



Response to
Department of Health and Social Care
Consultation
on
Hub and Spoke dispensing

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National Pharmacy Association response to the consultation on Hub and Spoke dispensing.

The National Pharmacy Association (NPA)

The NPA is the body which represents independent community pharmacy owners in the UK. We count amongst our members independent multiple regional chains through to single-handed independent pharmacies. This spread of members, our UK-wide geographical coverage, and our remit for NHS and non-NHS affairs means that we are uniquely representative of the independent community pharmacy sector.

In addition to being a representative voice, we provide members with a range of professional services to help them maintain and improve the health of the communities they serve. The NPA provides indemnity insurance via its wholly owned subsidiary NPA Insurance Limited (NPAI). The National Pharmacy Association Insurance Limited (NPAI) has been the main insurer for community pharmacy since 1899.

The National Pharmacy Association welcomes the opportunity to respond to this consultation.

General Remarks:

The NPA has led the sector-wide debate on Hub & Spoke since 2015. We have taken an evidence-based approach to our work on Hub & Spoke. We convened an expert group and published a review of research in 2016.

In 2020 we published a review of international experience with Hub & Spoke. Also in 2020, in association with the King's Fund, we convened a round table meeting involving representatives from the supply chain along with DHSC and MHRA. These reports are all available to view here and are attached to our submission:

<https://www.npa.co.uk/representing-you/thought-leadership/hub-and-spoke/>

Over the years, the NPA has also consulted with its members on Hub and Spoke dispensing, and found that the majority of the NPA membership, whilst sceptical about the opportunities that could be leveraged from Hub & Spoke at the current time, is keen that the following principles are maintained:

1. The decision to engage with Hub and Spoke remains with the pharmacy owner, and that pharmacies must not be penalised if they choose not to engage with Hub and Spoke
2. A level playing field is created and maintained so that all pharmacies would have the opportunity to participate in this concept equitably regardless of size or location. This means that any Hub & Spoke opportunities that emerge should be available throughout the country. It also means that the Hub market should be a competitive one and provide spoke pharmacies with choice over who to engage with
3. Patient safety is not compromised

The NPA believes that if all pharmacies are to truly benefit from hub and spoke dispensing, there needs to be a dynamic and competitive market in which hubs compete for the custom of pharmacies based on the quality of service and price. The NPA has developed the following five tests that, if met, would help to prevent unintended consequences in relation to competition and choice.

1. Hubs must be registered pharmacy premises and meet all GPhC/PSNI standards.
2. Hubs must be prevented from using their trusted position in the supply process to try to circumvent the relationship between the spoke and the patient, for example by using patient dispensing data for other commercial reasons or inserting branding or advertising material into the pack to be supplied to a patient.
3. The current barriers to entry for a hub provider presented by the Direct-To-Pharmacy (DTP) and limited wholesaler schemes must be removed so that any registered provider meeting standards can operate and compete in this market.
4. A common set of standards should set out the duties and accountabilities of a dispensing hub and professional metrics must be collected and published by the hub to assist the spoke in selecting a potential provider.
5. Any mechanism which is designed to prevent a pharmacy from easily switching hub provider should be prevented, thus ensuring that pharmacies can drive competitive pressures in this market.

Over these past two years, during the COVID-19 pandemic, community pharmacy demonstrated even more so than before, that it is integral to the health of its local community. As a cornerstone of the healthcare system, community pharmacy provides immediate face-to-face access to the NHS and healthcare services, including, the sale and supply of medicines through to the provision of public health services and support to people living with a long-term condition.

An NPA commissioned survey (2020), found that

- 7 in 10 people regard face to face advice from a pharmacist or other member of the pharmacy team as very important to them; the importance of the provision of face to face advice increases significantly among certain groups of heavy pharmacy users: 72% mothers, 76% carers and 80% women over the age of 65.
- Patients rate being able to speak with someone face to face, when ordering and collecting a prescription, as nearly five times more important than being able to order online (37% v 8%)
- Patients rate being able to speak with someone face to face as the single most important attribute when ordering and collecting a prescription (28% of all patients ranked this as being of the uppermost importance; compared to 2% ranking highest the ability to order prescriptions online and have them delivered)

Thus, it is important that the complete role of community pharmacists and their teams is taken into perspective when considering this consultation on Hub and Spoke dispensing.

