Contract and IT

June 2021

PSNC Briefing 017/21: Hub and spoke dispensing+

This briefing seeks to provide information for community pharmacy contractors on the regulatory aspects of current hub and spoke dispensing available to some, and the likely changes to the legal framework over the next year that will make such dispensing available to all.

Introduction

Enabling legislation

In February 2021, the Medicines and Medical Devices Act 2021 (MMDA) was introduced, paving the way for an updated regulatory framework for the manufacture, marketing and supply of medicines and medical devices. This includes provision for regulations to be introduced to permit 'hub and spoke dispensing between **different** retail pharmacy businesses (different legal entities)' (**H&S**), replacing such powers that were available through the now repealed European Communities Act 1972.

The Department of Health and Social Care (DHSC) is having discussions with community pharmacy stakeholders to identify relevant issues, before carrying out a formal, public consultation on the introduction of H&S in regulations under the MDDA. It is envisaged that H&S will be an option for all retail pharmacy businesses in late 2021 or the first half of 2022 (although the timetable legislation on H&S has been delayed to date due to the COVID-19 pandemic).

Hub and spoke dispensing now

Currently, hub and spoke dispensing is permissible only **within** a retail pharmacy business (within the same legal entity). Several retail pharmacy businesses already carry out hub and spoke dispensing between their respective pharmacies.

DHSC describes **hub and spoke dispensing** as 'arrangements where a retail pharmacy, notionally at the end of a spoke, receives prescriptions, and sends them electronically to a remotely located hub, which in turn takes in prescriptions from multiple spokes. At the hub, medicines are selected, packaged and labelled and then transported back to the spoke to be checked by the pharmacist and collected by the patient.' (**paragraph 170 of the impact assessment for the MMDA**)

Hubs are pharmacies registered with the General Pharmaceutical Council (GPhC), as required by the Medicines Act 1968. Hubs **assemble** medicines for dispensing at spokes and hubs may use an automated or manual dispensing process. **Spokes** are pharmacies registered with the GPhC, and, for the dispensing of NHS prescriptions (provision of NHS pharmaceutical services), are **on the relevant pharmaceutical list of NHS chemist premises held by NHS England and NHS Improvement** (NHSE&I) (pharmacies with an 'NHS contract'). Details of NHS listing requirements (including market entry applications and community pharmacy Terms of Service) are set out in the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (NHS Regulations) (the NHS regulations). NHS payments, for example, reimbursement and remuneration for dispensing NHS prescriptions, are made to the pharmacy with an NHS contract from which the supply was made, in accordance with the NHS Regulations and the Drug Tariff.

H&S in the future

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The impact assessment for the MMDA (paragraph 174) suggests that three models of H&S might be allowed for in new regulations:

- large retail pharmacy chains with large, automated hubs could expand their capacity. We would expect to see these businesses offer chargeable prescription assembly services to independent and small multiple pharmacies;
- independent and small multiple pharmacies could co-operate and centralise assembly of medicines in one of their pharmacies or through setting up off-site hub facilities; and
- new large-scale hub facilities could be developed by the NHS, wholesalers or new companies, although the hub would need to be a registered pharmacy.

The details around policy design of H&S will be provided for in MMDA regulations that are likely to amend the Medicines Act (MA) 1968 and the Human Medicines Regulations 2012 (HMRs).

Background to H&S

In March 2016, the Government proposed H&S as part of changes to the Community Pharmacy Contractual Framework (CPCF). The H&S proposal met strong resistance from many community pharmacy stakeholders, particularly Independent Contractors, and after a meeting in September 2016, DHSC put the proposals on hold (see the **DHSC consultation** and the **PSNC response**).

In 2019, legislative change to permit H&S was back on the agenda and agreed in principle between DHSC and PSNC as part of the **Community Pharmacy Contractual Framework (CPCF) for 2019/20 to 2023/24: supporting delivery for the NHS Long Term Plan**. This 5-year agreement set out an expanded role for the community pharmacy network as an accessible community health service integrated in NHS pathways with pharmacists' clinical skills better utilised. As part of this and amongst other things, DHSC and PSNC agreed DHSC would:

- pursue legislative on H&S and as part of this agree with PSNC which models will allow the whole sector to benefit fairly;
- explore and implement greater use of Original Pack (OP) dispensing;
- propose legislative changes that will allow for better use of the skill mix (e.g., between pharmacists and pharmacy technicians) in pharmacies and enable the clinical integration of pharmacists; and
- explore the impact of changes to funding and fee structures, including for different types of prescription, and whether these could support the market to move towards more efficient dispensing practices.

OP dispensing, skill mix and funding and fee structures have a relationship with H&S, as they have the potential to increase any efficiency that may be available from the use of large remote pharmacy hubs assembling medicines for dispensing at community pharmacy spokes.

