



March to May 2016

Pharmacists' Defence Association Response to The Department of Health Consultation on Amendments to the Human Medicines Regulations 2012:

'Hub and spoke' dispensing, prices of medicines on dispensing labels,
labelling requirements and pharmacists' exemption

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About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. It currently has more than 25,000 individual members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist

Executive Summary

When the initial idea of hub and spoke medicines assembly was first promulgated, the PDA supported the notion on the grounds that it would release pharmacists' time, enabling them to apply themselves to patient-facing services. However, it is clear that releasing pharmacists' time was not in the minds of the authors of this consultation. The Department of Health has made assumptions which lack robust evidence and credibility. It is clear that it was attempting to justify hub and spoke dispensing models as a means to facilitate cuts to pharmacy funding. Inherently, such an approach, as set out in the consultation document, would have the effect of reducing even further the amount of time that pharmacists have to deal with patients.

The PDA could not support hub and spoke medicines assembly on the terms described in the consultation document.

Our recommendations are:

Recommendation One

The PDA could only support hub and spoke medicines assembly models if the following were in place (and we would like to see the following in place as a minimum):

- Hub and spoke models were demonstrated through academic research to free up pharmacists' time to build clinical relationships with patients and were implemented to that end – not to justify labour cost reductions (staffing cuts).
- The pharmacy contract was split into the elements of supply and service provision; the service provision element should involve groups of pharmacists contracting directly with the NHS to provide those services.
- Pharmacists were freed from the process of procurement and medicines assembly, enhancing professional autonomy and enabling them to concentrate on changing how they are often perceived by the public – from a supplier of product to consumers to that of a healthcare professional enjoying clinical relationships and increased face-to-face contact with patients.
- A neutral or positive impact of hub and spoke models on patient safety had been demonstrated by extensive academic research.
- The market and competition issues caused by vertical integration of pharmaceutical wholesalers and pharmacies had been addressed, such that its introduction did not exacerbate those issues. The issues include the commoditization of the pharmacy service into a volume-driven medicines supply function, the lack of scrutiny of pharmaceutical wholesaler profit margins from the NHS and the potential oligopoly on the community pharmacy sector, forcing independent pharmacies out of existence.
- The benefits of an NHS-operated pharmaceutical wholesaler and NHS-operated hubs had been fully evaluated and implemented as appropriate.
- Issues around civil, regulatory and criminal liability had been fully explored and clarified and there was no criminal liability for pharmacists who made inadvertent dispensing errors.
- Minimum staffing levels were consulted upon, defined and enforced by the Department of Health in order to assure patient safety. Those staffing levels were based on robust evidence that they were effective in assuring patient safety.
- Access to pharmacists through national pharmacy network was not harmed by the introduction of hub and spoke models.

Recommendation Two

We identified significant issues and omissions within the content of the consultation document, meaning that respondents were poorly informed. By extension the consultation process was flawed. These issues and omissions included, with respect to hub and spoke operations:

- absence of robust evidence on the overall impact on patient safety
- lack of guidance as to how the EU falsified medicines directive would affect the operation
- lack of clarity on the effect on civil, professional and criminal liability
- absence of information on the data protection implications
- failure to adequately evaluate the effect on the community pharmacy sector and by extension the wider National Health Service
- inconsistency of message from the Department of Health with respect to the effect on staffing levels and the capacity to deliver additional services

Before implementing any change to the legislation which would allow all UK community pharmacies to participate in hub and spoke medicines supply models, the Department of Health should learn from this consultation, take no action in respect of amendments to legislation and conduct a more informed and informative consultation again at a later stage. This should be done at a time when conditions in the community pharmacy sector favour the introduction of hub and spoke models of medicines supply as described in Recommendation One of this response.

Recommendation Three

Before implementing any change to the legislation which would allow all pharmacies to access hub and spoke dispensing, the Department of Health should refer the matter to the Competition and Markets Authority (CMA) for evaluation and oversight. The referral should include a recommendation that the CMA examine the effects of vertical integration on both the pharmaceutical wholesale market and community pharmacy sector.

Recommendation Four

If the Department of Health moves to permit all pharmacies to operate hub and spoke dispensing models between different legal entities, it must secure, in advance of any legal changes, the publication of clear guidance with respect to the data protection implications, specifically:

- To what extent hub and spoke pharmacies providing NHS services, as public authorities, could rely on implied consent to share data
- The data protection implications for sharing NHS data with a hub pharmacy that does not have an NHS contract
- Whether and under what circumstances hub pharmacies are to be treated as data processors or data controllers
- Whether data sharing agreements and/or written contracts are required between the hub and spoke pharmacies and other organisations involved in providing the service, and their nature
- The nature of the consent to be obtained from patients in order to share their data with the hub, and whether and how the nature of that consent will change if the EU General Data Protection Regulation comes into force in 2018

Recommendation Five

Prior to any changes in legislation permitting the operation of hub and spoke pharmacy models between different legal entities, the Department of Health must provide guidance to the community pharmacy sector of the likely impact of the Falsified Medicines Directive on the various models. This would allow a more informed consultation on hub and spoke dispensing to be conducted in the future.

Recommendation Six

Prior to any changes in legislation permitting the operation of hub and spoke pharmacy models between different legal entities, a detailed legal analysis (based on appropriate experience) must be conducted of the implications of hub and spoke models in various forms on criminal, civil and professional liability. Its findings must be made public.

Recommendation Seven

The Department of Health should research the benefits of an NHS-operated full-line wholesaler and *large scale automated* dispensing hub.

Recommendation Eight

Before changing legislation which would facilitate the wider operation of hub and spoke models in community pharmacy between different legal entities, the GPhC must clarify how the Standards for Registered Pharmacies and the Standards of Conduct, Ethics and Performance have been or would be consistently applied to pharmacies not accessible to the public, such as the automated hub pharmacies being operated by Boots and Lloyds, and the pharmacists who work within such pharmacies.

Recommendation Nine

The consultation focuses primarily on assumed labour cost reductions (cuts to staffing levels) through the use of hub and spoke models, not freeing up time for pharmacists to spend with patients. This will lead to a reduction in the number of available jobs in the community pharmacy sector, with the job losses potentially delivered through redundancies. If the assumed reduction in labour costs is proportionate to the assumed reduction in workload (we dispute whether there will be any workload reduction), pharmacists will have no additional time to spend with patients. Freeing up time for pharmacists to spend with patients would improve the healthcare service provided to those patients; reducing labour costs would not. The Department of Health must not assume any labour cost reductions associated with changes to legislation permitting the use hub and spoke models. In addition, it must be entirely clear in its intentions else it risks appearing not to be transparent and forthright in the consultations it conducts.

Recommendation Ten

The Department of Health must consult on, agree and publish detailed enforceable requirements for minimum staffing levels in community pharmacies, beyond those present in the Drug Tariff. It is particularly important that this be done prior to any changes to law which permit Hub and Spoke dispensing operations between different legal entities. Pharmacy staffing levels should be publically visible as they are for hospitals.

Recommendation Eleven

Prior to introducing legal changes which would permit the operation of a hub and spoke dispensing model across separate legal entities, a detailed independent legal analysis must be conducted to assess the practical operational framework that would need to be implemented as a result, including whether the hub pharmacy could make a supply to the spoke pharmacy without having the original prescription in its possession.

Recommendation Twelve

We oppose any assumed reduction in labour costs as a result of the proposed changes in legislation enabling hub and spoke models to be operated between different legal entities. However, if the Department of Health decides to change pharmacy reimbursement as a result of these changes, it must take overall costs of operating hub and spoke models into account.

Recommendation Thirteen

If the Department of Health is to reduce pharmacy reimbursement as a result of projected cost savings, it must apply the same standard to large multiple pharmacies; to fail to do so would result in their increased profitability at the expense of the taxpayer and treat them differently to smaller multiples and independent pharmacies.

Recommendation Fourteen

The Department of Health must set out a robust logical rationale to support the assertions it makes and the statistics it uses in consultation documents.

Recommendation Fifteen

Before implementing any change to the legislation or financial reimbursement to pharmacies associated with hub and spoke dispensing, the Department of Health must commission academic research beyond the scope of this consultation to investigate:

- the cost of setting up a dispensing hub in various forms
- the effect of hub and spoke models on patient safety
- the percentage of medicines dispensed from a hub
- the percentage of medicines supplied by a hub pharmacy to a patient (provided that contact between the spoke pharmacy and the patient was mandatory)
- how much a hub could charge for the service
- the effect of hub and spoke models on stockholding.

The Department must evaluate the benefits of NHS-operated hubs and publish its findings in respect of the above.

Recommendation Sixteen

The Chief Pharmaceutical Officer for England and the Department of Health must make clear which they believe to be correct: a dispensing error rate of 0.04% or 3.32% in community pharmacy in the UK. They must also make clear whether they are trying to promote any approach to automated dispensing or not. If the Chief Pharmaceutical Officer's evidence to the All-Party Parliamentary Group for pharmacy on dispensing error rates in the UK requires any further clarification, he must issue that clarification at the earliest opportunity. If the APPG failed to capture key evidence in the minutes of its discussions with the Chief Pharmaceutical Officer on the 16th of March 2016, it must issue revised minutes if possible and take care to capture and issue comprehensive, accurate minutes in the future.

Recommendation Seventeen

Before implementing any changes to the Human Medicines Regulations allowing the prices of medicines and / or a statement about how the cost of a medicine is met to be included on a dispensing label, the Department of Health should commission academic research and a pilot study to investigate the positive and negative impacts of doing so. It should also clarify whether the price is to be included on a per-pack or per-item basis.

