Open consultation

Hub and spoke dispensing

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Executive summary

The Human Medicines Regulations 2012 govern arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing and sale and supply of all human medicines, including the governance of pharmacists selling or supplying prescription only medicines. Alongside the Human Medicines Regulations 2012, the Medicines Act 1968 sets out requirements relating to the operation of pharmacies and pharmacists. This consultation seeks views and comments on proposals to enable all community pharmacies to access ‘hub and spoke’ dispensing. Currently it is only possible when the hub pharmacy forms part of the same retail business as the spoke pharmacy. This consultation seeks views and comments on proposals to facilitate hub and spoke dispensing between pharmacies belonging to different legal entities. In addition, we are proposing to enable dispensing doctors access to hub pharmacies. Legislative changes will be required to deliver the proposals, including amendments to the Medicines Act 1968 and the Human Medicines Regulations 2012.

How to respond

This consultation document is intended to provide members of the public with information about the policy proposals and an opportunity to comment. This consultation is being made available in England, Wales, Scotland and Northern Ireland – it is being issued jointly by the UK Department of Health and Social Care and the Northern Ireland Department of Health – and the proposed changes would apply throughout the United Kingdom.

Responses will be accepted via the online survey over a course of 12 weeks from 16 March 2022.The consultation will close on 8 June 2022.

Responses to this consultation will be carefully considered and reviewed and will feed into the final decisions on the policy proposals. If it is decided to proceed with the policy, it will be delivered by making amendments to the relevant legislation through the affirmative procedure.

We are publishing the draft statutory instrument (SI) so that stakeholders can see how we have approached the proposals in terms of the proposed legislative changes – we have looked to provide a read across from our policy proposals to the draft SI.

Background

The government is committed to pursuing legislative change to enable all community pharmacies to benefit from ‘hub and spoke’ dispensing models. This would level the playing field between large chains and smaller pharmacies.

Dispensing covers a number of processes such as the receipt of a prescription, clinical and accuracy checks, sourcing, preparation, assembly and supply of medicines and liaising with the patient to ensure they know how and when to take the medicine. Traditionally, all these different processes are done in a single pharmacy. In hub and spoke dispensing, some elements of these processes are undertaken in a different pharmacy premises.

The restriction preventing hub and spoke arrangements taking place between different businesses means that at present only large pharmacy chains make use of this dispensing model. This consultation seeks views on removing this restriction by amending section 10 of the Medicines Act 1968, but also further policy proposals that are necessarily broader, to reflect the nature of the change and to ensure that patient safety is maintained, which will be done via additional amendments to the Medicines Act 1968 and with amendments to the Human Medicines Regulations 2012.

On a separate issue, we are also consulting on proposals to amend the Human Medicines Regulations 2012 to provide clarification within legislation that medicines are provided ‘at or from’ registered pharmacy premises.

The government previously consulted on hub and spoke in 2016 and published the consultation response in November 2021.

Freeing up pharmacy professionals' time and increased efficiency

It is recognised that the cost of setting up a hub is beyond all but the large chains and wholesale sector. Under these proposals smaller pharmacy chains and independent pharmacies could choose to group together to share the set-up costs, or new bespoke organisations could be created.

Enabling hub and spoke dispensing across separate businesses will free up time by allowing community pharmacies (the spokes) to outsource elements of the dispensing process, for example some of the simpler technical and/or routine parts of the process to other pharmacies (the hubs). By freeing up pharmacists and their teams in the spokes, this will give them the opportunity to provide other services and concentrate on more clinically focused tasks, including more difficult and complex prescriptions. This will also free up time for them and their staff to use their clinical skills to provide other services and more face-to-face patient care than can be done currently, while continuing to provide patients with the medicines they need.

However, realising efficiencies is not just about freeing up time. Hub and spoke introduces new steps in the dispensing process to take account of the movement of assembly function to the hub. Although the total number of steps are increased, this allows for greater overall efficiencies to be released at the hub. Hubs can utilise economies of scale such as making greater use of automation for the routine parts of the dispensing process. Focusing on one part of the dispensing process also allows hubs to become incredibly efficient on that aspect of the process.

