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

March 2016

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

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: Mark Stone
Job title: Project Pharmacist
Organisation: Devon Local Pharmaceutical Committee
Email: **mark@devonlpc.org**

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	X	
Other		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	

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 ( )** **Other (X see below)**

Comments

The aim of the legislative consultation and subsequent change is to:
“allow independent pharmacists to make use of ‘hub and spoke’ dispensing models - a ‘hub’ pharmacy dispenses medicines on a large scale, often by making use of automation, preparing and assembling the medicines for regular ‘spoke’ pharmacies that supply the medicines to the patient”.
(https://www.gov.uk/government/consultations/pharmacy-dispensing-models-and-displaying-prices-on-medicines)

When reading through the Hub and Spoke proposed legislation it is clear that there are a number of changes that are being made, some that don’t not facilitate the above aim. Hence, we can agree with only the necessary changes to remove barriers to independent community pharmacies accessing the hub and spoke model.

The committee at Devon LPC believe the consultation document is un-evidenced and appears a very rushed piece of work. We would urge caution on the DH and NHS England’s approach to this as there maybe unintended outcomes, for instance supply problems causing failure to provide medicines in a timely manner to patients. An example of this is the failure of a centralised dispensary, Pharmacy 2U in December 2015 causing 1,000s of patient to go without medicines.

There is a clear danger to the hub and spoke model does not decrease the costs of medicine supply for the NHS, and could actually increase cost due to a reduction in competition in the sector.

The NPA established a task and finish group to investigate this model. The group interviewed over 20 experts in the field, visited a hub, commissioned an academic literature review and received advice from a leading counsel. This is a highly complex area and the Department of Health has failed to identify significant barriers. We have the following major concerns:

1. There is a lack of understanding that the inter-company hub and spoke model that this regulatory change is intended to facilitate is fundamentally different to the existing, currently small-scale, intra-company arrangements.
2. DH has failed to provide any evidence for the efficiency and safety claims for an inter-company hub and spoke model. Our legal advice is that the spoke must perform an accuracy check, along with the safety feature checks required under the EU Falsified Medicines Directive (authentication and tamper evidence check). The requirement to undertake these checks undermines the claimed efficiency benefits of the hub and spoke model. In addition, the technology required in every pharmacy under FMD will provide safety checks that will replicate any benefits that can be derived from automated dispensing.
3. Those that portray the safety issue as simply a matter of "humans versus machines" show a lack of understanding of the processes that will be required to operate this model and supply medicines to patients within community pharmacies.
4. It would take considerable investment of time, money and intellectual resource for new providers to be in position to enter the hub market. Direct to Pharmacy and Limited Wholesaler Schemes present a significant barrier to market entry. We therefore believe that these proposals present a severe risk of creating a duopoly amongst hub providers. This will lead to a lack of choice and competition, and may lead to a significant increase in medicine costs for the NHS. A lack of competitive pressure on the hub service fee will create significant costs for independent businesses. Without the abolition of Direct to Pharmacy and Limited Wholesaler Schemes, it will be impossible to maintain choice and competition in the market.
5. A hub and spoke model may release some limited capacity within community pharmacy. However, there is little opportunity to release cash savings. To exploit any opportunity, the NHS should commission a new service from community pharmacies.

Devon LPC urge the Department of Health to set a reasonable time frame for this massive change in the market place, due diligence should be placed on investigating the evidence base and validating it before making commissioning decisions.

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 (X)**

Comments

An unintended consequence of the Hub and Spoke model could be that it causes a reduction of choice of wholesalers, that eventually produces an oligopoly that could increase costs not reduce it. The model of centralised dispensing is fraught with business continuity issues, i.e. a reduction in

system resilience leading to potential market failure.

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

Yes **(X)** **No** **( )**

Comments

Yes a pharmacist and respectively qualified dispensing team needs to be at the core in the hub and spokes to ensure a safe and quality medicines supply and that patients have the opportunity to consult a health care professional with the necessary skills to advise on medicines.

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

The DH and NHS need to work closely with all stakeholders to risk assess the 'Hub and Spoke' model before the profession can support a long term strategy of moving to Hub and Spoke dispensing.

