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

Royal Pharmaceutical Society Response

General comment:

The Royal Pharmaceutical Society (RPS) supports the proposed changes in legislation to allow independent pharmacies to operate similarly to corporate bodies. We do however have reservations around patient care and safety within the current “hub and spoke” models which should be addressed before any further changes are implemented. We also would like more evidence around the assumptions made in the consultation and the business models used in the impact assessment. We note that the consultation itself is very weak in terms of evidence and further evidence should be sourced and shared before the model is implemented. These concerns are outlined in more detail below.

In the second paragraph on page 6 it states that ‘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’. Where is the evidence that supports and substantiates these claims? Whilst it may be true that operating costs are lowered for some intra-organisational models it is actually likely that costs could increase, or at best be neutral, for inter-organisational models as pharmacies would need to pay the hub for the service it delivers.

In the first paragraph on page 7 it states that ‘An alternative model is the ‘hub’ pharmacy sending the medicines directly to the patient or via a delivery company’. Medicine optimisation is about an individual pharmacist interacting with an individual patient and meeting the patient’s individual needs. The suggestions to supply medicines in a different way could have a negative impact on this relationship. Also, there is evidence from the homecare models in the hospital services that suggests there are major governance problems, both financial and clinical, with direct to patient delivery of medicines. Confidentiality and storage issues also arise.

Medicines are not normal items of commerce and should not be supplied directly to the patient unless this is decided as appropriate between the pharmacist and the patient and only following a full clinical medicines review between the pharmacist and the patient. Systems should ensure patient choice and allow face to face interaction with the pharmacist on a regular basis. The pharmacist may be the only healthcare professional who the patient sees regularly.

Hubs should be there to relieve the pressure of volume dispensing on spoke pharmacies, allowing the pharmacist at the spoke to add more value to the process through face to face patient contact, not to take the spoke out of the process.
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, we agree that this impediment should be removed to enable all pharmacies to have access to a hub and spoke model should they choose to do so but we have a number of concerns about the viability and operation of an inter-organisational model which are described in more detail below. The increased risks identified in our response need to be mitigated prior to any changes in legislation. The key is personal accountability of the pharmacist working at the hub and the legal responsibilities of the owners of both the hub and spoke whereby the law requires the owners to have systems in place that allow the pharmacists involved in the process to fulfil their professional roles.

It is important that independents have the same opportunities as larger multiples but we believe there are a number of issues that would need to be resolved before the majority of independents would consider availing themselves of this potential opportunity.

We are concerned to see that dispensing doctors are currently ‘out of scope’. Surely the Government would like to see an equity of access and standards for the supply of medicines and if the new models of supply are deemed to be more effective and efficient then dispensing doctors should also have access to these models.

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. As above, medicines are not normal items of commerce. Good clinical governance is essential for patient safety and patient care must be the first priority. Legislation will be required to protect patients and ensure that patients have timely access to a pharmacist should they require it and that the pharmacist can contact the patient if pharmaceutical issues arise.

There should be a national standard that all hub pharmacies need to adhere to. Any separate company contracting with a hub would need to be assured of the minimum standards of service they could expect.

We are aware that it is up to the pharmacist working at the ‘spoke’ pharmacy to reassure themselves that the hub is practicing and delivering to the required standards. This would place a huge burden on the spoke pharmacies and may not actually be achievable in practice. If there are a number of hubs that a pharmacy could use then there should be some way of comparing these and we suggest that the national standards should contain key performance indicators (KPIs) that spoke pharmacies can use to assess which hub to contract with. There may be a need to develop professional standards to complement any General Pharmaceutical Council (GPhC) risk based approach.

In addition, there should be legislation that requires the hub to be based within the UK to ensure timely access. The patient should also be made aware of where the prescription is going and informed patient consent should be mandatory.

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

Yes they should all be registered by the GPhC. This is particularly important in relation to the use of the proposed statutory defence for a single dispensing error. If the hub is not a registered pharmacy then the pharmacist at the spoke would not be able to avail themselves of this defence. Also, if the
hub is a registered pharmacy it can be held to account but if it is not registered as such then this would be problematic.

Both the hub and spoke will have a statutory duty of care and it needs to be clarified how this is undertaken at the hub. The hub will also need to participate in incident reporting and learning from such incidents. In addition hub and spokes would need to share and feedback on incidents that related to each other’s practice and there should be a clear audit trail of learning from these.

