



Department
of Health

Amendments to the Human Medicines Regulations 2012: 'Hub and spoke' dispensing, prices of medicines on dispensing labels, labelling requirements and pharmacists' exemption

Consultation document

March 2016

<p>Title:</p> <p>Amendments to the Human Medicines Regulations 2012: ‘Hub and spoke’ dispensing, prices of medicines on dispensing labels, labelling requirements and pharmacy exemption</p>
<p>Author:</p> <p>Innovation Growth and Technology Directorate/Medicines, Pharmacy and Industry Division, Pharmacy Team/ IGT-MPI-P/17060</p>
<p>Document Purpose:</p> <p>Consultation</p>
<p>Publication date:</p> <p>March 2016</p>
<p>Target audience:</p> <p>Pharmacy professionals, pharmacy regulatory bodies, pharmacy professional and representative bodies, unions, dispensing doctors, health care professionals dispensing under patient group directions, patients and the public, health organisations (see Annex A).</p>
<p>Contact details:</p> <p>Pharmacy Team Medicines, Pharmacy and Industry Division Department of Health Ground Floor North Wellington House 133 – 155 Waterloo Road London SE1 8UG</p> <p>Email: HMR2016@dh.gsi.gov.uk</p>

You may re-use the text of this document (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit www.nationalarchives.gov.uk/doc/open-government-licence/

© Crown copyright

Published to gov.uk, in PDF format only.

www.gov.uk/dh

Amendments to the Human Medicines Regulations 2012: 'Hub and spoke' dispensing, prices of medicines on dispensing labels, labelling requirements and pharmacists' exemption Consultation document

Medicines Pharmacy and Industry Division, Pharmacy Team
Innovation Growth and Technology Directorate
Department of Health

Contents

Contents	4
1. Executive summary	5
2. 'Hub and spoke' dispensing.....	6
Background.....	6
Proposal.....	6
Different models of 'hub and spoke' dispensing	7
Regulatory framework.....	7
Data protection across different legal entities	7
Business Impact.....	7
3. Prices of medicines on dispensing labels.....	9
Background.....	9
The proposal.....	9
Implementation in the NHS in England	9
4. Labelling of medicines supplied under patient group directions and monitored dosage systems ...	12
Medicines supplied under patient group directions.....	12
Proposal.....	12
Labelling of monitored dosage systems (MDS)	12
Proposal.....	13
Background.....	13
Repeal of section 10	14
5. Equality assessment.....	16
6. The Human Medicines (Amendment) (No.2) Regulations 2016.....	17
7. Summary of consultation questions	18
8. Responding to this consultation.....	19
Consultation process	19
Criteria for consultation	19
Annex A - list of consultees	21
Annex B - Draft Human Medicines (Amendment) (No. 2) Regulations 2016	23
Annex C - Assumptions for the Impact Assessment for 'hub and spoke' dispensing	24
Annex D - Equality assessment	27

1. Executive summary

This consultation seeks comments and views on a number of proposed changes to the Human Medicines Regulations 2012¹ and the Medicines Act 1968². The regulations are UK-wide and a draft is attached at Annex B.

The proposals address four separate issues with the aim to:

- Enable the use of ‘hub and spoke’ dispensing models by ‘spoke’ pharmacies that do not form part of the same retail pharmacy business as the ‘hub’ pharmacy;
- Permit dispensing labels to include the indicative cost of a medicine and a statement about how that cost is met, should this be required under NHS terms of service for medicines dispensed as part of the NHS pharmaceutical services;
- Clarify the dispensing label requirements of the Human Medicines Regulations 2012, in particular by updating the labelling requirements for monitored dosage systems to reflect current practice and by ensuring products supplied under patient group directions have a dispensing label in line with professional guidance; 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 judgment³, so that businesses can be confident that the uses they are making of the relevant exemptions are legally secure.

The consultation will run for a period of 8 weeks from 22 March to 17 May.

¹ www.legislation.gov.uk/ukxi/2012/1916 (there are outstanding changes not yet made by legislation.gov.uk)

² www.legislation.gov.uk/ukpga/1968/67 (there are outstanding changes not yet made by legislation.gov.uk)

³ Judgment of the Court (Third Chamber) of 16 July 2015; Abcur AB v Apoteket Farmaci AB (C-544/13) and Apoteket AB and Apoteket Farmaci AB (C-545/13)

2. 'Hub and spoke' dispensing

The proposed amendments aim to deregulate and would enable all pharmacies to make use of 'hub and spoke' dispensing models.

