Hub and Spoke consultation:
8. 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?

Yes, we agree that this medicines legalisation impediment should be removed to give all types of pharmacy businesses the opportunity and choice to operate 'hub and spoke' services if this fits their chosen operational and business model. As indicated this currently is not possible across different legal entities and particularly affects independent pharmacies and restricts choices. There are some successful models already operating such as 'Mayberry Pharmacy' which is a small chain of pharmacy businesses but this is within the same legal entity. However, as an unforeseen consequence, APTUK are aware of the impact this may have on small businesses, where there may be financial implications for competing with larger organisations, wholesale backed models, based on economy of scale. Data researched on behalf of the National Pharmacy Association suggests that there are a slightly higher percentage of independent pharmacies who do not currently favour 'hub and spoke' model, particularly across different legal entities.
Operating pharmacy business and dispensing across different organisations and registered pharmacies brings additional considerations that need addressing and further clarity. The main consideration is the responsibilities and accountabilities of pharmacists and pharmacy technicians working across two or more pharmacies within the dispensing, assembly and final accuracy checking activities associated with one individual prescription.

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 we agree, however clarification on the types of hub and spoke needs to be confirmed as differences in interpretations of the definitions are currently leading to misunderstanding. APTUK believes that there should be consistent information so that patients are aware of the process and the different models. Patients would also need to be aware of where their prescription is being dispensed and who to contact in case of prescription queries and the supply. Assuming the prescription stays at the Spoke, given that the Spoke could use a number of different Hubs, patients would need assurance that wherever their prescription is being dispensed it is done to the same standard.
Given that both the Spoke and the Hub are registered pharmacies, guidance would be needed from the legislation and pharmacy regulator on the interface between the two or more pharmacies. This would need to be clear to patients, where governance lies and to whom they can raise issues and complaints to. Patients would need to be clear who to contact if there were any issues or differences that occurred during the assembly phase, ie any lifestyles changes, prescription changes or any aspect that would need clinical intervention.

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

Yes. Hubs should be registered pharmacies to ensure equal standards are maintained and are clear and transparent in the proposed regulatory framework. Standards at both the Spoke and the Hub need to assured so that patients can have confidence in the quality of the service being provided, given that they may have no choice as to where their prescriptions are being dispensed. Staff operating in both pharmacies needs to be assured that they are subject to the same legislative defence against single dispensing errors, when this is available.

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

Accountability, responsibility and liability, between the two entities, are not clearly defined so this may cause some complications and concerns. Different types of hub and spoke will need to be considered and specific standards set as necessary.
So yes there are a numbers to consider and resolve:

- As the Spoke will be entering the data to be dispensed at the Hub, who will be accountable and liable if the medication, is inaccurate due to data being entered in

error at the Spoke and this is issued to the patient. In this circumstance the accuracy check undertaken at the Hub would be accurate against the assembly but not against the prescription.

- In terms of the proposed dispensary error defence, would this be invalidated if an error occurred at the Hub but this wasn't notified to the patient either by the Spoke or the Hub?
- Or if an input error occurred at the Spoke and this was dispensed at the Hub but the patient wasn't notified.
- Whose responsibility is to notify the patient, as the prescription is held at the Spoke?
- Assuming that the clinical check is undertaken at the Spoke, is the Hub responsible in any way? How would the HUB access PMRs or SCRs if it was a different entity?
- Would the final accuracy check lie with the Spoke prior to issue to the patient? If this is the case, this is introducing an additional step. Also where will the FMD authentication take place?
- How do MDS systems fit with FMD and the Delegated act in the Hub and Spoke models, as the MDS will not be tamper proof original packs as the packs would be broken to fill the MDS.
- Would both registered pharmacies need to hold an NHS Contract? What would happen if the Hub was unable to supply the patient medication within the agreed timescales? Presumably service level agreements would need to be in place, indicating terms of service, quality monitoring etc by the Spoke.

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?

Whilst recognising that it is an obligation to provide assumptions to inform an impact assessment, APTUK do have substantial comments to make on the assumptions outlined in Annex C. It is unclear where these assumptions originated and as such the impact assessment appears ill informed. There is no evidence to substantiate the figures in the assumptions. It is assumed that automated dispensing on a large scale will reduce staff needed at the Spoke and some will transfer to the Hub. It is also assumed that reducing dispensing workload at the Spoke will release the Pharmacist to undertake clinical activities and be more patient facing. There are no assumptions as to the enhanced role of the Pharmacy Technician and utilising the released capacity of this registered professional. This is no information related to advanced skill mix reviews within the pharmacy team and there appears to be a disconnect in this document to the principal outputs of the Rebalancing Pharmacy Legislation with Regulation.

There are no assumptions that relate to change management and increased customer service issues that may occur during any transitional periods.

More comments from APTUK are provided under the specific assumptions outlined further into this response.

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?

