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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'Enable the use of 'hub and spoke' dispensing models by 'spoke' pharmacies that do not for part of the same retail pharmacy business as the 'hub' pharmacy.'

And

'Redesign the 'exemptions for pharmacists' in section 10 of the Medicines Act 1968 in respect of the preparation and assembly of medicines, using the clarification of the law provided by the Court of Justice of the European Union (CJEU) in a recent judgment, so that businesses can be confident that the uses they are making of the relevant exemptions are legally secure.'

Introduction

1. PSNC is supportive of the principle that there should be a level playing field between independent and multiple pharmacies, but vigorously opposes the proposals set out in the consultation because of the following significant concerns:

    a) it is impossible to create a level playing field for 'hub and spoke' dispensing between independents and multiples, where independents use hubs owned by third parties (to undertake the assembly) with the inherent risks this carries, for example, sharing patient lists (whereas multiples do not share patient lists with third parties);

    b) the draft regulations propose a structure for 'hub and spoke' dispensing that is wholly different from the narrative of the consultation and on which there is no consultation, in particular, they include 'hub and spoke' dispensing between any '*relevant clinical setting*';

    c) the proposal for unrestricted wholesale dealing between *relevant clinical settings* is arguably contrary to European legislation;

    d) the professional and legal implications of 'hub and spoke' dispensing between registered pharmacies have not been considered and could lead to patient safety issues;

    e) the *Abcur* judgment concerns magistral and officinal formulae and the activity complained about in the case would be contrary to section 10 of the Medicines Act 1968; repeal or redesign of the section is not necessary;

    f) Changing the emphasis of the 'manufacturing and assembly exemption' from registered pharmacies to registered pharmacists is unnecessary and could lead to patient safety issues;

    g) 'Hub and spoke' dispensing may not be able to comply with the Falsified Medicines Directive (FMD);

h) the alleged safety reasons for 'hub and spoke' dispensing are not evidenced and arguably such models will be less safe: sharing the dispensing process between two legal entities introduces new, unquantified risks that could lead to patient safety issues; and

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

2. PSNC will continue to examine the possible consequences of 'hub and spoke' dispensing. In the short time available we cannot be confident that we have identified all the relevant issues and possible consequences.

Impossible to create a level playing field

3. It is impossible to create a level playing field for 'hub and spoke' dispensing between independents and multiples (it is currently multiples that are able to use hub and spoke, within their corporate structures – independent pharmacies do not generally have sufficient branches to benefit from hub and spoke).

4. By the very nature of the proposal, independents would use hubs owned by third parties (to undertake assembly) with the inherent risks this carries for business, for example, sharing patient lists. Multiples carrying out 'hub and spoke' dispensing use an in-house assembly unit within a pharmacy that is part of the same business and, therefore, do not have to share patient lists with third parties. Multiples do not have the same risks. This imbalance in risk is the opposite of a level playing field and the proposal to create a level playing field is consequently inherently flawed and, therefore, unacceptable.

Draft regulations appear at odds with the narrative of the consultation

5. The draft regulations propose a structure for 'hub and spoke' dispensing that is wholly different from the narrative of the consultation and on which there is no consultation; in particular, they include provision for 'hub and spoke' dispensing involving '*relevant clinical settings*'. A *relevant clinical setting* is defined as '*a registered pharmacy, a hospital, a health centre, a surgery or a care home*'; a surgery is defined as '*a premises at or from which primary medical services are provided as part of the health service*' (draft regulation 5).

6. The narrative of the consultation refers to 'hub and spoke' dispensing models as follows: *'Typically, in a 'hub and spoke' dispensing model, the medicines are sent back from the 'hub' pharmacy to the 'spoke' pharmacy that will supply the patient. An alternative model is the 'hub' pharmacy sending the medicines directly to the patient or via a delivery company. Other models may develop in the future. In any model patient should have access to a pharmacist. We are not proposing to introduce any*

restrictions in the Human Medicines Regulations 2012 as to which 'hub and spoke' models can be operated. For pharmacies providing NHS pharmaceutical services there may be conditions for 'hub and spoke' dispensing as outlined above.' (paragraph 6).