The key reasons for PSNC's change of approach in 2019 include: assurances from DHSC that models of H&S that would allow the whole sector to benefit fairly will be agreed with PSNC, reduced impact of EU legislation, including the Falsified Medicines Directive (the MDDA now covers this issue), and because by addressing the issue afresh, safety and professional issues around H&S can be addressed in advance of any legislative change that allows H&S to commence.

Impact of H&S

DHSC has indicated there will be an impact assessment alongside a consultation on H&S, but in the meantime its views on the likely impact are set out within the **Impact Assessment (IA) for the MMDA dated 10th February 2020**. This **impact assessment** references the 5-year deal for the CPCF (paragraphs 40-43 of the MMDA) and considers hub and spoke dispensing (paragraphs 169-177 of the MMDA).

Key points in the IA include:

- the costs and benefits of H&S remain uncertain, as do some details around the policy design;

- The costs and benefits of different hub and spoke arrangements may result in different costs and benefits falling on different affected parties.
- costs would include for hubs, capital investment set-up costs, and for spokes, changing business processes, IT and logistics, with ongoing costs of employing pharmacy staff at hub facilities;
- benefits are expected to include reduced staff time on dispensing at the spoke pharmacy (freeing up time to provide other services), potential for reduced rates of dispensing errors and potential for a calmer working environment at the spoke pharmacy;
- in principle, any gains could be shared between hub operators, spoke operators, patients and the NHS;
- the cost of setting up hub facilities requires a significant number of spokes before savings can be made, and Independent and small chain pharmacies lack the scale to do this in a single legal entity;
- the regulations will make H&S permissible by all pharmacies, **and no pharmacy would be required to set up, use or offer hub services**; and
- uptake of H&S will depend on whether pharmacies consider H&S to be beneficial to their business.

It is relevant to note that while the MDDA regulations may not require pharmacies to set up H&S arrangements, it is important that H&S remains voluntary in terms of any future changes to the CPCF and other NHS initiatives.

The National Pharmacy Association has articulated pertinent issues for Independent pharmacies, primarily that H&S has the potential to increase cost for some pharmacies rather than reduce them – see later.

Regulatory issues

There are three main types of regulatory change either envisaged or likely as part of the introduction of H&S:

- UK medicines legislation;
- NHS Regulations; and,
- GPhC regulation.

There is likely to be a need for all three aspects to be developed simultaneously, or at least measures taken to ensure that any changes to UK medicines legislation do not lead to the introduction of H&S before models that are fair to the community pharmacy sector have been agreed in NHS Regulations, and professional and safety issues have been addressed, by the GPhC which regulates pharmacies and pharmacy professionals.

UK medicines legislation

Legal entities

In certain circumstances, the preparation, dispensing and assembly of medicines under the supervision of a pharmacist is exempt from the normal requirements around the manufacture and authorisation of medicines (regulations 17(1) and 46 of the HMRs respectively). In the case of medicines **assembled** within registered pharmacies this must be done 'with a view to such sale or supply either at that registered pharmacy or at other such registered pharmacy forming part of the same business' (my emphasis) and where the medicine has not been the subject of an advertisement (section 10(1)(b) of the MA 1968). The 'same business' restriction will need to be changed or superseded to enable H&S.

Supervision, responsible and superintendent pharmacists

Currently pharmacist supervision of assembly is required at the hub, as well as pharmacist supervision of supply at the spoke. Both pharmacies require a responsible pharmacist, and in the case of a single legal entity carrying out hub and spoke dispensing, there is one superintendent pharmacist.

In the case of H&S there may be two superintendent pharmacists, one for each legal entity involved and the two respective supervising and responsible pharmacists work for different pharmacies businesses where the culture, procedures, practices and support may be different. There is a need to regulate both legal entities, to ensure the safety of a single dispensing process.

Wholesaling

Wholesaling of medicines between different legal entities (regulation 18 of the HMRs) will also have to be considered, as may the applicability of Good Distribution Practice to the transfer of assembled or part dispensed medicines between different legal entities.

Labelling

The HMRs provide special labelling provisions for medicines assembled by pharmacies in accordance with section 10 of the MA 1968 and these must be labelled appropriately (regulation 4 of the HMRs). Labelling of assembled or partly dispensed medicines as part of H&S between different legal entities will need to be considered.