This could also ensure the full mitigation of any unintended consequences such as impact on health inequalities.

Impact on Competition

At NPA Hub and Spoke discussions and debates, NPA members have become increasingly concerned of the impact of a lack of competition and the funding implications of a Hub and Spoke model operating across different legal entities.

At the NPA roundtable (convened in February 2020), there was a general view that it was important to have a competitive market for “hub services” with a wide choice of providers for pharmacies. However, it was highlighted, that there is a high risk that only a handful of companies will be able to provide fully comprehensive hub services due to various impediments, such as restrictive distribution arrangements, a significant upfront capital investment, ongoing operational costs and logistics and distribution costs.

NPA members added that unless there was a proliferation of hub providers, a risk identified was that there would not be a level playing field for the independent sector as the hubs were likely to be operated by large companies, thus the balance of power would be shifted towards the hubs. A small number of hub providers may lead to less competitive procurement and higher costs for the taxpayer.

Fair access to procurement margin is integral to the current community pharmacy financial model and therefore the sustainability of individual pharmacies. A possible risk identified was that the hub and spoke model might impair margin distribution, for example due to an anti-competitive ‘hub services’ market.

Regarding the transfer of patient data to a hub, a risk identified for independents was that they would be sharing their commercial data with an external company, which may be a competitor. Regarding the opportunity for independent pharmacies to collaborate to set-up and operate a hub themselves, it was acknowledged that this might be difficult to achieve for a number of reasons.

The NPA suggests that DHSC ask the Competition and Markets Authority (CMA) to consider Hub & Spoke, and propose a market review both before and after implementation of ‘inter-company hub and spoke’ models, to ensure that these points are addressed and mitigated against.

Impact of Brexit and the Northern Ireland Protocol.

The impact of Brexit, following the departure of the UK from the European Union, is still being felt in Northern Ireland. Whilst discussions between the UK and the EU around the Northern Ireland Protocol are still to be finalised a number of NPA NI members inform us of the current instability of the medicine supply chain. Amplified by the requirement of FMD compliance, a number of short-line medicine suppliers have ceased trading in Northern Ireland, leading to medicine shortages in some specialised medicines. This instability has also led to an increase in medicine prices.

The MHRA has mitigated against this in some way through the NIMAR process, however, as this has only just been implemented, the full impact of this new mechanism is still to be realised.

It is well documented that a large proportion of medicines supplied through Northern Irish Pharmacies are supplied from England. Thus, how would Hub and Spoke work across Northern Ireland and Great Britain? Would a spoke in Northern Ireland be able to avail of the full services of a GB hub in a seamless fashion in all seasons, as would be the case with both the Hub and Spoke being based in Great Britain?

The NPA also suggests that the DHSC consider the implication of a Hub based in Northern Ireland supplying the spoke in Great Britain.

The Impact Assessment

We note that the Impact Assessment suggests that the total savings to the sector's operational cost will be £1m by 2024. This compares with well over a billion pounds being withheld from community pharmacy in England from 2019 to 2024 due to flat funding – based on efficiencies such as Hub & Spoke. This consultation provides evidence for a further review of community pharmacy funding in England, and we call for the lack of efficiencies from Hub & Spoke to lead to additional funding in years four and five of the contract.

The NPA notes that the impact of Hub and Spoke on rural pharmacies does not appear to be fully established within the impact assessment. These pharmacies will be more susceptible to medication delays. This could be further impacted in instances where the hub and spoke are in different parts of the UK, including different countries.

We would be happy to discuss the points raised in this response with the DHSC in more detail. To arrange this, please contact Helga Mangion, Policy Manager at h.mangion@npa.co.uk

The Questions:

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

The NPA broadly agrees that the impediment in medicines legislation that prevents the operation of hub and spoke dispensing models across different legal entities be removed.

It is important to add, that whilst this will level the playing field from a legislative perspective, it would not in itself provide a level playing field from an operational or commercial perspective.