7. The explanatory notes of the draft regulations state: '*There are four key changes from the previous arrangements. Firstly, the previous provisions prevented dispensed medicines assembled by retail pharmacy businesses being supplied first between different businesses and then on to or for the patient. This prevented the retail pharmacy business that sold or supplied a medicine to or for the patient from using the services of a different legal entity to dispense the medicine on its behalf. This bar has been removed. However, where retail pharmacy businesses do rely on this new flexibility, both the premises at which the product is dispensed and the premises at which the product is supplied will need to register as pharmacies.*'

8. 'Hub and spoke' dispensing appears to be related to pharmacy, however, the draft regulations introduce a new term '*relevant clinical settings*' and provide that:

    - *relevant clinical settings* may adopt 'hub and spoke' dispensing models;
    - pharmacy hubs may provide assembled or dispensed medicines to *relevant clinical settings*; and
    - spoke pharmacies will be able to use a hub that is a *relevant clinical setting* if this is decided as part of the consultation (and arguably can anyway if draft regulation 17 in the consultation (proposed section 69 2A of the Medicines Act) only applies where two retail pharmacies combine to form a 'hub and spoke' dispensing model).

9. The various 'hub and spoke' dispensing models that would or could develop involving *relevant clinical settings* other than pharmacies are not discussed in the narrative of the consultation.

10. The draft regulations also appear to permit the assembly of medicines without the supervision of a pharmacist, as part of 'hub and spoke' dispensing (draft regulation 4) and the distinction between dispensing and supply (draft regulations 6) suggests that in some models a hub may dispense and supply the medicine under the supervision of a pharmacist and a spoke would be little more than a pick up or collection point.

11. The draft regulations, by:

    - no longer requiring medicines assembled at one pharmacy business to be supplied/dispensed from that same pharmacy business;

- permitting 'hub' or 'spoke' dispensing from any *relevant clinical setting*;
- including surgeries in the meaning of *relevant clinical settings*; and
- exempting supplies of medicines between those *relevant clinical settings* from the requirement for a wholesale dealers licence,

provide an entirely new legislative framework for the retail supply of medicines.

Wholesale dealing

12. The proposal for unrestricted wholesale dealing between *relevant clinical settings* is arguably contrary to European legislation.

13. Article 1(17) of Directive 2001/83 as amended by Directive 2004/27/EC (the 'Directive') defines wholesale dealing as:

    "all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public… ."

14. Article 77 (1) of the Directive states that:

    "Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorisation to engage in activities as a wholesaler of medicinal products, stating the place for which it is valid".

15. Given previous discussions with the Department of Health in 2012, involving the removal of the former pharmacy exemption for limited wholesale dealing (former sub-section 10(7) of the Medicines Act 1968), because this was not in accordance with European legislation, it is questioned whether any 'hub and spoke' dispensing model between separate legal entities is lawful without a wholesale dealers licence.

Professional and legal implications

16. The professional and legal implications of 'hub and spoke' dispensing have not been considered in the consultation.

17. The assembly process carried out at a hub is the start of a single dispensing process that is completed at a spoke and for which the pharmacist at the spoke is responsible. The superintendent pharmacist of the spoke pharmacy, if any, also has professional accountability for the dispensing process. To what extent checks will be made of the medicines assembled at the hub pharmacy, a different legal entity, is unclear

and the extent to which a hub will be accountable is unclear. What, if any, contact the hub will have with the patient is unclear and who is ultimately responsible for the supply of a medicine is unclear. In addition, the draft regulations propose that where the 'hub and spoke' dispensing is between two pharmacies, the hub pharmacy is treated as supplying the dispensed medicine via an intermediary (draft regulation 17). Yet, surely the supply is made by the spoke pharmacy. This lack of clarity is likely to cause confusion and lead to patient safety issues. If assembly occurs at the hub and supply to the patient occurs at the spoke, this should be made clear in the regulations.

18. Criminal liability of pharmacists involved in the dispensing and supply process has not been considered and the implications of 'hub and spoke' dispensing on proposed amendments to any statutory defence for inadvertent dispensing errors has not been considered. Could the criminal liability of a pharmacist in a spoke pharmacy be dependent on the actions of those in a hub, rather than their own actions? For example, if an appropriate person in a hub pharmacy became aware of a dispensing error but did not communicate this to an appropriate person in a spoke pharmacy, is the pharmacist in the spoke pharmacy still liable?