Collection and Delivery

The HMRs provide that medicines that are not GSLs must be sold or supplied, or offered for sale or supply, by a retail pharmacy business, on pharmacy premises registered with the GPhC and under the supervision of a pharmacist (regulation 220). There are various exemptions to this including one for certain collection and delivery arrangements (regulation 248). This provides an exemption where a person takes or sends a prescription to a non-pharmacy premises (which is capable of being closed off to the public) and collects the dispensed medicine from that same premises; the prescribed medicine having been dispensed at a registered pharmacy under the supervision of a pharmacist. The exemption was originally provided in a statutory instrument under the MA 1968. It is clear that such collection and delivery arrangements are very limited and with good reason: they are an exemption to supply from pharmacy premises with appropriate professional oversight.

Original pack dispensing

OP dispensing is considered to be a key enabler of H&S, but, for example, a pharmacy may not supply 30 tablets against a prescription for 28 tablets, and a pharmacy may not supply only 28 tablets against a prescription for 30 tablets; to accommodate OP dispensing. The applicable legislation is the HMRs and NHS Regulations. (Generally, pharmacies must provide original packs if they are available for the quantity of medicines prescribed (schedule 4, paragraph 8(10) of the NHS Regulations)).

Changing the legislation

DHSC will have to determine whether changes to legislation should set out the broad principles of H&S, or provide more detail, for example, the level of pharmacist supervision required, depending on the extent of dispensing carried out by the hub or the spoke – this is in terms of dispensing accuracy (including, input of data and automatic or manual assembly) and a clinical check (including assistance from Artificial Intelligence).

The impact assessment for the MMDA suggests that spoke pharmacies in H&S will need to undertake an accuracy check, but it is not clear if this would also apply to hub and spoke dispensing within the same legal entity. Some pharmacy companies already using hub and spoke arrangements have suggested this would be an unnecessary duplication for them, within one legal entity.

Collection and delivery arrangements should also be considered to ensure supply of medicines from non-pharmacies remains an exception to supply from pharmacy premises and to confirm that this is not part of any hub and spoke arrangements.

Regulations to introduce H&S under the MMDA, are likely to make amendments to the HMRs and MA 1968.

NHS Regulations

Market entry and premises at which NHS pharmaceutical services are provided

NHS Regulations provide a market entry application system based on patients' needs for pharmaceutical services described in the local Pharmaceutical Needs Assessment. Applications to provide pharmaceutical services may be granted, and those premises at which, or (for example, Distance Selling Premises) from which, pharmaceutical services may be provided are included on pharmaceutical lists for Health and Wellbeing (HWB) areas. The lists include the address of the relevant premises (the chemist premises or NHS pharmacy premises) and the days and

times at which, at those premises, the listed contractor is to provide those services during core and supplementary opening hours for the premises.

Direct Supervision

Dispensing medicines and, in the normal course of business, the supply of appliances are part of Essential Services under the Terms of Service and must be provided under the **direct** supervision of a registered pharmacist (schedule 4 of the NHS Regulations). There is little guidance on the meaning of 'direct supervision' in the NHS Regulations compared with 'supervision' in terms of the HMRs, but the requirement will need to be considered in the context of NHS H&S.

Models of supply

There are two main types of pharmacy envisaged under the NHS Regulations, bricks and mortar (B&M) pharmacies and Distance Selling Premises (DSP) pharmacies. (Local Pharmaceutical Service (LPS) pharmacies and Dispensing Doctors (DD) may also provide pharmaceutical services as provided for in the NHS Regulations.) DSPs must not offer to provide Essential Services to persons who are present at (which includes in the vicinity of) the listed chemist premises, and the means by which they provide those services must be such that any person receiving them does so otherwise than at the listed chemist premises. They must also secure the uninterrupted provision of safe and effective Essential Services to persons anywhere in England during their opening hours; and do this without any (physical) face-to-face contact with patients or their representatives.

Both B&M and DSP pharmacies use the Electronic Prescription Service (EPS) and can use websites and apps' and liaise with patients through electronic means. DSP pharmacies provide dispensed medicines to patients from the pharmacy, as part of the provision of NHS pharmaceutical services. B&M pharmacies must provide dispensed medicines at the pharmacy; if they deliver them to patients' homes, generally, this is a private service. The B&M pharmacy may charge for this or provide it free of charge.

Thus, the main existing models for pharmacy supply are:

B&M pharmacy:	patient – pharmacy – patient at the NHS pharmacy premises
DSP pharmacy:	Patient away from the NHS contract pharmacy anywhere in England – pharmacy – dispensed medicine provided to the patient away from the pharmacy

The two models of supply currently envisaged for H&S appear to be:

1. **Patient – spoke pharmacy – hub pharmacy – back to spoke pharmacy – patient**

2. Patient – spoke pharmacy – hub pharmacy – patient

PSNC does not accept the second model as appropriate or fair for the sector, which with the Electronic Prescription Service, is in effect the supply of dispensed medicines from a DSP.