It is important to note that hub and spoke will not be practical for all pharmacies, for example those who rely on acute care where it might be less feasible. Nor will it be possible for all prescriptions, for example, for controlled drugs.

These proposed changes also align with policy proposals on original pack dispensing (OPD). Currently, pharmacists must supply the exact quantity of medicine prescribed. This means that where the quantity prescribed on a prescription is not equal to (or a multiple of) a pack size, pharmacy staff need to split a manufacturer's original pack in order to dispense the prescribed quantity, which takes time and reduces efficiency, particularly for the highly automated processes which hubs employ. The intention behind proposals for OPD is to allow pharmacies to make greater use of manufacturers' original packs, which in turn supports the greater use of automation. All of which supports the use of hub and spoke dispensing. OPD also has benefits even where automation and hub and spoke are not being utilised. A government consultation on proposals to update the requirements in legislation to enable OPD for pharmacy and to introduce requirements to ensure medicines that contain sodium valproate are

always dispensed in the original manufacturer's packaging was published on 1 November 2021 and concluded on 13 December 2021.

Patient safety

We think that on balance, allowing for the wider use of hub and spoke dispensing and with it the use of automation, with appropriate safeguards, can have an overall positive effect on patient safety.

Dispensing errors in community pharmacy are already very rare. Where automation is used in the delivery of hub and spoke, it is expected that there will be a decrease in error rates. Further, the arrangements may involve tracking each activity and having checks in place using technology. As hubs are focused on routine tasks these can be fine-tuned to limit if not remove errors. At the spokes, pharmacists and their teams should have more time to spot and deal with issues and more time to focus on the more complex tasks that have an increased risk if something goes wrong. Hub and spoke should deliver an environment that helps pharmacists and their teams and protects patient safety.

While it is expected that hub and spoke arrangements will improve error rates and patient safety, it will not eliminate all errors completely. We know there is the possibility of 'never events', for example, automation errors, which while extremely rare can potentially have a big impact. Also, the introduction of any new process can potentially increase the risk of errors, but having an agreement in place to ensure the hub and spoke know what each is doing and training for all staff mitigate against any potential risks.

Further information can be found in the 'accountability and patient safety' section below. We have also included questions in this consultation seeking views on how improving patient safety can be built into the proposed changes.

Business impact

An impact assessment on the measure to remove the impediment to hub and spoke dispensing across different legal entities has been developed and is being tested through this consultation process.

The proposed changes are enabling and pharmacies will be able to choose whether or not to adopt hub and spoke dispensing as part of their business. It is our expectation that hub and spoke will be utilised when efficiencies can be

gained from its implementation. However, by allowing all community pharmacies to access hub and spoke dispensing we are ensuring that everyone is able to access potential efficiencies, should they wish to.

The expanded use of hub and spoke dispensing is likely to lead to an impact on organisations involved in the hub market. For example, expanding capacity at existing hubs to offer services to new pharmacy businesses, noting the costs that would be incurred. Setting up new hubs requires investment in automation and, potentially, new facilities and staff. Currently, the cost of setting up a hub is beyond all but the large multiples and wholesale sector although smaller pharmacy chains and independent pharmacies could, under these proposals, group together to share the set-up costs, or new bespoke organisations could be set up.

We anticipate that the proposed legislative amendments, which align with other developments around original pack dispensing may lead to changes in pack size by manufacturers, to support greater use of automation, which in turn could support greater use of hub and spoke dispensing.

As above, not all pharmacies will be in a position to utilise hub and spoke dispensing – it will depend on their business model. Also, not all medicines are suitable for being dispensed through hub and spoke, for example for the delivery of acute care and the dispensing of controlled drugs.

We understand that pharmacies wishing to operate as spokes will also need to make necessary changes, for example with additional training for staff, and that some parts of the dispensing process will always be the responsibility of the spoke pharmacy. However, in implementing hub and spoke dispensing, we believe the benefit of the efficiencies would outweigh the costs and practicalities of setting up, over time.