Abcur v Apothek AB

19. The *Abcur* judgment concerns magistral and officinal formulae and the activity complained about in the case would be contrary to section 10 of the Medicines Act 1968; repeal or redesign of the section is not necessary.

20. The *Abcur* case was about the European exemptions for 'magistral formula' or 'officinal formula' preparations set out in Article 3 of Directive 2001/83/EC as amended by Directive 2004/27/EC, ['*the Directive*']. Article 2 of *the Directive* sets out the scope of the directive and relates to authorised medicines; Article 3 is an exemption for pharmacies (which are not defined in EU legislation) to prepare unauthorised medicines. In the *Abcur* case, a state pharmacy was manufacturing/assembling and distributing two unauthorised medicines in competition with authorised medicinal products distributed by the manufacturers.

21. The case provided clarification on the relevant European directive exemption for pharmacy (Article 3 of the Directive) as follows:

    - 'Magistral formula' medicines – the medicine must be prepared in response to a medical prescription (as well as *prepared in a pharmacy in accordance with a medical prescription for an individual patient (Article 3(1))*);

    - 'Officinal formula' medicines – the medicine must be supplied to the patient from the pharmacy premises/business that prepared the medicine (as well as *prepared in a pharmacy in*

accordance with the prescriptions of a pharmacopoeia and … intended to be supplied directly to the patients served by the pharmacy (Article 3(2))).

22. Section 10 of the Medicines Act currently prohibits the activity that was the subject of the *Abcur* case, to the extent that the exemption cannot be so wide as to make meaningless the purpose of the Act (and the Human Medicines Regulations) - that generally medicines should be subject to a market authorisation and manufactured, assembled and wholesaled by those with appropriate authorisation.

Pharmacy to pharmacist – unexplained and potentially unsafe

23. Changing the emphasis of the manufacturing and assembly exemption from registered pharmacies (section 10 of the Medicines Act) to registered pharmacists (the proposed draft regulations) is unexplained and could lead to patient safety issues.

24. Currently, section 10 of the Medicines Act 1968 (although described as an exemption for pharmacists) relates primarily to registered pharmacies. The additional 'pharmacist only' activities exempted relate to activities in hospitals and health centres carried out by or under the supervision of a pharmacist.

25. The draft regulations relate primarily to the activity of pharmacists – that pharmacists must supervise the dispensing process (although it is not clear that pharmacist supervision remains for assembly or supply in certain *relevant clinical settings*) and, in addition, extends the places at which the exempted activities can be carried out to surgeries. This is not discussed or explained in the narrative of the consultation.

26. With the proposed change, pharmacists supplying or dispensing medicines as part of a 'hub and spoke' dispensing model could be caught outside the recognised supervisory or management structures for pharmacists: those structures within registered pharmacies include statutory requirements for registered and inspected premises, responsible pharmacists, and crucially for a superintendent pharmacist with professional responsibilities for the pharmacists employed or engaged by the business; those within hospital have a recognised management structure with professional implications, even for those in purely management positions who are not involved in clinical activities.

27. Pharmacists caught outside the statutory or hospital supervisory or management structures, for example, those in surgeries, while still subject to professional requirements, could be subject to potential business and other pressures that those in registered pharmacies and hospitals are not. These pressures could lead to activities that risk patient safety, particularly with a new untried process.

Falsified Medicines Directive

28. 'Hub and spoke' dispensing may not be able to comply with the Falsified Medicines Directive (FMD).

29. The implications of the FMD have not been assessed. The Directive requires medicines to be commissioned with a unique identifier and have an anti-tamper device (ADT); and then decommissioned at the time of supply and the ATD checked. If an ADT check is not possible at the spoke, because the dispensed medicines have been assembled elsewhere, the spoke may be reduced to little more than a collection point. But, it is questionable whether a hub can comply with the FMD. The proximity to the point of supply to the patient of the decommissioning and checking of the ADT may be much more remote than envisaged in the Delegated Act.