Background

1. Dispensing covers a number of different processes such as the receipt of a prescription, clinical and accuracy checks and sourcing, preparation, assembly and supply of medicines. Traditionally, all these different processes are done in a single pharmacy. In a 'hub and spoke' model, however, parts of these processes are undertaken in another pharmacy.
2. This dispensing model, which is currently only allowed between pharmacies in the same retail business, is gaining popularity due to its potential to make the dispensing process more efficient, lower operating costs and free up pharmacists to spend more time with patients. The model allows for cost advantages to be exploited by expanding the scale of assembly and preparation which makes automation more viable. Automation in dispensing, implemented alongside a robust quality assurance system, is linked to safer dispensing with fewer dispensing errors. Large scale 'hub' pharmacies have the capability to increase efficiency and lower operating costs significantly.

Proposal

3. Section 10 of the Medicines Act 1968 only allows 'hub and spoke' dispensing if the 'hub' and the 'spoke' pharmacy are both part of the same retail pharmacy business. Section 10 provides an exemption from the need for a manufacturing licence for the assembly or preparation of medicinal products in a registered pharmacy and from the need for the resulting medicinal product to have a marketing authorisation, but only where the activities are done with a view to sell or supply the product from the same pharmacy or one which forms part of the same business. Therefore only where pharmacies are part of a chain are they currently able to use 'hub and spoke' dispensing models.
4. We propose to remove this impediment in legislation which will allow the operation of 'hub and spoke' dispensing models across legal entities and will create a level playing field. This will make it possible for independent 'spoke' pharmacies to make use of the services of 'hub' pharmacies that are part of a separate business or to work together and invest in automation in one 'hub' location. This will give independent pharmacies across the UK a wider choice as to which business model they adopt.
5. For pharmacies providing NHS Pharmaceutical Services the four countries of the UK would be in a position to consider introducing conditions for the use of 'hub and spoke' models. This would be a devolved matter and is not part of this 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?

Different models of 'hub and spoke' dispensing

- 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.

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?

Regulatory framework

- Both the 'hub' and the 'spoke' operations would continue to be required to be registered pharmacies. We will work with the regulators to develop the regulatory framework for these new types of pharmacy operations.
- Working with the regulators and the pharmacy sector, issues such as responsibility, accountability and liability will need to be addressed. Given the potential impact of operational failure in a large scale 'hub', business continuity also needs to be considered.
- The 'hub' pharmacies would not require a wholesale dealing licence.

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

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

Data protection across different legal entities

- Enabling 'hub and spoke' dispensing across different legal entities will mean that patients' data will be transferred between two pharmacies that are part of two separate legal entities for the purpose of providing the patient with the prescribed medication. The exchange of patient data between two pharmacies for the purpose of fulfilling a prescription, whether they are in the same legal entity or not, is capable of falling within the law governing disclosure of personal information as supported by the NHS confidentiality codes in each UK country.

Business Impact

- A full impact assessment for the deregulatory measure to remove the impediment in legislation that prohibits independent pharmacies from exploiting the benefits of 'hub and spoke' dispensing will be developed following this consultation. We have developed a set of assumptions that can be found at Annex C on which we would like to receive views.

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?

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?

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?

3. Prices of medicines on dispensing labels

The proposed amendments would allow for the price of a medicine to be displayed on the dispensing label should this be required under NHS terms of service for NHS medicines dispensed as part of the NHS pharmaceutical services.

Background

14. On 1 July 2015 the Secretary of State, in a speech to the Local Government Association annual conference on personal responsibility, announced that indicative prices would be put on all medicines dispensed by the NHS in England costing more than £20 as well as a statement about how the cost of the medicine is met such as for example 'funded by the taxpayer' and that this would be implemented in 2016. The aim of this initiative is to reduce waste by reminding people of the cost of medicines, but also improve patient care by improving patient adherence to medicines.
15. This initiative has been announced in England but not in Scotland, Northern Ireland and Wales.