NHS impact

As mentioned above, these proposals are enabling. Under these proposals, pharmacies are not required to operate hub and spoke dispensing and it will be for each pharmacy to decide if they want to utilise this model of dispensing.

We anticipate that hub and spoke dispensing will enable the increased provision of other clinical services at the spoke as a result of medicines being sent to be assembled at the hub. For example, the spoke could deliver an increase in additional services such as vaccinations, blood pressure monitoring and medication advice. Alongside that, the time saved on preparing prescriptions will result in health improvements for patients if the pharmacist and their teams will

have more capacity to spend more time on face-to-face patient care, which is linked to better outcomes. Also, the increased capacity for pharmacists to see patients at spoke pharmacies may also help reduce pressure on other parts of the NHS.

We are aware of concerns around market entry, and potential for impact on existing pharmacies. This issue is covered in the scope section, further on in the document.

Where pharmacies choose to make use of hub and spoke models for dispensing, it is expected that the responsibility for the majority of purchasing medicines will move to the hub, who will in turn need to charge the spoke for the services and costs of these medicines. Hub pharmacies with a higher volume of dispensing may be able to negotiate better deals with suppliers. To the extent that these savings are then passed onto spoke pharmacies, the spokes may also experience a cost saving. This could in turn result in savings for the NHS spend on medicines. Conversely, there is a risk that with the purchasing of medicines being concentrated through a smaller number of hubs than the current number of pharmacy businesses, the number of medicine suppliers may decrease, and as competition decreases, prices could increase which in turn would increase the NHS spend on medicines.

We have no evidence to suggest that these proposals will result in an increase or decrease in the total number of medicines dispensed.

Alternative options

When exploring alternative options on how best to remove the current restrictions preventing hub and spoke dispensing from operating across different legal entities, patient safety has been at the forefront of every policy proposal. We have explored different options in terms of how to ensure the proposals do not adversely affect patient safety, what needs to be in the legislation that give effect to these, and what should be addressed through professional standards to assure this. This needs to be balanced with not stifling innovation and enabling models to be flexible to local circumstances. The proposals being put forward through this consultation allow for such flexibility.

Proposals

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.

We propose 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. The proposals will facilitate independent ‘spoke’ pharmacies to enter arrangements with independent ‘hub’ pharmacies that are part of a separate business. This will give smaller pharmacy chains and independent pharmacies across the UK a wider choice as to which business models to adopt. Under the proposals, hubs will need to be registered pharmacies. This is to ensure that spoke and hubs operate within the same regulatory framework which promotes patient safety, accountability and good practice. In addition, we are proposing an enabling model so that dispensing doctors can access hubs, though they themselves will not be able to be a hub as they are not a registered pharmacy.

Hub and spoke models

We are proposing 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.

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.

Our proposed amendments to the Human Medicines Regulations 2012 and the Medicines Act 1968 will enable the use of both models.

We have ensured that there is no hindrance through the proposed changes as to how many hubs a spoke can contract with, thereby supporting business resilience and potentially allowing the use of different hubs for different dispensing needs, such as those which are dispensed in monitored dosage systems. However, to ensure patient safety and transparency, we are considering the inclusion of legislative requirements for arrangements to be in place between

the hub and spoke (in both models). This would set out how they want their dispensing responsibilities to work in practice.

We are aware of concerns that the second model, where the supply of medicines is direct to the patient from the hub pharmacy, could potentially undermine the patient relationship with the spoke pharmacy and NHS market entry. With regard to the first, pharmacies do not have to use this model or can use their contractual relationship with the hub to ensure continuity of patient contact. With regard to the second issue, in England we will be working with the Pharmaceutical Services Negotiating Committee (PSNC) to consider whether parallel changes are needed in NHS pharmaceutical services to protect market entry conditions (see the section on ‘Market entry concerns’ below).

