Response ID ANON-QTU5-E1G1-W

Submitted to **Changes to medicines legislation (including on 'hub and spoke' dispensing)**
Submitted on **2016-05-09 16:06:27**

Introduction

I What is your name?

Name:
Matthew Isom

II What is your email address?

Email:
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III What is your organisation?

Organisation:
Dispensing Doctors' Association

IV Please indicate whether you are:

A representative of a professional or regulatory body

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

VI In which country do you currently reside?

England

'Hub and spoke' dispensing

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

no

Comments:
We are concerned that the proposals refer exclusively to community pharmacies and do not include any reference to dispesning doctors, who currently dispense 7% of all NHS prescriptions issued. If hub and spoke is to become the delivery model of choice, then a way must be found to include these providers of rural services. The provisions of the Medicines Act relating to dispensing doctors are not referred to and it appears that you are not proposing to 'level the playing the field'. This discriminates against rural patients and cannot be acceptable.

We believe that the proposals will decrease the availability of medicines to patients and may cause harm. The DDA chairman's practice had 55 patients on Maundy Thursday who had run out of their medication before the Bank Holiday weekend. The practice was able to supply those patients only because it holds the stock. This would not be true if the practice was a 'spoke'. If Hub and Spoke is to be permitted, then it must be available to dispensing doctors as well. The way that the wholesalers work will change and, if dispensing doctors are excluded then they will need to receive extra funding, as the wholesalers are likely to charge more to deliver to practices.

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

Comments :
Hub and hub and spoke are two different models. Hub to patient is already covered in existing regulation as a distance selling (internet) pharmacy.

If there is no spoke, how are patients to receive tailored medicine advice?

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

no

Comments:
We fail to see any practical difference in the relationship between the hub and its unrelated business spoke and the current wholesaler/pharmacy set up: that being so, a spoke should be a registered pharmacy (or other outlet such as a dispensing practice) and the hub should be registered, and be governed, as a wholesaler.

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

yes

Comments:
By effectively splitting the process of dispensing into two separate parts, we wonder how responsiblitly will be apportioned in the event of a dispensiong error?

We do not believe that the implications of the proposed changes have been properly thought through.

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?

Assumption 1:
Without any references, it is difficult to know how these figures were derived.

As the current contract suggests minimum staff numbers per items, unless the contract changes the same number of staff will be required no matter how many sites there are.

Assumption 2:
We think the scope for staff savings is extremely limited.

Assumption 3:
We do not believe that there will be any overall savings between hub and spoke.

Assumption 4:
We disagree: our own estimate is that few, if any, small independent pharmacies will use hub and spoke, there being no obvious need or incentive to do so.

Assumption 5:
Given our previous answers this is a little academic, but since repeat medication is more likely to be dispensed should this service delivery model be adopted, the liklihood is that more than 70% of items would be affected.

Assumption 6:
No comments.

Assumption 7:
No comments.

Assumption 8:
No comments.

Assumption 9:
No comments.

Assumption 10:
No comments.

Assumption 11:
No comments.

Assumption 12:
Once a hub is supplying direct to patients, it is no longer a hub but rather, a distance selling pharmacy - a model that has been shown to be fraught with difficulties as demonstrated by the problems experienced by Pharmacy 2U.

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

Comments:
The DDA cannot see how, under the current pharmacy funding mechanism, such a model will generate significant savings.

We understand that a large hub supplying nursing homes in the South West went bust - which suggests that the model is more expensive.

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

Comments:
While the problems that Pharmacy 2U experienced over the Christmas period of 2015 are not striclty 'hub and spoke' they do appear to demonstrate the difficulties inherent in the proposed model when a hub fails to work.

The current proposals for the community pharmacy contract that are likely to see a large reduction in the numbers of pharamacies would have compounded the problem.

We know of no robust published evidence that shows that hub and spoke dispensing is safer.

Prices of medicines on dispensing labels

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

Comments:
It is one thing to change the regulations to permit prices to be displayed on a medicine lable, but quite another to implement such a policy safely. There is already a plethora of essential information on medicine labels and we are concerned that adding more may serve to confuse more than inform.

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

Comments:
There appear to be problems with inappropriate extrapolation from the studies you quote.

We do not have an issue with the School of Pharmacy/YHE paper, but it is not clear how the proposed changes will impact on the total medicines waste costs.

Hailsworth's paper applies only to hospital appointments and is London population based; this might not be replicable in other parts of the UK. In addition, it assumes that the costs of the intevention is £0 which we do not believe to be correct. Furthermore, it mentions that Trusts over book appointment slots based on DNA rates, so decreasing DNAs might not lead to any more patients being seen and thus negate any true cost saving.

Fogarty's study (Fogary AW, Sturrock N, Premji K, Prinsloo P (2013). Hospital clinicians' responsiveness to assay cost feedback: a prospective blind controlled intervention study. JAMA Internal Medicine, 173(17) examined doctors' behaviour - we are thus certain that its results can legitimately be extrapolated to that of patients.

Without submitting the proposals to a pilot process followed by rigorous academic evaluation, it is our view that these changes should not proceed.

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

no

Comments:
Please see above (Q9).

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

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

yes

Comments:
The description of the medical product should wherever possible include a picture of the medication to aid compliance. There should probably also be a warning that the product(s) are now unlicensed since they are being stored out of the original pack.

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

yes

Comments:
The size of the label needed to implement this change is likely to be unfeasibly large. There will be resource issues for dispensers and MDS manufacturers in providing the hardware and software to print them. Whatever solution is found must ensure that print size is large enough to be read by the average user of such systems.

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

yes

Comments:
Flexibility is essential.

Redesigning the ‘pharmacists’ exemption’ in section 10 of the Medicines Act 1968

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.

Comments:
No comments.

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?

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

Comments:
No comments.

Equality assessment

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

Comments:
What about the effects on rural patients?

Putting a price on the label could mean that the elderly might decide not to order the medicines that they need. The young might not be so concerned, so it might cause disproportionate harm based on age.

Draft regulations

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

no

Comments: