Response

Hub and Spoke Dispensing

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About the Company Chemists' Association (CCA)

Established in 1898, the CCA is the trade association for large pharmacy operators in England, Scotland and Wales. The CCA membership includes ASDA, Boots, LloydsPharmacy, Morrisons, Rowlands Pharmacy, Superdrug, Tesco, and Well, who between them own and operate around 6,000 pharmacies, which represents nearly half the market. CCA members deliver a broad range of healthcare and wellbeing services, from a variety of locations and settings, as well as dispensing almost 500 million NHS prescription items every year. The CCA represents the interests of its members and brings together their unique skills, knowledge, and scale for the benefit of community pharmacy, the NHS, patients and the public.

- **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 or disagree
Disagree
Strongly disagree

- **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 or disagree
Disagree
Strongly disagree

- **Are there any further hub and spoke models which should be considered?**

There are no additional models which should be considered. However, we wish to raise concerns about the second proposed model and its possible unintended impact to undermine current market entry processes. Distance Selling Pharmacies have clear requirements within current regulations (England). However, the second model proposed here confuses that line between physical and distance selling pharmacies. We suggest that there is a need to carefully consider unintended impacts, before making a decision on whether or not to adopt model 2. This is especially the case in the devolved nations as policy direction varies to that of England and this consultation appears to focus on the impact in England.

- **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 or disagree
Disagree
Strongly disagree

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

To allow safe and effective provision of Hub and Spoke services between legal entities there is a need for clear division of all responsibilities that sit within the dispensing process. To ensure this is consistently present across the country, there is a need for there to be an obligation to have an agreement which formalises this to be mandated in the regulations. The regulations do not need to specify the exacting requirements between legal entities. We believe that frameworks which govern these arrangements should sit within regulations, to be determined and monitored by the regulator, the GPhC. The practicalities for providing dispensing services should remain a commercial agreement between the Hub and the Spoke, with no further legal detail beyond the need for their presence and remit.

- **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 or disagree
Disagree
Strongly disagree

- **Please provide a reason for your answer and any evidence to support it**

We do not believe that the organisation/operations of individual steps within the dispensing process is of key interest to many patients. However, it is essential that patients have no doubt who is responsible for the dispensing of their medication. Patients need certainty in who to contact in the event of a query. This should be the same place/entity whether it is a concern regarding an error, query over the process, or a clinical/health related question.

One of the objectives for this change (as set out in the Impact Assessment) is allowing additional operational efficacies. This means enabling contractors to find different operating models to provide safe dispensing services. Many of the CCA's members already utilise Hub and Spoke facilities within their own businesses. During introduction of these services, patients were made aware of the change through a variety of different methods. Whilst some individuals will express interest, most patients have limited curiosity in the detailed operations of safe dispensing. Providing the information in a format that allows those patients with an interest to find out more, is the most pragmatic option. Any requirement to proactively inform individual patients of dispensing processes

risks reducing the possible operational benefits, confusing patients, and a loss of confidence in the dispensing process (given the likely confusion this may cause).

We note that the consultation also allows for a Spoke to use multiple Hubs. Whilst welcome, this further complication makes proactively and individually informing patients about Hub and Spoke arrangements even more confusing. Pharmacy teams may be uncertain which items are likely to be dispensed on-site or, if off-site, at which Hub at the point of initial patient engagement. As stated, clarity in how and where to raise queries is essential. This makes the proposed option (a simple and clear notice to patients) the most pragmatic approach.

- **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 or disagree
Disagree
Strongly disagree

- **Please provide a reason for your answer and any evidence to support it**

It is important that the requirement here is clear that the label must display only one name and address (not two). The label on dispensed medication should provide the patient with the necessary information to contact a pharmacy team with queries relating to that medicine. Answering queries would require both professional/pharmaceutical knowledge and training, as well as awareness of the dispensing process of that medication (and any possible explanations for errors or otherwise). This is almost certainly the pharmacy from which supply was made, which in model 1 is the Spoke pharmacy (as currently). If model 2 was in effect this could theoretically mean the Hub's details would be provided. Future innovations in technology or operating models may change this. We would expect Hubs and Spokes to agree this between themselves as part of any commercial agreement.

Aside from practical concerns of physically displaying multiple names and addresses on dispensing labels, two details will likely cause further confusion. As with the previous question on patient displayed information, there must be no doubt as to who the patient must contact to raise a query.

