



PSNC response to the Department of Health and Social Care's consultation on – hub and spoke dispensing

June 2022

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Introduction

The Pharmaceutical Services Negotiating Committee (PSNC) promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health and Social Care as the body that represents NHS pharmacy contractors. We work closely with Local Pharmaceutical Committees to support their role as the local NHS representative organisations.

Our goal is to develop the NHS community pharmacy service, and to enable community pharmacies to offer an increased range of high quality and fully funded services; services that meet the needs of local communities, provide good value for the NHS and deliver excellent health outcomes for patients.

We welcome the opportunity to be able to provide our response to the proposals set out in the Department of Health and Social Care's (DHSC's) consultation on **hub and spoke dispensing**.

We ask that our response as a national organisation representing all community pharmacies is given appropriate weight against other responses from, for example, individuals.

Summary

In principle, PSNC supports appropriate changes to the Medicines Act 1968 and Human Medicines Regulations 2012 (HMRs) to introduce hub and spoke dispensing between different retail pharmacy businesses, as anticipated in the 5-year community pharmacy contractual framework deal¹.

We have changed our position since 2016 primarily due to assurances from DHSC that it will *agree with PSNC which models will allow the whole sector to benefit fairly* – including larger pharmacy businesses already carrying on hub and spoke dispensing, and smaller, independent pharmacy businesses that could realistically only carry on hub and spoke dispensing with a separate (usually large, remote) hub pharmacy business, which may be associated with competitors. But also partly due to changes in the applicability of European legislation. We have always maintained that hub and spoke dispensing should be safe for patients.

PSNC considers that only Model 1 is appropriate, with manageable risks relating to patient safety, and is a model that has the potential to allow the whole sector to benefit fairly.

Our key observations are:

Patient safety

¹ The Community Pharmacy Contractual Framework for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan <https://www.gov.uk/government/publications/community-pharmacy-contractual-framework-2019-to-2024>

- Model 2 in the consultation, a hub direct to patient supply of dispensed medicines, raises patient safety issues and we cannot support this model.
- Remote, national supply pharmacies with no physical access for patients are already available as a choice for patients, for both private and NHS prescriptions.

Efficiencies

- There are virtually no financial efficiencies envisaged by these - hub and spoke dispensing – proposals, and , if used, are more likely to add cost to the community pharmacy sector.
- The value to the NHS and society of medicines supply through spoke pharmacies and the value to the public purse of community pharmacy purchasing of generic medicines should also be considered.

Legislation

- Aspects of the proposed legislation are not clear or ambiguous and require further consideration to ensure there are no unintended consequences, particularly associated with Model 2 in the consultation.
- Specifically, the wholesale licensing requirements could be disapplied to supplies of assembled medicines from hubs to spokes (with any necessary amendment of the rules around the assembly of medicines, particularly their labelling) rather than describe a new type of retail supply which is complex and potentially confusing.
- (and to assist small wholesale supplies of medicines between pharmacies, to alleviate temporary local shortages, pharmacies could be permitted to make wholesale supplies - rather than have to rely on the discretion of relevant authorities not to prosecute if certain criteria are met.)

'At or from'

- There should be no change to Section 220 of the HMRs and pharmacist supervision of supply prior to:
 - the envisaged consultation on skill mix later this year²; and
 - confirmation of the meaning of 'at or from' and the scope of *collection and delivery arrangements* (Section 248 of the HMRs) - an exception to supply at a pharmacy and under the supervision of a pharmacist.

NHS

- We consider that market entry concerns around Model 2 in the consultation, including the proliferation of hub pharmacies, would be problematic to address in NHS Pharmaceutical Regulations. Noting that this is not the subject of this consultation.

² Consultation outcome **Rebalancing medicines legislation and pharmacy regulation programme: consultation outcome** Updated 28 April 2022 <https://www.gov.uk/government/consultations/pharmacy-legislation-on-dispensing-errors-and-organisational-governance/outcome/rebalancing-medicines-legislation-and-pharmacy-regulation-programme-consultation-outcome>

Background

In 2019, PSNC agreed the *Community Pharmacy Contractual Framework for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan* (the 5-year deal) with DHSC and NHS England and NHS Improvement (NHSE&I).

One aspect of the 5-year deal was that:

1. This agreement between the Government, the NHS and the Pharmaceutical Services Negotiating Committee (PSNC) describes our joint vision for how community pharmacy will support delivery of the NHS Long Term Plan. The deal:

- *... Recognises that an expanded service role **is dependent on action to release pharmacist capacity** from existing work. The deal rationalises existing services and commits all parties to action which will maximise the opportunities of automation and developments in information technology and skill mix, to deliver efficiencies in dispensing and services that release pharmacist time ...*

And

31. A new and expanded role for community pharmacy will require the sector to adopt new and different ways of working. In particular, we need dispensing to become more efficient to free pharmacists up to provide new services, working at the top of their clinical licence in a way that is both more rewarding professionally but also adds maximum benefit for patients.