The proposal

16. We propose to amend the Human Medicines Regulations 2012 to permit dispensing labels to include the price of the medicine and a statement about how the cost of the medicine is met.
17. The proposed amendments would not make it a requirement to include this information on the dispensing label but would merely pave the way for the price of a medicine to be put on the dispensing label should this be required under NHS terms of service for medicines dispensed as part of the NHS pharmaceutical services. It is therefore for each country in the UK to decide whether or not to require that the prices of NHS medicines are put on dispensing labels.

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?

Implementation in the NHS in England

18. For England it has been announced that NHS dispensed medicines costing more than £20 are labelled with the price and a statement about how the cost of the medicine is met such as for example 'paid for by the taxpayer'. Initially, it is proposed that this will be only for NHS medicines dispensed in the community and not in hospitals. About 1 in 10 medicines will be affected. 10 percent of NHS medicines dispensed in England cost more than £20 but this 10 percent makes up 60 percent of the total budget spent on NHS medicines.
19. The implementation of the policy for NHS medicines in primary care will require separate consultation with providers of NHS pharmaceutical services in England.

20. The aim of the policy is to reduce medicines waste and improve patient adherence to medicines. The gross annual cost of medicines wastage in NHS primary and community care in England is £300m million per year, half of which is avoidable.⁴
21. There is some evidence of a positive impact on behaviour when people understand the cost of health services. In recent trials, the best form of words for the content of SMS hospital appointment reminders proved to be the message that told patients the cost of not attending, which reduced missed appointments by 23 percent compared to the standard message.⁵ Physician's understanding of the cost of testing has also been proven to prevent unnecessary tests.⁶
22. Increasing adherence to medicines is a complex issue. Existing initiatives include more effective prescribing, pharmacist managed repeat dispensing, medication reviews, and other medicines optimisation initiatives to improve outcomes, quality and value from the investment made in medicines. One single intervention will not provide a solution for patients who are not taking their medicines as prescribed. We believe, however, that making people aware of the price of their medicines will help contribute to increasing adherence to those medicines.
23. We recognise that the introduction of prices on dispensing labels will need to be carefully designed and tested to prevent any negative effects, for example patients deciding not to take their medicines because they think they are too expensive or patients concerned about the low price of their medicine. We are exploring how to best to support patients and at the same time enable pharmacists to deal with any questions quickly, and will seek input from patients and stakeholders on the detailed design of additional information regarding prices on labels before it is introduced.
24. Putting prices on dispensing labels on NHS medicines cannot be implemented without changes to the requirements for the provision of NHS pharmaceutical services, including in England, and providers of those services will be separately consulted.
25. The Scottish Government has indicated that it has no plans to introduce this measure in Scotland

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?

⁴ School of Pharmacy and York Health Economics (2010) Evaluation of the Scale, Causes and Costs of Waste Medicines

⁵ Hallsworth, Berry, Sanders, Sallis, King, Vlaev and Darzi (2015). Stating appointment costs in SMS reminders reduces missed hospital appointments: Findings from two randomised controlled trials. PLoS ONE 10(9).

⁶ Fogarty A.W., Sturrock N., Premji K., Prinsloo P. (2013). Hospital clinicians' responsiveness to assay cost feedback: a prospective blinded controlled intervention study. JAMA Internal Medicine, 173(17)

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

4. Labelling of medicines supplied under patient group directions and monitored dosage systems

The proposed amendments would ensure that the requirements for the dispensing label on medicines supplied under patient group directions are clear and the requirements for labelling monitored dosage systems are proportionate.

Medicines supplied under patient group directions

26. The Human Medicines Regulations 2012 currently exempt medicines supplied under a patient group direction (PGD) from the need for a prescription to be issued. Although the labelling provisions are not similarly dis-applied, there is no offence if no dispensing label is applied in these circumstances. Professional guidance in this area does recommend that it is good practice to ensure that patients supplied with medicines pursuant to PGDs are given the same information as if the medicine had been issued pursuant to a prescription. It would usually be the case therefore that a dispensing label meeting the current requirements would be applied.

Proposal

27. The proposed amendments to the Human Medicines Regulations 2012 would reflect this and ensure that a dispensing label must be applied to medicines supplied pursuant to PGDs or other forms of direction where the same issues arise.