We are pleased to see that the Hub must be a registered pharmacy, as that will provide a degree of assurance to spoke pharmacies using their services.

The NPA suggests, however, that there are still a number of key areas that would also need careful consideration. These include but not limited to, financial implications and competition.

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

The NPA broadly supports option 1 of the two proposed models, that is, hub-spoke-patient, and does **not** support model 2 of the proposed models, that of spoke-hub-patient.

The NPA supports proposal 1: Spoke-Hub-Spoke

1. This model allows for the straightforward system regulation by the pharmacy regulator/s in the interest of patient safety.
2. Minimises the risk of a significant destabilisation of the relationship between the pharmacy network and the patient .
 - a. This would only be possible when the medicines are supplied through the spoke-irrespective of where they have been assembled and dispensed.
3. Compliance and correct usage of medicines is key for effective treatment. Having the medication supplied to the patient or their carers through the *pharmacy*, in this case the spoke, would allow for further conversations and discussions to take place to maintain compliance.
 - a. In instances of a new medicine being prescribed, through a well and established service, the pharmacist would be able to follow up usage of this medication over the first few months, with the option of rectifying any issues as they arise. This may include but not limited to a change in medication.
4. Polypharmacy tends to be prevalent in certain demographics of the pharmacy patient base. In these instances, the relevant medication regime is not always aligned to start and finish at the same time. Having medication supplied through the spoke would ensure that any anxiety and patient safety concerns following a lapse of the ordering process by the patient are mitigated against.
 - a. This model provides the opportunity for further intervention (clinical or otherwise) in a timely manner.
 - b. This model is aligned to the future role of community pharmacists and their teams and their full integration into the primary care multi-disciplinary team.
5. This model continues to provide the foundation for a more clinically orientated pharmacy service, as determined by the four community pharmacy strategies across the United Kingdom- Pharmacy as the “front door” to the NHS.

The NPA argues against proposal 2: Spoke-Hub-Patient on the following basis:

1. Model 2 could undermine the relationship between the pharmacy (of the patient’s choice) and the patient and create uncertainty about accountability.
 - a. There are also significant concerns about Model 2 increasing the carbon footprint of medicines supply.
2. As the pandemic has highlighted, patients are finding it increasingly difficult to access GP appointments, however, through various pharmacy services such as the Community Pharmacy Consultation Service (CPCS) in England; Pharmacy First in Northern Ireland;

Pharmacy First and Pharmacy First Plus in Scotland; and the Common Ailment Scheme in Wales, the patient is able to access other parts of the healthcare system in a timely manner. Having medicines supplied through the Hub could adversely impact this service to the detriment of patient care and health inequalities.

3. An option where the Hub (perhaps a distance selling pharmacy), directly supplies medication to the patient could adversely affect the NHS Control of Entry regulations. Based on Pharmaceutical Needs Assessment, and examined and tested at a number of inquiries, these regulations are in place to ensure that there is a fair and equitable access to NHS services to patients including the supply of NHS prescriptions.
 - a. This mitigates against the widening health inequalities.
 - b. Improves accessibility to all pharmacy services through the community pharmacy estate (circa 14,000 pharmacies) across the United Kingdom.

3. Are there any further hub and spoke models which should be considered?

The NPA is not aware of any other Hub and Spoke models that should be considered, that also apply to the regulated process of the supply of medicines.

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
- Strongly disagree

The NPA strongly agrees that legislation should mandate clear accountability between the hub/spoke.

Routinely, as part of the supply process, the pharmacist undertakes a risk assessment each time a prescription item is dispensed and supplied.

In a Hub and Spoke arrangement, the Spoke should remain accountable for this process but with specific delegation to the Hub as appropriate.

In instances of inter-company Hub and Spoke arrangements, the NPA suggests that a framework be established to provide the basis for the accountability arrangements of the Hub and Spoke.

As highlighted by the NPA test 4:

a common set of standards should set out the duties and accountabilities of a dispensing hub...