32. To help achieve this, we have agreed that with the support of PSNC, the Government will ... pursue legislative change to allow all pharmacies to benefit from more efficient hub and spoke dispensing, enabling increased use of automation and all the benefits that that brings. As part of this we will agree with PSNC which models will allow the whole sector to benefit fairly; [as well as other potential efficiencies – financial and/or activity saving]

We recognise that hub and spoke dispensing can provide activity saving and free up pharmacists time for other clinical services, for some community pharmacy contractors.

Hub and spoke dispensing already provided within pharmacy businesses

The consultation recognises that hub and spoke dispensing is already carried on in community pharmacy stating:

- *Section 10 of the Medicines Act 1968 provides for hub and spoke dispensing if the hub and the spoke pharmacy are both part of the same retail pharmacy business. Section 10 provides an exemption from the need for a manufacturing licence for the assembly or preparation of*

medicinal products in a registered pharmacy and from the need for the resulting medicinal product to have a marketing authorisation. This means these exemptions apply where the activities are done with a view to sell or supply the product from the same pharmacy or one which forms part of the same business.

The current exemption is from:

- *the need for a manufacturing licence for the assembly or preparation of medicinal products in a registered pharmacy and*
- *the need for the resulting medicinal product to have a marketing authorisation.*

Notable is that the current exemption is for the preparatory stages of dispensing, essentially a manufacturing activity and the licences that are ordinarily associated with this – provided that the assembly is carried on in a **registered pharmacy** within the **same retail pharmacy business** and **supply³ is from one of that businesses' pharmacies**. **This process if carried out routinely by separate retail pharmacy businesses is subject to (assembly) licences or registration (additional to their pharmacy related licences) to ensure patient safety is safeguarded.**

The patient safety aspects of hub and spoke dispensing have been considered by those pharmacy businesses already carrying out this type of hub and spoke dispensing. Model 1 in the consultation seeks to replicate this type of hub and spoke arrangement. Model 2 is a different form of hub and spoke arrangement.

The Proposal

The consultation proposal is to:

- *to remove this restriction from section 10, and to make associated legislative changes which will allow the operation of hub and spoke dispensing models across different legal entities and create a level playing field.*

And

- *to introduce 2 different hub and spoke dispensing models.*
- *In the first of the models, the patient presents a prescription to the spoke pharmacy, who then sends the relevant information on to the hub pharmacy who prepares or assembles the medicines. The prepared or assembled medicines are then sent back from the hub to the spoke, who then supplies them to the patient.*

³ Supply is often a shorthand for supply, sale, or supply in circumstances corresponding to a retail sale

- *In the second model everything follows the same course, but instead of sending back to the spoke pharmacy, the hub supplies the medicine directly to the patient.*

By

- *proposed amendments to the Human Medicines Regulations 2012 and the Medicines Act 1968 amendments to the medicines Act 1968 [as well as professional standards and arrangements between hubs and spokes].*

Consultation questions

Question 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 background above is added in response to this question.

Question 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?

PSNC considers that only Model 1 is appropriate, with manageable risks to patient safety, and is a model that will allow the whole sector to benefit fairly.

Model 1

Patient – spoke pharmacy – hub assembly – spoke pharmacy supply – to the patient

Currently hub and spoke dispensing within a single legal entity, a retail pharmacy business, is carried out through an exemption in Section 10 of the Medicines Act 1968. The **supplying pharmacy** within that business is subject to all the usual legal and professional responsibilities associated with the supply or dispensing of a prescription only medicine to a patient, with the accountability and responsibility, and

professional advice given or available, that patients and prescribers rightly expect and value. There is a single point of contact for the patient, and a named responsible pharmacist for the pharmacy from which the medicine is supplied or dispensed. The **assembly of the medicine at another pharmacy** is exempt from licensing – because the assembly is carried out within another pharmacy owned by that retail pharmacy business and is under the supervision of a pharmacist.

Notable is that the current exemption is for the preparatory stages of dispensing, essentially a manufacturing activity and the licences that are ordinarily associated with this – provided that the assembly is carried on in a **registered pharmacy** within the **same retail pharmacy business** and **supply⁴ is from one of that businesses' pharmacies**. **This process if carried out routinely by separate retail pharmacy businesses is subject to (assembly) licences or registration (additional to their pharmacy related licences) to ensure patient safety is safeguarded.**

This is in effect what Model 1 in the consultation seeks to replicate between two separate retail pharmacy businesses.

PSNC supports Model 1 in the consultation since this effectively allows all community pharmacies to carry out hub and spoke dispensing that is currently permitted only within a single legal entity, a single retail pharmacy business. This is:

- remote assembly supervised by a pharmacist and carried on at pharmacy premises by one retail pharmacy business, which supports the legal and professional responsibilities of the supplying pharmacy of another retail pharmacy business, with system regulation provided by the General Pharmaceutical Council (GPhC).

Model 2 in the consultation, a hub direct to patient supply of dispensed medicines, raises patient safety issues and we cannot support this model.

