The PDA's response to the UK Department of Health and Social Care and the Northern Ireland Department of Health consultation: 'Hub and spoke dispensing.'

June 2022

Summary

This consultation is around certain legal changes around hub and spoke dispensing. In essence, the Government is consulting on whether hub and spoke dispensing arrangements between parties that are not part of the same legal entity should be allowed. The consultation also asks some questions around patient consent, data handling, governance arrangements between the hub and spoke, labelling requirements and so forth.

A simplistic impact assessment forms part of the consultation together with some questions around this impact assessment.

Introduction and overarching comment.

This consultation is a second attempt by the Government to "consult" on a matter which, during the first attempt exposed a whole range of inter-connected problems and issues which would need to be considered as part of any changes to enable hub and spoke dispensing between parties that are not part of the same legal entity.

This submission builds on our original response of 2016[1] to the first consultation and our focus is on some (not all) of the concerns which still have not been addressed.

We specifically note that in the Government response to the 2016 hub and spoke consultation published in November 2021, there is acceptance that there is not universal acceptance or appetite for these proposals in the pharmacy sector.

> ***"We note there was some support for the proposals."***

Indeed, the analysis of responses revealed that only 28% of all respondents supported the removing of the "impediment" to the use of hub and spoke operation for pharmacies that are no in the same legal entity. The "analysis" of the remaining questions is so rudimentary as to be meaningless.

Medicines are not usual items of commerce, and the safe supply to patients is a complex process with many risks at multiple points in the dispensing pathway.

[1] doh-human-medicines-regulations-consultation-may-2016.pdf (the-pda.org)

Pharmacists and their representative organisations are quite rightly concerned at risks that are being introduced at many of these multiple points along the pathway.

Any attempt to reconfigure this dispensing pathway needs to be properly considered and risk assessed. This is why it is necessary to consider the full wider impact of what may superficially seem a simple proposal.

The consultation is attempting to box-in responses so that the wider impact of the proposals would then "lie outside the scope of the consultation".

This restrictive approach also goes against what was stated by Government when the Medicines and Medical Devices Bill (First sitting) was debated on Monday 8 June 2020. Some Parliamentarians raised concerns around aspects of the Bill including hub and spoke, and there were views expressed that stated that a conclusion had been reached without much discussion. This is what the minister stated in her reply:

> ***"This will be done in consultation with pharmacists, in a discursive way.[2]"***

Most pharmacists are employed, or locum and we highlight the distinction between those, such as ourselves, who speak for the frontline professionals, and those who speak on behalf of pharmacy business owners/shareholders. This commitment was to consult with pharmacists and we believe that the current consultation does not fulfil this assurance from the minister, in that the process now underway does not aim to be discursive. In the consultation document the DHSC now insists:

> ***"Responses that cover areas which lie outside the scope of the consultation will not be analysed or considered in the government's consultation response."***

There are several critical and inter-related matters (pertaining to the supply of medicines) of which hub and spoke dispensing is part. To cut off the promised discursive engagement and to chip away at each of the matters individually would allow these proposals to bypass the true and real impact that they will have on future pharmacy practice. We believe that all inter-related issues which are part of the widening of the use of hub and spoke need to be formally addressed

[2] Medicines and Medical Devices Bill (First sitting) - Hansard - UK Parliament

holistically, to ensure that all benefits are thoroughly assessed alongside the impact of any unintended or previously not-foreseen consequences.

Response to 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 ☑

Hub and spoke operations when both parties are within one legal entity have been operational for over a decade. Despite these hubs being in existence for such a length of time, and despite this consultation being a repeat of the 2016 consultation, the DHSC has still not provided any data about the extent of usage of these existing hubs, nor has it provided any safety data about them. This data could have informed the discussion about these proposals which now seek to widen hub and spoke dispensing to parties that are not within one legal entity. The decisions and outcomes arrived at would have been driven by evidence rather than pre-determined endpoints.