Recommendation Eighteen

The wording of the proposed new part 258A of the Human Medicines Regulations 2012, paragraph 5b, should be revised. In particular, the phrase 'wherever possible' should be removed and replaced with a suitable alternative which would not effectively mandate the use of labels on the immediate and outer packaging in all circumstances.

Recommendation Nineteen

The Department of Health should place greater focus on the full decriminalisation of inadvertent dispensing errors rather than focusing on legislative changes relating to hub and spoke dispensing.

Recommendation Twenty

The Department of Health should consult on the proposed changes more widely in light of the fact that some of the amendments to legislation will have an impact on doctors, nurses, dentists and midwives.

Throughout our responses we make important distinctions. When we refer to *large scale automated* hub and spoke models, we mean those involving the use of machinery to automate a substantial proportion of the dispensing process, noting that some items will, in all likelihood, still need to be dispensed by hand at the hub. When we refer to *small scale collaborative* hub and spoke models, we refer to a small number of pharmacies with an arrangement wherein one pharmacy (the hub) prepares the medicines for supply, on behalf of a spoke pharmacy. In this case the hub pharmacy may use automated or manual process (human) dispensing.

There are multiple variants of both *large scale automated* and *small scale collaborative* hub and spoke models. For example, *small scale collaborative* hub pharmacies may label a prescription directly on to the spoke pharmacy's PMR system through a remote connection, or alternatively they may not have access to it at all.

The Consultation Document

As a general principle, we recommend that questions in a consultation such as this be asked in an entirely neutral manner. Commencing questions with leading wording such as 'do you agree' or worse 'do you agree that we should remove the impediment' could lead to acquiescence bias.^{1,2} This may mean that the responses obtained will not truly represent respondents' views.

Introduction

The PDA would like the Department of Health to focus on improving patient-facing pharmacist-led clinical services. The community pharmacy contract and indeed the sector are currently geared towards a medicines supply-based model which financially rewards volume rather than quality of patient outcomes.

When the initial idea of hub and spoke medicines assembly was first promulgated, the PDA supported the notion on the grounds that it would release pharmacists' time, enabling them to apply themselves to patient-facing services. However, it is clear that releasing pharmacists' time was

not in the minds of the authors of this consultation.

The Department of Health has made assumptions which lack robust evidence and credibility. It is clear that it was attempting to justify hub and spoke dispensing models as a means to facilitate cuts to pharmacy funding. Inherently, such an approach, as set out in the consultation document, would have the effect of reducing even further the amount of time that pharmacists have to deal with patients.

The PDA could not support hub and spoke medicines assembly on the terms described in the consultation document.

Recommendation One

The PDA could only support hub and spoke medicines assembly models if the following were in place (and we would like to see the following in place as a minimum):

- *Hub and spoke models were demonstrated through academic research to free up pharmacists' time to build clinical relationships with patients and were implemented to that end – not to justify labour cost reductions (staffing cuts).*
- *The pharmacy contract was split into the elements of supply and service provision; the service provision element should involve groups of pharmacists contracting directly with the NHS to provide those services.*
- *Pharmacists were freed from the process of procurement and medicines assembly, enhancing professional autonomy and enabling them to concentrate on changing how they are often perceived by the public – from a supplier of product to consumers to that of a healthcare professional enjoying clinical relationships and increased face-to-face contact with patients.*
- *A neutral or positive impact of hub and spoke models on patient safety had been demonstrated by extensive academic research.*
- *The market and competition issues caused by vertical integration of pharmaceutical wholesalers and pharmacies had been addressed, such that its introduction did not exacerbate those issues. The issues include the commoditization of the pharmacy service into a volume-driven medicines supply function, the lack of scrutiny of pharmaceutical wholesaler profit margins from the NHS and the potential oligopoly on the community pharmacy sector, forcing independent pharmacies out of existence.*
- *The benefits of an NHS-operated pharmaceutical wholesaler and NHS-operated hubs had been fully evaluated and implemented as appropriate.*
- *Issues around civil, regulatory and criminal liability had been fully explored and clarified and there was no criminal liability for pharmacists who made inadvertent dispensing errors.*
- *Minimum staffing levels were consulted upon, defined and enforced by the Department of Health in order to assure patient safety. Those staffing levels were based on robust evidence that they were effective in assuring patient safety.*
- *Access to pharmacists through national pharmacy network was not harmed by the introduction of hub and spoke models.*

There is much work to do to achieve the above, but we believe the government must do this first before implementing the changes proposed in the consultation. For the reasons which we set out in detail in our responses, we take the view that the proposals in this consultation would result in material changes which would put patient safety at risk, damage the fabric of the community pharmacy service and as a result, have a substantial adverse effect on the National Health Service.

It will become clear even from the mere extent of our response that we have serious concerns with the proposals set out in the consultation document. We make the following recommendation in light of those concerns.

Recommendation Two

We identified significant issues and omissions within the content of the consultation document, meaning that respondents were poorly informed. By extension the consultation process was flawed. These issues and omissions included, with respect to hub and spoke operations:

- *absence of robust evidence on the overall impact on patient safety*
- *lack of guidance as to how the EU falsified medicines directive would affect the operation*
- *lack of clarity on the effect on civil, professional and criminal liability*
- *absence of information on the data protection implications*
- *failure to adequately evaluate the effect on the community pharmacy sector and by extension the wider National Health Service*
- *inconsistency of message from the Department of Health with respect to the effect on staffing levels and the capacity to deliver additional services*

Before implementing any change to the legislation which would allow all UK community pharmacies to participate in hub and spoke medicines supply models, the Department of Health should learn from this consultation, take no action in respect of amendments to legislation and conduct a more informed and informative consultation again at a later stage. This should be done at a time when conditions in the community pharmacy sector favour the introduction of hub and spoke models of medicines supply as described in Recommendation One of this response.

Questions

1. **Do you agree that we should remove the impediment in medicines legislation that prevents the operation of ‘hub and spoke’ dispensing models across different legal entities?**

NO

In our view this question insidiously over-simplifies a broad and important issue and is worded in such a way that it will lead to the acquiescence of uninformed respondents. If the issue were as simple as removing a legal impediment in order to create a level playing field for all pharmacies, we would have answered this question ‘Yes’. Giving all pharmacies the right to use a hub and spoke dispensing model may seem fair at a superficial level. There are, however, effects on the pharmacy sector and pharmaceutical wholesale market considerations which require appropriate controls and oversight to be put in place before the legislation is amended.

Large Scale Automated Dispensing Hubs

For a *large scale automated* dispensing hub to operate with the requisite efficiency, it would need on-site access to a wide range of medicines and a delivery infrastructure capable of supporting a large number of pharmacies. *Small scale collaborative* models would involve a third party placing orders with one or more wholesalers and reduced overall buying power, which would introduce inefficiency and delay into the process and reduce cost effectiveness.

There are currently three full-line wholesalers in the UK; Alliance Healthcare, AAH and Phoenix.³ The parent companies of these wholesalers own Boots, Lloyds and Rowlands pharmacies respectively; the wholesalers are ‘vertically integrated’ with a major pharmacy chain. It is our view that only these wholesalers would have access to both a sufficiently wide range of medicines and the delivery infrastructure required to economically offer a service like this on a large scale. At present, only Boots and Lloyds operate what we would consider to be a *large scale automated* hub.^{4,5} The registered addresses of these pharmacies are ‘care of’ the vertically integrated wholesaler.

Each of the full-line wholesalers mentioned above operates ‘reduced wholesaler’ and/or ‘direct to pharmacy’ agreements; many manufacturers only supply to one wholesaler (or a reduced number).⁶

Since those agreements are already established, new market entry and competition with these three full-line wholesalers would, in our view, be extremely difficult. Therefore, it is our conclusion that if a pharmacy wanted to gain access to a *large scale automated* dispensing hub, it would have to purchase the service from Boots, Lloyds or Rowlands (if Rowlands were to build such a hub). AAH have already expressed an interest in offering the service to customers other than Lloyds pharmacies.⁵ This would further increase the hold these three wholesalers have on the market, increasing their influence on medicines pricing. Given that their NHS-derived profit margins are not regulated by the government, this may have adverse consequences for the taxpayer and the NHS.

Since both Boots and Lloyds operate automated dispensing hubs are able to site the hub within Alliance Healthcare or AAH premises, the parent company of Boots and Lloyds effectively gets the dispensing service at cost. We envisage that Boots pharmacies would obtain the automated dispensing service exclusively from Alliance Healthcare-sited hubs and Lloyds pharmacies would obtain the automated dispensing service exclusively from AAH-sited hubs.

Any changes permitting the operation of a hub and spoke model between different legal entities would involve the spoke pharmacy paying a fee to the hub pharmacy for its services. Therefore, pharmacies outside the Boots or Lloyds chains would be paying Boots or Lloyds directly for the service, permitting investment in the vertically integrated pharmacy chain from the profit made. Vertically integrated pharmacies would therefore benefit from the changes to the law proposed in the consultation document. The profitability of the parent companies would increase whilst smaller pharmacy chains and independent pharmacies became less profitable relative to a vertically integrated pharmacy, since they would have to pay for the service. This may contribute to the closure of up to 3,000 mostly independent pharmacies, which the Government has acknowledged as a distinct possibility. We view this as a substantial detriment to public healthcare provision. A patient safety survey by the PDA revealed that independent pharmacies generally fare much better than multiple pharmacies on safety measures.