Model 2

Patient – spoke pharmacy – hub pharmacy supply – to the patient

The proposed Model 2 hub and spoke dispensing between different legal entities would mean the supply of prescription only medicines from a hub pharmacy to which the patient has not taken the prescription, and concerns include:

⁴ Supply is often a shorthand for supply, sale, or supply in circumstances corresponding to a retail sale

- splitting responsibility for the patient, between two or more businesses, two or more pharmacies, two or more responsible pharmacists, and potentially two or more superintendent pharmacists and potentially two or more delivery arrangements – for a single dispensing process;
- this patient safety risk is compounded where a patient receives multiple prescriptions in a given time period
- pharmacy and pharmacist oversight and pharmaceutical care of the patient by the spoke pharmacy, the pharmacy from which the patient seeks such care is reduced;
- patient facing activity may not be through the chosen, accessible spoke pharmacy;
- patients may receive medicines from a number of hubs and, particularly if some supplies are delayed or not available, they are likely to have difficulties managing their treatment as it arrives, determining in some cases whether it has all arrived and who to turn to, to solve any problems;
- hubs cannot complete all the needs of a patient and sharing the patient facing legal and professional responsibilities and needs associated with a single shared dispensing process with a spoke is inherently risky (with the impact assessment assuming that 40% of items from a participating pharmacy would be sent to a hub, meaning 60% would not be sent through and would still be fully dispensed in the spoke pharmacy);
- patients are likely to be supplied prescription only medicines dispensed from a remote pharmacy which they have not chosen and of which they may not know the name or location;
- patients receiving medicines could have different relationships with each hub and spoke pharmacy they use, and the arrangements determining these relationships are likely to be invisible to the patient and likely to be different and confusing even if visible;
- there is a lack of clarity for the patient or anybody acting on behalf of the patient, including other healthcare professionals, of who to turn for advice or help if there is a crisis or problem;
- the ability of the spoke to intervene for patient safety reasons is reduced or lost;
- information provided at DHSC stakeholder meetings in 2021 suggested that current hub and spoke arrangements are safe at least partly because the one retail pharmacy business has joint visibility over the procedures at the hub and spoke and can stop the single dispensing process if patient safety issues arise in either the hub or spoke. There is no equivalent safeguard within Model 2 as there is no single pharmacy and pharmacist responsible for supply;

- while hub assembly without patient consent for supply from a spoke may be acceptable for preparatory services and services associated with assembly, it is questioned it is acceptable for the supply of dispensed medicines and pharmaceutical care and advice, by a hub pharmacy and its staff to be without patient consent;
- there is a lack of clarity on supervision requirements for hubs and spokes for the single dispensing process; and where both pharmacies supervise the process, there is the potential for confusion and gaps in supervision;
- a patient's understanding of who does what and who is responsible for what may not match the actual arrangement between a hub and spoke and such arrangements will vary between hub and spoke arrangements;
- the pharmacy to which a patient goes should be the one that supplies the dispensed medicines, in all aspects – supply, delivery, labelling and supervision and care – although a spoke pharmacy may rely on the accuracy of a hub's assembly process (with sufficient audit or other assurances);
- while consideration focuses on the possibility of large, remote, automated hubs provided by larger business, little consideration appears to be given to local, manual hubs provided by one or more smaller pharmacy businesses;
- the risks associated with a single dispensing process shared between smaller legal entities and larger corporate entities, each with different working practices and standard operating procedures, do not appear to have been considered; and
- patient complaint procedures are likely to be variable and complicated to navigate with different arrangements between hubs and spokes, no one person clearly responsible for supply; accountability and responsibilities divided; and liability determined by the courts.

Additional observations include:

- a patient's choice of pharmacy is compromised if they go to a spoke and receive a supply from a hub;
- while local pharmacies deliver, they are responsible for the delivery arrangements and will resolve them, this is not realistic with routine supply from a hub, even if on behalf of a spoke;
- if a patient goes to the spoke, the label should always be that of the spoke, which is inconsistent with supply from a hub;
- supply from a hub reduces the opportunity to drive value through spokes in the provision of clinical services – every contact should count;

- if the patient goes to a hub, supply of the dispensed medicine using a spoke pharmacy as a collection point is appropriate and should be available;
- generally, the retail supplier of a medicine is considered professionally responsible for the supporting or preparatory work that precedes supply;
- the operational safety features of automated assembly carry different risks for the process as a whole and are separate to the patient safety risks around split-facing patient care;
- if a patient wants to seek remote supplies of dispensed prescription only medicines this is already available both for private and NHS prescriptions;
- there are Distance selling Premises (DSP) pharmacies that are available to provide pharmaceutical services to the whole of England that patients may choose to use and therefore option 2 appears to be both unnecessary.

Accordingly, PSNC cannot support Model 2 in the consultation, because it raises patient safety issues.

Question 3

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

No.

Question 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?

Yes, we agree that arrangements between hubs and spokes should be mandated and we welcome the principle of flexibility for arrangements between hubs and spokes, however, we have concerns about the extent of the flexibility provided, in the absence of professional standards or guidance.