Dispensing Doctors

DDs provide pharmaceutical services in accordance with the NHS Regulations and H&S will need to be permissible for their provision of dispensed medicines.

Other Terms of Service

Various aspects of the Terms of Service are more easily managed with hub and spoke dispensing within a single legal entity. These include such matters as complaints handling, incident reporting, data protection issues, standard operating procedures, premises standards and maintenance of equipment. Where aspects of the dispensing process may be carried out by hub pharmacies that are not NHS pharmacies these issues need to be considered including NHS access to those premises for the quasi-regulatory role carried out by NHSE&I. Additionally, issues of

resilience planning may also need to be considered to ensure patients are not affected by disruptions to any H&S arrangement.

Professional Standards

The General Pharmaceutical Council (GPhC) sets standards for the profession and pharmacy premises it registers and inspects. The extent to which the GPhC seeks to provide standards and guidance for the pharmacies and pharmacists involved in H&S remains to be determined, but such professional regulation, of the supervising, responsible and superintendent pharmacists or owner pharmacist(s) is an alternative to more formal regulations. However, such standards and guidance are still subject to the legal provisions on, for example, supervision and the courts' (case law) interpretation of its meaning.

PSNC considers that it is important that H&S remains a shared dispensing process between pharmacists and registered pharmacies, to ensure that the process is managed between professionals with similar knowledge, expertise and training, and regulated as a system by one regulator, the GPhC, dealing with the premises, businesses and teams of people involved.

Funding and other considerations

Potential savings with H&S

The 5-year CPCF deal agreed in 2019, envisages that both pharmacists' time and funding from the CPCF may be freed up, partly through the use of H&S, and that this will be used to fund the delivery of new pharmaceutical services by pharmacies. However, those carrying out hub and spoke dispensing indicate that it provides **activity savings** (more dispensing can be carried out through a pharmacy with off-site assembly and/or pharmacists' time in the spoke may be partly freed-up), but there is no evidence of **cost savings**. On behalf of independent pharmacies, who would use hubs owned by others, the NPA is concerned that its use may increase dispensing costs. The MDDA IA indicates the views of the DHSC on the potential savings to be gained from H&S (see earlier).

PSNC does not consider that the current funding level for the CPCF is adequate and has been seeking an uplift to the global sum.

Margin

Implicit within the CPCF is the equal availability of Margin (an element of remuneration) as pharmacy businesses compete with each other with the purchase of generic medicines for NHS dispensing. This does not mean that pharmacies will achieve an equal amount of funding through Margin, since this depends on their purchasing compared to each other. A key issue with H&S is whether the arrangements between pharmacies will be sufficiently competitive for Margin to remain equally available to all community pharmacy contractors.

H&S voluntary – now and in the future

The impact assessment for the MMDA indicates that regulations will make H&S permissible by all pharmacies, but no pharmacy will be required to set up, use or offer hub services. It is important that H&S is and remains voluntary, both legally in the regulations and in practice – economically: that no **subsequent** funding, structural or other measures taken affect this principle. This is relevant as the 5-year deal includes the commitment to:

- *propose legislative changes that will allow for better use of the skill mix in pharmacies and enable the clinical integration of pharmacists; and*
- *explore the impact of changes to funding and fee structures, including for different types of prescription, and whether these could support the market to move towards more efficient dispensing practices, while increasing the clinical and public health content of any patient interactions.*

As well as H&S and OP dispensing.

Patient choice

Patient choice is central to the current competitive provision of pharmaceutical services. The government has committed to maintaining the market entry system which supports patients' needs (2018 review of the NHS Regulations) and to patient choice. In addition, in the 5-year deal, DHSC stated *we will continue to protect patients' free choice of which community pharmacy they wish to dispense their prescriptions*.

Automated or manual H&S

Hub and spoke dispensing is associated with automated dispensing and may include this, but not necessarily.

Once permitted, H&S may be possible between two or more pharmacies on a local level without any automation, with assembly or part dispensing carried out manually.

Automated dispensing is already carried out in some individual pharmacies without any hub and spoke dispensing.

Responsibility

Currently, one legal entity can adjust the dispensing process at either hub or spoke, to ensure that overall it remains safe and effective. Responsibility for any dispensing errors is clear, because one legal entity is responsible for the entire process. Who is responsible for what may need to be considered before the one process is shared between two legal entities, because the safety and effectiveness of the process may be highly dependent on the integrated actions of both parties. Arguably both hub and spoke must be confident that the processes of the other, on an ongoing basis, remains fit for purpose.

IT

In the 5-year deal, DHSC indicated it was seeking the transformation of pharmacy services through technology, stating:

Technology will transform the supply of medicines and delivery of pharmacy services just as it is transforming the wider NHS and economy. This is primarily an opportunity, not a threat; it is also an inevitability. We will have wider discussions on how community pharmacy can be clear with its IT suppliers what functionality it will require as the sector evolves.