- **Do you think that these proposals raise any issues regarding patient safety?**

Yes
No
I'm not sure

- **Please provide a reason for your answer and any evidence to support it**

We believe that it is worth noting that community pharmacy is an extremely safe clinical environment, with very low error rates. When compared with pharmacy sectors across the world, the UK performs favourably. Furthermore, there are likely different patient safety benefits provided by automation versus manual dispensing. Evidence from our members does indicate that automation at scale can reduce total errors by increasing the safety profile of dispensed medicines and reducing errors at the (now lower dispensing volume) spoke.

The introduction and adoption of any new operating process, especially one that introduces complexity and the transference of data and products between legal entities could initially introduce the risk of errors and new types of errors occurring. Experience has shown that significant investment is required in quality assurance to ensure that any initial teething problems are identified and rapidly overcome. There is some concern that Hub and Spoke errors, whilst less frequent, may impact more patients when they do occur. CCA members have significant experience in managing large Hub and Spoke operations and have made many changes responding to learnings throughout that time, including reducing the chance of compounded errors affecting many patients. It is unlikely that new entrants to the market will have the benefit of this experience, and so the risk of error from a new entrant is higher than that currently observed. This will likely improve over time but remains a factor if a commercial market develops with regular new entrants.

Understanding and investigating incidents is a critical way of improving safety and one concern is how easy this will be across legal entities. The transparency of the whole process to both pharmacies and patients is vital to enable the patient safety benefits.

There are additional patient safety considerations to using Hub and Spoke arrangements, including timeliness of dispensing, communication and visibility, and record keeping. However, all these considerations should be part of any risk management exercise completed, as part of safe dispensing. We would expect the regulator to set the standards for dispensing, regardless of location, and for pharmacies to demonstrate how they meet these during inspections.

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

It is important that the regulations mandate where accountability lies between a pharmacy and dispensing doctor. As these two entities will have different regulators, it is important that there is consistency across and between regulators.

- **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?**

Agree
Disagree
Not sure

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

Reviewing the proposed new wording, it is our belief that there may have been an error made. Section 222A (3) reads "this paragraph applies if the retailer has not entered into arrangements (whether or not legally binding)". This should be the opposite, and the word "not" needs to be removed.

- **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?**

The CCA believes that this should not be considered as part of this legislative change. Supply from the spoke to the hub will create an additional layer of complexity with minimal benefits. The need for a wholesale license creates added complexity that is not needed at this time.

- **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'**

We note that in the second proposed model (the supply of prescriptions directly from hubs to patients) raises additional considerations. Many patients attend pharmacies to collect their own medication, with private delivery services remaining a small proportion of the total dispensing volume. Many of these patient journeys are either by foot/bicycle or incorporated into other travel.

If adopted at scale the second proposed Hub and Spoke model will likely dramatically increase the total volume of vehicular traffic and have implications for NHS Net Zero ambitions. The first model uses existing links that bulk transport medicines from hubs to spokes. Whilst our members have seen an increase in total volume (due to the 'air' in dispensed medication packages) this can be accommodated within the existing wholesale/postal distribution. The second model, however, will likely have significant impacts on emissions produced overall within the medicines supply chain.

- **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?**

When reviewing the consultation, it appears to take an 'English-centric' view of the changes. The impact assessment links to the English Community Pharmacy Contractual Framework (CPCF) and the role of PSNC. This legislation will apply across the UK and there is a need to consider how it may impact on countries other than England. For instance, both Scotland and Wales have clearly expressed intentions to support the physical access to healthcare

through community pharmacies. Different mechanisms are used to support this, but this consultation does not fully consider this nuance.

The proposed second model, where medicines travel from a Hub directly to a patient, may have unintended consequences on market entry. The ability to create Hubs supplying medications directly to the patient could foreseeably create a scenario where there are many 'non-NHS' businesses/locations supplying NHS prescriptions. A pharmacy Hub could be opened on a high street with open access to the public but would not require an NHS contract. However, with this proposal that pharmacy location may supply NHS prescriptions.

Furthermore, the second model introduces a pseudo-DSP model via the back door. In Wales in particular, it is our understanding that the Welsh government wants to continue to ensure that people visit pharmacies to receive services; option 2 undermines that intention. Moreover, many pharmacy service designs (across Great Britain) assume patient attendance at pharmacies. It is this accessible provision and frequent touch points that makes many pharmacy services so attractive to commissioners. We suggest that DHSC engages more widely with devolved administrations and the relevant pharmacy negotiating bodies as option 2 may undermine contractual frameworks in those nations and make this option more unpalatable.

There is a risk that this may have a detrimental impact on market entry, with patients being uncertain whether a pharmacy is providing NHS care or not. This also risks wider efforts to promote community pharmacy as a first port of call, particularly for NHS commissioned services such as Common Ailments in Wales, Pharmacy First in Scotland, and the Community Pharmacist Consultation Service in England. We suggest that linked regulations, such as controls to market entry, are reviewed in tangent to any changes proposed here.

In particular, it is our view that the patient-pharmacy relationship should be between a Spoke and patient. Accordingly, we believe that the NHS contract must be held by the Spoke (and not the Hub).

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

It is likely that the solutions and business models' contractors and others choose to adopt will be shaped by the market. However, it is important to note that the modelling undertaken was completed before the recent changes to the economic environment. The 'cost of doing business' has risen sharply through inflation, increased costs to workforce, transport, and other factors. These increased costs could not have been accounted for but likely change how the market can and will adopt/respond to this legislative change.

When considering the implementation of Hub and Spoke solutions there are a few factors not incorporated into the impact assessment. For instance, integration with PMRs is a vital step to changing how dispensing is undertaken. This is extremely costly in both time and development costs but is not reflected in the impact assessment. This is not always about identifying obvious errors, but a need to quality check dispensing at a significant volume to ensure that low-incident errors are identified. With Hub and Spoke operations across (multiple) legal entities, there will likely need to be integration and testing with multiple PMR

systems. This magnifies the costs and complexity of Hub and Spoke provision above that experienced already by CCA members.

Furthermore, when considering the operating costs of Hubs, additional costs such as validation, operational infrastructure, ongoing maintenance, and business continuity have not been accounted for. These costs will vary widely depending on the exact business, making estimating them difficult. Again, these may be further magnified when working across legal entities.

We note the costs cited of £4,000 to support training and IT within a Spoke. We believe this may have been estimated for a 'simple' original pack Hub and Spoke system. Some CCA members have implemented more complicated Hub and Spoke arrangements, such as a 'pouching' system for compliance aids. The training and other Spoke requirements for these systems are much more onerous. There is also no reference to the work and associated costs outside of a pharmacy to support the implementation of new processes. This may be through data validation, operational queries, issue resolution etc. Quantifying this is difficult, but nonetheless remains another cost.

The complexity of different patients requires further consideration. Many patients have a mix of dispensed medication, including original packs, eyes drops, creams, large bottles of liquids, refrigerated items etc. This mixture of items creates additional complexity and cost. Many Hub and Spoke models appear to assume entirely original pack dispensing, and the assumptions within the impact assessment seem based on that. Future models may account for this mixture in different ways, or possibly future legislative changes allowing original pack dispensing may add additional complexity and costs.

It's also important to consider some of the external factors that impact the utilisation of Hub and Spoke dispensing. Patient need, and urgency, will of course influence which prescriptions should be dispensed off site. However, other factors such as the time taken to receive a prescription from a prescriber following a patient request will also impact this. Hub and Spoke systems are facilitated by electronic prescriptions for either operational or technical reasons. Electronci prescriptions are common (but not universal) in England, but not available in Scotland or Wales at present. Pharmacies cannot influence the usage of electronic prescriptions. The uncertain time scales to EPS systems in Wales and Scotland makes estimating the uptake of Hub and Spoke outside England difficult.

There are several (reasonable) assumptions made in the impact assessment, but there are instances where further assumptions are then made upon these, weakening the confidence of the conclusions. We encourage a review of the impact of any legislation change after the market has had time to adapt. We also note that the not-insignificant costs associated with the initial set up costs of hubs are not incorporated. Whilst the impact assessment attempts to include this with the operating costs, this does not recognise the substantial up-front costs required.

Hub and Spoke dispensing has never been undertaken across legal entities before, which makes predicting the impact and cost very difficult. However, without a secure financial future for community pharmacy it is difficult to understand how businesses could currently make any investment of the magnitude required here. The possible gains are not clear, casting doubt on any future market provision.