Labelling of monitored dosage systems (MDS)

28. MDS are medication storage devices designed to simplify the administration of solid oral dose medication. They may have the potential, for certain groups of patients, to increase patient adherence to medicines and therefore improve clinical outcomes. Different MDS are currently in use (e.g. NOMAD, Plus Pak, dossette and Venalink 7 Day systems).

29. The information which is currently required to appear on a dispensing label includes the patient's name, name and address of the supplier, the date of sale or supply, and, if specified by the practitioner or as judged appropriate by the pharmacist, the name of the product, directions for use of the product and precautions relating to the use of the product (see part 1 of Schedule 25, and Schedule 26, to the Human Medicines Regulations).

30. We want to ensure that the dispensing label requirements are suitable for MDS and do not lead to increased safety issues, for example a large number of labels may be needed on an MDS or it may be difficult for pharmacists to fulfil the requirements. We also want to ensure that the dispensing label requirements remain suitable and proportionate as new types of MDS enter the market.

Proposal

31. We propose that for MDS there will be, as now, a minimum requirement for the information on the dispensing label to include the patient's name, the name and address of the pharmacy and the date of sale or supply, and, if specified by the prescriber or as judged appropriate by the pharmacist, the name of the medicine(s), directions for use of the product and precautions relating to the use of the product. For MDS, we would additionally enable prescribers and pharmacists to include a description of the medicinal product, if they consider this appropriate, to aid understanding of which medicine is which.
32. Additional flexibility would also be given as to where this information should appear on MDS. The current requirement in relation to dispensing labels is for the information to appear on the outer packaging of the medicinal product, or if there is no outer packaging, on the immediate packaging. In relation to MDS there would be flexibility for the information to appear on a combination of both the outer and immediate packaging. This would enable, for example, the outer box to include certain information, and for the individual dosage packs within the box to include different information. However, if this flexibility is used, we would expect the patient's name and the name of the person who sells or supplies the product to appear on both the outer and the immediate packaging of an MDS. This is in line with current professional practice.

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

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

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?

The proposed amendments would ensure that the exemptions for pharmacists in respect of the preparation and assembly of medicines are clear and brought into line with a recent judgment of the Court of Justice of the European Union (CJEU).

Background

33. On 16 July 2015, the CJEU delivered its judgment in the case of *Abcur v Apotek AB and others* (C-544/13 and C-545/13). The case related to the ability of a state owned company in Sweden to produce unlicensed preparations of methadone and noradrenaline when licensed preparations were available on the Swedish market, produced by Abcur.
34. In reaching its decision, the Court had to consider the scope of the non-industrial products exemption in article 2 of Directive 2001/83, and the pharmacy exemption in article 3 of that Directive. Products covered by these articles are excluded from the scope of the Directive, their production therefore does not require a manufacturer's licence, and the medicines produced do not require marketing authorisations.
35. The clarification of law provided by the CJEU judgment is the basis for a proposed redesign of the pharmacists' exemptions in section 10 of the Medicines Act 1968, and amendments to the exemptions for doctors, dentists, nurses and midwives in regulation 3 of the Human

Medicines Regulations 2012. The changes will ensure that businesses can be confident that the uses they make of these exemptions are legally secure.

36. The judgment is relevant to 'hub and spoke' dispensing because it clarifies what activities the 'hub' can undertake under the pharmacists' exemption on behalf of the 'spoke' pharmacy.
37. The judgment clarified that, where reliance is being placed on the officinal formula in article 3 of the Directive, preparations of medicines made up in a pharmacy in accordance with the prescriptions of a pharmacopoeia (and not in response to a prescription for a named patient) must be supplied direct from the pharmacy where they are prepared to the patient for whom they are prescribed. A 'hub' can therefore only make up stocks of pharmacopoeia preparations in anticipation of the receipt of prescriptions if they supply those preparations direct to patients.
38. 'Hub' pharmacies, and hospital pharmacies supplying medicines to other hospitals, will therefore be unable supply pharmacopoeia preparations to other pharmacies and hospitals if these have been fully made up in advance of the prescription being received.
39. Legal uncertainty remains about the position with regard to products whose composition is specified by the prescriber but which are not pharmacopoeia preparations and that are partially made up in anticipation of a prescription being received.
40. In these cases, the composition of the product will only be completed once the prescription is received and the product can be individually customised to meet the needs of individual patients. Intravenous nutrition bags are an example of this. We do not think the CJEU intended to cut across these types of activities that may be a particular feature of hospital settings.
41. The rule that pharmacopoeia products, if they are pre-prepared, must be supplied direct to a patient of the pharmacy in question is therefore qualified by allowing products to be part prepared in advance of the prescription being received, provided the products need to be customised to meet individual patient needs.