We have considered whether the hub and spoke dispensing models need to take account of the possible flow of medicines from a spoke to a hub. For example, if the majority of a prescription is being supplied by the hub pharmacy directly to the patient but they do not have enough of a particular medicine, could the spoke send on that medicine to the hub so that a complete prescription can be delivered to the patient, avoiding any potential confusion. Currently the proposals do not enable this.

How we are proposing to enable the different models in legislation

To facilitate the supply of medicines via hubs and spokes in different legal entities, we are proposing changes to the Human Medicines Regulations 2012. To ensure appropriate governance and accountability, we are expanding what is currently meant by ‘retail sale’ in the context of dispensing under the 2 hub and spoke models. The proposals create 2 new regulations, 222A and 222B of the Human Medicines Regulations 2012. These new regulations introduce a retail sale under specific circumstances, which will operate alongside retail sale as it is currently governed. Regulation 222A (assembly and sale or supply with a view to onward sale or supply at another pharmacy) deals with the dispensing model where the medicines are returned to the spoke pharmacy before supply to the patient. Regulation 222B (assembly and sale or supply in fulfilment of order submitted at another pharmacy business) deals with the model where the hub pharmacy supplies medicines directly to the patient.

1. Regulation 222A creates a deemed ‘retail sale’ relationship to govern the movement of medicines from the hub to the spoke after they have been prepared or assembled. The introduction of this retail sale removes the need for the hub pharmacy to have a wholesale dealing license in order to move medicines back to the spoke. Through the retail sale it ensures that

there is responsibility on both the hub and the spoke for the supply of the medicines. It also provides a layer of governance as the hub must be a registered pharmacy in order to carry out the retail sale. Retail sale between the spoke to the patient, remains unchanged.

2. Regulation 222B creates a deemed ‘retail sale’ between the spoke pharmacy and the patient despite it being the hub pharmacy supplying the medicines to the patient. It establishes the spoke’s role in the dispensing process and ensures that both the hub and the spoke are responsible for the supply of medicine to the patient. The spoke must be either a registered pharmacy or a dispensing doctor.

The proposals also include amending regulation 18 (wholesale dealing in medicinal products) of the Human Medicines Regulations 2012 as a consequence of the dispensing model facilitated by regulation 222A, to provide that the transaction between the hub and the spoke is a retail sale and not wholesale dealing.

The proposals also include the removal of section 131 of the Medicines Act 1968, so that the definitions of wholesale dealing, retail sale and related expressions will be the same as those within the Human Medicines Regulations 2012.

Patient safety and accountability

Moving to a system where the ‘hub’ and the ‘spoke’ could be from separate legal and commercial entities will require clear accountability between the 2 entities. Accountability arises first of all from the fact that both the spoke and the hub are involved in the process and both have responsibility. In addition, proposing that the hub must be a registered pharmacy and the spoke must be either a registered pharmacy or a dispensing doctor, ensures a degree of governance as a registered pharmacy and a dispensing doctor must meet the standards set out by the General Pharmaceutical Council (GPhC) and the Care Quality Commission (CQC) respectively.

The other area we have looked at, following stakeholder input, is the requirement to have arrangements in place between the hub and the spoke. Such arrangements would ensure that there would be agreed accountability between the 2 organisations for each step of the dispensing process. There are different options as to how we could address this in legislation.

Options considered included doing nothing, which would allow for maximum innovation but risks duplication of work or steps being missed out in the dispensing process as the hub and the spoke each think that the other is carrying out the step. Another option would be for the responsibilities of hubs and spokes

to be clearly set out in legislation, however this risks stifling innovation and the approach set out may not suit all pharmacy business models. Finally, a third option would be for the hub and spoke to divide responsibility and accountability between themselves, by agreeing who is to be responsible and accountable for each step in the dispensing process, including the accuracy and clinical checks, and having this clearly documented between them. This is important because it allows the hub and spoke to create a bespoke arrangement between themselves, to maximise efficiency depending on local circumstances and remove any potential duplication of work, while ensuring there is clear accountability and ownership for each step in the dispensing process.