It is important that every hub and spoke configuration delivers high quality pharmaceutical care, irrespective of which type of pharmacy organisation operates it. There needs to be integrity in the transfer of information, medicines and responsibility for pharmaceutical care.

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

Yes. We have concerns around the clinical governance in the overall process. Clarity is required on several issues and to ensure patient safety the legislation should not be changed until all of these issues have been demonstrated to have been resolved:

- Who is responsible for the accuracy of the dispensed medicines (is this responsibility at the hub or with the pharmacist supplying the medicine to the patient?). Both the hub and the spoke will have a statutory duty of care. The spoke would still need to check the accuracy of the dispensed medicine as the prescription remains at the spoke pharmacy. This means the hub will only dispense and supply according to the information that it is provided with from the spoke. If the spoke makes an error in entering the data it will lead to an inaccurate supply of the medicine in relation to the prescription, so the medicine needs to be checked prior to supplying to the patient.
- Who is responsible for providing the clinical check and at what point in the process would this be undertaken? We believe the safest system is for the clinical check to be undertaken when the prescription arrives at the spoke and before it is sent off for dispensing.
- How does liability transfer between the hub and spoke? There needs to be clarity around exactly how clinical accountability is apportioned and where responsibility lies.
- Is there access to the SCR at the hub so checks can be made prior to dispensing?
- How does this fit with the requirement to snip some packs? Will this require original pack dispensing (OPD)? There will be issues relating to the requirement for a wholesaler dealer’s licence and supplying medicine in the original pack.
- How does this fit with EPS? Currently the EPS system in use does not support hub and spoke dispensing
- Does this model comply with the European Union Falsified Medicines Directive 2011 (FMD)? The delegated act requires that authentication of the medicine is at the point of dispensing which although not clearly defined is expected to be as close to when the medicine is handed to the patient as possible. We anticipate a proportion of medicines sent back to the hub to be re-entered into the system if they aren’t collected before the 10-day deadline following authentication at the hub. This issue is likely to only impact pharmacies that use hub services from an external organisation.
- Who is responsible for safe storage and transportation between the hub and the spoke? There are potentially more issues that will emerge as more details emerge as to how such a model would operate in practice.
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?

There is no evidence provided to substantiate the figures used in this impact assessment.

The assumption is that use of a hub and spoke model will reduce staff and increase capacity within the spoke pharmacy. However, if staff numbers are reduced this also reduces the capacity of the pharmacy to provide additional services. The hub and spoke model will potentially reduce a percentage of the proportion of the workload i.e. the assembly process but it will not be such a high percentage of the overall workload. The pharmacist handing out the prescription medicine to the patient (or patient representative) will still be legally liable for the supply, but this is similar to the current situation where a different pharmacist has dispensed a medicine the previous day. Some pharmacists may feel a need to undertake a clinical check, and an accuracy check before supplying the medicine at the spoke.

We also have concerns in relation to Direct to Home supply. If a percentage of medicines is dispensed by the hub then this decreases the ability of the spoke to procure medicines effectively from wholesalers which could lead to an increase in the cost of medicines to the NHS. In addition it could lead to a reduction in the number of deliveries to the pharmacy per day from the wholesaler and this could have an impact on patient care. There are potential learnings to be made from the Homecare model where there have been a number of issues in relation to data breaches, patients not receiving their medicines in a timely manner and providers unable to meet demand. There needs to be a business contingency plan in case the hub stops functioning for any reason bearing in mind the issues the sector faced when Pharmacy Plus went into receivership. And lessons also need to be learnt from Pharmacy2U who were unable to supply medicines over a period of time in 2015.

There is no clarity as how the business model will operate when the hub and spoke are two separate organisations. The spoke pharmacy will need to pay for the services undertaken by the hub for the assembly, accuracy checking and transportation of the dispensed medicines and the cost of this may not make it financially viable for the spoke. This is different to a vertically integrated model where the hub and spoke belong to the same organisation. Also, if there were to be a major problem at the hub then there would probably be insufficient capacity at the spoke to revert back to spoke dispensing and this needs to be taken account of in any business continuity plan.

The impact assessment does not take into account any transportation costs and these need to also be included. The depreciation of any automation over time is also not included.