As regards H&S, this is likely to be important to ensure that hubs have interoperability and pharmacy spokes have a genuine competitive choice of hub.

Community pharmacy competitive purchasing

PSNC has indicated the need to protect the resilience and competitive purchasing of community pharmacy – which ensures the continuity of supply of essential medicines to patients, with significant savings to the public pursue. This arrangement has saved the public purse £billions over the last decade or so, as generic dispensing has increased and has helped to make generic medicines some of the cheapest in Europe over the last decade (see the **2019 Oxera report into the supply of generic medicines in the UK**).

Related commercial considerations

During discussions on H&S, various commercial and competition issues have been raised, but these are not for direct consideration by PSNC, although they have the potential to be relevant to identifying a model that is fair for the sector as a whole. These commercial issues include:

- the comparative bargaining power of a larger hub with a single independent spoke;
- any mechanism for margin distribution or sharing that is part of the financial agreement between the spoke and the hub.
- whether there is a competitive market of hubs; and

- whether all hubs have equal access to dispensations around Direct to Pharmacy arrangements and manufacturers' quotas;

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Annex A: The views of the pharmacy stakeholders

PSNC

The views of PSNC have changed between 2016 and 2019. In 2016, PSNC opposed H&S whereas in 2019, PSNC agreed to work with DHSC and NHSE&I to introduce it. The broad reasons for this change are as follows:

- **Agreed on the basis that DHSC will agree with PSNC which models will allow the whole sector to benefit fairly, particularly Independents (not simply a legal level playing field).** Previously opposed on the basis that it was impossible to create a level playing field for 'hub and spoke' dispensing between independents and multiples and that alleged economic efficiency reasons for 'hub and spoke' dispensing are not evidenced and arguably such models will cost more overall.
- **Agreed on the basis that concerns around the interpretation and application of EU legislation are now less applicable.** Previously opposed for concerns around wholesaling and the Falsified Medicines Directive and that a complete redesign of the use of chemist nostrums was unnecessary.
- **Agreed on the basis that concerns around the professional, legal and safety implications of H&S can be addressed in a new consultation and the safety risks associated around H&S are being considered.** Previously, there appeared to be a professional justification for H&S which has not been evidenced.
- **Agreed on the basis that any new consultation could consult on the relevant issues.** Previously opposed on the basis that the then draft regulations proposed a structure for 'hub and spoke' dispensing that was wholly different from the narrative of the consultation.

There remains concern that current efficient and competitive pharmacy procurement, which has generated £billion of savings to the public purse may be lost if purchasing of medicines for NHS dispensing is concentrated in fewer remote hubs.

In 2020, responding to the MMDA, PSNC indicated that:

- Hubs and spokes to have recognised standards and validation/quality assurance of the shared dispensing processes;
- Only spoke pharmacies with NHS pharmacy 'contracts' to supply dispensed medicines to patients, not hubs;
- Only registered pharmacies to be hubs and spokes to ensure one continuous pharmacy process;
- Hubs to have interoperability and be competitive; and all spokes to have full access to pharmacy funding;
- All hubs to have equal access to dispensations around Direct to Pharmacy arrangements and manufacturers' quotas;
- No fee or other differential (direct or indirect) between bricks and mortar and distance selling premises (remote) pharmacies;
- Original Pack Dispensing or pharmacy flexibility to provide calendar packs;
- Recognition that there is no evidence of financial savings, only evidence of potential capacity release;
- Protect the resilience and competitive purchasing of community pharmacy – which ensures the continuity of supply of essential medicines with significant savings to the public pursue; and
- Hub and spoke dispensing between different legal entities to remain voluntary and no **subsequent** funding, structural or other measures taken that affect this Government commitment.

CCA

The Company Chemists Association (CCA) has had a number of H&S related meetings and discussions including a virtual Q&A event on 1st October 2020 to help parliamentarians to understand more about automation of medicines assembly and the role of hub and spoke models. Their report identifies three key enablers which CCA considers need to be addressed for the full potential of hub and spoke technology to be realised:

- **Original pack dispensing** – DHSC agreed with the need for OP dispensing and indicated the hope that this issue would be resolved within the timescale of the five-year current community pharmacy funding deal agreed between DHSC, NHSE&I and PSNC in the summer of 2019.
- **Government support for infrastructure investment** – CCA has estimated that less than 10% of NHS prescriptions are dispensed using hub and spoke technology and that CCA members companies have invested tens, if not hundreds of millions of pounds in the technology to achieve this; and that there is no longer any Margin available in community pharmacy funding to continue this level of investment. Therefore, Government capital expenditure is needed for this infrastructure to expand further. The CCA was not confident that the efficiencies expected to be gained from further hub and spoke technology would be realised within the five-year period of the current community pharmacy funding deal.
- **Fair community pharmacy funding** – The CCA has indicated that the level of community pharmacy funding has been a challenge for some time and the base level of funding needs to be increased to enable pharmacies to deliver the urgent care and services the NHS desperately needs, especially in the current COVID environment.