We are proposing the third option, that there is flexibility for the spoke and the hub to agree responsibility and accountability between themselves, but in all cases an agreement must be in place. This is reflected in the proposed amendments to regulations 222A and 222B of the Human Medicines Regulations 2012. In the case of draft regulation 222A it stipulates that the transfer of medicines from hubs to spokes should be considered a retail sale rather than a wholesale dealing, but only if an agreement has been reached between the hub and the spoke.

The combination of the changes we are proposing are key:

1. Both the hub and the spoke are part of the retail sale.
2. The hub must be a registered pharmacy.
3. The spoke must be either a registered pharmacy or a dispensing doctor.
4. There must be an agreement between the hub and the spoke, which determines who is accountable for each step of the dispensing process.

Together, this provides for clear accountability.

Patient choice, transparency and information

In developing the proposals, we have considered the information that patients need to know in relation to hub and spoke dispensing and how that information can be shared with them. This ensures transparency and will allow patients to make an informed choice about the dispensing of their medicines if a pharmacy is engaging in hub and spoke activity. They could, for example, take their prescription elsewhere should they have any concerns around the hub pharmacy that the spoke is engaging with. Other factors considered involving information to be provided to a patient included, for example, the contact details of the pharmacy that the patient should contact should there be an issue with their prescription.

Information to appear on the packaging

We have considered what information must appear on the packaging of dispensed medication in accordance with a prescription. There is currently an obligation to specify the name and address of the registered pharmacy who has sold or supplied the medication. If hub and spoke models are in operation, this will mean that there are scenarios where it could be either the hub or the spoke.

Therefore, based on feedback from engagement undertaken so far, we are proposing legislative changes to allow the flexibility for either the hub or the spoke's name and address to be displayed. Importantly, the name and address of one party must appear on the packaging. As part of this consultation, we are seeking views on whether you agree with this proposed flexible approach.

These proposals are reflected in the proposed amendments to regulation 258 and Schedule 25 of the Human Medicines Regulations 2012, specifying that the name and address of either the hub or the spoke must appear on the packaging of any medicine, and this is to be determined by the arrangements between the hub and the spoke.

Transparency and information for patients about dispensing models in operation

As patient choice is an important factor, this consultation will also look at the information that should be provided to patients. We have considered whether a member of the pharmacy's team should personally speak to patients about the dispensing model to be used for their prescription or whether a clear notice in the pharmacy would suffice. We have also considered what would happen if a patient declines to have their prescription dispensed using the hub and spoke model operating at the pharmacy and whether pharmacies should be required to be flexible with their business model to accommodate patient preference for dispensing model used, and if so, to what extent. Stakeholder engagement on this subject indicated that as a minimum, pharmacies should display a notice informing patients that hub and spoke is being operated and the identity of who runs the hub or hubs that are being used.

An explicit opt in model was considered unnecessary as most patients are likely not to be concerned or interested. Opt in would also be a burdensome extra step and would reduce the potential efficiency gains. In regard to opt out, it is for the pharmacy to decide how they provide dispensing services. They may choose to operate such that patients have their medicines dispensed on site, if that is what

the patient wants. The patient also has the choice to decide to go to another pharmacy.

We are proposing amendments to the Medicines Act 1968 to include a legal obligation for a spoke pharmacy to display the name and address of any hub pharmacies that they are engaged in hub and spoke activities with.

This is reflected in the proposed amendments to Sections 70, 71 and 72 of the Medicines Act 1968, introducing this requirement.

Sharing of patient information

Moving to hub and spoke dispensing will mean that some prescription data will need to be shared between the spoke and the hub. Existing data protection regulations will apply, ensuring that data will continue to be secure under hub and spoke dispensing. As medicine dispensing via hub and spoke is direct patient care, and the transmission of the prescription data from the spoke to the hub is a necessary part of dispensing the medicine, it is therefore exempt from additional UK GDPR arrangements.