Question 5

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

Our concerns on the extent of the flexibility provided for arrangements are as follows:

- whether hubs and spokes will reach appropriate and practical arrangements with each other to ensure patient safety, recognising that in the one dispensing process, each party is reliant on the other to ensure patient safety is maintained – for example, will parties assign accountability or

responsibility appropriately; will parties always recognise their responsibilities and their accountability for any actions or inaction on their part; will two separate legal entities that may have very different organisational and staff procedures and protocols and IT systems have the same understanding of the arrangement; and will all staff in each retail pharmacy business, including locums understand the specific arrangement, when many different types may be encountered.

- Whether hubs and spokes will seek to assign accountability and responsibilities that should properly remain with the hub or spoke. This is particularly so with model 2 in the consultation, where there is an overlap and confusion of roles, where both the hub and the spoke may supply the dispensed medicine to patients, this may vary between patients of the spoke and may vary for a patient month to month.
- whether hubs and spokes within such arrangements will have commitments to appropriate training and induction for staff and audits of the processes such that patient safety concerns of the single dispensing process are minimised or identified as early as possible and generally before they affect a patient – for example, how will a hub assure itself of the accuracy of spoke’s inputting of any relevant prescription or patient information, initially and on an ongoing basis.
- Local non-automated hub and spoke arrangements that are informal and unwritten could result in misunderstandings or responsibilities between hubs and spokes and, therefore, such arrangements should at least be in writing.
- How will a patient know which hub has been used if the spoke uses more than one hub (and whether the pharmacy will keep easily accessible records of this).
- Whether accountability of one party can or should be assigned to another party in an arrangement – it is accepted that responsibilities can be assigned, as appropriate.
- How the GPhC and NHSE&I and other relevant authorities can have easy access to such arrangements, and whether for Model 2 in the consultation this should be approved in advance, to seek to prevent patient safety incidents, rather than respond to patient safety issues after they have occurred.
- Whether it is appropriate to open up hub and spoke arrangements to the innovation inherent in Model 2 in the consultation without any transitional step.
- the safeguards, for example in Model 2, on shared patient facing pharmaceutical care, which must be met jointly by two different retail pharmacy businesses carrying out a single dispensing process and supplying dispensed medicines to patients; and
- the responsibilities of spokes and hubs to assure themselves of the accuracy of the other parties’ processes and procedure on which they rely (for example, in Model 2, any relevant patient history held by the spoke pharmacy where physical supply is by the hub pharmacy).

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)

Yes, we agree 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, is appropriate. There is precedent for the use of such notices with the notice that must be displayed for the responsible pharmacist which provides relevant information to patients and the public.

We accept that this is a reasonable manner in which to inform patients about assembly of the medicine by the hub pharmacy for supply from the spoke pharmacy, without the need for specific consent. This is for Model 1 in the consultation.

While it may be helpful for some to add the relevant information to the responsible pharmacist notice, for others this may add unnecessary cost because they may have to replace existing notices and may need to do so as and when additional hubs are used by the community pharmacy.

Accordingly, it is suggested that the requirement should be to display a relevant notice which may be combined with the responsible pharmacist notice.

We do not accept that this is an adequate way for a patient seeking to have their prescription dispensed by one pharmacy to give consent for their prescription to be supplied by a different (hub) pharmacy and potentially, be provided with pharmaceutical care and advice on the medicine by that different pharmacy and its pharmacist (by a different retail pharmacy business).

Question 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)

We consider that only Model 1 in the consultation is appropriate and that the label on the dispensed medicine should be that of the spoke pharmacy, the pharmacy supplying the medicine to the patient, for reasons given in responses to other questions.

Question 8

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

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

Yes. See the issues raised in response to question 2 concerning Model 2 in the consultation.

Question 9

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

Yes, supply from an GP surgery should be only as part of the provision of NHS pharmaceutical services – i.e. by dispensing doctors and from listed premises for dispensing doctors.

Supply from a spoke GP surgery should be only as part of the provision of NHS pharmaceutical services by the dispensing doctors, to ensure that the system regulation of professionals, premises and retail pharmacy businesses by the General Pharmaceutical Council for both hubs and spokes, for one pharmacy process is the standard, applicable to the vast majority of medicines dispensed through hub and spoke arrangements; and the provision of pharmacy services through a GP practice is the exception; and that this exception is limited to levelling the playing field for NHS dispensing doctors providing NHS pharmaceutical services.

The intention of the drafting appears to be to provide for this limited exception, but arguably the current drafting permits hub and spoke services from any GP practice premises providing NHS pharmaceutical services, even if that hub and spoke arrangement is not related to the provision of those NHS pharmaceutical services.

Question 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?

Yes, there should be consistency and equity with standards for pharmacies premises as far as is practicable.

Please see our answer to question 6.

Question 11

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

Notice of hub use, sections 70, 71 and 72 of the Medicines Act - should specify that a conspicuously displayed notice must identify the name and address of who runs the hub, if a hub and spoke arrangement is being used by the (spoke) pharmacy.

GP surgery, regulation 8, general interpretation of the HMRs – as stated, the definition is too wide and should refer to, for example, premises on an NHS dispensing doctor list (other than registered pharmacy premises) and as with supply from a spoke pharmacy (part of the business of that pharmacy), be part of that dispensing doctor's provision of NHS pharmaceutical services.