Although one cannot contract out of personal injury, having a clear framework of who is responsible and when, will help in the assessment of legal liability. Also, where there are two (or more) insurers it will also help those insurers determine who should deal with a claim, saving a considerable amount of time/money.

Thus, the NPA suggests that in conjunction with the pharmacy regulator (GPhC/ PSNI), a tripartite conversation including, the Department of Health, the Pharmacy Regulators and Pharmacy Insurers, be enabled to create a template outlining the key patient risks of a Hub and Spoke arrangement from which specific accountabilities can then be established.

As with all significant changes to practice, pharmacies should consult with the professional indemnity provider before proceeding with Hub & Spoke arrangements.

5. Do you have any comments on the proposed requirement for arrangements between the hub and the spoke?

The arrangements should be legislated and should cover the areas of accountability between both parties.

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

The NPA believes that there should be a clear duty for the patient to be informed about any Hub and Spoke arrangements by the pharmacist in the provision of medicines supply.

This, in addition to signs being displayed will in some way mitigate against any complaints and claims from patients who may feel that their data has been breached.

The NPA would also like to confirm that the data protection and compatibility with the Data Protection Act 2018, has been considered by the DHSC as part of this consultation.

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

As outlined in our earlier response, **ONE** pharmacy must take overall responsibility for the patient interaction. This pharmacy should be the service provider for the NHS service (receive the prescription on EPS and claim for it), deal with any patient queries and therefore be identified as the dispenser of the medicine on the label. In this instance, this would be the spoke pharmacy.

Question

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

The NPA has undertaken international research in order to test out the impact of Hub and Spoke. There is very limited published information available on the impact of Hub & Spoke on safety.

Using Hub & Spoke, and particularly when the Hub and Spoke are in different legal entities, introduces potential new risks into the process. A risk management process would need to be undertaken that would allow for the mitigation of any potential concerns.

Careful monitoring, through risk assessments, will be required of Hub & Spoke dispensing to ensure that a different way of working is at least as safe as the established method.

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

The NPA suggests that if the legislation is enabled to allow dispensing doctors to make use of Hub and Spoke, that they should be operating under the same regular standards as those for community pharmacists, and that they also provide pharmaceutical services.

9. 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

As per our arguments in relation to community pharmacy, patients must be presented with information about Hub & Spoke arrangements.

Question

10. 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.

In the absence of further clarification, the NPA argues against the proposal to make changes to the Human Medicines Regulation 2012 to change references, to supplies of medicines “on pharmacy premises” to “at or from pharmacy premises”

The rationale for such a change is not fully outlined in the consultation document, including any impact that this change may have on patient safety.

Also, the NPA suggests that the introduction of the “*At or from*” may lead to a number of interpretations, leading to the emergence of different medication supply models that may or may not involve a registered pharmacy premises, outside the jurisdiction of the pharmacy regulator/s.

For instance, a shared dispensing process (not Hub and Spoke) between two different legal entities, or different supply to patients including the use of locker boxes or the use of another technological hardware.

This may lead to patient safety risks.

The NPA also requires clarification as to how such a change would impact the NHS regulations, terms of service.

In summary, the NPA suggests that this proposal ought to be considered on its own merit, as highlighted in Rebalancing medicines legislation and pharmacy regulation programme: consultation outcome and not part of a consultation pertaining to Hub and Spoke dispensing.

This separate consultation ought to also include further clarification and detail on the implications and jeopardies of changing the proposed term pertaining to community pharmacy.

11. 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 may be limited scenarios in which a Spoke may have a reason to supply to a Hub. The NPA would like the repeal of section 10(7) of the Medicines Act to be reversed, now that the UK is not subject to EU law. The provisions within 10(7) would allow for the transfer of stock from the Spoke to the Hub where that may be necessary, such as to deal with supply issues.

12. 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’?

13. 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?

There needs to be a dynamic and competitive market in which hubs compete based on quality of service and price for the custom of pharmacies that want to operate this model.