Dispensing doctors

In addition to pharmacies, we also propose to enable hub and spoke for dispensing doctors. Dispensing doctors are NHS GPs who are also able to dispense medicines, providing NHS commissioned dispensing services for patients who live more than 1.6km from their nearest pharmacy. They usually serve remote and rural areas where a pharmacy may not be easily accessible. Under our proposed amendments to the HMRs, dispensing doctors will be able to utilise pharmacy hubs if they wish to. Dispensing doctors may not themselves operate as hubs, as it is a requirement that a hub must be a registered pharmacy, but they can operate as a spoke. As dispensing doctors will be acting as spokes and will be subject to the same conditions as spoke pharmacies, they will need to have the same type of arrangements with the hub and will need to include the same information on the packaging of the medicines. Dispensing doctors are regulated by the CQC, whereas pharmacies are regulated by the GPhC. We are seeking views on whether there should be a legal obligation for the GP to display the name and address of any hub pharmacies.

Scope

This consultation focuses on the necessary changes to the Human Medicines Regulations 2012 and Medicines Act 1968 to provide for wider access to hub and spoke dispensing.

Each of the devolved administrations will need to consider how this dispensing model will operate in their respective NHS pharmaceutical services provisions and the consequences for NHS regulations and reimbursement.

During stakeholder engagement, a number of areas were raised which cannot be addressed through these proposed amendments of the Human Medicines Regulations 2012 and Medicines Act 1968. These issues are set out below alongside potential routes for further exploration.

Regulatory and inspection frameworks for hubs

Hubs will need to be a registered pharmacy and a spoke must be the same or a dispensing doctor. Alongside that, every pharmacy professional is accountable for meeting professional standards. The General Pharmaceutical Council is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. The Pharmaceutical Society of Northern Ireland is the regulatory and professional body for pharmacists in Northern Ireland. It is for these regulators to consider how they will regulate hub and spoke dispensing. Dispensing doctors are regulated by the CQC.

Market entry concerns, for example where hubs supply direct to the patient

In England, the NHS (Pharmaceutical and Local Pharmaceutical Services (PLPS)) Regulations 2013 sets out arrangements around pharmaceutical lists and the pharmacy applications that may be made. We understand the concern that hub to patient supply model could potentially undermine market entry conditions if, for example, a hub was located next door to pharmacy on the NHS pharmaceutical list. However, this is not a consideration of the Medicines Legislation framework where mitigations are needed, these need to be addressed through amendments to the PLPS in discussion with the PSNC.

Ensuring that hubs receive a fair distribution of medicines

Conduct which forecloses markets or dampens competition may breach competition law, which is a matter for the Competition and Markets Authority (CMA). Competition law prohibits the abuse of a dominant position and anticompetitive agreements. CMA guidance states that restricting supplies or other conduct which distorts competition could breach the law. Alleged illegal conduct would be for the CMA to consider and would be assessed on a case-by-case basis.

Access to a fair and competitive hub market that is not dominated by one supplier

Again this would be for the CMA to consider. Where a business grows through acquisitions, the CMA may investigate if it has jurisdiction to do so (that is if the target company has a UK turnover of £70 million plus or the merger partners account for 25% or more of the supply of goods or services in the UK or a substantial part of the UK).

‘At or from’ pharmacy premises

We are also using this opportunity in making changes to the Human Medicines Regulation 2012 to make a clarification to current wording.

Amendments to regulations 220 (sale or supply of medicinal products not subject to general sale), 221 (sale or supply of medicinal products subject to general sale) and 274 (exemptions from regulation 273) of the Human Medicines Regulations 2012 provide for clarification that medicines are provided ‘at or from’ registered pharmacy premises, for example a home delivery service or vaccination service delivered off-site from the registered pharmacy premises. This aims to provide clarity in the law, and is not intended to require any change to current practice. This change mirrors the widespread changes that we are making in The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order, to the Medicines Act 1968 to change references (expressed in a variety of ways) to supplies of medicines “on pharmacy premises” to “at or from pharmacy premises”.

Five-year review

Amendments to regulation 346 of the Human Medicines Regulations 2012 meet an existing requirement that certain provisions in the HMRs are subject to a 5-year review.