Supervision, regulation 220 of the HMRs– it is inappropriate to change this section of the HMRs and potentially the meaning of supervision, prior to a public government consultation later this year.

Packaging requirements, regulation 258 and schedule 25 of the HMRs – clarity and explanation is sought on these proposed changes.

Hub and spoke provisions, proposed regulations 22A and 22B of the HMRs – the language is not consistent between the two proposed sections. Existing well understood terms such as *retail pharmacy business* could be used rather than new terms. It may would be helpful to confirm whether deemed supply by a spoke pharmacy is supply etc for the purposes of regulation 220 of the HMRs and, therefore, requires pharmacist supervision by the spoke pharmacy, as appropriate.

Supplies of assembled medicines from hubs to spokes - the wholesale licensing requirements could be disapplied to supplies of assembled medicines from hubs to spokes (with any necessary amendment of the legislative rules around the assembly of medicines, particularly their labelling) rather than describe a new type of retail supply which is complex and potentially confusing.

(and **to assist small wholesale supplies of medicines between pharmacies, to alleviate temporary local shortages**, pharmacies could be permitted to make wholesale supplies - rather than have to rely on the discretion of relevant authorities not to prosecute if certain stated criteria are met.)

Question 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?

We do not consider that this change is either necessary or desirable to support hub and spoke dispensing, but as stated elsewhere we would support a change in the Medicines Act 1968 to allow pharmacies to wholesale small quantities of medicines to each other to support patient welfare.

Question 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’?

‘At or from’

There should be no change to Section 220 of the HMRs and pharmacist supervision of supply prior to:

- the envisaged consultation on skill mix later this year⁵; and
- confirmation of the meaning of ‘at or from’ and the scope of *collection and delivery arrangements* (Section 248 of the HMRs) - an exception to supply at a pharmacy and under the supervision of a pharmacist.

The *rebalancing medicines legislation and pharmacy regulation programme: consultation outcome* indicates that:

As to the meaning of supervision, these proposals will not add any references to ‘supervision’ into the legislation, but will build on existing references. So, the question about the level of supervision required to amount to supervision is the same legal question as arises in relation to ‘supervision’ at a retail pharmacy.

This will be the subject of further consideration in the context of the work to make more efficient use of the rich skill mix in pharmacy teams, as envisaged under the Community Pharmacy Contractual Framework and work of the Cross-Sector Supervision Practice Group.

In early 2019, DHSC provided informal clarification to PSNC that ‘at or from’ confirms the current arrangements in the sector – that in effect they both mean the same thing and the additional words ‘or from’ add clarity and sense in terms of the description of remote supply to the patient, but otherwise make no change to the meaning of supply on pharmacy premises. However, the general understanding of this term may change with the introduction of hub and spoke dispensing and there is concern that the words could be interpreted to mean supply at the pharmacy and collection by the patient (as part of an ongoing or second supply ‘from’ the pharmacy) at another non-pharmacy premises.

⁵ Consultation outcome **Rebalancing medicines legislation and pharmacy regulation programme: consultation outcome** Updated 28 April 2022 <https://www.gov.uk/government/consultations/pharmacy-legislation-on-dispensing-errors-and-organisational-governance/outcome/rebalancing-medicines-legislation-and-pharmacy-regulation-programme-consultation-outcome>

The current exemption on collection and delivery arrangements (Section 248 of the Human Medicines Regulations) provides such secondary supply at non-pharmacy premises and was drafted to be specific and limited in application, as an exception to supply at a pharmacy with pharmacist supervision. Arguably, this exception is applicable only to paper prescriptions and not electronic prescriptions, but if applied to electronic prescriptions it may not adequately protect the public.

Question 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?

NHS

- **We consider that market entry concerns around Model 2 in the consultation, including the proliferation of hub pharmacies, would be problematic to address in NHS Pharmaceutical Regulations. Noting that this is not the subject of this consultation.**

The NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations provide a patient needs-based, market entry system that seeks to regulate the entry of new NHS pharmacist (contractor) and new NHS pharmacist premises – new pharmacy premises from which contractors provide NHS pharmaceutical services.

New pharmacies are established only as provided for and agreed under the Regulations. Decisions on entry of new contractors or pharmacies are taken by NHSE&I (this is being delegated to Integrated Care Boards (ICBs)) and are subject to appeal. Existing contractors, and parties that may be affected by an application, have an opportunity to comment on the application and, if necessary, appeal any decision to grant the application; ultimately appealing to the courts by way of judicial review, if relevant and desired.

The market entry system means that contractors may provide NHS pharmaceutical services only at pharmacy premises which have an NHS contract (only from NHS pharmacist premises). These activities include, for example, receipt of NHS prescriptions from patients and the provision or supply of NHS dispensed medicines. If an NHS pharmacist or contractor is able to provide NHS pharmaceutical services from premises that are not NHS pharmacist premises, a contractor, for example, may then have many satellite pharmacies as collection points and/or supply points for the provision of NHS prescriptions and medicines, all linked to one or more NHS pharmacist premises. These non- NHS listed pharmacies from which NHS pharmaceutical services are provided circumvent the regulations and undermine their purpose.