APTUK are not aware of any published data to provide evidence that Hub and Spoke is more efficient and cost-saving. It can be assumed that Hub and Spoke will produce change not cost-savings.
The initial capital costs of Hub and Spoke automated dispensing, estimated to be between £35-180k may prove challenging for some businesses.
Human resource for the provision of such an entity would possibly reduce in the long term which would impact on the workforce. Some duplication of work, where processes need to be repeated in the Spoke, will mean efficiency and cost saving will not be as anticipated.
MDS dispensing may offer the most cost-savings as these are very labour intensive currently and present risk. There is some information, collected by the NPA Oral evidence to Task and Finish Group that suggests that dispensing time could be reduced from 20-25minuts per patient to 2-3 minutes per patient. Error rates could also be reduced.
There is evidence in Denmark related to automated dispensing which is alkin to Hub and Spoke. There are 9 pharmacies in Denmark providing automated prepacking of unit doses.

Then they ship and sell the prepacked unit doses to the individual pharmacies, which then sell the unit dose packages to the patient. Pharmaconomists (equivalent to Pharmacy Technicians) do the check at the counter, and pharmaconomist provides the service at the unit dose pharmacies. The unit dose pharmacies are different legal entities than the pharmacies selling the unit doses.
Exploring the impact of an automated prescription filling device on community pharmacy technician workflow, provides some data of this activity- attached to submission.

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?

APTUK are not aware of any substantial evidence to state that hub and spoke dispensing is safer. An automated system may prove to make less picking errors but other safety issues need to be considered in addition to this such as the transfer of prescriptions, information and medicines to patient. As there may be additional steps in the process, this may increase the potential for error, particularly at the point of inputting data for transfer from the Spoke to the Hub. It is not clear if EPS will impact in any way on this.

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?

More detail is needed in order to make an informed decision, but APTUK recognises that displaying the indicative price of the dispensed medicine on the label for any costing more than £20 could help reduce medicines waste. However, this is not evidenced based so APTUK has reservations about this. Some pharmacy companies also receive medicines at a highly discounted rate. Would this be taken into account if the price of medicines were to be included on the label? Also APTUK would be professional concerned if patients felt pressured to take their medicines simply based on the cost, particularly with the elderly population who are more waste averse, and this was detrimental to their health and wellbeing. There are other ways that medicines wastage could be reduced and this could utilise the role of the registered pharmacy technician.
http://committee.nottinghamcity.gov.uk/documents/s24389/Reducing%20Medication%20Waste%20Notts%20CCGs%20May%2015.pdf
It is known that 50% of medicines are not taken as intended, Pharmacy Technicians could be utilised to support many patient facing activities to help address this.

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?

APTUK are unaware of any evidence that correlates knowledge of cost of medicines and adherence improvements. Patients are usually unaware of the costs of their medicines. The older generation are often reluctant to take their medicines if they feel that they can do without it and it is expensive, so may not reorder their medication as a result of this. This would obviously be detrimental to the patient. Alternatively, in the long term, all patients may be less likely to hoard unused medicines as a result which could improve the volume of waste returned to the pharmacy. As indicated above there are other methods of helping patients understand their medicines that may improve compliance and reduce waste. One aspect could be to support patients when ordering repeat prescriptions, synchronising repeat schedules of multiple medicines and not stock piling medicines so not to alert the prescriber that the medicines are not being taken.

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

APTUK believe that this should not be implemented in England until there is further evidence based research to indicate that this effective to both cost-savings, waste reduction in parallel to patient safety and health and wellbeing.

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

The labelling of MDS or PGD dispensed medicines must meet the general labelling requirements, although the medicines possibly being handled for supply in an MDS unit. A minimum requirement should be that the dispensing label includes the patient's name, the name and address of the pharmacy and the date of sale or supply, the name of the medicine(s), directions for use and any precautions relating to its use. MDS packs should include a description of the preparation, to enable the patient or carer to identify each medicine within the compartment/sachet.

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

There are practical issues including space but these would need to be overcome in order to maintain patient safety.

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?

Information must appear on the immediate packaging wherever possible in combination with labelling on the outer pack.

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, APTUK understands that this follows a judgement from the Court of Justice of the European Union over the exemption for pharmacists over producing unlicensed medicines that are not in a pharmacopoeia. This then impacts on the Hub and Spoke process.

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?

It is not usual now for a pharmacy to produce chemist’s nostrums, or have the need to produce such items. Specials supplies can be obtained from the appropriate manufacturer and produced in a safe and controlled environment appropriately regulated as such.

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

Under the Medicines Act 1968 Section 10 exemption, extemporaneous dispensing and ‘Specials’ is allowed, that is utilised by NHS Trusts Pharmacy Aseptic units, preparing CIVAS, TPN and chemotherapy as well as creams, ointments, solutions, suspensions etc. Any legislative changes need to be cognisant of this type of named patient dispensing and preparation.

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. See below.

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

No. APTUK is pleased to be able to contribute to the comments from other stakeholders on these regulations. However APTUK note that this has only been proposed for England and would require amending the Human Medicines regulations 2012.
APTUK is the professional representative body of Pharmacy Technicians across the whole UK.

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?