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.

Repeal of section 10

42. The opportunity has been taken to repeal section 10 of the Medicines Act 1968 and so all the relevant provisions now appear in the Human Medicines Regulations 2012.
43. The restructuring means that the exemptions now follow the scheme of the Directive, i.e. they are split between the provisions that rely on article 2 of the directive and those which rely on article 3.
44. Taking the lead from the Abcur judgment, the article 2 provisions are essentially those which are about non-standardised, patient specific products - i.e. patient specific products other than 'Magistral formula' products where the prescriber specifies the composition. The most

common examples of these patient specific products are "snip and box" cartons and multiple dosage systems. These patient specific products have been "assembled" and are supplied to the patient under the supervision of a pharmacist.

45. The standard forms of preparation at a pharmacy, referred to in the Directive as 'magistral formula' and 'officinal formula', are put in a separate regulation, so that the Abcur judgment qualification can be applied.
46. Section 10 was however also the basis for two sets of other retail pharmacy activities that we understand are uncommon. Firstly, occasionally, a patient or health care professional caring for a patient may ask a local pharmacist to prepare a specific remedy for them on essentially an ad hoc basis - and this practice is enabled to continue. Secondly, a patient or carer may ask the pharmacist for a recommendation, and the pharmacist, in the exercise of their own skill and judgment may suggest a remedy that they can prepare or of which they have a small supply that they have already made up. These latter preparations are sometimes known as 'Chemist's Nostrums'. Currently, any advanced preparation of these products must be done in the pharmacy, or the same retail pharmacy business that sells or supplies the medicine.
47. Any preparation of a 'Chemist's Nostrums' must be non-industrial to meet the requirements of the Directive, and we understand that the practice is currently very rare. Although the draft amending regulations reproduce the substance of these exemptions, consideration needs to be given to whether this type of preparation still has a place in the modern world of pharmacy.

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?

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

5. Equality assessment

48. Our initial equality assessment of the proposals to amend the Human Medicines Regulations 2012 and the Medicines Act 1968 can be found at annex D.

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?

6. The Human Medicines (Amendment) (No.2) Regulations 2016

49. The amendments to the Human Medicines Regulations 2012 can be found at Annex B.

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

7. Summary of consultation questions

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?

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?

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

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

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?

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?

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?

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?

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?

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

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

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

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?

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.

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?

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

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?

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

8. Responding to this consultation

Consultation process

This document launches a consultation on proposed changes to the Human Medicines Regulations 2012. The consultation is being run, as far as is practical, in accordance with the Cabinet Office Code of Practice on Consultations (reproduced below). The closing date for the consultation is 17 May 2016.

There is a response form on the GOV.UK website which can be printed and sent by post to:

Pharmacy Team
Medicines, Pharmacy and Industry Division
Department of Health
Ground Floor North
Wellington House
133 – 155 Waterloo Road
London
SE1 8UG

Completed response forms can also be sent electronically by e-mail to:

HMR2016@dh.gsi.gov.uk

Alternatively you may also complete the online consultation response document at:

<http://consultations.dh.gov.uk>

It will help us to analyse the responses if respondents fill in the online consultation response document. However, responses that do not follow the structure of the questionnaire will be considered equally. It would be helpful if such responses could indicate who has contributed. It would also help if responses were sent in Word format, rather than in pdf format.