Alleged safety reasons

30. The alleged safety reasons for 'hub and spoke' dispensing are not evidenced and arguably such models will be less safe: sharing the dispensing process between two legal entities introduces new, unquantified risks that could lead to patient safety issues.

31. While, arguably, an automated process may be less prone to error, dispensing will always involve a human dimension, such as input of instructions at the 'spoke', preparation of the automated process at the 'hub', checking of dispensed medicines and supply of medicines to patients or patient's representatives at the 'spoke'. These are susceptible to human error and errors would not be reduced through automated processes.

32. Data on error rates should be used with caution to ensure that 'like with like' is compared, in particular, that the same types of errors are compared and, also, that these relate to patient safety. Attached is a copy of PSNC's note earlier this month (PSNC article 'Dispensing errors and automated research', published on 12th May 2016) which concluded with the following:

    - The level of labelling errors (1.6%) identified in the research (quoted by the Chief Pharmaceutical Officer) are now unlikely to occur at the same rate due to the introduction of EPS. Automated dispensing systems are unlikely to further reduce this type of error.

    - Wrong quantity content errors are now less likely to occur due to the predominance of dispensing from original packs rather than from bulk containers.

    - Content errors, excluding wrong quantity errors, accounted for 0.7% of errors. Some of these errors could be avoided by the use of automated dispensing systems, but point of dispensing authentication in community pharmacies could similarly prevent many of these errors.

33. There are also documented failures of large scale automated dispensing services, one of which occurred during Christmas 2015. While the risk of failure of an automated process may be small, the consequences or significance of any failure is likely to be very high, because of the numbers of

prescriptions and patients involved. Such risks should be considered as part of the resilience of the medicines supply chain.

34. There could also be errors relating to a dispensing process shared between two pharmacy premises and two separate businesses, each with its own protocols and procedures, culture and values. That 'hub and spoke' dispensing is safer is not evidenced in the consultation and question 7 suggests such evidence, if there is any, is sought. It would be necessary to consider any evidence as part of any consultation.

Alleged economic efficiency reasons

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

36. It is understood that those retail pharmacy businesses in the multiple sector currently using 'hub and spoke' dispensing, do so for reasons other than economic efficiency. For example, to enable one or more existing pharmacies in a business to manage higher dispensing volume without increasing the size of the dispensary: in effect, the 'hub' is activity saving. The consultation does not provide evidence to support the argument that 'hub and spoke' dispensing provides economic efficiencies and question 6 suggests that such evidence, if there is any, is sought as part of the consultation exercise. The basis on which the assumptions in Annex C have been calculated should be available as part of the consultation.

37. The National Pharmacy Association has produced a 2016 report on 'hub and spoke' dispensing. It is suggested the NPA is consulted on this report, which assesses that the likely cost benefits are minimal and the likely burden and risks considerable. Furthermore, the report assesses that the greater the vertical integration between wholesale dealers and pharmacies, the greater the loss of competition; and that this is likely to lead to significant additional costs (lost savings) to the NHS. Cost efficiencies will only be achieved if the pharmacist's time can be freed up in the hub to provide other commissioned clinical services. As there is currently no significant proposed additional commissioning of pharmaceutical services by NHS England, the opportunity to make use of freed up time does not exist; therefore, there will be no cost benefit for pharmacies.

Conclusion

38. Given the consultation's lack of clarity about what is proposed and uncertainty about the models of 'hub and spoke' dispensing models that might develop, it is difficult to answer the consultation questions.

39. PSNC is supportive of the principle that there should be a level playing field between pharmacies, but vigorously opposes the proposals set out in the consultation.

Question 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?

Not as currently proposed.

It is impossible to create a level playing field for 'hub and spoke' dispensing between independents and multiples (it is currently multiples that are able to use hub and spoke, within their corporate structures – independent pharmacies do not generally have sufficient branches to benefit from hub and spoke).