There is no account for the spoke having to change its IT system to one which is interoperable with the hub.

If the hub operation is tied to only one wholesaler then this could cause problems when medicines become out of stock, hubs need to have the ability to access a variety of wholesalers. This could be a particular problem with manufacturers who deal with only one wholesaler.

Most of the evidence around this type of operation is from the USA but the health system they operate under is completely different and the efficiency savings are in what the patient pays for and are not real efficiencies within the overall system.

The current supply of medicines function within a community pharmacy actually subsidises a whole range of other activity including opportunistic public health advice, general advice and supporting patients to get the most from their medicines.
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 we are not aware of any other evidence available in the world for the type of hub and spoke model proposed in this consultation (inter-organisational) and we have concerns in relation to the hub and spoke model and the impact on patient safety.

Anecdotal evidence suggests that it frees up pharmacists’ time, within pharmacies, to provide more face to face services to patients and the public but there are also the issues outlined above which means that depending on economics of scale implementation of the model from an independent pharmacy point of view could be unlikely.

In addition, any evidence needs to consider patient safety and what the impact will be on this.

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 and we have concerns in relation to patient safety if the legislation is implemented prior to all the issues outlined above being resolved. There is the potential for additional error as information is transcribed between the spoke pharmacy and the hub.

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 – we would not recommend that prices of medicines are put on labels. We believe that the label is there to provide clinical information and should remain focused on that.

We agree with the intent to make sure people take their medicines as prescribed and reduce medicines waste, however this area is complex; people don’t take their medicines for many different reasons. Having the cost on labels could potentially have several different outcomes:

- There is a risk that through knowing the cost of their medicine, some people would presume they were a burden on the NHS and for that reason didn’t order or collect their medicines. This would increase NHS costs as illnesses would deteriorate and potentially much more expensive hospital treatment may be needed.
- Inexpensive medicines could be regarded as a cheap option or sub-standard, particularly in relation to the prescription charge which could cause resentment and put both pharmacists and doctors in difficult positions. It could also impact negatively on medicines adherence.
- Patients with similar conditions may compare medicines and feel undervalued if their medicine is cheaper than a person with a similar condition.
- This places an inherent risk into the system of ‘selling on’ of medicines as the individual value of medicines are defined.

A potential solution is for labels on medicines to contain some overarching statement which promotes the value of the NHS and medicines, such as ‘every year the NHS spends £15 billion on medicines to ensure you can receive the care you need’.

It’s important that people understand the value of their medicines. We know that around 30-50% of patients don’t use their medicines as intended and there is around £150 million of avoidable medicines waste every year. Pharmacists are now spending more time with patients providing one-to-one support to understand the range of reasons why medicines may not be taken. Although knowledge of the cost of medicines may play a part, it’s equally important we focus on factors such
as peoples' understanding of the side effects and benefits from medicines, which will also influence whether a condition is treated effectively or the medicine ends up being discarded.

There is no evidence base one way or the other and we recommend that this is probably researched and evidenced before a change in the legislation is implemented. There is a caveat here as different health systems have different drivers and influencers and examples from overseas might not be directly applicable to the UK. We would also like clarity as to why medicines have been singled out in particular? If you really want to make patients aware of costs then why not present them with information every time they visit their GP practice, visit A&E, attend outpatients or undergo an operation for example. Medicines are just one single part of a more complicated equation and the whole question deserves wider thought and debate.

**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 we are not aware of any evidence base and would recommend that research is undertaken and evidence sought prior to any changes being made in legislation to enable the prices of medicines being shown on labels.

Is there any evidence to demonstrate improved adherence as it states on page 10 paragraph 3 that ‘We believe, however, that making people aware of the price of their medicines will help contribute to increasing adherence to those medicines’. What data is this belief based on?

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

Yes, we would not wish to see this implemented in England, please see our answer to Q8. We believe that putting prices of medicines on labels goes against the whole ethos of patient care and medicines optimisation.

In addition thought needs to be given to how pharmacists and their teams are equipped to have conversations with patients and their carers about the price of the medicine and the time required to do this were this to be implemented.

In addition we recommend that there is a review of the exemption categories for prescription charges.