CCA members have repeatedly shared that Hub and Spoke arrangements do not provide financial benefits. There is, however, the potential for widespread use of Hubs to create capacity in the spoke pharmacies. Any theoretical financial benefits rely on using the capacity created to earn additional money elsewhere. The financial calculations set out do not appear to account for either, fixed costs (rates, rent etc.) that must be attributed to dispensing (the impact assessment considers a 40% time saving of total costs) or the minimum staffing levels required in a Spoke. Regardless of the dispensing volume moved to a Hub, for security and regulatory purposes there must remain a base level of staffing that cannot be removed.

The Impact Assessment cites an increased opportunity to generate income by providing clinical services, however the funding for community pharmacy in England is currently fixed, meaning the sector is unlikely to benefit from this opportunity. Previous answers have considered the alternate challenges that may be found in Wales and Scotland. There are other references to private and local services. Whilst local service provision may well form a growing part of community pharmacy funding, its variable nature makes national level predictions difficult. We estimate it will require a doubling in current local service income to support the necessary changes. Similarly, whilst private services already exist and may grow within the market, this opportunity is not available uniformly. Community pharmacy has a recognised, vital role in supporting health inequalities. Pharmacies located in the most deprived areas are less likely to benefit from private services – disadvantaging those pharmacies. This is contrary to NHS and government strategies to level up across the country and tackle health inequalities.

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

No response

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

We cannot comment on how the market may react to changes in this legislation. However, given the costs of setting up new hubs and the previously cited recently increasing costs of doing business, the impact of the change of legislation will need reviewing after it is made.

- **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?**

There are likely additional costs to sector-wide implementation of Hub and Spoke services. Contracting across legal entities adds risks, the need for assurances, and additional processes, which add costs to the model. Furthermore, both parties will need to ensure it is financially viable. This means there will be a need to be able to generate a reasonable return, which is very unlikely within a constrained financial envelope. Hubs will need to engage in normal business practices such as marketing and competing to secure business, all of which are not required with the existing models.

The added complexity of Hub and Spoke across legal entities is unknown and unexplored. We do not know which models will be explored by the market. These facts combined suggest that the benefits of Hub and Spoke are likely reduced and may well take longer to realise than predicted.

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

No

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

The implementation of Hub and Spoke operations requires a high cash investment, which considering a fixed funding envelop (in England) and a recently rapidly increased cost of business, appears less attractive. It is likely that the market will develop models not yet considered and the implications of these will need to be assessed as evidence becomes available. If there is a strong desire to see Hub and Spoke adopted rapidly across the country the DHSC should consider investing and pump-priming the system.

Many of the costs of operating across legal entities are unknown. Some can be predicted, such as legal costs. The need for a legal agreement between the two parties is an added cost to this cross-legal entity model. There are probably also yet undefined costs associated with governance agreements.

Finally, the setup of Hubs has additional management costs which depend greatly on the model and business. This is compounded by the possible development of new or different Hub and Spoke operations such as the 'pouching' system referenced earlier. Combined this makes assessment of the figures used difficult. It is important to note that the potential savings are very small in the context of overall community pharmacy funding.

Our members report an opportunity offered through Hub and Spoke to move workload away from frontline pharmacies. This is not a complete transfer of workload, as some activity will remain with the Spoke such as (dependent on the operational model) data entry, pharmacist checks, and patient support. There are also new processes to add to Spokes, such as checking, and processing prescriptions dispensed off-site. Despite this there remains the potential for capacity gains. This could create the capacity to complete further activity, such as clinical services. It is important to note that any workload moved from the Spoke to a Hub will take the cost of dispensing with it. Therefore, any capacity released in the Spoke will need additional funding if that clinical capacity is to be retained. Without additional opportunities to earn with the capacity of the spoke it is difficult to quantify financial benefits or operational incentives that could generate the business case to justify an uptake in Hub and Spoke.

Whilst using the proposed models remains entirely optional, we are concerned about the inferred link to clinical care within national NHS contracts. We are very clear that hub and spoke models do not reduce the overall cost of supply (it is simply moved to the Hub). We encourage commissioners to consider how to invest new funding into the delivery of clinical services in pharmacies. Only through the creation of a clinical service led model for spokes can the workload and funding of supply be moved to hubs.

- **Do you think there are any other impacts that we have not considered?**

No