By the very nature of the proposal, independents would use hubs owned by third parties (to undertake assembly) with the inherent risks this carries for business, for example, sharing patient lists. Multiples carrying out 'hub and spoke' dispensing use an in-house assembly unit within a pharmacy that is part of the same business and, therefore, do not have to share patient lists with third parties. Multiples do not have the same risks. This imbalance in risk is the opposite of a level playing field and the proposal to create a level playing field is consequently inherently flawed and, therefore, unacceptable.

PSNC is supportive of the principle that there should be a level playing field between pharmacies, but vigorously opposes the proposals set out in the consultation.

Question 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.

The draft regulations propose a structure for 'hub and spoke' dispensing that is wholly different from the narrative of the consultation and on which there is no consultation; in particular, they include provision for 'hub and spoke' dispensing involving '*relevant clinical settings*'. A *relevant clinical setting* is defined as '*a registered pharmacy, a hospital, a health centre, a surgery or a care home*'; a surgery is defined as '*a premises at or from which primary medical services are provided as part of the health service*' (draft regulation 5).

The narrative of the consultation refers to 'hub and spoke' dispensing models as follows: *'Typically, in a 'hub and spoke' dispensing model, the medicines are sent back from the 'hub' pharmacy to the 'spoke' pharmacy that will supply the patient. An alternative model is the 'hub' pharmacy sending the medicines directly to the patient or via a delivery company. Other models may develop in the future. In any model patients should have access to a pharmacist. We are not proposing to introduce any restrictions in the Human Medicines Regulations 2012 as to which 'hub and spoke' models can be operated. For pharmacies providing NHS*

pharmaceutical services there may be conditions for 'hub and spoke' dispensing as outlined above.' (paragraph 6).

The explanatory notes of the draft regulations state: '*There are four key changes from the previous arrangements. Firstly, the previous provisions prevented dispensed medicines assembled by retail pharmacy businesses being supplied first between different businesses and then on to or for the patient. This prevented the retail pharmacy business that sold or supplied a medicine to or for the patient from using the services of a different legal entity to dispense the medicine on its behalf. This bar has been removed. However, where retail pharmacy businesses do rely on this new flexibility, both the premises at which the product is dispensed and the premises at which the product is supplied will need to register as pharmacies.*'

'Hub and spoke' dispensing appears to be related to pharmacy, however, the draft regulations introduce a new term '*relevant clinical settings*' and provide that:

- *relevant clinical settings* may adopt 'hub and spoke' dispensing models;
- pharmacy hubs may provide assembled or dispensed medicines to *relevant clinical settings*; and
- spoke pharmacies will be able to use a hub that is a *relevant clinical setting* if this is decided as part of the consultation (and arguably can anyway if draft regulation 17 in the consultation (proposed section 69 2A of the Medicines Act) only applies where two retail pharmacies combine to form a 'hub and spoke' dispensing model).

The various 'hub and spoke' dispensing models that would or could develop involving *relevant clinical settings* other than pharmacies are not discussed in the narrative of the consultation.

The draft regulations also appear to permit the assembly of medicines without the supervision of a pharmacist, as part of 'hub and spoke' dispensing (draft regulation 4) and the distinction between dispensing and supply (draft regulations 6) suggests that in some models a hub may dispense and supply the medicine under the supervision of a pharmacist and a spoke would be little more than a pick up or collection point.

The draft regulations, by:

- no longer requiring medicines assembled at one pharmacy business to be supplied/dispensed from that same pharmacy business;
- permitting 'hub' or 'spoke' dispensing from any *relevant clinical setting*;
- including surgeries in the meaning of *relevant clinical settings*; and

- exempting supplies of medicines between those *relevant clinical settings* from the requirement for a wholesale dealers licence,

provide an entirely new legislative framework for the retail supply of medicines.

Question 3: Do you agree that 'hubs' should continue to be registered pharmacies?

Given the consultation's lack of clarity about what is proposed and uncertainty about the models of 'hub and spoke' dispensing models that might develop, it is difficult to answer the consultation question. Please see the issues discussed earlier.

PSNC is supportive of the principle that there should be a level playing field between independent and multiple pharmacies on 'hub and spoke' dispensing, but vigorously opposes the proposals set out in the consultation.

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

The professional and legal implications of 'hub and spoke' dispensing have not been considered in the consultation.