The PDA is not opposed to the use of technology and the levelling of the playing field for pharmacy operators, but this must only be considered in the context of patient safety and not to the detriment of the clinical input that pharmacists provide to the supply of medicines.

The DHSC has failed to provide any evidence that there is any desire or appetite from smaller pharmacy operators for this enabling legislation. In fact, there appears to be significant concern within the independent pharmacy sector that these proposals will, when taken together with other policy measures, lead to a significant reduction in the viability of the existing independent pharmacy network and thus lead to reduced access to pharmacies and pharmacists.

The impact assessments also need to reflect pharmacy models and operations across each of the UK nations. The question whether to remove the impediment in medicines legislation that prevents the operation of hub and spoke dispensing models across different legal entities is too simplistic and needs to be examined through the lens of each UK nation and how strategic decisions taken by the governments in those nations around the role of pharmacists in delivering patient care could be undermined by this change.

Finally, we recommend that these proposals need to be considered in the round by the Competition and Markets Authority for their impact before they are introduced.

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 ☑

Both of the proposed hub and spoke models have the potential to undermine patient contact with pharmacies and pharmacists if not introduced properly and with a broader assessment of the risks and benefits.

The consultation states (without any evidence) that the proposals would free up time for pharmacists to reach vulnerable patients. During the stakeholder consultation, existing users of the hub and spoke model (i.e. those within the same legal entities) confirmed that they had not offered ANY additional services to patients as a result of them operating a hub spoke model for many of their pharmacy premises. This is a statement of fact as admitted in the pre-consultation with stakeholders.

As no evidence has been presented around releases in efficiency, it is unclear how any “freed up time” would be utilised by pharmacists, especially as the Health Departments have not confirmed a plan for any agreed additional services that

could be commissioned from pharmacies were hub and spoke proposals enabled in legislation.

A clue about the actual outcome of existing hub and spoke dispensing can be revealed by considering the recent survey of staffing in English community pharmacies undertaken by Health Education England (HEE). Many large chains already operate hub and spoke dispensing (as they are part of the same legal entity).

The evidence from the HEE surveys shows that pharmacy owners are cutting back on staffing (and even more worryingly trainee staff) and these owners are increasingly relying on pharmacists to work singlehandedly. Far from being freed up – pharmacists are becoming increasingly bogged down into checking off deliveries and such like.

Data from this HEE community pharmacy workforce survey clearly showed that there was a 14% reduction in pharmacy support staff in England in the period 2017-2021. Alongside the reduction in government funding for pharmacies in England, the reduction in support staff could, in part, have been caused by the growing adoption of hub and spoke arrangements within that 4 year period (i.e. more spokes coming on stream within the same legal entities) with these legal entities (who between them own many thousands of pharmacies) choosing to cut staffing at the spokes. We can only surmise that, as the main legal entities utilising large scale hub and spoke models at this time operate in all UK countries, that this would be the case across the home nations.

The very same 2021 survey from HEE showed that there were 5,951 FTE driver positions in existence in 2021 within community pharmacies in England. As pharmacy operators continue to cut their costs, the option to deliver directly to patients from the hubs will ultimately lead to an increase in this whether patients choose this option or not.

In practice this may mean that a GP could send a prescription to a spoke pharmacy, the spoke pharmacy having previously obtained consent from the patient could send the prescription to the hub, and the hub following assembly of the prescription, send it directly to the patient. The patient would have had no contact with a pharmacy or a pharmacist and the opportunity for counselling or advise will be lost. In Scotland the patient would lose contact with the many

pharmacy and public health services provided by pharmacists under the Scottish Pharmacy Contract, not least of which is Pharmacy First.

The point of medicines supply is a key opportunity for pharmaceutical care and this should be enabled, not disabled through the widening use of technology.

The direct to patient hub model also makes a mockery of "making every contact count" where the NHS has the ambition of utilising brief and very brief interventions, at every possible point of contact, to engage patients in conversations about their health. The impact of the loss of these multiple small contacts has not been considered in the consultation document nor in the "impact assessment".

