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

We neither agree nor disagree that hub and spoke dispensing should be permitted across legal entities. We acknowledge that it is anomalous that pharmacies in common ownership can provide a dispensing service for each other without the need for an assembly licence, whereas pharmacies that do not form part of the same business are unable to do so. We do not comment here on the political or economic reasons for or against enabling hub and spoke dispensing to be carried out between pharmacies that are not part of the same business.

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?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

We agree that the hub-to-spoke model provides sufficient flexibility. We consider a hub-to-patient model provides too much flexibility with potentially unforeseen consequences, particularly the effect on market entry provisions. We do not consider it is sufficient to leave this to

further discussions between NHS England and Improvement and the Pharmaceutical Services Negotiating Committee: it is not only a matter of Regulations. The Regulations in each part of the UK are made pursuant to primary legislation, for example in section 129 of the National Health Service Act 2006. In addition, a hub-to-patient model would make the remuneration of pharmacy contractors even more complicated, since the Drug Tariff is predicated on supplies being made from premises that are included in a pharmaceutical list.

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?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

We strongly agree.

Question 5

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

Yes. We do not consider it is adequate merely to refer to arrangements that may or may not be contractual and leave the hub and spoke to agree on something. This is too vague and unenforceable. Regulation 4 of the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 may provide a suitable model for setting out the details of arrangements without being over-prescriptive.

If the Human Medicines Regulations permit a hub to supply medicines direct to patients, the requirement for supervision in regulation 220 of the Human Medicines Regulations should apply to the hub, not the spoke.

Question 6

Do you agree or disagree that the Human Medicines Regulations 2012 should ensure that pharmacies utilising hub and spoke dispensing must display a prominent notice to inform patients that hub and spoke dispensing is being used, as well as the name and address of any hubs being used?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Agree.

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

Patients are entitled to know whether their medicines are assembled by the pharmacy to which their prescriptions are sent or brought. However, the name and address of the hub is not likely to be information that is useful to patients. The proposal in the draft Regulations to add information to the responsible pharmacist notice may be sufficient, though it is not necessarily prominent. Pharmacies already display many notices and public health messages. Yet one more, however prominent, may not even be taken in by patients.

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

We disagree.

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

This is not something that should be left to the spoke and hub to agree. One of the main purposes of having a name and address on the dispensing label is to enable patients to know where to seek advice or help. The name and address of the spoke will be most useful. The name and address of the hub, perhaps a long distance away, is likely to be less helpful. It is the spoke to which the patient has presented a prescription and with which the patient would regard themselves as having a relationship. The simplest and most effective way to deal with this issue would be to require dispensing labels to say something like: “Assembled by X (Hub) Ltd on behalf of Y (Spoke) Ltd of [address of spoke]”.

Question 8

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

- Yes
- No
- Not sure

Yes.

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

Although hubs are not required to use automation, we expect that hubs will generally use robotic technology and this will reduce the incidence of picking errors in pharmacies. However, it will be important to support the use of this technology by enabling original packs to be dispensed even if the quantity on a prescription form does not specify a quantity that matches an original pack.

Question 9

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

Yes. We agree that equivalent provisions should enable dispensing doctors to outsource dispensing. Pharmacists have expertise in medicines and pharmacology that GPs lack. For this reason, the NHS Regulations only allow prescribed medicines to be supplied by dispensing doctors as an exception, usually in rural areas where there is no pharmacy within 1.6km. We consider that, amongst other things, supplies by a hub may make supplies to patients of dispensing doctors safer and more effective if the medicines will have been supplied from a pharmacy where a pharmacist's clinical assessment is carried out. This depends on whether the arrangements between a dispensing doctor and a hub involve clinical assessment being carried out at a hub, but in any event a pharmacist's expertise is generally not available when medicines are dispensed and supplied by dispensing doctors.

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?

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Agree. The requirements should be the same as for pharmacies, though, we do not consider it is essential in either case that the name and address of the hub pharmacy are displayed.

Question 11

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

Yes.