The NHS pharmaceutical regulations are made under the NHS Act 2006, section 129 of which provides that they must include provision for the premises from which the relevant person will undertake to provide those

services, as well as the removal of premises, as appropriate. The regulations also reference proper planning in respect of the provision of pharmaceutical services and the arrangements in place for the provision of pharmaceutical services in an area. Disregarding the market entry regulations disregards the existing arrangement of pharmaceutical services and is not consistent with the provision of services in response to patient needs under the Act or regulations.

Provision of NHS pharmaceutical services from non-listed premises also jeopardises the main policy objectives of the Regulations⁶. These are:

- **to ensure a proportionate regulatory regime which encourages the supply of NHS pharmaceutical services without excessive provision in areas already meeting demand;**
- to ensure benefits of the new entry system outweigh its costs; and
- to align provision more transparently with local needs.

If pharmacies that are not NHS pharmacist premises provide NHS services (they may also only provide limited services because they are outside the scope of the Terms of Service), this is also likely to result in the excessive provision of some pharmaceutical services in areas where demand is already met, because new pharmacies can establish separate to the market entry system and without reference to patient needs in an area. This is unnecessary and is detrimental to existing provision of services by established community pharmacies; and may be detrimental to patients if this affects the viability of established community pharmacies providing the full range of NHS pharmaceutical services.

Established community pharmacies provide NHS pharmaceutical services in competition with each other and patients may choose which pharmacy to which to take their prescription or receive other NHS pharmaceutical services.

See also our response to question 11 –

(and **to assist small wholesale supplies of medicines between pharmacies, to alleviate temporary local shortages**, pharmacies could be permitted to make wholesale supplies - rather than have to rely on the discretion of relevant authorities not to prosecute if certain criteria are met.)

The questions on the **impact assessment** are:

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

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

⁶ [Post-implementation review: NHS \(Pharmaceutical and Local Pharmaceutical Services\) Regulations 2013](#)

PSNC considers that:

- **There are virtually no financial efficiencies envisaged by these - hub and spoke dispensing – proposals, which, if used, are more likely to add cost to the community pharmacy sector.**
- **The value to the NHS and society of medicines supply through spoke pharmacies and the value to the public purse of community pharmacy purchasing of generic medicines should also be considered.**

We note that DHSC expects minimal financial efficiencies as a result of hub and spoke, with an average annual net benefit being only £3.3m p.a. once the transition into using hub and spoke is complete (which equates to 0.13% of the NHS's current annual funding in pharmacy) [P3 Summary of Policy Option 2; being £23.2m best estimate of annual costs less the corresponding £19.9m best estimate of benefits].

However, if the assumptions in the impact assessment are considered, this minimal financial benefit is itself highly doubtful.

For example, the actual realisation of the financial benefit of the **suggested 40% dispensing time saving reduction** (paragraph 63) would be heavily restricted in practice. A pharmacist must always be present in the pharmacy (and in most cases there is only one pharmacist in a pharmacy at one time, so their working hours cannot be cut without reducing the overall opening hours of the pharmacy). Equally, if non-pharmacist financial time savings are sought to allow the pharmacy to pay for the hub service, then non-pharmacist time must be aggregated into a meaningful block to allow payroll hours for these in-pharmacy staff to be reduced.

The impact assessment also **notes non-financial benefits** (e.g. calmer working environment, more time to deal with patients; paragraph 79). These are very welcome, but to the extent that this happens it is likely to reduce the realisation of the hypothesised 48p per item cost saving in the spoke.

The impact assessment should include a further assumption on the ability to **'convert' the dispensing time saving into a financial benefit** (which is then needed to enable a pharmacy to pay for the new additional cost of the sub-contracted assembly service).

At a sector wide level, if the **hypothesised 48p per item benefit** is realised through additional Advanced Services, this will add in operating cost to the sector overall (funded from the existing Global Sum and not be new income across the sector). This will further exacerbate the significant cost pressures on pharmacy. There may however be a benefit at individual pharmacy level (as the Advanced Service income would be received 100% by that pharmacy, but the dilution of funding it created would be spread over the 11,000+ pharmacies in England), meaning that individual pharmacies are incentivised to undertake these additional services despite the increased financial pressure this will put on the sector overall. This constraint is noted in paragraph 72 of the impact assessment but does not appear to have been taken into account in the financials themselves.

Due to the factors above, it seems most likely that hub and spoke will add in incremental operating cost for English pharmaceutical provision, and further undermine financial sustainability of all individual pharmacies.

We are not familiar with the unattributed ‘**commonly cited figure for automated costs of 40p per item**’ (paragraph 62) and would welcome transparency on this assumption. For example, how much of this 40p per item represents hub operating costs, a per-unit contribution to the hub build costs, and then how much is the commercial return on investment allowed to hub operators (i.e. what discount factor would be applied to this part of the hub’s business case to break even on a NPV basis, as this is not apparent in the methodology used)?

The **risk profile of developing hubs will be much higher** due to the inability (quite rightly due to competition law constraints) to coordinate hub provision versus pharmacy demand. This itself (mismatch of supply and demand) could cause issues with continuity of supply and wider supply chain disruption.