Far from freeing up pharmacist time, it may be the case that the 2 models of hub and spoke gives too much flexibility and results in putting more pressure for a singlehanded pharmacist to do even more low level work (rather than provide services) as there are insufficient staff to carry out non clinical work (like checking deliveries of stock).

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

No.

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

Were these proposals to go ahead, then legislation should mandate that arrangements are in place between hub and spoke in the interests of patient safety. Transformative legislation such as this must be drafted in a way that

provides clarity and certainty for patients, and this will be especially important if a patient comes to harm.

It should not be left to lengthy investigations and blame shifting to determine who was accountable following patient harm – it should be mandated in legislation that clear accountability arrangements MUST be in place before any hub and spoke activity between parties (which are not within the same legal entity) takes place.

The arrangements must specify each step of the end-to-end process and who is responsible and accountable for each specific part within that process. There should be no ambiguity around which party does what and when. Please also see our response to Q5 below.

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

Were these proposals to be adopted then requirements must include:

1/ A clear signed legal document which details every step of the process and where accountability lies for each individual step.

2/ A clear obligation for the parties to document and inform the other of EVERY error/incident they become aware of (irrespective of whether patient harm occurs).

3/ A clear obligation for the hubs to publish and send to every spoke it supplies on a periodic basis (with a requirement that this period must not exceed 3 months) full datasets of every error/incident that it is aware of or has been reported to it. This then informs the spoke on whether it wishes to continue with the contract with the hub in light of the overall error rates at the hub.

4/ The arrangements must be legally appropriate – hub owners will be larger entities when compared to small pharmacies and arrangements must be fair and proportionate in how accountability is distributed.

5/ There should be an overarching presumption of full openness and transparency in the sharing of data between the hub and spoke relating to errors and incidents and it should be mandated that this be so within any legislation.

6/ It should be clear how the pharmaceutical care of patients, such as clinical checks on prescribed and assembled medication, patient contacts and any interventions will be carried out, recorded and managed.

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 NHS Constitution[3] for England states;

> ***"You have the right to transparent, accessible and comparable data on the quality of local healthcare providers, and on outcomes, as compared to others nationally.***
>
> ***You have the right to make choices about the services commissioned by NHS bodies and to information to support these choices. The options available to you will develop over time and depend on your individual needs".***

Patients must have full knowledge of how their medicines are being supplied. As such there must be explicit consent obtained. The explicit consent can be verbal and documented on the spoke pharmacy's patient record system (this is a process which is familiar to pharmacy staff and has been utilised by many pharmacies when patients give verbal consent to their electronic prescriptions being sent to that pharmacy).

[3] https://www.gov.uk/government/publications/the-nhs-constitution-for-england/the-nhs-constitution-for-england

Obtaining explicit consent is not burdensome, it is not costly and it is likely to be a one off event – so it is vital that ALL patients have an option to make an informed choice.

In ADDITION, there must be a clear and prominent notice within the SPOKE pharmacy (whenever any spoke pharmacy enters into a hub and spoke arrangement) and that notice must include full details (including the trading name, company name, and registered address of the legal accountable entity) of all the hubs that the pharmacy has entered into arrangements with. Patients must understand the process and how their requests for medications will be managed to ensure they understand any timing changes and manage their expectations.

The consultation fails to consider situations where, or make specific provisions for, patients who may not want their prescriptions to be dispensed at a hub. Within the United Kingdom there are many geographical areas where there is only one registered pharmacy. The patient must have an absolute right of choice.

As more and more healthcare is being driven online, it is important remember that there are wide sections of the public who do not have access to the internet or have literacy in this area, and this includes people who regularly rely on medicines to help manage or treat a health condition.

We would welcome clarity from the DHSC as to how patient choice can be meaningfully exercised in locations that have only one pharmacy in the locality, as well as how the widening of health inequalities can be avoided through the introduction of this change

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

This question demonstrates the fundamental lack of understanding of the role of pharmacists in ensuring the safe and appropriate dispensing of medicines to patients.

