



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

Response form

# Instructions for responding to the consultation

The Government wants your views on the proposals to change the Medicines Regulations 2012 and the Medicines Act 1968. 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 judgment, so that businesses can be confident that the uses they are making of the relevant exemptions are legally secure.

The response form below can be used to help you do that.

You can find out more and respond to this consultation at:

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

**The closing date for responses is 17 May 2016.**

Responses received after this date may not be read. Consultation responses should be returned to: [mailto: HMR2016@dh.gsi.gov.uk](mailto:HMR2016@dh.gsi.gov.uk)

Or if you would prefer to send your response by post:

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

## What we will do next

We will read and consider all responses and publish a response to the consultation. The Government response will set out how comments and views shaped the final decisions taken in respect of the two areas, the subject of this consultation.

## Your details

**Full name:** Vanessa Taylor

**Job title:** Professional Executive Officer

**Organisation:** East Sussex Local Pharmaceutical Committee

**Email:** [vanessam.taylor@btopenworld.com](mailto:vanessam.taylor@btopenworld.com)

**Please indicate whether you are:**

A member of the public

A pharmacist/member of a pharmacy team

A pharmacy owner

A dispensing doctor

Another healthcare professional

A representative of a professional or regulatory body

Other

<input type="checkbox"/>
X
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
X
<input type="checkbox"/>

Please specify:

**If you are pharmacist/member of a pharmacy team or a pharmacy owner please indicate the size of your organisation:**

1 store

1-4 stores

5-99 stores

100 or more stores

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

**In which country do you currently reside?**

England

X
---

Scotland

--

Wales

--

Northern Ireland

--

Other

--

# Consultation questions

## 'Hub and spoke' dispensing

**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?

Yes (  )                      No                      (  )

### Comments

To enable a level playing field for all contractors this impediment should be removed, however any proposals beyond what is strictly necessary to ensure a level playing field should not be taken forward.

**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?

Yes                      (  )                      No                      (  )

### Comments

The Human Medicines Regulations should impose restrictions in order to maintain a network of local pharmacy contractors it would be necessary to allow the hub to only provide a dispensing service to spokes and not directly to the public and patients, which must be a registered pharmacy.

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

Yes                      (  )                      No                      (  )

### Comments

This would be necessary to allow compliance with GPhC Regulations and to be regulated by the GPhC. Medicines dispensed by a pharmacy must be registered as such.

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

Yes (X) No ( )

**Comments**

Accountability for the dispensing process would need to default to the Hub responsible pharmacist/pharmacy superintendent, however the clinical appropriateness of the medicine for the patient would need to be the accountability of the spoke responsible pharmacist. The hub only provides part of the total dispensing process. This would need to be clearly defined in the Regulations and overseen by the GPhC.

**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?

Yes (X) No ( )

**Comments**

There is no evidence that hub and spoke dispensing is more efficient and cost saving for independent community pharmacies. There is also no evidence that hub and spoke dispensing is safer. The basis on which the assumptions have been made in Annex C need clarification before full consideration and credence can be given to them.

**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?

Yes ( ) No (X)

**Comments**

The lack of clarity in the proposals make proper responses to the consultation difficult.

**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?

Yes ( ) No ( X )

**Comments**

Prices of medicines 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?

Yes ( X ) No ( )

**Comments**

What price to indicate on the label will be important when a decision is made. "Drug Tariff price/ cost price or retail price? Per quantity prescribed."  
We feel there are problems with cluttering the medicine with further labelling which may obscure important clinical information - it will also add in a cost. There is no evidence that adding a price to medicines increases adherence and reduces waste. It may have a detrimental effect and could lead to sale of those expensive medicines on the black market.

**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?

Yes ( X ) No ( X )

**Comments**

A small amount of work with patients show that photos of patients, returned medicines can have a powerful effect when promoting waste campaigns. It is important to remember that 80% of patients receive their medicines with no charge and in general little value is attributed to items that are provided free of charge regardless of whether a price is applied to the label.







personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances this will mean that your personal data will not be disclosed to third parties.