It is also noted that a **3.5% discount factor is assumed for pharmacy within the impact assessment, which is very low** given the current financial risk profile for pharmacy and the current wider economic circumstances. This artificially low discount factor will flatter the already marginal net present value figure in Option 2 (page 3), and also artificially flatter the sensitivity analysis of key assumptions needed to break even (paragraph 63).

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

Please see the comments above. Existing companies using hub and spoke should be able to provide figures or already have provided information to help refine the impact assessment (e.g. proportion of time savings actually convertible to payroll savings, the extent to which additional services drive additional income from outside the constrained Global Sum, and the real cost of financing commercial businesses measure investment decisions against).

[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

[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?](#)

Although the parts of the sector already using hub and spoke will be able to share insight that informs the potential sector-wide costs and benefits of the proposed changes, there are a number of key differences that should be borne in mind.

For example, as the existing hubs and spokes are part of the same legal entity, there are a number of efficiencies / simplifications that are unlikely to be the case between different legal entities.

Where the hub and spokes are part of the same legal entity, there will over-arching operational control. This will have several benefits, such as the ability to enforce operational consistency more rigorously (such as with training and SOPs), to ensure each individual spoke relates in the same way operationally to a given hub.

This consistency will also allow the 'handover' of processes between the hub and spoke to be consistent and simplified, minimising the need to check that there are no omissions in the overall process whilst ensuring safety standards (at levels that unrelated entities may not be confident with, with any additional checking that are introduced by unrelated entities – either formally or informally – eroding some of the time savings that out-sourcing processes to the hubs produce).

Equally, there will only be one set of IT for current operators (typically one single PMR system common across all spokes interfacing with the particular in-house hub system, which will have been designed to relate to that single IT system). New hubs relating to spokes from different legal entities will need to interface with several PMR systems.

Existing vertically integrated companies, or those recently vertically integrated companies, are also likely to purchase more of their medicines through their in-group wholesaler or associated wholesaler respectively (with hubs often co-located inside the wholesalers), rather than those pharmacies 'shopping around' from several wholesalers.

Finally, it should be recognised that current companies operating existing hubs will be facing a different financial decision in respect to using their hubs. Where hubs have already been built by a company to serve its own pharmacies (and the development and build costs are already spent/sunk), it will still make financial sense for that company to operate the hubs even if their spoke benefits just cover the ongoing operational costs (staffing, maintenance and logistics costs).

New hub entrants would also need to be confident they can charge a rate (to unrelated customers that are not under common ownership) that will cover not just the ongoing operational costs, but also the development and built costs (as well as enough to cover the financing costs, plus enough to incentivise them to take the financial risk).

[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?](#)

- [Strongly agree](#)
- [Agree](#)
- [Neither agree nor disagree](#)
- [Disagree](#)
- [Strongly disagree](#)

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

Value of community pharmacy

In addition, other benefits of the community pharmacy network should be considered in any overall assessment of the sector. In 2015/16, PSNC commissioned PricewaterhouseCoopers LLP (PwC) to examine and quantify the economic contribution of community pharmacy in England in 2015. The resulting report analysed the value (net benefits) to the NHS, public sector, patients and wider society of 12 specific services provided by community pharmacy. Services analysed included supervised consumption, emergency hormonal contraception provision, minor ailments, delivering prescriptions and managing drug shortages.

Key findings of the report were that:

- *through the services considered in this report, in 2015 community pharmacy in England contributed a net increase of £3.0 billion in value in that year, with a further £1.9 billion expected to accrue over the next 20 years.*
- *the in-year benefit in 2015 of £3.0 billion is net of the £247 million in compensation which pharmacy received through funding from national and local sources for the 12 services evaluated. Even considering just this limited list of 12 services, and applying conservative assumptions, the single year net benefit identified exceeds the total £2.8 billion community pharmacy was paid by NHSE in 2015.*
- *on top of this, we estimate that indirect health system cost savings could be worth up to a further £2.5 billion in 2015 from the knock-on effects of self-care and medicines support.*
- *apportioning the single year net benefit evenly across all the 11,815 pharmacies which operated in England at the end of 2015 leads to a benefit of more than £250,000 per pharmacy in 2015 alone. This rises to more than £410,000 when considering the long term effects as well, and up to £625,000 per pharmacy when potential knock-on health impacts are included.*
- *... the NHS itself is the biggest beneficiary: community pharmacies contributed a net value of £1,352 million in the short run; this is net of the funding received by community pharmacies for the 12 services, both directly from the NHS and from local commissioners (which was £247 million – hence the gross value was £1,599 million). Of this net value to the NHS, the majority was direct NHS cash savings as a result of cost efficiencies, worth £1,111 million in 2015. In addition, the NHS saved an extra £242 million as a result of avoided treatment, and a further £172 million in avoided long term treatment costs.*
- *further, 55% of in-year benefits and 91% of long run benefits (69% of total benefits) accrued outside the NHS. Other public sector bodies (e.g. local authorities) and wider society together received over £1 billion of benefits in 2015 as a result of the community pharmacy services covered. A further £1.7 billion is expected to accrue over the next 20 years.*