It is also noteworthy that the parent company of Boots – Walgreens Boots Alliance – also owns the Alphega brand. This is a network of over 1,000 pharmacies served by Alliance Healthcare (who created the brand).⁷

These pharmacies and Walgreens Boots Alliance may benefit from the proposed changes to the law as it would allow Alliance Healthcare to extend the service to Alphega pharmacies, whereas a non-Alphega independent pharmacy may potentially be charged a different price.

Small Scale Collaborative Dispensing Hubs

Small scale collaborative hub and spoke models are, in our view, likely to be of little benefit to the NHS or to individual pharmacies. Hubs would first need access to a wide range of medicines, which would need to be purchased from a pharmaceutical wholesaler. We expect that the discount obtained on medicines purchases would be less than for a *large scale automated* dispensing hub, since the volume of medicines purchased would be less.

Broadly speaking, there could be two alternative *small scale collaborative* models; one using automation and another which relies upon *manual process* human dispensing. We would expect there to be little, if any, efficiency saving using an automated solution in a *small scale collaborative* model and a higher overall workload if *manual process* dispensing was carried out at the hub (see our answer to question 5 for the rationale). Again, our view is that at present, given the nature of the community pharmacy and pharmaceutical wholesale markets, the only potentially viable option for smaller independent pharmacies would be to purchase a service from Boots / Alliance Healthcare and / or Lloyds / AAH.

If so, the Department of Health would have taken steps which increased the profitability of pharmacy for the owners of large multiple pharmacies and decreased it, both relatively and in absolute terms, for smaller businesses. That is, of course, unless the pharmacy contract were changed to reimburse independents and smaller pharmacy chains for the costs of paying for a hub service, at the same time as ensuring that wholesalers could not make a profit from providing that service.

We are extremely concerned by the Department of Health's comment on vertical integration on its website. It appears to acknowledge the fact that wholesalers can keep the profits from the NHS (and ultimately the taxpayer) 'upstream' by flaunting the Discount Inquiry system – which itself is designed and exercised by the Department. It reads '*Wholesalers offer discounts to their customers. However, because of the way the Discount Inquiry works, wholesalers may have an incentive to offer reduced discounts to integrated pharmacies: in this way, a wholesaler can reduce the overall claw-back rate determined in the Discount Inquiry while keeping its profits upstream with the wholesale arm.*'¹³

Most or all community pharmacies are required to hold contracts with Alliance Healthcare, AAH and Phoenix due to exclusive deals between manufacturers and these wholesalers. We take the view that vertical integration may have driven the introduction of these deals, as wholesalers attempted to secure medicines supplies for the pharmacies with which they are vertically integrated. We are concerned that hubs operated by vertically integrated pharmacies and wholesalers could require pharmacies to participate in a hub and spoke model as part of their supply contract, or provide incentives for doing so (such as rebates on medicines purchases). This may be against the wishes of a patient. The hub provider may stand to benefit from the data shared with it by the spoke and be in a position to stipulate how it may use that data and/or the processes it needed to follow.

Recommendation Three

Before implementing any change to the legislation which would allow all pharmacies to access hub and spoke dispensing, the Department of Health should refer the matter to the Competition and Markets Authority (CMA) for evaluation and oversight. The referral should include a recommendation that the CMA examine the effects of vertical integration on both the pharmaceutical wholesale market and community pharmacy sector.

GPhC and Other Standards for Hub Pharmacies

Before removing the impediment, the Department of Health would need to establish standards for hub pharmacies, beyond those set by the GPhC. This may include the development of a Publicly Available Specification by the British Standards Institute in order to assure patient safety and public confidence in the pharmacy service. Standards must be set for business continuity planning and disaster recovery.

Data Protection

It is clear from the consultation document that the Department of Health understands that there are data protection considerations associated with the operation of a hub and spoke model, but it has in our view it has failed to adequately describe these issues.

Organisations providing NHS pharmaceutical services are considered to be public authorities under the Data Protection and Freedom of Information Acts.^{8,9,10} Pharmacies may therefore be able to rely to some extent on implied powers to share NHS data if the operation of a hub and spoke model is permitted in legislation and data sharing is reasonably incidental to that operation.¹⁴ However, hub pharmacies without an NHS contract would likely not be classed as such at all; the Department of Health has made no proposal that hub pharmacies be required to have an NHS contract. Furthermore, data related to the provision of NHS pharmaceutical services (including patient data) may need to be shared with (or would be accessible to) other organisations which are not public authorities, such as IT companies, couriers and wholesalers involved in providing the service; this would depend on the mechanics of the hub and spoke model, but further guidance is required from the Department of Health.

It may be important to understand whether the hub pharmacy will be functioning as a data controller or as a data processor. A data controller means a person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be, processed. A data controller must be a 'person' recognised in law, that is to say:

- individuals;
- organisations; and
- other corporate and unincorporated bodies of persons.¹¹

If both the hub and spoke pharmacies are deemed to be data controllers, a data sharing agreement may be required. If the spoke is functioning as the data controller and the hub is functioning as the data processor, the seventh data protection principle of the Data Protection Act 1998 requires that a data controller using a data processor must ensure, in a written contract, that:

- the processor only acts on instructions from the data controller; and
- it has security in place that is equivalent to that imposed on the data controller by the seventh data protection principle.^{12,13}

The use of a hub will be initiated by the pharmacy, not the patient. The patient's primary concern will be their own health and that the service provided to them is safe, effective and otherwise meets his or her needs (for example, from a privacy perspective).

They should be entitled to expect exactly the same standards of safety, efficacy and privacy regardless of whether the pharmacy they chose to visit prepares the medicine or a hub pharmacy completes part of the operation. In a hub and spoke model, the patient's data would be shared to meet the pharmacy's needs, not the patient's.

The EU General Data Protection Regulation will come into force in 2018 (subject to the upcoming referendum).¹⁴ It redefines the concept of consent to 'any freely given, specific, informed and unambiguous indication of his or her wishes by which the data subject, either by a statement or by a clear affirmative action, signifies agreement to personal data relating to them being processed'.¹⁵ It would be helpful, therefore, to understand the Department's view on the nature of the consent that would need to be obtained from a patient in order to use a hub and spoke model.

Recommendation four

If the Department of Health moves to permit all pharmacies to operate hub and spoke dispensing models between different legal entities, it must secure, in advance of any legal changes, the publication of clear guidance with respect to the data protection implications, specifically:

- *To what extent hub and spoke pharmacies providing NHS services, as public authorities, could rely on implied consent to share data*
- *The data protection implications for sharing NHS data with a hub pharmacy that does not have an NHS contract*
- *Whether and under what circumstances hub pharmacies are to be treated as data processors or data controllers*
- *Whether data sharing agreements and/or written contracts are required between the hub and spoke pharmacies and other organisations involved in providing the service, and their nature*
- *The nature of the consent to be obtained from patients in order to share their data with the hub, and whether and how the nature of that consent will change if the EU General Data Protection Regulation comes into force in 2018*

EU Falsified Medicines Directive

At the time of writing, a referendum is scheduled for the 23rd of June 2016 to determine whether Britain should remain part of the EU. Consideration must be given as to how hub and spoke models will operate if the EU Falsified Medicines Directive is introduced in 2019. The directive states that the authenticity and integrity of the safety features placed on the packaging of a medicinal product at the beginning of the supply chain should be verified at the time the medicinal product is supplied to the public. The intention is that immediately before supply to the patient, pharmacy staff would have to access the most up-to-date information concerning the product and would thereby avoid supplying products which are expired, recalled, withdrawn or indicated as stolen, although certain derogations may apply. In practice this is to be performed by scanning a unique barcode and checking a tamper-evident seal at the end of the supply chain when the medicinal product is supplied to the public (Article 25).¹⁶

The directive does state that it should be possible for member states to exempt specific institutions or persons authorised or entitled to supply medicinal products to the public from the obligation of verification of the safety features, in order to accommodate the particular characteristics of the supply chain in their territory and ensure that the impact of the verification measures on those parties is proportionate. However, Article 23 of the directive details the circumstances in which the exemptions may be applied, and this does not include supply of medicinal products to a pharmacy.

Member states may allow persons authorised or entitled to supply medicinal products to the public operating within healthcare institutions to perform the verification of the authenticity and the decommissioning of a unique identifier earlier than the time the medicinal products is supplied to the public, subject to certain conditions. However, this only applies to persons operating in hospitals, in- or out- patient clinics or health centres, but does not apply to supplies from community pharmacies (Article 25, paragraph 2).

As far as we can see, there are no derogations within the directive that would permit the verification of the medicinal product to be performed at a hub pharmacy, unless the hub was supplying directly to the patient. It seems that in a hub and spoke model where the supply was made from the spoke pharmacy to the patient, the spoke pharmacy would still need to perform the verification. In these circumstances, since the spoke pharmacy will need to handle the medication in order to scan it, the workload associated with the implementation of a hub and spoke model would increase (and any workload reduction

associated with the model would be less likely). There are also implications in terms of liability which must be considered; if the spoke pharmacy retains access to the prescription form and must also handle the packages prepared by the hub pharmacy for the purposes of scanning them, this may increase the ability to intervene, and therefore the liability, of staff at the spoke pharmacy for an error made at the hub.

In our view, the Falsified Medicines Directive will lead to significant changes in workload and as such will have a substantial impact on the staffing levels required to assure patient safety in community pharmacy.

