accountability across the system
- The hubs need to be inspected by GPhC and rated in a similar way to community pharmacies and adhere to national minimum standards set by the regulator
- Business continuity, in terms of hub failure and being unable to undertake dispensing, needs to be covered
- If a hub is unable to supply medicines for the whole prescription, there needs to be clear arrangements in place as to whether part of the prescription is supplied immediately or if the medicines are not sent until all of the medicines are available. This could impact on patient safety
- The arrangements need to include the best way to maintain contact between hub and spoke, particularly if there are issues with a particular prescription
- How to report and act on errors or near misses need to be part of the arrangements

6. Do you agree or disagree that the Human Medicines Regulations 2012 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?

- Strongly agree
- **Agree**
- Neither agree nor disagree
- Disagree
- Strongly disagree

Give a reason for your answer and any evidence to support it

Having a prominent notice ensures transparency and enables patient choice. Patients can take their prescriptions to a different pharmacy if they are not content with the particular hub and spoke arrangement.

We believe that there should not be a requirement for informed consent as this would make the process too onerous / burdensome for the community pharmacy.

Overall accountability remains within the pharmacy spoke for the supply of meds to the patient, using the hub to dispense the medicine is just a way of using a different mechanism to provide the medicine to the patient.

7. Do you agree or disagree that we allow flexibility and that the label should carry the name and address of either the hub or the spoke, depending on what their agreed arrangements are?

- Strongly agree
- Agree
- Neither agree nor disagree
- **Disagree**
- Strongly disagree

Give a reason for your answer and any evidence to support it

The contract for supplying the medicine is between the spoke and the patient, therefore we believe that it should be the pharmacy / dispensing doctor address (spoke) and contact details on the label. If the patient has any issues they want to discuss about their medicines, then they should contact the original spoke pharmacy/dispensing doctor.

Alternatively, hub medicines could have a label that contains a 'dispensed in partnership with' type for the medicines it dispenses. This would need to be different for each pharmacy that it dispenses medicines for.

8. Do you think that these proposals raise any issues regarding patient safety?

• Yes

- No
- Not sure

Give a reason for your answer and any evidence to support it

- We agree that the two models provide sufficient flexibility but are concerned about patient safety in the second model proposed (spoke to hub to patient). If this model is to be adopted, then there need to be triggers within the process that mean a patient is required to interact with a pharmacist about their medicine(s). The triggers would include a change in medicine (stopped, started, dose change) or a change in the person's condition(s), high risk medicines etc. If a trigger is activated, then the person would need to be notified that they either pick up the medicine from the spoke where they can have a conversation with the pharmacist or they have a remote interaction with the pharmacist where this is appropriate. There must also be the ability for the spoke to notify the hub that the medicine needs to come back to the pharmacy as they feel that there is a need to speak to the patient following a clinical check of the prescription. This would also need to be included in the process.
- In all models, patients need to continue to have access to a pharmacist at the time of supply of medicines to be able to discuss their medicines with a pharmacist including having the opportunity to ask questions or raise concerns and to access appropriate information with counselling and advice from a pharmacist via a route that is appropriate for them
- There are questions about the impact on sustainability of these models. If the hub sends the medicine directly to the patient, then this significantly increases the transportation costs vs sending a number of patients' medicines back to one pharmacy.
- Patient safety could be impacted if patients are unable to access their medicines in a timely manner. If hubs, for instance, don't send out medicines until the whole prescription medicines are available then this could mean a delay in patients receiving their medicines and continuing their treatment.
- There needs to be good electronic information flow between systems to ensure that accurate and timely information about prescriptions is passed from spokes to hubs and vice versa.
- If a spoke has a concern about a hub, or if a hub is found not to meet national minimum standards as set by the regulator, then spokes must have the ability to change hubs easily.

- There also need to be robust business continuity processes in place for instances when a hub goes offline for any reason
- Consideration needs to be given as to how pharmacies are able to continue to dispense and supply acute prescriptions in terms of stock levels of medicines within pharmacies etc. This also applies to the supply of urgent medicines.
- Pharmacy staff who were mainly employed to dispense prescriptions may not be kept on in the pharmacy which could lead to an overall reduction in pharmacy staff numbers which could impact on their ability to provide services to patients and the public.
- Hub and Spoke dispensing will change the current risk profile in a community pharmacy. Whilst the consultation does not mandate automation or use of emerging technologies this will inevitably be one of the outcomes of this and this brings a different risk profile. Whilst data shows that automation is safer than manual dispensing this is all dependent on the design and testing and when things go wrong the scale that they can go wrong at is larger.