The accountability should and will always sit with the 'spoke' as the point of patient supply. This will add complexity in legal complaints and claims as different Superintendent pharmacists (from the hub and spoke), with different Standard Operating Procedures, will be involved. This adds a significant level of risk over and above intra-company hub and spoke arrangements, where spokes and associated personnel work to mutual SOPs under a single superintendent.

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

The assumptions made in Annex C are not referenced or evidence based. We urge the DH to undertake comprehensive due diligence that is focussed on investigating the evidence base and validating it before making commissioning decisions.

The suggestion that capital investment should be excluded from the cost calculation appears to be a highly material omission, as this would need capital funding and suffer depreciation losses.

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 NPA has undertaken a thorough literature review, they state we have yet to see any evidence that a hub and spoke operation releases cash savings, although we believe that it may release a small amount of capacity which could be re-deployed within the pharmacy to provide additional clinical services (if commissioned).

The NPA legal advice suggests that some processes that will be undertaken in the hub must be repeated in the spoke (for example, the accuracy and authentication checks) undermining the case that a hub and spoke arrangement will be more efficient.

Hubs will make a considerable investment in technology – and they will then seek to re-coup this investment through a hub service fee. As we have already highlighted, a lack of competition between hubs will lead to the risk of high fees and therefore considerable costs to independent pharmacy businesses. There will also be considerable costs for spokes in quality assuring the hub that they use and re-modelling their own business processes.

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

The NPA has undertaken a thorough literature review, they state they have yet to see any evidence that a hub and spoke operation improves safety.

Automated medicine picking machines may reduce errors however there are still a number of human steps in the process as it is not just the picking of a medicine to assemble the prescription:

- The maybe huge transfer of data risks from the spoke to the hub presents significant new risks.
- The hub and spoke model relies heavily on the quality of data entry at the spoke pharmacy (ie, the hub will provide the item requested by the spoke with a high degree of accuracy). However, if the spoke has asked for the wrong item, they have an equally high chance of receiving that item, which would be accurate but not valid. We contend

this presents a material risk to patient safety.
- The authentication checks mandated by the EU Falsified Medicines Directive present an alternative technological means of reducing the risk of incorrect medicines being supplied to patients

Devon LPC would like to state the error rate in community pharmacy is low and the number of complaints is insignificant thus the scope for improvement is therefore limited.

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 **( )** **No** **(X)**

Comments

This change is likely to have unintended consequences such as patients not complying with doing instructions because of concerns placed on the NHS.

Dispensing labels have a very limited space and the wording could be too small to allow elderly and visually impaired to read it.

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 **( )** **No** **(X)**

Comments

No

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

Yes **(X)** **No** **( )**

Comments

The DH needs to be aware that the change could overburden a very stretched sector. As this change will cause and increase work load on the pharmacy team, because patients will seek clarification.

Pharmacy dispenses 30% more medicines than in 2008, however the 2016 funding cuts will reduce the total remuneration paid to the levels seen in 2008! This will cut staffing hours in pharmacies.

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

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

Yes **(X)** **No** **( )**

Comments

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

Yes **( )** **No** **(X)**

Comments

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?

Yes **( )** **No** **(X)**

Comments

Redesigning the pharmacists' exemption

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.

Yes **( )** **No** **(X)**

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 **(X)** **No** **( )**

This allows flexibility to meet patients' needs.

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

Yes **( )** **No** **(X)**

If "yes" please explain any specific impacts on small or micro businesses**.**

Equality assessment

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?

Yes **( )** **No** **(X)**

Draft regulations

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

Yes (X) **No ( )**

When reading through the Hub and Spoke proposed legislation it is clear that there are a number of changes that are being made, some that don't not facilitate the above aim. Hence, we can agree with only the necessary changes to remove barriers to independent community pharmacies accessing the hub and spoke model.

Confidentiality of information

If you would like any part of the content of your response (as distinct from your identity) to be kept confidential, you may say so in a covering letter. We would ask you to indicate clearly which part(s) of your response are to be kept confidential. We will endeavour to give effect to your request but as a public body subject to the provisions of the Freedom of Information legislation, we cannot guarantee confidentiality.

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter. Information we receive, including 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.