The definition of 'at the time of supplying it to the public' provided in Article 25 needs to be explored. If tamper-evident seals are to be checked 'at the time of supplying it to the public', this would have implications for the supply of a Monitored Dosage System to a spoke pharmacy (the seals could be broken, for example, if tablets or capsules were to be transferred to another blister pack). The requirement needs to be evaluated in the context of delivery to patients; if the required checks were made prior to handing the medicine to a delivery driver, would this constitute 'at the time of supplying it to the public'? What would happen if the driver was subsequently unable to deliver the medicine to the patient?

There are further implications in respect of deliveries to patients; in order to avoid handling the medicine at the point of supply to the patient (scanning it and checking the tamper-evident seal), spoke pharmacies may prefer to have the medicine delivered to the patient by the hub pharmacy. The proportion of delivered prescriptions may therefore increase, with environmental, safety and cost implications.

Recommendation Five

Prior to any changes in legislation permitting the operation of hub and spoke pharmacy models between different legal entities, the Department of Health must provide guidance to the community pharmacy sector of the likely impact of the Falsified Medicines Directive on the various models. This would allow a more informed consultation on hub and spoke dispensing to be conducted in the future.

Liability

The Pharmacy Legislation on Dispensing Errors and Standards consultation was conducted in 2015. It was heralded as the initiative which would remove the prospect of criminal prosecution for inadvertent dispensing errors. Its brief, however, was limited to introducing a defence to only two specific sections of the Medicines Act – sections 63 and 64. The rebalancing board lacked the requisite expertise to fully recognise and advise others as to the limitations of the scope and impact of the changes. The consultation document unhelpfully stated ‘the intention is to remove the threat of criminal sanction for inadvertent preparation and dispensing errors’,¹⁷ which may have contributed to confusion as to what it has achieved.

The consultation document proposed a conditional defence to two specific sections of the Medicines Act 1968, 63 and 64, through legislative changes which have not yet been enacted by parliament. Even if the changes are enacted, the exposure to prosecution will not be removed. In addition, legal opinion indicates that a criminal offence will be committed in the event of an inadvertent dispensing error as a result of other legislation not addressed by the consultation, to which the proposed defence will not apply.¹⁸

Criminal, civil and professional liability is attributed to specific individuals. It is a GPhC requirement that registrants carry professional indemnity insurance. The implications of hub and spoke models on civil and criminal liability have not been given sufficient consideration by the Department of Health. An error made at the hub or spoke pharmacy may go undetected at the other pharmacy and, if the Department’s proposals are implemented, the medicine may be supplied from either.

Further, the changes proposed in the consultation document may introduce new criminal offences – such as the failure to correctly label an item supplied under a Patient Group Direction.

We would like to see the benefits (or otherwise) of an NHS-operated full-line wholesaler and *large scale automated* dispensing hub fully evaluated and implemented as appropriate (see Recommendation One). This would confer several benefits. It would give the Department of Health insight into the true costs of providing the service, provide greater assurances with respect to the service level, reduce the risk of profiteering from taxpayers and allow accurate costs to be set for medicines purchases.

Recommendation Seven

*The Department of Health should research the benefits of an NHS-operated full-line wholesaler and **large scale automated** dispensing hub.*

Recommendation Six

Prior to any changes in legislation permitting the operation of hub and spoke pharmacy models between different legal entities, a detailed legal analysis (based on appropriate experience) must be conducted of the implications of hub and spoke models in various forms on criminal, civil and professional liability. Its findings must be made public.

2. ***Do you agree that in the Human Medicines Regulations we should not impose any restrictions as to which ‘hub and spoke’ models can be operated?***

NO

We are extremely concerned that the Department of Health would consider not imposing restrictions on hub pharmacies delivering directly to patients or using a delivery company to do so. We are also concerned that the question has been phrased such that it does not allude to the context provided in the consultation document – specifically that the ‘hub’ pharmacy will send the medicines directly to the patient in some cases.

We anticipate that hub pharmacies would charge a fee for supplying a dispensed prescription back to the spoke pharmacy and a different, higher fee for delivering it to a patient. We anticipate that the increased workload and costs associated with returning the medicine to the spoke pharmacy for it to be delivered by their staff, alongside the EU Falsified Medicines Directive requirements for the spoke staff to scan the medicines before supply to the patient and the liability implications for spoke staff if they supply the medicine, will result in a move towards prescription delivery directly to patients even where it is not absolutely required by the patient.

We must consider a theoretical example to illustrate the risks and practical issues of hub pharmacies delivering directly to patients in the absence of any mandatory contact with the spoke pharmacy prior to delivery. A patient may order his or her prescription electronically. Alternatively, a pharmacy may manage the ordering of repeat medicines for a patient. Once the prescription has been created by the prescriber, it may then be transmitted electronically to the pharmacy, forwarded electronically to the hub (via some mechanism yet to be introduced) and delivered out to the patient at a pre-arranged date and time without any mandatory contact with the pharmacy. Some patients would therefore not have any contact at all with a pharmacy when ordering their prescriptions. In this simplistic theoretical example, the spoke pharmacy could be removed from the equation; patients could be asked to deal directly with the hub.

It appears that the Department may be trying to implement a model which removes the spoke pharmacy, or attempting to pave the way to that model in the future. Without ‘and spoke’, ‘hub and spoke’ becomes ‘hub’. If the entire dispensing process moved from one pharmacy to another, it would no longer be appropriate to call it a ‘hub’,

since the term implies that it is at the centre of something. It would have simply become a high-volume pharmacy with little, if any, patient contact.

Delivering medicines to patients without the need for any contact with a pharmacist would further commoditize pharmacy services and we suggest would be inherently dangerous. It would give a message to the public that contact with a pharmacist is not necessary and thereby diminish the nature and importance of medicines. It would likely encourage patients to treat them more like sweets.

Hub pharmacies delivering directly to patients could have the following adverse implications (not exhaustive):

- Important counselling or potential clinical interventions could be missed if contact with the spoke pharmacy was not made mandatory or face to face contact was reduced
- Patients may be unclear which pharmacy to contact in the event of a query
- Patients may be unclear which pharmacy owed items to them in the event that some of the medicines could not be supplied
- Patients wouldn’t have access to the hub pharmacy directly since it may be located many miles away from them
- Disputes over civil liability could put patients at risk of being unable to seek remedy for negligence
- Staff at both the hub and spoke pharmacies could be at greater risk of professional or criminal liability if the likelihood of an error increases
- Having paid for the dispensing service, spoke pharmacies may still need to carry out modifications to someone’s medicines e.g. in a Monitored Dosage System (but note that MDS hub and spoke dispensing may not be possible if the Falsified Medicines Directive is implemented). This would increase costs to them as well as creating liability issues
- There may be no feedback loop from delivery drivers to the spoke pharmacy, who can be an invaluable source of information with respect to a patient’s wellbeing

We would much prefer the Department of Health to lead initiatives which increase patient contact with pharmacies and pharmacists. This would likely increase the public benefit from pharmacy services.

At present, according to the Department of Health's own figures, 99% of the population can get to a pharmacy within 20 minutes by car and 96% by walking or public transport.¹⁹ The statistic was used recently by the Department in the context of cuts to pharmacy funding announced on 17 December 2015, leading to the closure of up to 3,000 pharmacies (mostly smaller independents).²⁰

We are sceptical about the validity of this statistic. It was published in a Department of Health white paper in 2008 entitled 'Pharmacy in England: Building on Strengths—delivering the future'.²¹ A more recent study in 2014 said of this statistic '*it was not clear which methodological approach was used to obtain this result, as, to the authors knowledge, no supporting data were published outlining methodology; and—crucially—the Department of Health report did not assess how varying levels of social deprivation influence the accessibility to a community pharmacy.*'²²

The study in 2014 found that 89.2% of the of the population has access to a community pharmacy within a 20-minute walk, based on a postcode to postcode straight line analysis and an average walking speed of 3mph. Given that it was a straight-line analysis, the true percentage will be less. The Department's assertion that 99% of the population can get to a pharmacy within 20 minutes by car seems optimistic since the RAC reported (again in 2008) that just 81% of households had access to a car²³ and the survey said nothing of the timeframe within which a car could be accessed, the reliance upon another individual to be able to drive the car etc.

The Government taking steps which it expects could lead to the closure of up to 3,000 pharmacies, thereby increasing the travelling time of the average person to their nearest pharmacy and reducing ease of public access to face to face contact with a pharmacist through the community pharmacy network. This may itself increase the proportion of patients requesting a prescription delivery. It is also taking other steps proposed within this consultation document which we believe will further increase the proportion of patients requesting a prescription delivery, reducing face to face contact with pharmacists.

We are of the view that the pharmacy contract ought to be split into the elements of supply and service provision; the service provision element should involve groups of pharmacists contracting directly with the NHS to provide those services. This would facilitate the engagement of (and public access to) a second pharmacist whose time was dedicated to delivering clinical services.

The community pharmacy premises network itself provides the physical space for pharmacists to deliver clinical services directly to the public. However, it also provides the public with access to a pharmacist as part of the medicines supply function – which creates important opportunities for counselling and other health interventions (though this may be done under pressure due to the nature of the current pharmacy funding arrangements and the apparent influence and modus operandi of large corporate organisations; there are other legislative and regulatory changes needed to mitigate this effect, beyond the scope of this consultation).

