

The Association of Independent Multiple Pharmacies response to the Department of Health and Social Care's consultation on Hub and Spoke

Consultation questions

Respond to the questions asked within the scope of this consultation. Responses that cover areas which lie outside the scope of the consultation will not be analysed or considered in the government's consultation response. If possible, cite evidence to support your views. If you are opposed to the proposal, provide alternative suggestions that would help the government to achieve its objectives.

Question

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

Question

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

Question

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

We need to accept that ETP and use of patient Apps will allow there to be variations on the two models, such as;

Hubs delivering direct to secure lockers for collection- these might or might not be on pharmacy premises.

Co-assembly hubs might spring up which specialise in difficult prescriptions such as controlled drugs so more than one hub might be engaged in assembling prescriptions, (in the way that appliance contractors currently specialise). In this case the main hub might transfer part of the prescription to a secondary hub.

Business interruption hubs- if the regular hub fails because it is too expensive to maintain a back-up redundant system, there might be contractual arrangements in place for a secondary hub to be used, in this case the original hub might transfer the whole prescription to that secondary hub.

Question



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

Question

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

Accountability: between the hub RP and spoke RP is going to be critical for patient safety, legal compliances, any investigations from errors and to prevent anyone trying to save money by cutting corners. The regulations need to be very clear on who is professionally accountable for what part of the process. If something goes wrong and a patient comes to harm, the appropriate person needs to know that they had accountability for it.

Supervision: Supervision between the Hub pharmacist and the spoke pharmacist should be shared and clearly stated by an agreement in an SOP.

Patient safety; the number of patients per pharmacist at all hubs- including DSP's, needs to be limited and regulated by the GPhC. This is because there can be a clear commercial advantage for a hub operating to say 100,000 patients per pharmacist versus a hub operating to 10,000 patients per pharmacist. Any lack of regulation on this might lead to a race to the bottom on pharmacists costs. There is another incentive to race to the bottom due to the current pharmacist work force shortage.

Training: Training on delivering medicines safely & effectively direct to patients should apply fully to all Hubs- including DSP's.

Delivery: Minimum standard for delivery by mail must be a "tracked and signed for" package so to be reasonably certain medicines are delivered into the hand of the intended recipient- as per existing regulations. Clearly an untracked and unsigned package can not be guaranteed to finish in the hands of the intended recipient.

Temperature management standards: From dispensing point to patient must be stated by the MHRA. The MHRA are responsible for medicines reaching the patient in a safe condition but currently do not involve themselves in temperature management after a wholesale license holder supplies a pharmacy hub. This is clear double standards and could lead to MHRA license holders "levelling down" on regulation rather than have all the extra cost and disruption such as Enterprise OTC had recently.

Controlled Drugs; What is and is not allowed within a Hub for controlled drugs should be clearly stated by the GPhC.

Question



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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

Patient Consent; Consent for a patient to be dispensed by a (legally separate) Hub should be to the standard of “informed consent” as defined by GDPR (for consistency GDPR is a reasonable standard to pick). If this standard is demanded and enforced, then a notice is superfluous.

Question

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 is a simple decision to make, individual community pharmacists are clearly capable of making the decision that they feel works best for their circumstances and patients.

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

However, we believe this only if there is detailed accountability, policed by strong and consistent regulation, of all hub pharmacies and of the hub RP and spoke RP.

Question

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

Question

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

Question

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.

Impact assessment P8.20 references Distance Selling Pharmacies (DSP's) and P8.21 states that ... distant selling pharmacies would benefit from the proposed changes in legislation..... It is clear therefore that all models involving a prescription being assembled from any type of hub should be included in the consultation and subject to the same regulations. There must be a level regulatory playing field between DSP and community pharmacy hub and spoke models. Allowing a regulatory competitive advantage to DTP hubs might lead to community pharmacy closures which will in turn lead to unemployment and a reduction in the care services in those local communities which are usually in areas of higher deprivation.

Medicines Packs: Split packs must end for safety and efficiency reasons. They are incompatible with robotic systems and stopping them will allow a greater percentage of medicines to be dispensed by the automated dispensing systems.

Dispensing: Pharmacists should be able to exercise their professional judgement to round up or down by one weeks treatment. This would bring an advantage of Pharmacists being able to align patient's medication, where a new medication is prescribed out of sync., with their existing repeat medication. The pharmacist could use their professional judgement to increase or decrease the prescribed quantity to provide the patient with sufficient of the new medication until their regular repeats are due to be ordered. This would allow all the patients items to be ordered together. *(as per AIM response to Open consultation Original pack dispensing and supply of medicines containing sodium valproate 2021 1104).*

Manufacturing: Medicines must only be manufactured in 28-day packs as this will increase the amount of medicines that can be dispensed by the robotic dispensing machines.

Manufacturing: Bulk tubs of tablets should be made more widely available and at comparable price to original packs because monitored dose robotic systems need the tablets to be de-blistered and put into cassettes, this is clearly highly inefficient, wasteful, adds to the carbon footprint and creates safety risks. These bulk packs should not be used for pricing until use is widely established.