- *in addition, patients experienced around £600 million of benefits, mainly in the form of reduced travel time to alternative NHS settings to seek a similar type of services as the ones provided by community pharmacy*
- *through the services covered in our analysis, community pharmacy made more than 150 million interventions in 2015 – including nearly 75 million minor ailment consultations and 74 million medicine support interventions – and supported 800,000 public health users.*
- *for many of these interventions the scale of value created is substantial and greatly exceeds the cost to the NHS of delivering them. Each patient treated with supervised consumption, for example, generated in excess of £4,000 in value in 2015 alone, and a further £7,500 in the long term. Figure 2 shows for each service the number of transactions/users and the value generated (the size of each circle shows the relative size of the total value generated in 2015).*
- *finally, based just on the 12 services considered in our analysis, community pharmacy was self-funding in 2015. More specifically, as illustrated in Table 1, we estimate that the activities of community pharmacy will avoid costs for the public sector, including the NHS and other public sector bodies, in both the short- and long-term, totalling an estimated £3,017.5 million – £1,771.4 million to the NHS and £1,246.5 million to other parts of the public sector. This compares with total funding for community pharmacy in England provided by DH in 2015 of £2.8 billion and estimated additional funding from local sources for the 12 services analysed of £135 million. **So, the expected amount of public sector spending saved directly as a result of the 12 services analysed is enough, by itself, to offset the entire amount of public funding provided for community pharmacy in 2015.** Effectively this means that all the other benefits of community pharmacy – including the patient, society and knock-on health benefits of the 12 services we analyse, and, more importantly, the benefits of the core NHS prescription service itself – can be seen as additional net benefits of community pharmacy that are provided at no cost to the Exchequer.⁷*

Competitive purchasing of generic medicines

Furthermore, in our 2016 response to the Government’s then consultation on hub and spoke dispensing we indicated raised concern that:

.. the alleged economic efficiency reasons for ‘hub and spoke’ dispensing are not evidenced and arguably such models will cost more overall: efficient pharmacy procurement, which has generated savings to the public purse of £10 billion pounds in the last ten years, may be lost.

⁷ The value of community pharmacy – summary report PSNC September 2016 <https://psnc.org.uk/wp-content/uploads/2016/09/The-value-of-community-pharmacy-summary-report.pdf> The full report is available at <https://psnc.org.uk/psncs-work/about-community-pharmacy/the-value-of-community-pharmacy/>

The value of community pharmacy competitive purchasing of generic medicines is recognised⁸:

Executive summary - A comparison of prices across five European countries suggests that prices of generic medicines in the UK are generally lower than in the other countries—and often by a large amount. The prices of the analysed products in several of these countries, are, on average, 3 to 4.5 times more expensive than in the UK. As shown in the figure below, although the relative magnitudes have changed to some extent over time, these results have broadly held since 2012, indicating that the lower prices for generic medicines in the UK may be due to long-standing features of the UK system such as freedom of pricing.

...

4.55 In particular, the UK price regulation system provides strong incentives to all key players to encourage generic medicines use. Doctors are incentivised to write open scripts without brand names. Pharmacies are provided incentives to dispense the least expensive generic product, given the reimbursement structure, which in turn incentivises generic suppliers to offer competitive prices to pharmacies, thereby driving prices down. The system in this way creates certainty in the formation of the generics market, allowing low price offerings on the basis of securing volume. The pressure on generic prices is supported by the regular revisions (typically, reductions) of the Drug Tariff price which is used to reimburse pharmacists.

Additional Comments:

We are concerned about the likely patient confusion (and safety issues this causes) if medicines are delivered to patients in an uncoordinated way. This is particularly the case with 'model 2' where, for a patient with con-morbidities or complex needs, some items are likely to be dispensed in the spoke (due to restrictions on what can be dispensed in the hub, with 60% remaining in the spoke within the key assumptions on P3 of the impact assessment), whereas the remaining 40% are assumed to be processed in one or more hubs.

Receiving prescriptions (or different parts of the same prescription) in an uncoordinated from different sources are (at best) likely to cause increased patient queries (eroding time savings in the spokes) or more seriously lead to patient confusion and potential harm in patients taking their medicines properly.

The impact assessment does not suggest a financial benefit from using Model 2 versus Model 1. Given the increased risk to patients of Model 2, it is recommended that this second proposed model is not enabled. If this second model is pursued, the likely costs should be quantified and incorporated into the impact assessment.

Where patients want to use remote delivery from a hub (which would be the case using Model 2), this option already exists as patients are already able to get their medicines through Distance Selling Pharmacies.

Additional comment: Equality assessment Please consider whether the role local community pharmacies have in addressing health inequalities is affected by any of the policy proposals and if so, to what extent.

⁸ The Supply of generic medicines in the UK, a study by Oxera, 26 June 2019 <https://www.britishgenerics.co.uk/uploads/Oxera-study-on-the-supply-of-generic-medicines-in-the-UK-26-June-2019.pdf>