The assembly process carried out at a hub is the start of a single dispensing process that is completed at a spoke and for which the pharmacist at the spoke is responsible. The superintendent pharmacist of the spoke pharmacy, if any, also has professional accountability for the dispensing process. To what extent checks will be made of the medicines assembled at the hub pharmacy, a different legal entity, is unclear and the extent to which a hub will be accountable is unclear. What, if any, contact the hub will have with the patient is unclear and who is ultimately responsible for the supply of a medicine is unclear. In addition, the draft regulations propose that where the 'hub and spoke' dispensing is between two pharmacies, the hub pharmacy is treated as supplying the dispensed medicine via an intermediary (draft regulation 17). Yet, surely the supply is made by the spoke pharmacy. This lack of clarity is likely to cause confusion and lead to patient safety issues. If assembly occurs at the hub and supply to the patient occurs at the spoke, this should be made clear in the regulations.

Criminal liability of pharmacists involved in the dispensing and supply process has not been considered and the implications of 'hub and spoke' dispensing on proposed amendments to any statutory defence for inadvertent dispensing errors has not been considered. Could the criminal liability of a pharmacist in a spoke pharmacy be dependent on the actions of those in a hub, rather than their own actions? For example, if an appropriate person in a hub pharmacy became aware of a dispensing error but did not communicate this to an appropriate person in a spoke pharmacy, is the pharmacist in the spoke pharmacy still liable?

Question 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 data underpinning the assumptions, or the reasons for the assumptions, are required before any meaningful comment can be made, particularly when it is understood from those currently carrying out 'hub and spoke' dispensing that it is not cost-saving.

The National Pharmacy Association's 2016 report on 'hub and spoke' dispensing assesses that the likely cost benefits are minimal and the likely burden and risks considerable, which suggests the consultation assumptions on uptake of 'hub and spoke' dispensing are unrealistically optimistic. Furthermore, the report assesses that the greater the vertical integration between wholesale dealers and pharmacies, the greater the loss of competition. The report suggests this is likely to lead to significant additional costs (lost savings) to the NHS.

Also, due to Direct to Pharmacy (DTP) and other restrictive distribution practices, there are limited opportunities for hubs independent of the major wholesalers. The hubs would need to have a commercial relationship with at least two of the vertically integrated wholesalers who also have their own pharmacy chains. Whilst the wholesalers will be able to maintain commercial confidences, it is likely that many independent pharmacy businesses would feel uneasy at providing details of their patients and their medication to a wholesaler linked with a pharmacy competitor.

Question 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.

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

It is understood that those pharmacy businesses in the multiple sector currently using 'hub and spoke' dispensing, do so for reasons other than economic efficiency. For example, to enable one or more existing pharmacies in a business to manage higher dispensing volume without increasing the size of the dispensary: in effect, the 'hub' is activity saving. The consultation does not provide evidence to support the argument that 'hub and spoke' dispensing provides economic efficiencies and question 6 suggests that such evidence, if there is any, is sought as part of the consultation exercise. The basis on which the assumptions in Annex C have been calculated should be available as part of any consultation.

The National Pharmacy Association has produced a 2016 report on 'hub and spoke' dispensing. It is suggested the NPA is consulted on this report, which assesses that the likely cost benefits are minimal and the likely burden and risks considerable. Furthermore, the report assesses that the greater the vertical integration between wholesale dealers and pharmacies, the greater the loss of competition; and that this is likely to lead to significant additional costs (lost savings) to the NHS. Cost efficiencies will only be achieved if the pharmacist's time can be freed up in the hub to provide other commissioned clinical services. As there is currently no significant proposed additional commissioning of pharmaceutical services by NHS England, the opportunity to make use of freed up time does not exist; therefore, there will be no cost benefit for pharmacies.

Question 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.

The alleged safety reasons for 'hub and spoke' dispensing are not evidenced and arguably such models will be less safe: sharing the dispensing process between two legal entities introduces new, unquantified risks that could lead to patient safety issues.

While, arguably, an automated process may be less prone to error, dispensing will always involve a human dimension, such as input of instructions at the 'spoke', preparation of the automated process at the 'hub', checking of dispensed medicines and supply of medicines to patients or patient's representatives at the 'spoke'. These are susceptible to human error.