NPA

The National Pharmacy Association (NPA) has consistently challenged claims that H&S will deliver efficiency and patient safety benefits and remains concerned that H&S will not deliver benefits to many Independents and could have unintended adverse consequences for Independents.

The NPA's Evidence-Based Policy Review of H&S carried out in 2016 is available at https://www.npa.co.uk/wp-content/uploads/2021/04/2016-03-NPA-Hub-Spoke-Report.pdf The key findings were stated as:

- Inter-company Hub & Spoke could result in serious unintended consequences, including inflationary pressures on medicines costs for the taxpayer, due to reduced competition and choice in the pharmaceutical wholesale/Hub market.
- Although Hub & Spoke could provide capacity to deliver more healthcare services through community pharmacy, the system is complex with a number of implementation problems, including professional and legal challenges.
- There is currently no basis for claims that Hub & Spoke will allow pharmacies to reduce their operating costs.
- The NPA made key recommendations which could enable Hub & Spoke technology to operate more safely and effectively for those who wish to use it.

In February 2020, the NPA held a roundtable discussion on H&S chaired by Richard Murray, Chief Executive of The King's Fund, https://www.npa.co.uk/wp-content/uploads/2020/09/NPA-Hub-and-Spoke-roundtable.pdf which considered the opportunities, risks and barriers and enablers of H&S. The NPA's report of the roundtable discussion concluded that:

- Opportunities have been identified for the sector, such as releasing capacity at pharmacies and improving patient safety. However, it was acknowledged that hub and spoke dispensing may release little or no capacity unless the risks and barriers are overcome.
- Numerous potential risks and barriers have been identified which need to be addressed to avoid unintended consequences.
- Hub and spoke is not the only possible answer to releasing capacity and other capacity building initiatives would also need to be considered and explored.
- Simply changing the law to enable inter-company hub and spoke dispensing will not create a level playing field for independent pharmacies and will not guarantee that the desired outcomes for the NHS, taxpayers and patients will be achieved. There are many factors which need careful consideration, and a holistic approach needs to be taken.
- Various enablers have been identified which need to be considered and explored. This will require relevant stakeholders from across the whole system coming together to discuss and develop potential solutions.
- For the entire community pharmacy sector to rise to the challenge, effective and responsible innovation is required. However, expectations need to be clear and realistic.

In June 2020, responding to the MMDA, the NPA indicated that: https://publications.parliament.uk/pa/cm5801/cmpublic/Medicinesandmedical/memo/MMDB18.pdf

- Hub and spoke dispensing is just one way of embracing new technology in order to automate dispensing. There are other options to consider, such as automating locally by putting a robot in a pharmacy. On-site pharmacy automation has been implemented quite widely in the community pharmacy sector and very widely in the hospital pharmacy sector for several years.
- Government needs to fully assess and consider the potential unintended consequences of hub and spoke dispensing, including the potential impacts on patient choice, availability of medicines in the UK, medicines prices and competition and choice in the pharmacy and pharmaceutical wholesale markets.
- It is a concern that the Government has acknowledged in its own Impact Assessment of this Bill that the costs and benefits of hub and spoke dispensing remain uncertain.
- The Government's Impact Assessment of this Bill states that individual pharmacy businesses would need to consider whether it is beneficial for them to offer or use hub dispensing services, however there are various factors beyond the control of individual pharmacy businesses that undermine a level playing field for H&S.
- If all pharmacies are to benefit from inter-company hub and spoke dispensing, then the Government needs to consider how to ensure that there is a dynamic and competitive market for 'hub dispensing services' with a wide choice of hub providers competing for the custom of pharmacies.
- Overall, there needs to be sufficient parliamentary scrutiny of any proposed changes under this Bill and a robust consultation process for any proposed changes to enable extensive consideration and scrutiny by all relevant stakeholders.

The response to the MMDA included a report published by the NPA in 2020 on hub and spoke dispensing worldwide. https://www.npa.co.uk/wp-content/uploads/2020/02/Hub-and-Spoke-research-review-NPA-published-February-2020.pdf This research identified that large scale automated dispensing remains very limited globally, despite the technology being established for at least 15 years. Except for the Netherlands, the large-scale automated dispensing of original pack medicines to third party pharmacies is not operational in any global market. Where third party automated dispensing has had most traction, its focus is on multi dose dispensing.