We do applaud the recent announcement that funding is to be provided for an additional 1500 pharmacists to work in GP surgeries by the year 2020. However, we must urge the Department of Health to exercise caution; the changes proposed in the consultation document and the changes which will arise from the closure of up to 3,000 mostly independent pharmacies will, in our view, diminish the positive impact of the increase in pharmacists working in GP surgeries by simultaneously reducing face to face access to, and contact with, pharmacists within the community pharmacy network. According to the Government, the number of *pharmacies* may reduce by up to 25% (3,000 pharmacies in England out of 11,674)^{20,24} as a result of the pharmacy funding cuts; if the number of *pharmacists* accessible to the public reduced by the same percentage as a result of their displacement, taking into account the increase in the number of pharmacists working in GP surgeries, there would be an overall net reduction of pharmacists accessible to the public for face to face contacts. We welcome developments which would increase such face to face contact, but in our view the proposals related to hub and spoke dispensing would in all likelihood reduce it.

3. Do you agree that ‘hubs’ should continue to be registered pharmacies?

YES

If a pharmacy was not registered, it would not be subject to any regulatory oversight – which in our view would create an extremely high risk to patients. We believe this should be self evident and in fact we are quite surprised that this question has been asked.

Further, it may be necessary to insist that hub pharmacies be required to have an NHS contract. In the absence of such a contract, they could not be held to NHS terms of service or information governance requirements, for example (unless a separate and potentially expensive legal contract was drawn up between the pharmacy and the hub binding them to the NHS contract).

4. Do you think ‘hub and spoke’ dispensing raises issues in respect to the regulation of pharmacies? If so, please give details.

YES

In a *large scale automated* dispensing hub, such as that operated by Boots or Lloyds, there may be no contact between staff and members of the public and no public access to the pharmacy. Therefore, the GPhC’s Standards for Registered Pharmacies would need to be interpreted in an entirely different way in order to apply them to such an environment. In any event, clarity is required from the GPhC as to how the standards have been or would be applied to those pharmacies. Some of the standards may be difficult to demonstrate – for example ‘the pharmacy services provided are accessible to patients and the public.’

Some parts of the Standards of Conduct, Ethics and Performance would have limited relevance to pharmacists working at the hub. For example, without any patient contact, the expectation that the pharmacist would ‘be satisfied that patients or their carers know how to use their medicines’ and ‘encourage patients and the public to participate in decisions about their care’ may be difficult for a pharmacist to demonstrate or would require a different interpretation in order to apply them. The Standards of Conduct, Ethics and Performance are currently being revised; a separate consultation is being conducted by the GPhC at the time of writing. Similar examples could be given of the limited relevance of the proposed new standards to pharmacists working in such hub environments. The GPhC’s ‘*Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet*’ does not address these points.

Recommendation Eight

Before changing legislation which would facilitate the wider operation of hub and spoke models in community pharmacy between different legal entities, the GPhC must clarify how the Standards for Registered Pharmacies and the Standards of Conduct, Ethics and Performance have been or would be consistently applied to pharmacies not accessible to the public, such as the automated hub pharmacies being operated by Boots and Lloyds, and the pharmacists who work within such pharmacies.

5. Do you have any comments on the assumptions for our Impact Assessment (Annex C) for the proposal to make ‘hub and spoke’ dispensing possible across legal entities?

The content of Annex C is, in our view, flawed.

With two exceptions, no research has been quoted to support the many statistics used. The Department of Health has not distinguished in the majority of its assumptions between different models of hub and spoke dispensing. The substantial differences in the models mean that a broad-brush approach using a single statistic intended to represent all the different models is not appropriate. It is not clear what aspects of hub and spoke operations have been taken into account within the figures. In any case, we have concerns, albeit subjective, that the figures used are inaccurate. In our view the final result is that the Annex represents, in succinct terms, a significant risk to public safety and the functioning of the National Health Service (including the community pharmacy sector).

Assumption 1

Do you agree with our assumptions on the efficiency of ‘hub’ pharmacies?

NO

Assumption 1 – Freeing up Time vs. Labour Cost Reductions

If the purpose of automating the dispensing process is to ‘free up pharmacists to spend more time with patients’, as stated in the consultation document, the ‘reduction in pharmacist labour costs’ (and other labour costs) must necessarily reflect a time saving less than that introduced by the use of automation. If the reduction in labour costs (staffing levels) was proportionate to the time saved by the use of automation (the reduction in workload), nobody’s time would be ‘freed up’ and there would be no additional capacity to deliver other services. People may have less work to do, but would have less time to do it – meaning that no additional time could be spent with patients. The Department of Health has not acknowledged this in the consultation document.

A ‘reduction in labour costs’ is synonymous with cutting staffing levels. Since it appears to be the Department of Health’s expectation that staffing levels will be significantly reduced on a national scale, in the absence of any published plan for the continued employment of affected staff, the Department appears to be attempting to justify

a reduction in the number of available jobs in the community pharmacy sector, with the job losses potentially delivered through redundancies nationwide.

The PDA believes that major pharmacy contractors use the same spin to justify the use of automation to their staff, when in reality the use of automation is simply about cutting labour costs rather than freeing up time. Both Boots and Lloyds have said that their large automated dispensing solutions will result in time being freed up for pharmacists.^{4,5} PDA members inform us that staffing cuts have been implemented in both cases. The National Pharmacy Association (NPA) surveyed its members (pharmacy contractors) on the matter, and around 60% agreed or strongly agreed that hub and spoke would reduce pharmacy staffing levels, with only 20% saying it would improve the operational efficiency of the business.²⁵

Annex C of the consultation document is focused on the efficiencies (cost cutting) introduced by automation, not the amount of time which could be freed up. If the Department is planning labour cost savings equivalent to the time saved, then we fail to see how the introduction of automation is about freeing up time.

Recommendation Nine

The consultation focuses primarily on assumed labour cost reductions (cuts to staffing levels) through the use of hub and spoke models, not freeing up time for pharmacists to spend with patients. This will lead to a reduction in the number of available jobs in the community pharmacy sector, with the job losses potentially delivered through redundancies. If the assumed reduction in labour costs is proportionate to the assumed reduction in workload (we dispute whether there will be any workload reduction), pharmacists will have no additional time to spend with patients. Freeing up time for pharmacists to spend with patients would improve the healthcare service provided to those patients; reducing labour costs would not. The Department of Health must not assume any labour cost reductions associated with changes to legislation permitting the use hub and spoke models. In addition, it must be entirely clear in its intentions else it risks appearing not to be transparent and forthright in the consultations it conducts.

Assumption 1 – Impact on Staffing Levels and Patient Safety

Reduced staffing levels will reduce the size of the workforce. The remaining workforce would have less flexibility to respond to absences including holidays, sickness absence and other forms of absence such as bereavement and maternity leave. With a larger number of staff present at any given time, some of whom may be involved in necessary administrative tasks at any given point in time, the workforce may be able to postpone those tasks until a later point in time in order to respond to an acute influx of patients / customers. If, for example, five patients walked through the door of a pharmacy, it may be possible to care for those patients within a reasonable timeframe. If the workforce was reduced in size, there would be fewer staff present at any given time. The staff would therefore have less capacity to cope with an influx of patients at a particular time of day. This we believe would increase pressure on pharmacy staff with a potentially adverse effect on patient safety.

In a recent PDA survey, members were asked 'When you are working for your main employer, how often are there enough suitably qualified and skilled staff, for the safe and effective provision of the pharmacy services provided?' 53.3% of the 2,849 respondents said this was the case half the time or less, with substantially poorer results in multiple pharmacies than independents. The survey results make it clear the public are already at risk due to poor staffing levels; it appears that the Department of Health is about to take measures which place public safety at an even greater risk through assumed reductions in labour costs (staffing levels).

Recommendation Ten

The Department of Health must consult on, agree and publish detailed enforceable requirements for minimum staffing levels in community pharmacies, beyond those present in the Drug Tariff. It is particularly important that this be done prior to any changes to law which permit Hub and Spoke dispensing operations between different legal entities. Pharmacy staffing levels should be publically visible as they are for hospitals.

Assumption 1 – Understanding the Impact on Workload

We believe that the Department of Health may need assistance in understanding the robustness of the information provided by pharmacy contractors about labour cost reduction. Expert knowledge would be needed in order to ask the right questions to challenge its robustness. In particular, the Department should seek to understand the contractor's staffing model. If a pharmacist needs to spend less time on accuracy checking, his or her apparent 'free time' would increase. In a staffing model this may mean that this additional 'free time' was simply reallocated to be spent on the healthcare counter, for example, carrying out over-the-counter (OTC) transactions, reducing the healthcare advisor labour costs on the healthcare counter. The reduction in labour costs in this case should be calculated using a healthcare assistant's hourly rate, not a pharmacist's. The saving, however, would be a reduced cost of carrying out OTC transactions – which is not a cost to the NHS. A question arises as to whether the cost saving could then be realised by the NHS. In addition, the pharmacist would have no additional time to spend with NHS patients per se, since his / her time would be spent on OTC transactions instead of accuracy checking.

In our experience, the majority of pharmacies have access to just one pharmacist throughout their opening hours. In these pharmacies, it would not be possible to reduce the number of pharmacist hours in any hub and spoke model. This would be particularly true in pharmacies with a lower dispensing volume and / or services uptake – such as newer pharmacies and some essential small pharmacies in rural areas. Therefore, a blanket approach to reducing pharmacist labour costs would be inappropriate.

In any hub established from scratch, the *increase* in labour costs will be from zero. Where we discuss percentage changes, we make reference to pharmacies that are already established.