Data on error rates should be used with caution to ensure that 'like with like' is compared, in particular, that the same types of errors are compared and, also, that these relate to patient safety. Attached is a copy of PSNC's note earlier this month (PSNC article 'Dispensing errors and automated research', published on 12th May 2016) which concluded with the following:

- The level of labelling errors (1.6%) identified in the research (quoted by the Chief Pharmaceutical Officer) are now unlikely to occur at the same rate due to the introduction of EPS. Automated dispensing systems are unlikely to further reduce this type of error.

- Wrong quantity content errors are now less likely to occur due to the predominance of dispensing from original packs rather than from bulk containers.

- Content errors, excluding wrong quantity errors, accounted for 0.7% of errors. Some of these errors could be avoided by the use of automated dispensing systems, but point of dispensing authentication in community pharmacies could similarly prevent many of these errors.

There are also documented failures of large scale automated dispensing services, one of which occurred during Christmas 2015. While the risk of failure of an automated process may be small, the consequences or significance of any failure is likely to very high, because of the numbers of prescriptions and patients involved. Such risks should be considered as part of the resilience of the medicines supply chain.

There could also be errors relating to a dispensing process shared between two pharmacy premises and two separate businesses, each with its own protocols and procedures, culture and values. That 'hub and spoke' dispensing is safer is not evidenced in the consultation and question 7 suggests such evidence, if there is any, is sought. It would be necessary to consider any evidence as part of any consultation.

Question 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.

The report identified in the consultation (School of Pharmacy and York health Economics (2010) Evaluation of the Scale, Causes and Costs of Waste Medicines) indicates that displaying on a dispensed medicine its price may have the following adverse effects:

- patients in need of effective treatment might become worried about the cost to the public purse;
- it might encourage selling on of costlier treatments; and
- those who should be targeted would not care about the price of their medicines.

This section of the report concludes with the following:

'In conclusion, the interpretation offered here is that even it were possible within the European setting to implement such an idea, relatively few people are on consideration likely to judge the option of printing UK prices on all NHS medicine packs advisable. Most may be more inclined to think that it would cause more problems than it would solve.' (page 84, *Should NHS medicine packs be priced*).

In addition, dispensing labels already include considerable information and further requirements to include the price determined for a product (the calculation of which may be subject to argument) and a statement about how the cost of the product is met (for example, a statement to the effect that it is met by taxpayers) is likely to result in an additional dispensing label for which there may not be room on a medicine pack without obscuring important clinical or safety information.

Question 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.

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

This is a consultation on changes to the medicines legislation. It is inappropriate to consult only on changes to the NHS in England. This should be a separate NHS consultation (which will be repeated as required in the different home countries). However, we make a preliminary observation that there would be additional costs associated with implementation of 'hub and spoke' dispensing in the NHS in England. An additional label will also introduce additional costs, which would have to be borne by the public purse.

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

No comment.

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

No comment.

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

No comment.

Question 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.

No comment.

Question 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?

Yes.

The pharmacy exemptions within Article 3 of Directive 2001/83/EC as amended by Directive 2004/27/EC should be retained in UK legislation.

Chemist nostrums remain an essential part of pharmacy practice and important for patient care; they also provide flexibility and resilience in the supply chain. They remain in use by some pharmacies and PSNC is not aware of any problems with them.

Question 16: Is there anything else you would like to raise with regards to the proposals for restructuring the pharmacists' exemption?

Yes.

The *Abcur* judgment involved a state pharmacy manufacturing/assembling an unauthorised medicine and distributing this in competition with the authorised product. Unsurprisingly, the manufacturer of the authorised medicine took issue with this.

Section 10 of the Medicines Act currently prohibits the activity that was the subject of the *Abcur* case, to the extent that the exemption cannot be so wide as to make meaningless the purpose of the Act (and the Human Medicines Regulations) - that generally medicines should be subject to a market authorisation and manufactured, assembled and wholesaled by those with appropriate authorisation.

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

No comment.

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

Yes.

Please consider the earlier paragraphs in this document that precede the answers to the questions.