9. Do you have any views on proposed enablement of hub and spoke for dispensing doctors?

We are pleased to see that dispensing doctors are included within the scope of these proposals.

10. Do you agree or disagree that dispensing doctors must also 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?

- Strongly agree
- **Agree**
- Neither agree nor disagree
- Disagree
- Strongly disagree

11. Do you have any views on the amendments we are proposing to the Human Medicines Regulations 2012 and the Medicines Act 1968?

If your response relates to the draft statutory instrument which will enable the proposed changes, highlight the relevant paragraphs in your response.

12. Currently, the proposed legislative changes do not allow for the supply of medicines from the spoke to the hub. Do you have any views on whether a possible change should be considered here?

There are various options that could be considered here. If the hub is unable to supply the full prescription then there is an argument that they should just reject the whole prescription and send it back to the spoke. However, the spoke itself may not have all of the medicines in stock to fulfil the prescription.

If the spoke is enabled to send medicines to the hub, then there needs to be a process in place as to how this medicine is sent to the hub (currently not allowed via Royal Mail) which could be that the hub arranges for collection of the medicine.

If the hub is sending the dispensed prescription back to the spoke, they could always mark it as an incomplete prescription and the spoke could then add the additional medicines before it is supplied to the patient.

13. While potentially outside the scope of the regulatory changes being proposed in this consultation, is there anything else we should consider with regards to the storage, distribution and transportation of medicines in respect to removing the current impediment in medicines legislation around 'hub and spoke'?

The supply of fridge items and controlled drugs need to be considered.
Manufacturers need to update to ensure OPD is enabled

14. In enabling the wider use of hub and spoke dispensing, are there other areas that we need to consider, either in respect to the change to the Human Medicines Regulations and the Medicines Act 1968 or areas outside scope of these proposed amendments?

- Behaviour change – there needs to be an understanding of how new technology and inter-company hub and spoke models will affect behaviour. This needs to include building trust within the process so that pharmacists not rechecking bagged prescriptions at the spoke
- Hub ownership and direction of prescriptions. Ownership of hubs could have an impact on where prescriptions are sent. Another concern is that there could be incentives to move pharmacies in order to use a particular hub.
- Resilience of the medicines supply chain needs to be considered if purchasing, dispensing and distribution of medicines is only via a handful of hubs
- Transportation issues if dispensing is only via a number of hubs e.g. snow days
- Investment in community pharmacies to enable them to provide the clinical services required by the NHS
- It must be ensured that the use of hub and spoke arrangements does not undermine market entry

Impact assessment

If your response relates to the impact assessment, highlight the relevant paragraph in the impact assessment in your response.

15. Do you have any comments on the impact assessment (not already provided under any of the previous questions)?

No comments

16. Can you provide any evidence that would help us to develop the cost-benefit analysis on these proposed changes?

No

17. To what extent do you agree or disagree with the assumed uptake and profile of hub and spoke dispensing?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

18. Estimates of potential sector-wide costs and benefits are informed by evidence from the sector already accessing hub and spoke dispensing.

How well do you think these apply to other business models?

The current model is only available to hub and spokes that are of the same legal entity so it is difficult to see how the model will operate when it becomes an inter-company model

19. Do you have any information on the associated costs and benefits of alternative business models?

No

20. To what extent do you agree or disagree with the assumptions, figures or conclusions in the impact assessment?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

21. Do you think there are any other impacts that we have not considered?

No

Northern Ireland respondents

In Northern Ireland new policies must be screened under Section 75 of the [Northern Ireland Act 1998](#) which requires public authorities to have due regard to rural needs.

Question

The Department of Health in Northern Ireland do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland. Do you have any views on this?

Question

Do you think the proposals risk impacting people differently with reference to their [or could impact adversely on any of the] protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998? If so, provide details.

Equality assessment

Question:

Do you have any evidence that we should consider in the development of an equality assessment?