It is seeking to reduce the supply of medicines to a commoditised, mechanical thought-free process, whereas in reality pharmacists perform a vital role in clinically checking each and every prescription prior to it being dispensed (and this includes a repeat prescription which has been issued for periodic dispensing).

A clinical check on every prescription is required before it is dispensed. This clinical check MUST be undertaken by a pharmacist. The clinical check should only be undertaken by the spoke pharmacist as the patient-pharmacist relationship is with the pharmacist at the spoke, and the patient will be registered with the spoke pharmacy. The hub is merely a mechanism by which a prescription may be assembled. The clinical check and issuing of the prescription is a key role for the pharmacist especially giving an opportunity to engage with patients.

As a minimum, the label must therefore specify the name and address of the spoke pharmacy as this is the pharmacy from which the pharmacist will have undertaken the clinical check for appropriateness for that particular prescription.

We strongly disagree that there should be any flexibility and we advocate that the names of BOTH the spoke and the dispensing hub should be present on the label for full clarity.

This is especially important were a spoke pharmacy to utilise the services of more than one hub. If the arrangements allowed for only the name of the spoke to be on the label it may increase the complexity of identifying where an error occurred.

Similarly, many patients use more than one (spoke) pharmacy. Thus, if a hub made an error and sent the item to the patient it should be immediately identifiable which spoke pharmacy had sent the prescription to the hub.

In every case it is important that the correct parties are easily identifiable from the labels on the dispensed medicines. The regulator will need to ensure the meaning of such labelling is clear to patients and their carers.

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

1/ Error Rates:

The consultation document repeatedly mentions that hub and spoke could reduce errors and also states:

> ***"As hubs are focused on routine tasks these can be fine-tuned to limit if not remove errors."***

but fails to provide any credible evidence to support this. The error rate should be transparent and also the type of error, prescribing, dispensing or assembly.

Annex A in the impact assessment around published peer reviewed data relates to hospital robot dispensing which is totally different in scale and remit to the current proposals.

It is incumbent on those making claims that error rates could decline to substantiate this with evidence. The DHSC has had ample opportunity since the publication of the 2016 consultation to arrange independent verification of error rates within existing hubs but has singularly failed to do so.

Instead, it has relied on information which the impact assessment terms "evidence", which cannot be tested and which has been provided by those with a clear commercial interest in the outcome of this consultation.

We thus have no independently verified knowledge of error rates in existing hubs.

Also notable is that the pharmacy regulator, the GPhC has also failed in its obligations to publish full and meaningful inspection reports of all the existing hubs that have been operational for over a decade.

We can only assume that the GPhC fails to understand the operational models in place, and the risks that hubs can pose and is failing to fully risk assess these hubs and their relationship with the spokes, during their inspections.

2/ Regulatory Failure

Furthermore, despite the GPhC being given evidence of a failure by spokes and hubs (within one legal entity) who are following processes which are counter to universally accepted professional practice (which the regulator failed to discover during its own "inspections") – we are not aware of any evidence that the regulator has failed to stop these processes and from this systemic risk continuing.

The PDA wrote an open letter[4] to the GPhC following a significant increase in calls regarding online pharmacy service provision and the deployment of certain automation technologies as part of medicines supply operations.

In their response[5], the regulator welcomed the PDA's comments, and stated;

> "***Given the number and range of concerns raised in your letter, some of which are complex and interrelated, we will take some time to review the information you have provided and carefully consider what regulatory activities would be most appropriate to take, how and when. The concerns you raise are likely to be of interest to a number of other organisations who have a direct remit or interest in these areas. This may need to include some collaborative work going forwards.***
>
> ***In the short term we will be looking into the concerns raised about existing pharmacy operations that may present current risks to patient safety. This will also be helpful to better inform further regulatory activities***".

The PDA remains committed to working collaboratively to mitigate against areas of concern which could have an impact on patient safety, however were the scope of hub and spoke widened as proposed, we are unclear of the current capacity or aptitude of the GPhC to actually undertake meaningful inspections that would be able to follow an end to end dispensing process and whether that process is fit for purpose.