We take the view that *small scale collaborative* dispensing hubs are unlikely to result in significant reductions in overall costs (including labour costs) to the hub and spoke pharmacy. We believe that an increase in costs is more likely.

In an *automated small scale collaborative* hub, there would, we expect, be a percentage increase in pharmacist or ACT costs. The magnitude of the increase would depend on whether dispensing, clinical checking and/or accuracy checking were carried out at the hub.

In a *manual process small scale collaborative* hub, the figure for the increase in labour costs should be equivalent to or greater than the reduction in labour costs in the spoke pharmacy. We see no reason why the actual increase in labour costs in the hub would be less than any areas of decreased cost at the spoke in such circumstances (and we question whether there would be any decrease). The same quality of dispensing, accuracy checking and clinical checking processes will need to be followed, with exactly the same rigour. Dispensing more items does not change that; each item will need to be labelled on the PMR, stock will need to be picked and assembled, and accuracy and clinical checks will need to be completed. Stock will need to be picked patient by patient, item by item. There may be some relative efficiencies in some aspects of stock management (e.g. ordering larger quantities on a computer screen rather than one item at a time) but these are likely to form a relatively small percentage of the overall workload.

It is important to remember that the use by a patient of a hub and spoke model would be initiated by the pharmacy (and possibly the government, if it became a necessity for pharmacies to use hub and spoke models). It would not be initiated at the patient's request. The patient's primary concern will be their own health; a choice to provide care to the patient by using a hub for the dispensing process must have no adverse impact on the care provided or the level of safety. This is an important concept to be borne in mind when considering the implications of using hub and spoke models.

Offset against any areas of workload *reduction* in a *small scale collaborative* hub and spoke model, such as ordering larger quantities on a computer screen rather than placing several orders one at a time, we would envisage the following *increases* in overall workload (and therefore cost):

- Telephone calls between the hub and spoke pharmacies. Patients will retain the relationship with the spoke pharmacy, since that was the pharmacy they initially chose to visit (for example due its proximity to the patient's home). These calls may be necessary, for example:
 - In the event of a patient being prescribed a new medicine, such as a medicine for an acute condition (e.g. an antibiotic). If the spoke pharmacy staff do not retain access to a full, up-to-date PMR (since the medicines may be labelled and dispensed at the hub pharmacy), they will need to call the hub pharmacy to inform them that a new medicine has been prescribed, agree any necessary steps in light of the new prescription and who would have ownership and accountability for each step.
 - In the event of a medicine being out of stock and unavailable for supply to the patient – the hub pharmacy may need to inform the spoke pharmacy and / or to discuss the course of action.
 - In the event of an urgent request from the spoke pharmacy to the hub, on behalf of the patient.
 - In the event of a change to the patient's medicine requirements or delivery arrangements.
- Conversations between the spoke pharmacy's staff and the patient explaining the arrangement with the hub and obtaining their consent to use the hub (since the patient's data will be transferred there).
- Conversations between staff at the spoke pharmacy and the patient in the event of a new medicine being prescribed, to ascertain what other medicines the patient was taking (as an alternative to a telephone call to the hub or accessing the Summary Care Record where possible, but in any event this would increase workload).
- Conversations between staff at the spoke pharmacy and the patient in the event of any error arising at the hub pharmacy or a medicine being out of stock. The use of a hub pharmacy would involve some discussion about whether the hub or spoke pharmacy was going to supply the out of stock medicine.
- Transferring prescriptions (or copies thereof) between the hub and spoke pharmacy. An independent, detailed legal analysis is required to assess whether or not a hub pharmacy that is a separate legal entity from the spoke pharmacy could make a supply to the spoke pharmacy without having the original prescription in its possession. It may be required, for example, to check that the prescription had been signed in ink by the prescriber (Human Medicines Regulations, regulation 217). Even if it was determined that the hub pharmacy did not need the original prescription, the hub may insist on seeing a 2-sided photocopy or fax of the original prescription, where paper prescriptions were involved; this would increase workload as the spoke pharmacy would be required to get the copy to the hub pharmacy, for example by photocopying (and delivering) or faxing it. The prescription would also need to be signed by the patient, the exemption status completed, and the repeat slip filled in (if the patient was on a managed prescription collection service). A hub and spoke service would likely be most used by patients on a managed prescription collection service and in our experience many prescriptions for such patients are collected by the pharmacy from the GP surgery,

so there would be no opportunity to obtain a patient signature before supply. The pharmacy that delivered to the patient would, in those circumstances, need the original prescription in order to obtain a signature and to ensure exemption status details were completed.

- Administrative workload in communicating with GP surgeries that a prescription was being ordered for collection by another pharmacy.
- Administrative workload in arranging for the spoke pharmacy to pay the hub for its services – for the drugs it was dispensing, dispensing fees, container allowances, labour costs etc.
- Increase in overall labour costs to maintain safe staffing. As already set out, we believe that the overall workload may increase when using a *small scale collaborative* hub and spoke model. However, if a reduced staffing requirement at the spoke pharmacy was assumed, if it were to drop below a certain level it could introduce risks to patients visiting the pharmacy in person. For example, reduced dispensing assistant or pharmacy technician cover may decrease the availability of a second check on a prescription, meaning dispensed items were assembled and self-checked by a pharmacist. Reduced staffing levels may also increase the physical security risk to staff working in pharmacy alone, so an increase in labour costs may be necessary to reduce that risk.
- We believe that *small scale collaborative* hub and spoke models would cause additional issues for multiple pharmacies that use staffing models based on the number of items dispensed from a particular pharmacy. If pharmacy S (the spoke) was claiming from the NHS for an item dispensed at pharmacy H (the hub), pharmacy S would receive an allocation of staff funding since it would be dispensing the items. The management information or data showing the number of items dispensed by pharmacy H would not include the items from the spoke since it would not be claiming for them. An adjustment would have to be made to the multiple's internal systems to provide appropriate labour funding for both pharmacy H and pharmacy S.
- A reduction in labour funding (and therefore staffing levels) would result in a short-term increase in workload to manage redundancies and the consultation process.

Recommendation Eleven

Prior to introducing legal changes which would permit the operation of a hub and spoke dispensing model across separate legal entities, a detailed independent legal analysis must be conducted to assess the practical operational framework that would need to be implemented as a result, including whether the hub pharmacy could make a supply to the spoke pharmacy without having the original prescription in its possession.

Assumption 1 – Other Costs

Costs of operating such a model would also be increased as a result of:

- Redundancy costs and, potentially, litigation costs in the event of a forced reduction in labour costs
- Delivery costs – prescription collection from one pharmacy and transport to the other and charges for delivering dispensed medicines to patients.

We have been advised by the PDA membership that *small scale collaborative* hub and spoke models have established in the past, within the same legal entity, for their perceived efficiency, and due to the current broad legislative framework applicable to the sector, in fact they introduce considerable difficulties and increased workload. When established for such reasons, they may later be dissolved. Alternatively, they may be established due to lack of physical space for prescription assembly and storage in the spoke pharmacies despite the increase in workload.

Any hub and spoke model would lead to increased staffing costs to facilitate due diligence processes, SOP rewriting and staff training. There would be other costs alongside this, such as IT costs.

Assumption 1 – Pharmacy Funding Cuts

We are concerned that the figures in Annex C are intended to justify the recently announced cuts of £170m to the pharmacy global sum, and any subsequent cuts, which the government has said it expects will force the closure of up to 3,000 mostly independent pharmacies.²⁰ The figures must be realistic and must not be used to that end.

Assumption 2

Do you think there are labour savings for other staff that we should consider?

NO – we do not support hub and spoke models being used for labour cost savings, which we believe is the intended meaning of this question.

We have set out our views with respect to staffing levels elsewhere in our response. We take the view that the hub and spoke models should be implemented if they were to free up pharmacists' time to spend with patients rather than in order to reduce labour costs, and we are doubtful, in light of the proposals in the consultation document, that workload could be assumed to reduce where hub and spoke pharmacies were in separate legal entities – but if the Department of Health is to assume changes in staffing levels, we do not understand why it would not consider dispensing assistant costs. Pharmacy technicians in community pharmacy are, in many cases, routinely and typically involved in dispensing. In fact, their duties may be confined to it.

Assumption 3

Do you agree that the labour savings in 'spoke' pharmacies are the same for independent, small multiple, and large multiple pharmacies?

NO

Two of the large multiple pharmacy chains – Boots and Lloyds – collectively own 4100-4400 pharmacies in the UK. Since they each operate a *large scale automated* dispensing hub, they are unlikely to use any model other than this.

We are sceptical, pending the presentation of further robust evidence, as to whether *small scale collaborative* dispensing hubs actually reduce overall workload; they may increase it.

We understand that *large scale automated* dispensing hubs, which have access to a wide range of medicines on-site, can reduce workload at the spoke under certain circumstances within the same legal entity, including where no accuracy check is carried out at the spoke after the items have been dispensed at the hub (though we reserve judgement as to the legal implications of not conducting such a check). The impact of the EU Falsified Medicines Directive may change this.

At the moment, only Boots / Alliance Healthcare and Lloyds / AAH operate *large scale automated* schemes. It would take a considerable amount of time for any competitor to develop a solution to the same standard, and in any case the competitor would struggle to compete in light of existing agreements between manufacturers and wholesalers. Before this materializes we anticipate that these companies will start to charge small pharmacies for the privilege of using their automated solutions. If that does happen, it is not just the *labour* costs which would be relevant – it is the overall costs, as smaller pharmacies would need to pay for the privilege of using a Walgreens Boots Alliance-owned or Celesio-owned service.