Equality assessment

In considering the amendments to the Human Medicines Regulations 2012, Ministers must comply with the Public Sector Equality Duty (PSED). We will

develop an equality assessment based on the proposal to enable the use of ‘hub and spoke’ dispensing in all community pharmacies.

Hub and spoke dispensing creates the opportunity to free up pharmacists’ and their teams’ time. Released time may allow for more face-to-face patient care and could also enable pharmacies to deliver additional services that could strengthen a pharmacy’s ability to reach patients, including those with vulnerable characteristics. We expect those patients who normally use more medicines, such as the elderly, disabled people, and pregnant women, to benefit more from this. In addition, increased capacity to see patients within pharmacies may also help reduce pressure on other parts of the NHS.

Forty-three per cent of the pharmacy workforce are from ethnic minorities communities with 27% from an Asian background. We have found no data to indicate whether the percentage of ethnic minority pharmacy staff is any different for independent pharmacies compared to those working for multiple pharmacies. It is not therefore possible to say whether pharmacy staff from ethnic minorities would benefit more or less from the policy to enable independent pharmacies to make use of hub and spoke dispensing.

Eighty-eight per cent of pharmacy technicians are female. Hub and spoke dispensing relies largely on automated processes to assemble in a hub pharmacy and we expect the savings in spoke pharmacies to be mostly on pharmacy technicians’ time. Freeing up time from their routine tasks will also enable pharmacy technicians to utilise their skills in other parts of the pharmacy’s business.

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?

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?

Question

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

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

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

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.

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?

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’?

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.

Question

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

Question

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

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?

Question

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

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?

Northern Ireland respondents

In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998 which requires public authorities to have due regard to rural needs.

Question

The Department of Health in Northern Ireland do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland. Do you have any views on this?

Question

Do you think the proposals risk impacting people differently with reference to their [or could impact adversely on any of the] protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998? If so, provide details.

Equality assessment

Question

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

Legislative background and basis

Section 45(1) of the Medicines and Medical Devices Act 2021 includes a statutory requirement for the appropriate authority (here the Secretary of State for Health and Social Care and Northern Ireland Department of Health) to carry out a public consultation on proposed amendments to the Human Medicines Regulations 2012. This consultation is conducted in line with that requirement.

Section 2(1) of the Medicines and Medical Devices Act 2021 requires that, in making regulations about human medicines, the appropriate authority's overarching objective must be 'safeguarding public health'. In considering whether the proposed changes would contribute to this objective, section 2(3) states that the appropriate authority must have regard to:

- the safety of human medicines
- the availability of human medicines
- the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to:
    - carry out research relating to human medicines
    - conduct clinical trials
    - manufacture or supply human medicines

Section 2(4) of the Medicines and Medical Devices Act 2021 specifies that where the regulations may have an impact upon the safety of human medicines, the appropriate authority may only make the regulations if the benefits outweigh the risks. In conjunction, section 45(3) requires that the consultation carried out by the appropriate authority must include a summary assessment of how proposed changes contribute to the overarching objective of safeguarding public health, including whether there is an impact on the safety of medicines.

See the section above on patient safety for more detail. Patient safety is at the heart of these proposals. We consider the proposals to directly contribute to the overarching objective of safeguarding public health and the aim is to improve patient safety. We believe that the overall benefits of the proposals outweigh the risk – that the use of automation can decrease error rates, that the pharmacist and their teams may have time freed up, which should allow them to spot and deal with issues more quickly and effectively. Although the proposals allow for 2 separate legal entities to be involved in hub and spoke dispensing, we intend to ensure clear accountability between those legal entities and thereby maintain high standards of patient safety. Ensuring that a patient knows who is responsible means that there is a level of accountability there as well.