The report identifies two modes of automated dispensing:

- **Automated Dose Dispensing (or ADD)** whereby one or more medicines are dispensed into a container or pouch for a patient to take at a particular date or time. This mode of automated dispensing is common across northern Europe.
- **Standard Dispensing** whereby medicines for a period of supply are dispensed either by original pack or into vials. This mode of dispensing – often referred to as Central Fill – is most frequently associated with dispensing loose pills into vials and is most common in Northern America.

The exception to this is The Netherlands, where automated "central fill" using original packs, is common practice. Most multiple community pharmacies use this process, and circa one third of independent pharmacies use such a process provided by a 3rd party.

The report concluded that:

- The economic case for the aggregation and automation of dose dispensing appears to make good economic sense in principle. However, demonstrable cost benefit cases have not been uncovered by this research, and many independent researchers also point towards the absence of hard economic evidence to support further investment. In The Netherlands, where this mode of dispensing may be most embedded, pharmacies receive premium remuneration for ADD patients.
- The majority of independent studies also identify a similar absence of definitive evidence in respect of patient safety.
- Several studies identify that whilst accuracy gains may be made in the part of the process that is automated, new processes are introduced pre and post automation. New processes introduce new risks, and no studies that address the patient safety impact of the full end to end process have been conducted to date.
- In the round, independent studies consistently question whether both the economic, or patient / consumer benefit cases for large scale automation have been established by independent data and evidence.

In light of the findings, the report recommends that the following factors should be considered:

1. **Feasibility** - At the present time, there do not appear to be any large-scale pharmacy hubs in operation serving more than hundreds of third-party pharmacies and thousands of patients. Where automated volumes are greatest, they are concentrated on multiple chains, and on loose pills counted into vials as opposed to original pack dispensing.
2. **Economic** - Building on the above, several academic researchers have identified the absence of cost benefit cases in the automated dispensing scenarios they have researched. It would therefore be welcome to see evidenced cost benefit cases.
3. **Patient safety** - Many claims for the patient safety benefits of large-scale automation have been made. A much more conservative tone is observed amongst academic researchers, who note the case may not be proven one way or the other. More rigorous independent research is required.

Annex B: Glossary

From medicines legislation

"**assemble**" in relation to a medicinal product includes the various processes of dividing up, packaging and presentation of the product, and "assembly" has a corresponding meaning; (Regulation 8, HMRs)

"**labelling**" in relation to a container or package of medicinal products means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents (and "label" has a corresponding meaning); (Regulation 8, HMRs)

"**manufacture**", in relation to a medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, a substance used as a vehicle for the purpose of administering it; (Regulation 8, HMRs)

"**registered pharmacy**" means— (a) in relation to Great Britain, premises entered in the register required to be kept under article 19 of the Pharmacy Order 2010 for the purposes of sections 74A and 74J of the MA 1968(a); and (b) in relation to Northern Ireland, premises entered in the register required to be kept under section 75(b) of the MA 1968; (Regulation 8, HMRs)

"**retail pharmacy business**" means a business (other than a professional practice carried on by a doctor or dentist) which consists of or includes the retail sale of medicinal products that are not subject to general sale; (Regulation 8, HMRs)

"**supply**" means supply in circumstances corresponding to retail sale; (Regulation 213, HMRs)

Informal

Accuracy check - ensuring that the data input into the system (that is required by the hub for assembly) is correct before it is transferred to the hub. This is an essential step where automation is being used; and ensuring that the dispensed medicine is the medicine prescribed for the patient.

Automation – assembly undertaken by a 'robot'

Clinical check – confirming the appropriateness of prescribed medicines for the patient

Consent – agreement of the patient based on relevant information; in the case H&S, the patient's agreement that the prescription may be dispensed at a hub.

Data input – a process of adding accurate information to a computer system, for example, patient details, dosage instructions, etc. for assembly or part dispensing by a hub. This is an essential step where automation is being used and is crucial to ensuring the correct medicines are selected in a hub's automated computer system and that the medicine is correctly labelled.

Distance Selling Premises (DSP) Pharmacy – this is a specific type of NHS pharmacy in England which receives the prescription and delivers the dispensed medicine directly to the patient - where the pharmacy procedures for the premises must be such as to secure, for example, the safe and effective supply of those dispensed medicines, with reasonable promptness, and without (physical) face to face contact between the patient or the patient's representative and the pharmacy staff.

GPhC registered premises – a premise registered with the General Pharmaceutical Council in accordance with the relevant legislation.

Hub – this is a pharmacy, registered with the GPhC, which assembles, or part dispenses medicines on behalf of one or more spoke pharmacies.