It is highly likely only a few companies in the market will be able to provide fully comprehensive external hub dispensing services to pharmacies. This could result in a number of potential unintended consequences, such as:

- The purchasing, dispensing and distribution of medicines could become concentrated in only a handful of hub providers.
- A reduction in competition and choice in the pharmacy and pharmaceutical wholesale markets.
- A negative impact on patient choice of pharmacy if only a few companies have market power and dominance.
- A reduction in the resilience of the medicines supply system and thus potential increases in medicine shortages.

- A potential rise in medicines prices for the NHS, the taxpayer and the public.

As competition and market matters do not come under the remit of the DHSC, we strongly recommend to the Department that they formally consult with the Competition and Markets Authority and seek a market review before and after implementation of the hub and spoke policy.

Impact assessment

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

Question

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

We note that the Impact Assessment suggests that the total savings to the sector's operational cost will be £1m by 2024. This compares with well over a billion pounds being withheld from community pharmacy in England from 2019 to 2024 due to flat funding – based on efficiencies such as Hub & Spoke. This consultation provides evidence for a further review of community pharmacy funding in England, and we call for the lack of efficiencies from Hub & Spoke to lead to additional funding in years four and five of the contract.

The NPA notes that the impact of Hub and Spoke on rural pharmacies does not appear to be fully established within the impact assessment. These pharmacies will be more susceptible to medication delays. This could be further impacted in instances where the hub and spoke are in different parts of the UK, including different countries.

Question

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

Please see appendices that include the various NPA reports and findings on this concept.

Question

16. 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

Question

17. 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?

Having undertaken extensive international research the NPA has not found any evidence of this.

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

19. 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**

The impact assessment appears to be based on a number of assumptions, and the NPA suggest that a robust economic impact assessment also be undertaken as part of this consultation process.

We note that the Impact Assessment suggests that the total savings to the sector's operational cost will be £1m by 2024. This compares with well over a billion pounds being withheld from community pharmacy in England from 2019 to 2024 due to flat funding – based on efficiencies such as Hub & Spoke. This consultation provides evidence for a further review of community pharmacy funding in England, and we call for the lack of efficiencies from Hub & Spoke to lead to additional funding in years four and five of the contract.

Question

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

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?

The impact of Brexit, following the departure of the UK from the European Union, is still being felt in Northern Ireland. Whilst discussions between the UK and the EU around the Northern Ireland Protocol are still to be finalised a number of NPA NI members inform us of the current instability of the medicine supply chain. Amplified by the requirement of FMD compliance, a number of short-line medicine suppliers have ceased trading in Northern Ireland, leading to medicine shortages in some specialised medicines. This instability has also led to an increase in medicine prices.

The MHRA has mitigated against this in some way through the NIMAR process, however, as this has only just been implemented, the full impact of this new mechanism is still to be realised.

It is well documented that a large proportion of medicines supplied through Northern Irish Pharmacies are supplied from England. Thus, how would Hub and Spoke work across Northern Ireland and Great Britain? Would a spoke in Northern Ireland be able to avail of the full services of a GB hub in a seamless fashion in all seasons, as in the case of both the Hub and Spoke being based in Great Britain?

The NPA also suggests that the DHSC consider the implication of Hub and Spoke models, of a Hub based in Northern Ireland supplying the spoke in Great Britain.

Equality assessment

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

The NPA suggests that the following five tests would also go some way to mitigate against any unintended consequences including those pertaining to widening health inequalities, following the set-up of a Hub and Spoke operation within community pharmacy:

1. Hubs must be registered pharmacy premises and meet all GPhC/PSNI standards.
2. Hubs must be prevented from using their trusted position in the supply process to try to circumvent the relationship between the spoke and the patient, for example by using patient dispensing data for other commercial reasons or inserting branding or advertising material into the pack to be supplied to a patient.

3. The current barriers to entry for a hub provider presented by the Direct-To-Pharmacy (DTP) and limited wholesaler schemes must be removed so that any registered provider meeting standards can operate and compete in this market.
4. A common set of standards should set out the duties and accountabilities of a dispensing hub and professional metrics must be collected and published by the hub to assist the spoke in selecting a potential provider.
5. Any mechanism, which is designed to prevent a pharmacy from easily switching hub provider, should be prevented, thus ensuring that pharmacies can drive competitive pressures in this market.