These proposals rely on the aptitude of the GPhC to undertake inspections when it is ***carefully considering what regulatory activities would be most appropriate to take, how and when*** and the apparent failure (through the inspection reports

[4] https://www.the-pda.org/letter-to-gphc-automation-and-safety/
[5] https://www.the-pda.org/reply-from-gphc-automation-and-safety/

available), to understand the existing hub and spoke dispensing and all the separate stages of the process (even within the limited context of hub and spoke within the same legal entity).

3/ Operational Failure (of Hub)

The 2016 hub and spoke consultation noted the

> ***".. potential impact of operational failure in a large scale 'hub', business continuity also needs to be considered."***

This 2022 consultation makes no acknowledgement for how the risks around operational failure would be addressed.

We have one real world example in England of a large online hub which suffered a catastrophic failure. Whilst this was not a hub and spoke operation it was similar to Model 2 in that the online pharmacy dispatched prescriptions directly to patients. Just before Christmas 2015 (and continuing into early 2016) the Company faced a catastrophic failure with severe delays to patients receiving their medicines.

This consultation glibly states:

> ***"We know there is the possibility of 'never events', for example, automation errors, which while extremely rare can potentially have a big impact. Also, the introduction of any new process can potentially increase the risk of errors, but having an agreement in place to ensure the hub and spoke know what each is doing and training for all staff mitigate against any potential risks."***

As evidenced in 2015/2016, a large online pharmacy (the biggest operation of its kind in England) which was reliant on automated dispensing suffered this "never event" and it stopped supplying medicines to its registered patients.

The chaos caused to GP surgeries, 111 services and local community pharmacies, over a busy period just before Christmas, was unprecedented. The regulator has failed to publish any report on lessons to be learnt from this event, despite visiting the premises to undertake an inspection with NHS England.

This consultation demonstrates zero cognisance of this event, which could be classified as a "never event" and merely states:

> ***"We know there is the possibility of 'never events', for example, automation errors, which while extremely rare can potentially have a big impact."***

There seems to be a mindset to overplay the benefits and simply ignore anything which does not fit the chosen narrative.

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

We have no comment.

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

We have no comment.

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.

The amendments are technical changes to facilitate hub and spoke dispensing. In the parliamentary debate to the Medicines and Medical Devices Bill on the 8th June 2020 this observation, recorded in Hansard, was made:

> ***"The argument is going on sector-wide. I do not think that there has been much of a political conversation on it. I cannot remember it in the Conservative manifesto, but I might be wrong. It feels a little bit as though we have reached the conclusion without having done all the work behind it—the Minister may well have done; I mean more generally."***

This consultation feels exactly the same – it has reached a conclusion without taking into account (if it ever intended to) the responses from the first consultation.

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?

This should absolutely not be possible. The integrity of a supply chain is crucial for safety and if hundreds of pharmacies supplied medicines to a hub the likelihood of some catastrophic error occurring increases.

Hubs are by design set up to handle large volumes of individual items. For example, a hub may be dispensing thousands of boxes of a common diabetes medicines daily. The hub would follow a process for these boxes to be entered into a computer system. If these thousands of boxes came from multiple different pharmacies – it would be logistically challenging to enable robotic dispensing with stock with a variety of package sizes, identity markings, barcodes, batch numbers and expiry dates.

The supply arrangements within any hub-spoke arrangement should ONLY be possible in one direction – hub to spoke.

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 implications of cross border operations between spokes and hubs in different nations need to be considered to ensure that there are robust measures and processes in place around contingency plans, for example.

There is a significant issue around the distribution agreements entered into by large pharmaceutical companies who nominate one wholesaler as their sole

distributor. There are also issues when wholesalers impose “quotas” based on data or information which is not disclosed.

Existing hubs are co-located with wholesalers and given the setup and operational costs it is likely that only large vertically integrated wholesalers will be able to setup more hubs to supply their existing customer base (i.e. those pharmacies that are not owned by them).