Recommendation Twelve

We oppose any assumed reduction in labour costs as a result of the proposed changes in legislation enabling hub and spoke models to be operated between different legal entities. However, if the Department of Health decides to change pharmacy reimbursement as a result of these changes, it must take overall costs of operating hub and spoke models into account.

In the meantime, however, there will remain a distinct difference between the labour cost savings of large multiple pharmacies relative to the labour cost savings of smaller multiples and independents – large multiples achieving a labour cost saving through *large scale automated* solutions and smaller chains achieving a much smaller cost saving or cost increase as a result of using a *small scale collaborative* scheme.

Assumption 4*Do you agree with our assumptions on uptake?***NO**

We do not understand (since it has not been made clear) how the Department of Health intends to use the projected labour cost savings set out in the consultation document. If it is for the purposes of designing a pharmacy contract reimbursement mechanism which distinguishes between large multiples and independents, or for the purposes of justifying the cuts to the pharmacy global sum, we do not understand why it would not consider the labour cost savings for multiples, unless it intends to allow those multiples to make an even greater profit from the NHS (and ultimately the taxpayer).

Recommendation Thirteen

If the Department of Health is to reduce pharmacy reimbursement as a result of projected cost savings, it must apply the same standard to large multiple pharmacies; to fail to do so would result in their increased profitability at the expense of the taxpayer and treat them differently to smaller multiples and independent pharmacies.

Assumption 5*Do you agree with our assumption for the percentage of medicines that will be dispensed by making use of ‘hub and spoke’ dispensing?***NO**

We cannot agree since the Department of Health has provided no indication of what this assumption is based upon. It has cited no data or research paper nor, as far as we are aware, has it commissioned any academic research. It cannot expect us to agree with this assumption in those circumstances, other than that we might be persuaded to do so as a result of it asking a biased question.

Since prescribers do not always prescribe quantities which match the available pack sizes, split packs may need to be used at hub pharmacies. This may necessitate manual dispensing, thereby reducing efficiency even in *large scale automated* hubs. Issues with maintaining cold chain storage may affect the ability of hub pharmacies to supply refrigerated items to spoke pharmacies. Existing legal requirements may mean that controlled drugs could not be supplied from the hub to the spoke; further legal analysis would be required to evaluate this.

Recommendation Fourteen

The Department of Health must set out a robust logical rationale to support the assertions it makes and the statistics it uses in consultation documents.

Assumption 6*What proportion of ‘hub’ capacity will be provided by large ‘hubs’ and what percentage by small collaborative ‘hubs’? Or do you foresee other ‘hub’ models?*

We do not support the widespread use of hub and spoke pharmacies as described in the proposals in the consultation document as it does not accord with our stipulations set out in Recommendation One.

Assumption 7*How many pharmacies can a ‘hub’ pharmacy serve? How much would it cost to build a ‘hub’ pharmacy? How much would you expect a ‘hub’ pharmacy to charge per dispensed item?*

Accurate figures could be obtained through an academic research project to set up an NHS-operated hub. This would be an appropriate means to obtain this data. This could include obtaining quotes from manufacturers of large industrial warehouse equipment. Alternatively, Boots or Lloyds could be asked to provide data (backed by invoices and other evidence) showing the cost of setting up a *large scale automated* hub pharmacy. The charge per dispensed item may be affected by the distance of the hub from the spoke (due to transport costs) and the cost of the medicine dispensed (we assume the spoke will submit the prescription for payment).

Assumption 9

Do you agree with our assumptions on staff salaries?

NO

The links provided in the consultation document did not work. We had some difficulty in finding the data to which this question refers, but ultimately obtained the correct link directly from the Department of Health. We are concerned that other respondents to this question may not have been as resourceful and will have simply agreed with this question due to its biased wording.

The data are based on UK averages. There were marked variations in the average salaries between different countries and areas of the country. For example, in Wales the median pharmacist salary was £44,508 whereas in the West Midlands it was £31,675. The data set likely included hospital, primary care and community pharmacists; there are likely to be marked differences in salaries between these groups, with primary care pharmacy generally attracting more experienced pharmacists. We are advised by the PDA membership that in 2015, one large community pharmacy multiple did not distinguish between pharmacy technicians and dispensing assistants in the pay rate it awarded, unless those pharmacy technicians were qualified as Accuracy Checking Technicians. In our view the salary attracted by pharmacy technicians is likely to differ between the community pharmacy and hospital pharmacy sectors. Since the hub and spoke changes will affect community pharmacy most significantly, the blanket approach used is inappropriate. Given that there are marked differences between many different groups of pharmacists within the data, we see no reason why there would not also be a marked difference in average salaries between independent and multiple pharmacies. We implore the Department to conduct more robust academic research.

Assumption 10

Do you agree with our assumptions on dispensing activity across different pharmacies?

NO

We cannot agree with this assumption since the Department of Health has not provided sufficient data to allow us to support or refute it.

Assumption 11

What level of stock reduction is realistic?

We cannot comment on the level of reduction or increase since the Department of Health has not provided sufficient data to enable us do so. This should be supported by robust academic research, commissioned by the Department of Health, which extends beyond the responses to this consultation.

Assumption 12

What percentage of medicines is likely to be supplied directly by a ‘hub’ pharmacy to a patient?

We have made the recommendation elsewhere that supplies to patients can only be made directly from a hub pharmacy to a patient provided that there has been contact between the patient and the spoke pharmacy. We cannot comment on the percentage since the Department of Health has not provided sufficient data to enable us do so. This should be supported by robust academic research which extends beyond the responses to this consultation.

It is clear, however, that spoke pharmacies could not go below a certain level of stock else they would be unable to satisfactorily respond to acute prescription requests – where the patient needed the medicine more quickly than would be the case if the item was dispensed by the hub or where the patient did not want their details to be sent to the hub. To go below that minimum level could put patients at risk of delay in receiving their medicines. However, by retaining that minimum, if the stock was not used by the spoke pharmacy before its expiry date by virtue of the fact that there was lower turnover of the spoke pharmacy’s stock because some of its prescriptions were being fulfilled by the hub, this would increase medicines waste.

Recommendation Fifteen

Before implementing any change to the legislation or financial reimbursement to pharmacies associated with hub and spoke dispensing, the Department of Health must commission academic research beyond the scope of this consultation to investigate:

- *the cost of setting up a dispensing hub in various forms*
- *the effect of hub and spoke models on patient safety*
- *the percentage of medicines dispensed from a hub*
- *the percentage of medicines supplied by a hub pharmacy to a patient (provided that contact between the spoke pharmacy and the patient was mandatory)*
- *how much a hub could charge for the service*
- *the effect of hub and spoke models on stockholding.*

The Department must evaluate the benefits of NHS-operated hubs and publish its findings in respect of the above.

6. Are you aware of or able to provide evidence that ‘hub and spoke’ dispensing is more efficient and cost-saving, including according to the scale of the ‘hub’ operation?

NO

We understand from PDA members that *large scale automated* can be cost saving within the same legal entity, in certain circumstances and in the absence of the effects of the Falsified Medicines Directive. We are not aware of any research which would robustly demonstrate changes in efficiencies or costs outside of these parameters. Information could be obtained from multiple pharmacies operating *large scale automated* hub and spoke models but it would be subject to the limitation that the data will be based on operations within the same legal entity. In fact, any data obtained will have limitations, since the UK’s legislative framework and community pharmacy operations are unique to the UK and the proposals constitute changes to that framework. For this reason, we have made the recommendation elsewhere in our response that robust academic research be conducted in order to evaluate such issues.

7. Are you aware of or able to provide evidence that ‘hub and spoke’ dispensing is safer, including according to the scale of the ‘hub’ operation?

NO – in fact the opposite may be true under certain circumstances and we are concerned about the effect of the proposals set out in the consultation document on patient safety.

General Comments on Patient Safety

We are reliably informed by the PDA membership that *large scale automated* dispensing may in fact be less safe than manual dispensing in some circumstances, depending on the level of human involvement. We trust that the large multiple pharmacy that is aware of this information will share it with you, including its view on the implications and its findings since becoming aware.

Machines themselves may be very accurate, but they respond only to human instructions, so extensive safety validation of the end to end process is required. The output of a machine is only as accurate as the human input, so the accuracy of the dispensing process will remain reliant on human margins of error.

In the human (manual) dispensing process, several people may be involved in labelling, assembling, clinically checking, accuracy checking and handing out a prescription. During the handling of the prescription, generating labels and applying them to the medicines, clinical checking, accuracy checking and handing out, there are numerous opportunities to identify an issue with the prescription itself, an issue with the label that was generated or an issue with the stock selected for the prescription. Within the same legal entity, when a machine is told to carry out the dispensing process, there may be no need for a human accuracy check on what was dispensed. This, however, relies on the accuracy of what the machine was told to dispense in the first place.

Assume for the purposes of illustration that the work carried out by a machine is perfect (or close to it). There is a much shorter period of human involvement in telling the machine what to dispense than would occur in a traditional dispensing process. Therefore, there are far fewer human opportunities to intervene in the event of an error, since the human exposure to the prescription, label and medicines will be greatly reduced. A machine will dispense what it was told to dispense; but if those instructions contain an error, it will faithfully dispense the item including that error.

Errors arising on handout or delivery of medicines – such as handing a bag of medicines to the wrong patient or failing to provide the necessary counselling to the patient, would likely not be affected by the use of a *large scale automated* dispensing machine (but may change as a result of the overall process).