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

Yes, we would agree with this to ensure that labelling is made easier but is still safe for patients. There needs to be sufficient information and detail on the dispensing labels to enable nurses and others to positively identify medicines within the MDS. Sometimes, nurses are unable to administer a medicine from a MDS in a hospital setting as they are unable to identify which of the medicines within the MDS is the particular one they need to administer.

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

The labelling requirements that are proposed for medicines supplied under a Patient Group Direction (PGD) could cause a practical issue when medicines are supplied in these circumstances in emergency situations such as a pandemic. If the medicine is being administered there and then to
the patient this is not an issue but if the patient is taking the medicine away or if it is being administered by another healthcare professional then this is an issue.

The wording in the consultation document (page 12) states that ‘ensure that a dispensing label MUST be applied to medicine supplied pursuant to PGDs or other forms of direction where the same issues arise’, however, there is no definition of what the label needs to contain When the PGD medicine provided is a P medicine in an appropriate pack, assuming the directions fit the PGD, there is no legal requirement for any other label.

Many hospitals procure POM medicines in packs that have a marketing authorisation that allows normal dosage to be included on the pack, for example an antibiotic, and these are provided to patients through A&E with no further labelling.

In both cases best practice would suggest you include supplier, date and patient name when the medicine is given to the patient.

A similar situation occurs in GUM clinics where it is normal practice to not add any additional labels.

Clarity is required as to whether practicing pharmacists have been engaged in the proposed changes prior to the proposals coming out to consultation.

**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?

We agree with this proposal. Having flexibility would be useful and potentially make information clearer to patients and carers.

**Question 14:** Do you think pharmacies that supply medicines to other healthcare settings, e.g. 'hub' pharmacies and some hospital pharmacies, will need to 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.

The key element of this practice is that if a pharmacy is to provide such a medicine then there should be an evidence base for the product, and one that could ideally be shared with the patient so they understand what they are receiving. The preparation of such products need to be based on clinical need rather than convenience for the patient or the healthcare professional (https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials).

Whether there is a need for such a medicine to be ‘available’ in advance of a prescription has to be based on a discussion focused on 'clinical need' between relevant professionals i.e. how likely is any delay in supply to cause a patient either harm or reduced benefit. This is where the risk scoring within the Council of Europe resolution could be used (https://wcd.coe.int/ViewDoc.jsp?p=Ref=CM/ResAP(2011)1&Language=lanEnglish&Ver=original&Site=CM&BackColorInternet=DBDCF2&BackColorIntranet=FDC864&BackColorLogged=FDC864&direct =true).

**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 ability to do this should remain. However, it should be made clear that these products are only appropriate where a licensed product is unavailable and their preparation should be based on evidence that can be shared with the patient so the patient knows what they are receiving. While the production of these such products may not be to full Good Manufacturing Practice guidelines
there must still be a suitable quality system in place and the professionals involved should have the evidence base to suggest benefit outweighs potential harm.

WE believe that this practice is increasingly rare.

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

A very large proportion of all the chemotherapy dispensed in NHS hospitals and a smaller but still significant amount of parenteral nutrition and the extemporaneous preparation of oral liquids and creams and ointments dispensed in NHS hospitals are prepared utilising the Section 10 exemption to the Medicines Act 1968. A high degree of care needs to be taken to ensure that any changes to this part of the medicines legislation do not unwittingly jeopardise the continued legal preparation of medicines for NHS patients by NHS pharmacy teams.

The key issue is whether preparation under ‘Section 10’ exemption in a pharmacy is inherently safer than preparation on a ward. Tools are available that enable suitable risk assessment based on type of ‘ward/department’ environment and ‘problems’ with individual medicines and there is also guidance available on IV risk 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?**

On page 28 the second bullet point states that ‘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’. We would like to see the evidence that such models provide a more efficient and safer method of dispensing.

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

No

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For further information or any queries you may have on our consultation response please contact Heidi Wright at heidi.wright@rpharms.com or 0207 572 2602.

About us

The Royal Pharmaceutical Society (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors and specialisms of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition, it promotes the profession’s policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

**Leadership, representation and advocacy:** Ensuring the expertise of the pharmacist is heard by governments, the media and the public.

**Professional development, education and support:** helping pharmacists deliver excellent care and also to advance their careers through professional advancement, career advice and guidance on good practice.

**Professional networking and publications:** hosting and facilitating a series of communication channels to enable pharmacists to discuss areas of common interest, develop and learn.