APTUK raises that there is no clear evidence to support these assumptions but are extremely concerned about the negative consequences on the Pharmacy Technician workforce i.e. 25% reduction in pharmacy technician labour costs at Spoke pharmacies and only between 6.25% and 12.5% increase in pharmacy technician labour costs at Hub pharmacies. This appears to potentially displace 12.5% to 18.25% of the Spoke Pharmacy Technician workforce at a time when the Rebalancing Programme Board is reviewing utilising this role to support innovation of pharmacy services and the clinical role of community pharmacist.
Moving Pharmacy Technicians from the Spoke to the Hub may have an adverse effect on work life balance for a number of staff, as many work, part time and in a locality by choice to suit their current family commitments.
A Hub and Spoke pharmacy in Wales, Mayberry Pharmacy, had not reduced staff at the Spoke but had instead focused on different activities that involved direct communication with patients and delivering services such as targeting non-compliant groups and smoking cessation etc
APTUK also believe that the estimated dispensing of 45% of medicines in the Hub is high. Other assumptions in publications suggest that the optimum could be 25-30%

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?

All staff should be considered, but APTUK, as the Professional Leadership Body for Pharmacy Technicians, is concerned with safeguarding the Pharmacy technician workforce as their priority, particularly at a time when this role is pivotal to future clinical pharmacy services. The impact of the Community Pharmacy 2016/17 and beyond review, currently, is that this staff group are being reduced or replaced by Dispensing Assistants as a cheaper labour option. There is already a high vacancy rate within this staff group, as training figures have reduced across the NHS in recent years. This has been highlighted to HEE on a number of occasions. APTUK feels that pharmacy technician workforce planning needs to be addressed along with vision for the future of pharmacy within the wider healthcare platform, to realise services that it aspires to deliver to an increasing population, whom the majority are elderly patients.

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?

NO: APTUK disagrees with this. There are differences depending on the type of pharmacy and the staffing numbers, the mix of the pharmacy team related to the volume and services provided. Reducing staffing numbers for any of the pharmacy team in a small pharmacy presents safety risks to both patients and the staff, who may have to work in isolation.

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
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• 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?

APTUK would be interested to see where these assumptions have been originated from as there is very limited data to suggest this.

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?

APTUK would be interested to see where these assumptions have been originated from as there is very limited data to suggest this.

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?

Other models would include Automation (although not hub and spoke) whereby robots may be the solution to increasing capacity in a single pharmacy when extra capacity is needed. Some systems claim they are cost effective for pharmacies dispensing a certain amount of prescriptions per month. There are some advantages of automation such as creating a calmer environment with a more positive working environment. Automation may result in reduced picking errors and also enable pharmacy staff to deliver more patient facing roles.
Standard hub and spoke, hub and satellite and the hub and spoke Co-operative are all to be considered. The model currently in use in the Netherlands whereby the wholesaler supplies pharmacies with patient ready packs complete with dispensing label is also a consideration although here the responsibility for the clinical and accuracy checks lies with the spoke as the hub is a supply unit and not a registered pharmacy. There are obvious issues surrounding this. We must also consider Nationalised Centralised dispensing whereby dispensing is carried out in a small number of hubs for example automated NHS units. However, this is totally untested so cost efficiencies are unidentified. As stock would perhaps be obtained through the NHS this would then potentially threaten the current contractual frameworks.

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?

This is currently unknown. APTUK would require more data in which to provide an informed reply to this question.

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?

NO, APTUK does not agree with these figures. The figures for the Pharmacy Technician salaries are higher than expected. Data that APTUK has received, from various community pharmacy technician members, gives an average of £17,5136 pa pro rata based on a 40 hour week. This is substantially lower than the figures provided in this consultation.

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 27
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?

This is currently unknown. APTUK would require more data in which to provide an informed reply to this assumption.

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?

There is no clear audited evidence to suggest reduction in stock holding currently. To maintain an acute prescription service in the Spoke, sticks levels could not be reduced significantly. Particularly as lack of availability could be detrimental to patients health and wellbeing if a new medicine was required urgently. Patient satisfaction could reduce significantly.

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?

As this is currently unknown; APTUK would require more data in which to provide an informed reply to this assumption. However, this relates to the definition of Hub and Spoke, where the assembled items are issued back to the Spoke to give to the patient. Is the scenario in assumption 12, centralised dispensing?

Please provide comments on these assumptions under question 5.

APTUK is concerned with regards to the assumptions as detailed in this document and lack of evidence as to where these assumptions have originated.

To ‘assume’ is to suppose or believe something without any proof. It also means to take over, usually responsibilities and duties, such as with a job, or to take on a look or attitude. On the contrary, to ‘presume’ is from the Latin pre "before" and sumere "to take," like taking something for granted. It means to be sure of something before it happened. When you presume, you suppose something without proof, based on probability.

APTUK is mindful of the need for evidence based data and notes the lack of this within this consultation. APTUK feel strongly that any propositions should be based on evidence, or at the very least on probability, rather than on unsubstantiated assumptions.

The document states that Hub and Spoke 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. However, cost advantages may be open to abuse by increasing the scale of assembly and preparation which makes automation more viable. By this, larger hub pharmacies would be able to increase efficiency and lower operating costs significantly. This will impact smaller businesses.

This could also have an adverse impact on the Pharmacy Technician workforce and unforeseen consequences highlighted must be considered and addressed.