If your response relates to the draft statutory instrument which will enable the proposed changes, highlight the relevant paragraphs in your response.

1. Draft regulation 3 is a key amendment in enabling a pharmacy to assemble medicines for another pharmacy that is not in common ownership. However, it appears that the amendment that removes the words “forming part of the same retail pharmacy business” will not permit a hub pharmacy to assemble medicines and supply them to a dispensing doctor without an assembly licence.
2. **Draft regulations 4, 5 and 6** would amend sections 70, 71 and 72 of the Medicines Act 1968 which contain conditions to satisfy the definition of “lawfully conducting a retail pharmacy business”. These draft regulations refer to orders that are “submitted at the premises”. However, the use of these words is unclear. Do the words “submitted at” mean “submitted to the spoke by a patient or submitted by the spoke to the hub? If the former, it would be simpler to say “if orders for the sale or supply of medicinal products are **received** at the premises…”

3. **Draft regulations 4,5 and 6** would also amend the condition in sections 70, 71 and 72 of the Medicines Act for a notice to be displayed, giving the name and registration number of the responsible pharmacist. It appears from the draft regulations that the notice does not have to say the prescriptions will be dispensed elsewhere or identify the hub that will dispense a specific script. It appears that the same notice must be used as the one giving the name and registration number of the responsible pharmacist. This may create logistical difficulties for spoke pharmacies that use a standard form of notice, because existing standard notices will all have to be replaced.

4. Draft regulation 9 contains a definition of NHS GP surgery that would be inserted into regulation 8 of the Human Medicines Regulations. This definition seems very wide and could catch a registered pharmacy that is located within the surgery premises. Since the premises of dispensing doctors must be included in a dispensing doctor list (see regulation 46 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013), we suggest the definition should refer to the premises on a dispensing doctor list other than registered pharmacy premises.

5. **Draft regulation 10**, addressing what would otherwise be a requirement for a hub to have a wholesale dealer's licence, designates a sale or supply by a hub to a spoke as a retail transaction. Thus, the Human Medicines Regulations and the Medicines Act will have retail transactions, transactions in circumstances corresponding to retail sale and wholesale transactions that are reclassified as retail transactions. This is unnecessarily complex. It would be simpler and neater if either the Human Medicines Regulations included an exemption from the need for a wholesale dealer's licence any supply under regulation 222A or 222B arrangements, or if t HMR 18(5A) of the Human Medicines Regulations was amended to say:

> "In these Regulations references to distributing a product by way of wholesale dealing do not include any sale or supply by virtue of regulation 222A.".

See also our comments below on regulation 13.

6. **Draft regulation 11**, would amend regulation 220 of the Human Medicines Regulations by changing of "at or from" instead of "on" registered pharmacy premises. Regulation 220 is, of course, the provision that requires transactions involving Pharmacy medicines and Prescription Only Medicines to be carried out under the supervision of a pharmacist (unless a pharmacist personally makes the supply). It is unfortunate that this change is being proposed before the consultation on supervision, because there is no clarity over what supervision amounts to when a home delivery is made or medicines are collected from a machine that is not on registered pharmacy premises.
7. **Draft regulation 11: the inclusion of "at or from" in regulation 220 of the Human Medicines Regulations will be inconsistent with the requirement in section 129(2) of the National Health Service Act 2006 and regulation 10(1) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, which require listed pharmacies to provide services "from premises". It would make sense to amend the**

Act and the 2013 Regulations so that they are consistent with the Human Medicines Regulations.

8. **Draft regulation 13**, would insert regulation 222A into the Human Medicines Regulations treating a sale by hub to spoke as retail. This is confusing, because the spoke is then defined as "retailer". Yet in the proposed regulation 222B, the spoke is the "first business". Why not define them respectively as "the spoke" and "the hub"? This would make for consistency and clarity.