Criteria for consultation

This consultation follows the Government Code of Practice, in particular we aim to:

- Formally consult at a stage where there is scope to influence the policy outcome;
- Consult for a sufficient period.
- Be clear about the consultations process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- Ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- Keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- Analyse responses carefully and give clear feedback to participants following the consultation;

- Ensure officials running consultations are guided in how to run an effective consultation exercise and share what they learn from the experience.
- The full text of the code of practice is on the Better Regulation website at: www.bis.gov.uk/policies/better-regulation/consultation-guidance

Annex A - list of consultees

Patients and the public

Community pharmacists and pharmacy technicians

Hospital pharmacists and pharmacy technicians

Health care professionals dispensing under patient group directions

Dispensing doctors

Action Against Medical Accidents

ASDA Group plc

Association of Independent Multiple Pharmacies

Association of Pharmacy Technicians UK

Association of Teaching Hospital Pharmacists

Boots plc

British Pharmaceutical Students' Association

Care Quality Commission

Centre for Pharmacy Postgraduate Education

College of Mental Health Pharmacy

Commission in Human Medicines

Community Pharmacy NI

Community Pharmacy Scotland

Community Pharmacy Wales

Company Chemists' Association

Crown Office and Procurator Fiscal Service

Crown Prosecution Service

Day Lewis Pharmacy Group

Dispensing Doctors Association

General Pharmaceutical Council

Guild of Healthcare Pharmacists

Health Education England

Health Inspectorate Wales

Healthcare Improvement Scotland

Healthwatch

Independent Hospital sector

Independent Pharmacy Federation

J Sainsbury's plc

Lloydspharmacy

National Pharmacy Association
National Voices
NHS Confederation
NHS Education for Scotland
NHS Employers
NHS England
NHS Pharmacy Education Development Committee
Northern Ireland Centre for Pharmacy Learning and Development
Northern Ireland Health and Social Care Trusts
Patients' Association
Pharmaceutical Services Negotiating Committee
Pharmaceutical Society of Northern Ireland
Pharmacists' Defence Association
Pharmacy Law Ethics Association
Pharmacy Forum – Northern Ireland
Pharmacy Schools Council
Pharmacy Voice
Professional Standards Authority for Health and Social Care
Public Prosecution Service of Northern Ireland
Regulation and Quality Improvement Authority
Rowlands Pharmacy
Royal Pharmaceutical Society
Royal Pharmaceutical Society, English Pharmacy Board
Royal Pharmaceutical Society, Scottish Pharmacy Board
Royal Pharmaceutical Society, Welsh Pharmacy Board
Superdrug Stores plc
Tesco plc
The Co-operative Group
Ulster Chemists' Association
United Kingdom Clinical Pharmacy Association
Welsh Centre for Pharmacy Professional Education
Wm Morrisons Supermarkets plc

Annex B - Draft Human Medicines (Amendment) (No. 2) Regulations 2016

See separate document.

Annex C - Assumptions for the Impact Assessment for 'hub and spoke' dispensing

In order to estimate the costs and benefits of the proposed legislative changes that make it possible for independent pharmacies to use 'hub and spoke' dispensing models, we propose to use the following assumptions:

Assumption 1

If 60% of medicines would be dispensed through 'hub and spoke' dispensing models (compared to nothing right now), this would see:

- 10% reduction in pharmacist labour costs at spoke pharmacies
- 25% reduction in pharmacy technician labour costs at spoke pharmacies
- Between 2.5% and 5% increase in pharmacist labour costs at hub pharmacies
- Between 6.25% and 12.5% increase in pharmacy technician labour costs at hub pharmacies

The assumption is therefore that 'hub' pharmacies are two to four times as efficient (excluding capital investment) as spoke pharmacies. That is, that for every labour saving of 2wte at spoke pharmacies, there will be an increase of between 0.5 and 1wte at a hub pharmacy. We expect the 'hub' to be more efficient as it increases in size.

Where a lower proportion of medicines are dispensed through hubs, there will be a proportionate reduction in the above. The changes outlined above are our high estimate; our central estimate is that 45% of medicines will be dispensed through 'hub and spoke'.

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

Assumption 2

There may potentially be labour savings for other staff (e.g. dispensing/pharmacy assistants, managers) but we have not taken these into account.

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

Assumption 3

The potential labour savings are the same (as a proportion) for independents, small multiples, and large multiples. We recognise that where there is only 1 pharmacist in a pharmacy a reduction in pharmacist labour costs is not feasible.

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

Assumption 4

Take-up of 'hub and spoke' dispensing will vary by pharmacy type:

- Between 25% and 50% of independent pharmacies will use 'hub and spoke' dispensing
- Between 25% and 50% of small multiple pharmacies will use 'hub and spoke' dispensing

- Large multiple pharmacies are not taken into account because they are already allowed and of sufficient scale to exploit this business model within their own legal entity, and so are not affected by the proposed change.