There are well documented examples of community pharmacies facing problems in receiving medicines needed for their patients because of these issues and the consultation makes no acknowledgement of this well documented distribution issue.

The whole distribution system has evolved into a state of chaos with pharmacies having to send anonymised prescriptions to wholesalers or pharma companies in order for them to receive stock.

If a scaled up to hub dispensing is going to be viable, then there has to be some mechanism to ensure that businesses receive the medicines they need to satisfy prescriptions. This applies equally to those that make use of hubs or those that do not.

The Government has increased visibility of the pharmaceutical wholesale market since the introduction of legislation, Health Service Products (Provision and Disclosure of Information) Regulations 2018[6], which requires mandatory disclose of information about health service medicines. The Government needs to consider imposing duties on pharma companies and wholesalers to supply medicines as ordered by pharmacies (or hubs) without restrictions.

Given that the large vertically integrated pharmacy operators (i.e. these entities own the wholesaler and the community pharmacy) are likely to be the primary operators of hubs there must be provision to ensure that they do not preferentially supply their own pharmacies and restrict access to other pharmacy owners of certain medicines (especially if they are in restricted supply).

We strongly recommend a full and holistic Competition and Markets Authority (CMA) review of the overall medicine distribution network and the restrictive

[6] The Health Service Products (Provision and Disclosure of Information) Regulations 2018 (legislation.gov.uk)

practices that are preventing pharmacists from obtaining medicines for their patients.

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?

The draft statutory instrument must include a provision that the General Pharmaceutical Council (GPhC) must produce detailed standards for these hubs and their relationship with the spoke pharmacies, that inspections of these hubs should be on an annual basis and that the hubs must release data into the public domain about their error rates. This could be achieved by adding an amendment to Part 4 of the Pharmacy Order 2010 as amended by The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016.

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)?

The Impact Assessment is absolutely not fit for purpose.

The full economic assessment outlines the main quantified costs associated with the set-up and operational costs of hubs. These are described as the setup costs for spoke pharmacies reflecting investment in IT systems, training and process redesign. Many very large hubs are already well established, and the impact assessment does not clarify if they are included in the estimates, or how the estimated set-up and operating costs have been reached. It is also unclear about how government funding decisions will be impacted by the adoption of the proposals if they were introduced.

A significant part of the community pharmacy contractual frameworks in each country are based on retention of margin from the procurement of medicines on behalf of the NHS, yet the impact assessment does not look at how each of the financial models would be changed, nor consider options for the future funding model around hub and spoke. This is a significant factor in deciding the scale and scope of the proposals and is fundamental to the viability of the community pharmacy sector, and its ability to fulfil the current and future needs, for example Pharmacy First in Scotland.

The Scottish Pharmacy Contract states that responsibility for clinical and final checks take place at the spoke, with assembly only taking place at the hub. It is imperative that the impact assessment must take account of differences in the devolved nations, in order to reduce the chance of unintended consequence damaging their pharmacy networks.

Will there be a divergence of funding based on whether a contractor decides to engage in hub and spoke or not, and what is the objective if this is the case? The impacts could be different in each UK country, yet this doesn't seem to have been considered.

There is a discussion around the impact of medicines cost but not a single analysis of how this cost of medicines could rise (or fall) in light of the proposals.

Instead, the impact assessment has a superficially detailed analysis of how many items could be dispensed via a hub and a NPV of £27.3m based on a 10-year cycle. There is no analysis of how even a small change in the cost of medicines, which in England alone is currently £8,300,000,000 would wipe out all the "potential savings". A mere 1% increase in the cost of medicines due to reductions in competition would be £83m. We expect there would be much more than a 1% increase in prices and the so-called efficiency gains would be wiped out by the increases in prices that would ensue from reduced competition.

An impact assessment is meaningless and of little value when ALL the potential impacts are not factored in and costed honestly.