Further, an error at the hub, for example caused by a flaw in the IT software or picking process, for example, could lead to errors reaching many patients rather than just a single patient. In addition, in the event of an issue which prevented the operation of a *large scale automated* hub, such as a fire, an IT failure or an issue with the distribution network, medicines supply to many patients may be affected.

Position and Comments from the Chief Pharmaceutical Officer for England

The Pharmaceutical Journal reported on the Chief Pharmaceutical Officer for England's evidence to the All-Party Parliamentary Group on the 16th of March 2016. The Journal reported that he said large scale automated technology was safer and more efficient and '*with the traditional system approach to dispensing, the error rate in community pharmacy is around 3%*', referring to the error rate in pharmacies in England. He said it was much higher than in countries that have adopted automated dispensing.²⁶ We were surprised by this, because the

Department of Health used an error rate of 0.04% in the impact assessment paper which accompanied the 'Rebalancing Medicines Legislation and Pharmacy Regulation: draft Orders under section 60 of the Health Act 1999' consultation in 2015. The impact analysis reads '*In order to estimate the actual unprevented dispensing errors that occur in community pharmacies, the findings from the NHS and evidence by James et al (2009) have been used. These suggest that dispensed errors represent 0.04% of the total volume of NHS medicines dispensed by community pharmacies.*'²⁷ The impact analysis referred elsewhere to the paper by James et al in 2009, which itself cast doubt on the validity of the 3.32% figure determined in one study examined in the meta-analysis.²⁸

We note also that the minutes of the APPG meeting did not capture any figures quoted by the Chief Pharmaceutical Officer, if these were indeed quoted at that meeting.²⁹

The Chief Pharmaceutical Officer offered a clarification of his evidence to the APPG, published in May 2016.³⁰ He did, however, reassert that '*The only UK observational study of dispensing error rates within that paper [James et al, 2009] quotes a rate of 3.32%*' and '*In conclusion, there is observational evidence of dispensing error rates in community pharmacy of around 3%*'.³¹ We were surprised by this clarification because the paper by James et al states '*Four reviewed papers investigated the incidence of dispensing errors in UK community pharmacies.*'²⁸ The paper makes it clear that the study by Franklin and O'Grady, which quoted a rate of 3.32%, was an observational study. We do not understand why the Chief Pharmaceutical Officer would choose to use figures from that one study in isolation; three other UK studies were quoted in the paper which used incident forms.

An additional surprise came from the Chief Pharmaceutical Officer's comment in his clarification that '*I would like to confirm that I am neither trying to promote any approach to centralised and automated dispensing*'.³¹ The Pharmaceutical Journal quoted him as saying that community pharmacists had a 'professional obligation' to adopt automated dispensing.²⁶ He was quoted in the Chemist and Druggist in February 2016 as having said automated dispensing has 'extraordinary capability'³² and in fact this consultation document written by the Department of Health states '*Automation in dispensing, implemented alongside a robust quality assurance system, is linked to safer dispensing with fewer dispensing errors.*'

Recommendation Sixteen

The Chief Pharmaceutical Officer for England and the Department of Health must make clear which they believe to be correct: a dispensing error rate of 0.04% or 3.32% in community pharmacy in the UK. They must also make clear whether they are trying to promote any approach to automated dispensing or not. If the Chief Pharmaceutical Officer's evidence to the All-Party Parliamentary Group for pharmacy on dispensing error rates in the UK requires any further clarification, he must issue that clarification at the earliest opportunity. If the APPG failed to capture key evidence in the minutes of its discussions with the Chief Pharmaceutical Officer on the 16th of March 2016, it must issue revised minutes if possible and take care to capture and issue comprehensive, accurate minutes in the future.

Human involvement may theoretically introduce errors which were not present on the prescription itself. However, a study carried out on behalf of the General Medical Council showed that 5% of general practice prescription items contain a prescribing or monitoring error, affecting one in eight patients. 0.18% of items included a serious error.^{33,34} If the error rate in the traditional manual process dispensing is estimated by the Department of Health to be 0.04%, one might conclude that manual process dispensing is effective at preventing errors reaching patients. Any hub and spoke model which did not require an accuracy check on prescriptions generated in general practice – or which reduced the potential for human intervention – may increase risks to the public.

8. Before changes can be made for the price to be displayed on NHS dispensed medicines, enabling amendments need to be made to the Human Medicines Regulation 2012. Do you agree with these amendments to the Human Medicines Regulations 2012?

NO

This question relates to the inclusion of the price of medicines on dispensing labels for medicines costing £20, accompanied by the phrase 'funded by the taxpayer' (or similar). Clarification as to whether the £20 threshold is to be applied per pack or per dispensed item would be helpful.

Prior to implementing changes to the Human Medicines Regulations which permit each country in the UK to decide whether or not to include the information (and which would see the change implemented in England), research should be carried out to understand the impact. For example, it is possible, as acknowledged in the consultation document, that some patients may stop taking their medicines as intended because they perceive that they are placing a burden on the public purse. Such research would help understand the magnitude of any positive or negative impact on medicines waste. We believe that contractors may be concerned that including the trade price of NHS medicines on the label would reveal the mark-up they were charging if the patient were to purchase the medicine on a private prescription.

Recommendation Seventeen

Before implementing any changes to the Human Medicines Regulations allowing the prices of medicines and / or a statement about how the cost of a medicine is met to be included on a dispensing label, the Department of Health should commission academic research and a pilot study to investigate the positive and negative impacts of doing so. It should also clarify whether the price is to be included on a per-pack or per-item basis.

9. Are you aware of any other evidence that supports the impact of patients' understanding of the prices of health services on their behaviour, including from local initiatives? If so, please give details?

NO

10. Do you have any views on the proposed implementation in the NHS in England? If so, please give details?

We have set out our views in response to question 8.

11. Do you agree with the set of information that is proposed to appear on the dispensing labels for MDS?

NO

The new part 258A of the Human Medicines Regulations 2012, paragraph 5b, requires that the information in paragraph 1 and 2 of Schedule 26 (the name of the patient and the name and address of the person who supplies the product) must be included on both the outer and immediate packaging of a monitored dosage system 'wherever possible'. It is hard to envisage circumstances where it would not be possible to do so by some means. We would recommend that this wording be revised.

Recommendation Eighteen

The wording of the proposed new part 258A of the Human Medicines Regulations 2012, paragraph 5b, should be revised. In particular, the phrase 'wherever possible' should be removed and replaced with a suitable alternative which would not effectively mandate the use of labels on the immediate and outer packaging in all circumstances.

The proposed paragraph 11B of the Human Medicines Regulations 2012 proposes to allow information to be included on dispensing labels, helping the patient to identify and distinguish between products in a monitored dosage system, where the person responsible for the assembly considers it appropriate. It is our understanding that this was not explicitly prohibited in the past. If it was not, this change in legislation achieves little.

12. Are there practical issues with what is proposed that would make application difficult in practice? If so, please give details.

YES

We are concerned about how paragraph 7 of the new part 258A of the Human Medicines Regulations 2012 would apply to a monitored dosage system. It suggests that the information required by that regulation and by Schedule 26 should be visible through the transparent or open part of that package.

13. Do you have views on the proposed flexibility for the information to appear on a combination of both the outer and immediate packaging?

YES

We have no issue with the information being duplicated such that it appears on both the outer and immediate packaging, if the pharmacist supervising the supply deems it appropriate.

14. Do you think pharmacies that supply medicines to other healthcare settings, e.g. ‘hub’ pharmacies and some hospital pharmacies, will need to part prepare some pharmacopoeia and other preparations in advance of the prescription being received? If so, please provide examples of the sorts of part preparation that are necessary.

As stated above, we do not believe that the proposed legislative changes related to hub and spoke dispensing should be implemented at this juncture.

15. Do you think that pharmacists in a registered pharmacy should continue to be allowed to prepare ‘Chemist’s Nostrums’? If so, could you provide us with examples of ‘Chemist’s Nostrums’ that are being prepared?

We are not aware of any current examples.

16. Is there anything else you would like to raise with regards to the proposals for restructuring the pharmacists’ exemption?

YES

Extent of Legislative Changes

We note that extensive changes to the Human Medicines Regulation 2012 have been proposed. In our view, the Department’s time would have been better spent on securing more comprehensive legislative changes resulting in the decriminalisation of dispensing errors. We are cognisant of the pace with which the Department has secured proposed legislative changes relating to hub and spoke dispensing in contrast to the pace with which it is addressing decriminalisation of inadvertent dispensing errors.

Recommendation Nineteen

The Department of Health should place greater focus on the full decriminalisation of inadvertent dispensing errors rather than focusing on legislative changes relating to hub and spoke dispensing.

17. Do you have any comments on the initial equality assessment or evidence that we should consider in the development of final equality assessment?

YES – see notes Annex D

18. Do you have any comments on the draft Human Medicines (Amendment) (No. 2) Regulations 2016?

Many parts of Regulation 3 of the Human Medicines Regulations apply to nurses, midwives, doctors and dentists. We are therefore of the view that bodies representing doctors and nurses such as the British Medical Association, the British Dental Association, the Medical Defence Union, the Royal College of Nursing and the Royal College of Midwives should have been among the consultees. We can see from list of consultees in Annex A that they were not.

Recommendation Twenty

The Department of Health should consult on the proposed changes more widely in light of the fact that some of the amendments to legislation will have an impact on doctors, nurses, dentists and midwives.

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