It will take up to 3 years for this level of uptake to be reached depending on how quickly 'hub' capacity develops.

Do you agree with our assumptions on uptake?

Assumption 5

Those 'spoke' pharmacies using 'hubs' will do this for between 30% and 60% of all the medicines they dispense i.e. between 30% and 60% of the medicines they dispense will be assembled/prepared by a 'hub' that sends the medicines back to that 'spoke' for supply to the patient.

Do you agree with our assumption for the percentage of medicines that will be dispensed by making use of 'hub and spoke' dispensing?

Assumption 6

Some of the 'hub' capacity will be provided by large, automated, purpose-built hubs, and some by smaller pharmacies collaborating to provide their own 'hub'.

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?

Assumption 7

A new, hub can serve, on average, 250 spoke pharmacies and such a hub would cost £5 million to build. A large hub can serve, on average, 1500, pharmacies and such a hub would cost £20 million to build. A collaborative hub will not require additional capital except for the introduction of automation.

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?

Assumption 9

The median average salary of a pharmacist working in community pharmacy is £36,441⁷ and the median average salary of a pharmacy technician working in community pharmacy is £19,462⁸. We assume the same salaries for staff at independent, small multiple, and large multiple pharmacies and the same salaries for staff in 'hub' and 'spoke' pharmacies.

Do you agree with our assumptions on staff salaries?

⁷ ONS, Annual Survey of Hours and Earnings, 2015 Provisional Results, Table 15.7a. Available at: <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-400803>

⁸ ONS, Annual Survey of Hours and Earnings, 2015 Provisional Results, Table 15.7a. Available at: <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-400803>

Assumption 10

30% of dispensing activity is performed by independent pharmacies (fewer than 5 pharmacies), 20% by small multiples (between 5 and 99 pharmacies), and 50% by large multiple pharmacies (100 or more pharmacies).

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

Assumption 11

There will be a reduction of stock holding in 'spoke' pharmacies that use the services of 'hub' pharmacies.

What level of stock reduction is realistic?

Assumption 12

Under certain circumstances 'hub' pharmacies are likely to provide patients directly and not via the 'spoke' pharmacy.

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

Please provide comments on these assumptions under question 5.

Annex D - Equality assessment

Public Sector Equality Duty and Family test for the Human Medicines (Amendment) (No. 2) Regulations 2016

Introduction

- In considering the amendments to the Human Medicines Regulations 2012 and the Medicines Act 1968, Ministers must comply with the Public Sector Equality Duty (PSED) and consider the Family Test. Some further information about these duties is given below.
- The need to comply with the PSED and the Family Test arises on each occasion that Ministers perform their public functions.
- The following proposals to amend the Human Medicines Regulations 2012 and Medicines Act 1968 are considered in this assessment:
 - Enabling the use of 'hub and spoke' dispensing models by 'spoke' pharmacies that do not form part of the same retail pharmacy business as the 'hub' pharmacy;
 - Permitting dispensing labels to include the indicative cost of a medicine and a statement about how that cost is met should this be required for NHS medicines dispensed as part of the NHS pharmaceutical services;
 - Clarifying the dispensing label requirements of the Human Medicines Regulations 2012, in particular by updating the labelling requirements for monitored dosage systems to reflect current practice and by ensuring products supplied under patient group directions have a dispensing label in line with professional guidance; and
 - Redesigning the 'exemptions for pharmacists' in section 10 of the Medicines Act 1968 in respect to 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.

Public Sector Equality Duty (Section 149 Equality Act 2010)

This duty comprises of three equality objectives, each of which needs to be considered separately. Ministers must have regard to the need to:

- Eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010;
 - Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
 - Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.
- The protected characteristics covered by this duty are age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation.

- We have considered the implications for each of the three equality objectives in relation to the proposals outlined above.

Enabling the use of ‘hub and spoke’ dispensing models by ‘spoke’ pharmacies that do not form part of the same retail pharmacy business as the ‘hub’ pharmacy

- These proposals will allow independent pharmacies to make use of more efficient and safer ways of dispensing medicines that are currently only available to large multiple pharmacies.
- ‘Hub and spoke’ dispensing will free up pharmacists’ time to spend on clinical work including advising patients. We expect those patients that use more medicines, such as the elderly, disabled and pregnant women, to benefit more from this.
- 39 percent of pharmacists are from black and minority ethnic (BME) communities with 27 percent from an Asian background⁹. We have found no data that indicates that the percentage of BME pharmacists is any different for independent pharmacists compared to pharmacists working for multiple pharmacies. Therefore, it is not possible to say whether BME pharmacists would benefit more or less from the policy to enable independent pharmacies to also make use of ‘hub and spoke’ dispensing.
- 90 percent of pharmacy technicians are female¹⁰. ‘Hub and spoke’ dispensing relies largely on automated processes to assemble in a ‘hub’ pharmacy and we expect the savings in ‘spoke’ pharmacies to be mostly on pharmacy technicians’ time. We expect that less pharmacy technicians will be needed when ‘hub and spoke’ dispensing models are used and therefore, women are affected disproportionately.

Permitting dispensing labels to include the indicative cost of a medicine and a statement about how that cost is met should this be required for NHS medicines dispensed as part of the NHS pharmaceutical services

- The proposed amendments would allow for the price of a medicine to be displayed on the dispensing label should this be required for NHS medicines dispensed as part of the NHS pharmaceutical services.
- However, putting prices on dispensing labels on NHS medicines cannot be implemented without changes to the requirements for the provision of NHS pharmaceutical services, including in England, and providers of those services will be separately consulted.

⁹ CPWS Briefing Paper GPhC Register Analysis 2011

¹⁰ Briefing paper: GPhC Pharmacy Technician Register Analysis 2012

- Although prices will not be displayed on dispensing labels of NSH medicines as a consequence of these proposals, we have considered the equality impact of the proposal for England,
- We expect that people who use more medicines, such as people with a disability or the elderly, will be more likely to come across the price of their medicines on the dispensing label. One of the expected benefits of this policy is increased adherence to medicines, and these patient groups will therefore benefit in particular from understanding the cost of medicines.
- Although the price is aimed at increasing patients' adherence to medicines, the price may create confusion with some people, particularly elderly patients, who may think their medicines are too expensive and that therefore they should not take them, or not take them as prescribed. We will develop and test supporting messages for patients to ensure that any potential negative impact is mitigated.
- The price will be printed automatically on the label and we believe there will be no additional burden on pharmacists and pharmacy technician but there will be a cost burden on pharmacy owners to amend their IT systems. No diversity data is available for pharmacy owners.

Clarifying the dispensing label requirements of the Human Medicines Regulations 2012, in particular by updating the labelling requirements for monitored dosage systems to reflect current practice and by ensuring products supplied under patient group directions have a dispensing label in line with professional guidance

- These proposals are aimed at ensuring that all medicines are labelled and are labelled clearly. We expect all patients to benefit from this.
- We expect those patients that use more medicines and take multiple medicines at the same time, such as the elderly and disabled people, to benefit more from this, in particular from the greater clarity of the dispensing labels on their medicines. This policy could therefore advance equality of opportunity for these groups, who are potentially less able to understand medicines labelling, either because they have to take a large number of medicines or because their condition or frailty make it more difficult for them to do so.

Redesigning the 'exemptions for pharmacists' in section 10 of the Medicines Act 1968 in respect to 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

- These proposals clarify what can and cannot be done under the 'pharmacists' exemption'. We do not expect a differential impact on any of the groups with protected characteristics.

The Family Test

- The Secretary of State for Health of the United Kingdom must consider, and where sensible and proportionate, apply the Family Test when making policy. The five family test questions are:
 - What kinds of impact might the policy have on family formation?
 - What kind of impact will the policy have on families going through key transitions such as becoming parents, getting married, fostering or adopting, bereavement, redundancy, new caring responsibilities or the onset of a long-term health condition?
 - What impacts will the policy have on all family members' ability to play a full role in family life, including with respect to parenting and other caring responsibilities?
 - How does the policy impact families before, during and after couple separation?
 - How does the policy impact those families most at risk of deterioration of relationship quality and breakdown?
- We have considered the Family test and consider it not applicable to any of the proposals to amend the Human Medicines Regulations 2012 and the Medicines Act 1968.