The proposals do not include anything that would necessarily either restrict or increase the supply of medicines to patients in themselves, but we are conscious and aware of concerns including around the direct supply of medicines by a manufacturer to a pharmacy, which will be impacted by these changes. We are also aware of the potential future impacts, for instance a potential reduction in competition, if for example there were limited numbers of hubs in the market which could in turn affect supply. These areas fall under UK mergers and competition law and have been picked up as areas for further work outside of this consultation. However, we will continue to work with appropriate parties to identify and, as appropriate, seek to address issues. Similarly, we do not believe that enabling hub and spoke dispensing will impact on the United Kingdom being seen as a favourable place to carry out research, conduct clinical trials or manufacture or supply medicines. We would welcome any further views and evidence on these assessments from respondents.

Privacy notice

Summary of consultation

The Human Medicines Regulations 2012 govern the arrangements across the United Kingdom for the licensing, manufacture, wholesale dealing and sale and supply of all human medicines, including the governance of pharmacists selling or supplying prescription only medicines. Alongside the Human Medicines Regulations 2012, the Medicines Act 1968 sets out requirements relating to the operation of pharmacies and pharmacists. This consultation seeks views and comments on proposals to enable all community pharmacies to access ‘hub and spoke’ dispensing.

Currently it is only possible when the hub pharmacy forms part of the same retail business as the spoke pharmacy. This consultation seeks views and comments on proposals to facilitate hub and spoke dispensing between pharmacies belonging to different legal entities. In addition, we are proposing to enable dispensing doctor access to hub pharmacies. Legislative changes will be required to deliver the proposals, including amendments to the Medicines Act 1968 and the Human Medicines Regulations 2012. This is a joint consultation between the Department of Health and Social Care (DHSC) and the Department of Health (Northern Ireland).

Data controller

DHSC is the data controller.

What personal data we collect

The type of personal information we will collect is as follows:

- name of the individual or organisation
- area of UK respondents are based in
- email address

How we use your data (purposes)

The data we collect is to inform the DHSC of the demographic of respondents. The Department will process your personal data in accordance with the Data Protection Act 1998 (DPA) and in most circumstances this will mean that your personal data will not be disclosed to third parties. We may need to contact you if

we have had a request under the Freedom of Information Act 2000 (FOIA). We will also email you to let you know if we have published a response to the consultation.

Legal basis for processing personal data

Under the UK General Data Protection Regulation (UK GDPR), the lawful bases we rely on for processing this information are:

- your consent

Data Processors and other recipients of personal data

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 2018 (DPA) and the Environmental Information Regulations 2004).

International data transfers and storage locations

Any personal information collected will be stored in the UK and managed in line with the DHSC's personal information charter.

Retention and disposal policy

We manage the information you provide in response to this consultation in accordance with the DHSC's data protection policy. We will retain your data for 12 months after the consultation closes.

How we keep your data secure

Anyone managing and handling personal information understands that they are contractually responsible for following good data protection practice, is appropriately trained to do so and is appropriately supervised.

Your rights as a data subject

By law, data subjects have a number of rights and this processing does not take away or reduce these rights under the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act 2018 applies.

These rights are:

- the right to get copies of information – individuals have the right to ask for a copy of any information about them that is used
- the right to get information corrected – individuals have the right to ask for any information held about them that they think is inaccurate, to be corrected
- the right to limit how the information is used – individuals have the right to ask for any of the information held about them to be restricted, for example, if they think inaccurate information is being used
- the right to object to the information being used – individuals can ask for any information held about them to not be used. However, this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case
- the right to get information deleted – this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case

Comments or complaints

Anyone unhappy or wishing to complain about how personal data is used as part of this programme, should contact data_protection@dhsc.gov.uk in the first instance or write to:

Data Protection Officer
1st Floor North
39 Victoria Street
London
SW1H 0EU

Anyone who is still not satisfied can complain to the Information Commissioners Office. Their website address is www.ico.org.uk and their postal address is:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Automated decision making or profiling

No decision will be made about individuals solely based on automated decision making (where a decision is taken about them using an electronic system without human involvement) which has a significant impact on them.

Changes to this policy

This privacy notice is kept under regular review, and new versions will be available on our privacy notice page on our website. This privacy notice was last updated on 16 March 2022.