Manufacturing: Manufacturers/wholesalers must be made to proactively agree quota redistribution from pharmacy to Hub. At present manufacturers are generally recalcitrant and unhelpful with this and while it is a arguably an abuse of their dominant market position, community pharmacists are way too busy and lack the expertise to spend their time referring anti-competitive practises by manufacturers to the Competition and Markets Authority.

Prescribing: Medicines must only be prescribed as 28-day multiples as this will increase the amount of medicine that can be dispensed by the robotic dispensing machines.



Remuneration: Remuneration must always be paid as dispensed and not as prescribed.

HUB sharing: To maintain business continuity through hub breakdowns, hub operators need to be allowed to legally co-operate and have contractual agreements to allow sharing of production because it is unrealistic to expect a level of investment that allows a complete set of redundant back up robotics in the event of failure.

HUB registration: Hubs must be a premises registered with the MHRA or GPhC.

Hub Dispensing: Can only take place from pharmacy premises registered and inspected by the GPhC.

Dispensing: Of each medicine must be carried out under the supervision of a pharmacist.

Lockers & Collection points; Lockers should be limited to the supply and collection of dispensed medicines at or from a Pharmacy registered premises. The current regulations for lockers are perverse and open for abuse in that contractors are asked to de-register a footprint at the periphery of the registered premises for a locker. Lockers should always be on registered premises. The provision of medicines through lockers should be anchored in Pharmacies.

Question

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?

Pharmaceutical supply chains can be fragile, as evidenced by the persistent shortages in recent years. The more potential supply opportunities of medicines there are then the greater is our capacity to complete prescriptions. It clearly makes sense to allow the spokes to supply their hubs with product that they might have and the hub might not have.

Question

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 believe that MHRA regulations for all the above should apply throughout the supply chain, into the hands of the patients. It is hard to argue against this, particularly in respect of chilled items which in a direct to patient delivery chain can languish in delivery depots, unmonitored, for unspecified amounts of time.

Question

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?

Impact assessment

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



When a spoke pharmacy is using a third party hub there needs to be legal protection preventing the hub from using the patient data to try to set up a direct relationship with the patient, filling their future prescriptions and excluding the hub from that.

Question

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

Costs P2;

The pressures of competition and unintended outcomes from the legislative change might force pharmacies into reactive and unplanned expenditure into Hub models (either alone or collaboratively with other pharmacies) and ROCE might be neglected leading to financial harm to their businesses and even closure. Under the current funding regime pharmacy income is so tight that there is zero margin for failures with business matters such as ROCE. Community pharmacists are trained healthcare professionals, not trained businesspeople and likely to fall into such financial pitfalls.

The time and complexity in matching up part completed prescriptions in branch has not been sufficiently investigated. Page 13.40 of the impact assessment suggests 40-60% of items can go through the hub but does not review how many of these would result in part prescriptions that would need to be completed at the spoke. This is sufficiently disruptive and costly to need a dedicated financial model.

Full economic assessment P3;

The “low take up” cost number stated is totally unrealistic when compared against the costs of buying Hub robotics, making premises changes and giving staff training. Viewed against the background of the number of pharmacies in the group that it potentially applies to (P5.7 & P7.17) it will obviously be a much higher cost.

The “low take up” also neglects to consider that pharmacies smaller than the assumed volumes in the impact assessment necessary to support a hub, might consolidate into co-operatives and jointly invest in hubs, to react against competitive pressures. Third party models are not always going to be trusted with patient data by sole traders as they might fear that data will be used to “steal” their patients.

Possible activities of disruptors are not predicted or modelled. Legislative change always opens doors for disruptors to challenge boundaries until they are established in legal precedents. That has happened in the recent past as a result of legislative change to the control of entry regulations, it is unrealistic to not expect that to happen again with this legislative change.

Likely number of hubs P15.53 “A collaborative hub will not require additional capital except for the introduction of automation”, this assumption is incorrect, pharmacies are structured and set up for their current work flows so moving significant numbers of prescriptions to a hub will mean those workflows will have to change. For instance, staff will have to be re-trained and re-deployed, taking on more professional services will require re-structuring and refitting of the pharmacy, etc., etc. It is impossible to effect organisation and structural change without incurring costs.

Question

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

Many of our members operate Hub & Spoke models, some of them have done so for 12 years, we have a wealth of experience to help with cost-benefit analysis, please ask us.

Question

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

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?

I am not aware of anyone in our sector who has experience of implementing hub and spoke that has been asked to supply detailed costs and benefits information therefore we do not believe the data you have gathered is properly representative. As we believe the data gathered is incomplete it renders the future modelling inaccurate. There has also been neglect of modelling un-intended outcomes of legislative change, a good example of this from the recent past is the wide ranging and very damaging un-intended outcomes caused by disruptors behaviour from legislative change on the control of entry regulations.

Question

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

Our members have a significant amount of information on this subject. Please ask us.

Question

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

Question

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



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Our members would have significant insights into this if we are asked.

Final observation: We are concerned that the introduction to this consultation states *“In your response to questions in the consultation, please do not include any information that could identify you or somebody else. For example, do not include anyone's name, age, job title or email address where it is not asked for.”* This anonymity can potentially allow an organisation or pressure group to complete multiple responses supporting their preferred views and so it surely allows for potential manipulation of this consultation?