9. **Draft regulation 13**, in the wording of regulation 222A(1) (b)(ii) in the Human Medicines Regulations could be less tortuous if it said:

> "sold or supplied to a person who is lawfully conducting a retail pharmacy business at or from that pharmacy"

because the term "lawfully conducting a retail pharmacy business" is well-defined in sections 69 to 72 of the Medicines Act 1968.

10. **Draft regulation 13** would insert regulation 222B into the Human Medicines Regulations and deem that a sale or supply direct from a hub from patient is a sale or supply from the spoke, but it may **also** be a sale or supply by the hub. If the hub supplies to a patient (ie physically hands over the medicine), a pharmacist at the spoke cannot be supervising and, indeed, the hub may supply at a time when the responsible pharmacist is absent from the spoke. The draft regulations aim to tackle this in 222B of the Human Medicines Regulations by treating the sale by the hub as being made when the prescription was submitted to the spoke (or anything else that forms part of dispensing is done at the spoke. The draft Regulations stop short of saying that for the purpose of regulation 220, supervision is deemed to have taken place at the spoke. It would be better if it did. Alternatively, it would be better to require supervision by a pharmacist at a hub that makes supplies to patients to supervise, analogous to the way that regulation 248 of the Human Medicines Regulations deals with supervision when a collection and delivery arrangement is used. Without such a provision, it is not clear how supervision is exercised at a spoke when a delivery is made by a hub to a patient's home.

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?

Yes. We do not consider there is any need for change except to allow the spoke to provide to the hub the medicines that the hub is asked to assemble. While there may not be circumstances in which this is likely to happen, we believe it should not be unlawful.

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'?

No. The GPhC has the power to inspect premises and already has adequate regulatory powers in relation to registered pharmacy premises and ancillary premises. The GPhC also has the ability to enforce professional standards and these standards already cover storage, distribution and transportation.

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?

Yes.

(a) Draft regulation 9 amends the interpretation regulation 8 in the Human Medicines Regulations, including:

> "medicinal products on a general sale list" means medicinal products subject to general sale, as provided for by regulation 5(1)".

This change is needed because no medicines have been added to the general sale list since 2001: since then, the classification of medicines has been dictated by the marketing authorisation of each product and the Human Medicines Regulations usually refer to "medicines subject to general sale" rather than "medicines on a general sale list". However, sections 70, 71, 72 and 72A of the Medicines Act 1968 all refer to "medicines on a general sale list". These sections stipulate what medicines superintendent pharmacists and responsible

pharmacists are or are not responsible for. Because the wording of the Medicines Act has not been brought into line with the wording in the Human Medicines Regulations, there is a lacuna in the requirement for superintendent pharmacists and responsible pharmacists. For example, a pharmacy owned by a body corporate is **not** required to be under the management of a superintendent pharmacists so far as general sale list medicines are concerned, but the pharmacy **is** required to be under the management of a superintendent so far as concerns medicines subject to general sale.

The simple way to address this would be to make exactly the same amendment to the interpretation provisions of the Medicines Act 1968 as are proposed in relation to the Human Medicines Regulations 2012.

(b) Regulation 253 of the Human Medicines Regulations requires a pharmacy conducting a retail pharmacy business to make a record of the supply of Prescription Only Medicines. It is not clear from the draft Regulations whether, when a supply is made by a hub to a spoke, the hub must comply with regulation 253 if the prescription. Is the supply to be treated as exempt from the requirement under regulation 253(4)(a) because, in the case of an NHS prescription, the supply is deemed to be “in pursuance of a health prescription”? If the prescription is a private one, does the hub have to comply with regulation 253 whether it makes a supply either to the spoke or to the patient.

Impact assessment

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

Question 15

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

No.

Question 16

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

No.

Question 17

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

- Strongly agree
- Agree
- Neither agree nor disagree
- Disagree
- Strongly disagree

Neither agree nor disagree.

Question 18

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?

This question is beyond our remit.

Question 19

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

No.

Question 20

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

Neither agree nor disagree. This question is beyond our remit.

Question 21

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

The impact on the market entry regulations and on the Drug Tariff has not been 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.