Hub and spoke dispensing – a single dispensing process shared between a pharmacy spoke and pharmacy hub (currently this may be undertaken only within a single legal entity)

H&S (in this briefing) – hub and spoke dispensing between **different** retail pharmacy businesses (different legal entities) (not currently permissible)

Human Medicines Regulations 2012 (HMRs) – legislation that deals with the manufacture, distribution and supply of medicines in the UK

Liability – This can be split into a number of areas and could include civil liability and professional liability/responsibility:

- Prescription liability –generally, this would be with the prescriber
- Clinical liability – generally, this would be with the prescriber and the dispensing pharmacies and pharmacists, particularly the supervising and responsible pharmacists
- Data accuracy liability – generally, this would be with the pharmacies and pharmacists, particularly the supervising and responsible pharmacists, but could also partially be with any technicians or accuracy checkers involved in the process
- Assembly accuracy liability – generally, this would be with the pharmacy and pharmacists, particularly the supervising and responsible pharmacist, at the hub
- Transit liability – generally, this would be with the person responsible for the transit process, and the pharmacy and pharmacists at the spoke pharmacy
- Supply liability – this is the supply/handout process and generally would be with the pharmacy, pharmacists and pharmacy team in the spoke.

  It is notable that relevant superintendent pharmacists have relevant liability and pharmacists in management and senior company positions may also have relevant liability.

Manual hub – this is a pharmacy hub which assembles medicines using appropriately qualified personnel rather than automation. NB some automated hubs may have a partial manual process

Margin-sharing – the hub purchases medicines to assemble medicines and, therefore, purchase Margin is at the hub stage of the supply chain and is shared with the spoke pharmacy.

Medicines Act 1968 (MA 1968)– legislation that deals with pharmacies in the UK and includes the relevant legal provision on hub and spoke dispensing, section 10 (much of this legislation has been transferred to the HMRs)

Medicines and Medical Devices Act 2021 (MMDA) – new 2021 legislation which enables regulations to be introduced which will permit H&S

NHS Regulations – the NHS (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 which deal with market entry, performance and breach notices, remuneration (through the Drug Tariff) and in schedule 4 the majority of NHS pharmacies' Terms of Service.

Original Pack Dispensing – dispensing a full medicine pack (even if the quantity prescribed is different – slightly less or more).

Prescription – the legal 'order' for prescribed items to be supplied, usually by a pharmacy. Currently, in most cases the prescription remains in the spoke and is not transferred to the hub and the patient remains nominated to the spoke.

Public Consultation – this phrase relates to any formal consultation issued by the Government or other relevant body to which anyone can respond, including national pharmacy bodies, contractors, pharmacists and the general public.

Spoke – A GPhC registered pharmacy included on the relevant NHS Pharmaceutical List.

Supply – handing over, or the collection of, a dispensed medicine by a patient.

Terms of Service – an NHS pharmacy requirement for the provision of NHS pharmaceutical services, for example, Essential Services set out in the NHS Regulations and the Drug Tariff. They include Essential service requirements and Clinical Governance provisions.

Annex C: Q&As

What is hub and spoke dispensing?
Broadly, H&S dispensing is where a patient presents a prescription to a pharmacy (the spoke) either in person or via EPS transfer nomination from the GP practice/pharmacy nomination, and the spoke asks another pharmacy (the hub) to assemble the items. The hub may only receive information about the items to be assembled. The hub then returns the assembled items to the spoke. The spoke supplies the dispensed medicines to the patient. Broadly, clinical responsibility for the supply/dispensing of the medicine to the patient remains with the pharmacy spoke. The spoke submits the claim for the dispensed items to the NHS and receives payment.

Prescription arrives in pharmacy
↓
Clinical check completed
↓
Data entry and transfer to hub
↓
Hub assembly (including accuracy checks)
↓
Delivery of assembled items to the spoke
↓
Supply of items to the patient or representative
↓
Prescription supply claimed from spoke

What hub and spoke dispensing is not?
A patient asking a remote pharmacy to dispense their medication and deliver it to them by post; this is a patient using a Distance Selling Premises (DSP) Pharmacy.

Is hub and spoke always automated?
No. The hub may or may not use automation to assemble the items. This will depend upon the business model of the hub operator.

Can pharmacy spokes be automated?
Yes and some are. Any community pharmacy may choose to invest in automation.

What is H&S in this briefing
In this briefing H&S means hub and spoke dispensing between **different** retail pharmacy businesses (different legal entities). Currently this is not permitted.

What still needs to be done to allow H&S?
The legislative changes and professional standards around H&S need to be done (for example, by DHSC and DHSC).

What does PSNC need to do?
PSNC has to agree with DHSC the models that will allow the sector to benefit fairly from H&S.

(… The 5-year deal included the following: 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…)

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