We are also disappointed that paragraph 7 on page 5 of the impact assessment confuses automation with hub and spoke dispensing.

Reference 11 within the impact assessment itself acknowledges that there is nothing like the current proposal for hub and spoke in Europe. That reference itself notes existing "hub and spoke" within Europe is primarily concerned with multi-dose compartment dispensing and limited groups of patients.

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

Contract funding arrangements are a fundamental to the future direction of the community pharmacy network in all countries and must be explored as a holistic part of this process. We also suggest that the DHSC includes the impact of small increases in the cost of medicines that would follow reduced competition in the wholesale market.

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

Currently the assumptions are flawed.

The funding element needs to be thoroughly explored to enable contractors to make an informed decision. As there is also no defined legal framework around the roles and responsibilities between each legal entity, it is difficult to build business cases around such proposals. If there was clarity on funding, a clear framework of accountability and governance, and a strong long-term vision around a pipeline of services which facilitates viability, then potential uptake could be properly assumed.

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

There appears to be very little evidence available from the sector already utilising hub and spoke dispensing to be able to fully assess the appetite of others who are currently not. Therefore, this makes sector wide costs and benefits difficult to estimate. What robust evidence has the Department received to build its assumptions around costs?

There is also a strong bias towards the 'potential' of other key non-monetised benefits in relation to the 'main affected groups'. This includes the potential for reduced rates of dispensing errors and associated patient harm and time spent resolving errors, potential for increased clinical service provision reducing pressure in other parts of the healthcare system and health improvement for patients and potential for calmer working environment at the spoke pharmacy to the benefit of staff and patients. All of the claims for potential benefits are unqualified or backed by little published evidence.

Anecdotal evidence from members of the PDA, whether they work in a hub, or spoke environment indicates that these potential benefits may not be at all realistic, indeed the potential for some hub and spoke models to increase the risk of patient harm due to the growing utilisation of standard operating procedures which negate the requirement of a clinical check for each dispensing as part of eRD has been raised with GPhC as a significant concern.

Pharmacists working in spokes where these models are well established also tell us that hub and spoke does not create significant capacity for increased service provision, and their working environment is not calmer. More evidence and evaluation of optimal staffing levels and skill mix is required.

The PDA is not opposed to the introduction of hub and spoke on a larger scale than is currently utilised if it is done so within governance structures and supports the professional role of the pharmacist in ensuring clinical appropriateness and the provision of pharmaceutical care, however the impact assessment needs to be based on factual information.

Hub and spoke is not a silver bullet which can solve all the challenges that are laid out above.

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

No comment

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

No comment

21. 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 ☑

As given in previous responses to questions on the impact assessment.

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

Yes, impact across the devolved UK nations and their contractual and service delivery models.

As already mentioned, funding considerations and the potential impact on medicines budget.

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.

23. 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?

No comment.

24. 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.

No comment.

Equality assessment

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

The DHSC needs to consider that while pharmacy operators may decide to take up the option of hub and spoke, this must be fully transparent to patients. The emphasis around the increasing use of technology in healthcare delivery needs to consider the access to IT, equipment and devices and tech literacy of patients interacting with the NHS. Assumptions need to consider how patients will interact within the proposed models and the support and assistance that they may need.

About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for profit defence association and trade union for pharmacists. It is the only organisation that exclusively looks after the interests of employee and locum pharmacists across all sectors of pharmacy. Currently with a membership of more than 34,000, the PDA is the largest independent representative membership body for employed and locum pharmacists in the UK and this membership continues to grow.

Delivering more than 5,000 episodes of support provided to members who have found themselves in a critical incident situation in the last year alone, provides the PDA with a rich vein of up-to-date experiences which have informed policies and future strategy.

This experience has recently been informed by the very considerable number of Covid-19 related issues being faced by members. The practical experience gained in supporting member issues from the coal face is further enhanced by regular member surveys and focus group interactions. The information in this document is largely built upon the experience of our 34,000 members.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Arrange insurance cover for individual pharmacists to safeguard and defend their reputation.