Community Pharmacy Wales response to the Department of Health Consultation

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

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Part 1: Introduction

Community Pharmacy Wales (CPW) represents community pharmacy on NHS matters and seeks to ensure that the best possible services, provided by pharmacy contractors in Wales, are available through NHS Wales. It is the body recognised by the Welsh Assembly Government in accordance with *Sections 83 and 85 National Health Service (Wales) Act 2006* as 'representative of persons providing pharmaceutical services'.

Community Pharmacy Wales is the only organisation that represents every community pharmacy in Wales. It works with Government and its agencies, such as local Health Boards, to protect and develop high quality community pharmacy based NHS services and to shape the community pharmacy contract and its associated regulations, in order to achieve the highest standards of public health and the best possible patient outcomes. CPW represents all 716 community pharmacies in Wales. Pharmacies are located in high streets, town centres and villages across Wales as well as in the major metropolitan centres and edge of town retail parks.

In addition to the dispensing of prescriptions, Welsh community pharmacies provide a broad range of patient services on behalf of NHS Wales. These face to face NHS Wales services, available from qualified pharmacists 6 and sometimes 7 days a week, include, Medicine Use Reviews, Emergency Contraception, Discharge Medicines Reviews, Smoking Cessation, Influenza Vaccination, Palliative Care Medicines Supply, Emergency Supply, Substance Misuse and Common Ailments services.

CPW is pleased to have the opportunity to respond to this important consultation as any changes to the Human Medicines Regulations 2012 will govern the practice of pharmacy in Wales and have a direct impact on the community pharmacy network.

Our response to this consultation has been constructed from the perspective of a statutory representative body. The Board of CPW is made up of directly elected representatives of the contractor network in Wales and the views of the board members have informed subsequently informed the CPW response.

CPW is particularly sensitive to the fact that; the recommended changes to facilitate the introduction of inter-pharmacy 'hub and spoke' dispensing arrangements are primarily driven by imminent changes to the pharmacy remuneration model in England. However, as this change could facilitate the establishment of 'superhubs', which would operate across national borders, CPW is concerned that there is the real potential, albeit as an unintended consequence of changes to regulation, to significantly distort the pharmacy market in Wales.

In addition, if these superhubs or 'Amazon type' arrangements are not sited in Wales, an amendment of this nature has the potential to result in the net export of highly skilled jobs from Wales, which, we are sure, will be of particular concern for the incoming Welsh Government.

In addition the Welsh Government has resisted the establishment of internet or Distance Selling Pharmacies (DSPs) in Wales and its current strategy for community pharmacy is built on a 'bricks and mortar' pharmacy model so that the essential link between dispensing and face to face pharmaceutical care is maintained. CPW feel that it is imperative that any changes to regulation do not inadvertently result in 'loop holes' that could be exploited to change these arrangements or to open up the market to centralised dispensing or direct to patient schemes.

While England appears to be pursuing a financially driven agenda, Wales is looking to more effectively use its community pharmacy network to deliver improved care at the heart of the communities they serve. To support this agenda, contractors require a period in which to focus on the Welsh Government driven roll out of the Choose Pharmacy IT Platform and the accompanying suite of services, and the uncertainty created by, what appears to be, a poorly researched proposals, is both unwelcome and unhelpful.

CPW would ask that the Department of Health fully considers the potential impact on the market in Wales of any changes to Regulations.

Part 2: response to specific elements of the consultation

General Observations

CPW is concerned that, for a consultation as important as this one, that the consultation period is unreasonably short and we would have expected, as a minimum, the courtesy of a 12 week consultation period especially given the fact that the consultation period covers two bank holiday periods. As this consultation covers devolved administrations outside England, it would be appropriate for the usual practices of our countries and governments to be matched and that would have involved a longer period for meaningful consultation and iteration.

CPW also feels that the Impact Assessment is not of an acceptable quality and does not consider the impact of changes on the devolved countries. If the Department of Health is taking this consultation forward on behalf of all of the UK countries then it has a responsibility to ensure that any impact assessment is an across the UK assessment.

From the viewpoint of our board members, the impact assessment is based on a number of assumptions that they feel are inadequate and in many instances, not backed up by quality research or evidence. In addition it is unclear from the consultation document to what extent patient views have been sought and CPW would have wished to see a higher level of patient consultation.

The proposed changes to regulation could be far reaching and have a profound impact on the pharmacy market and CPW feel that, in these circumstances, it is extremely concerning that DH are willing to make decisions without adequate assessment of the consequences.

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

YES: CPW feel that on balance it is appropriate to ensure that independent pharmacies that may wish to put in place hub and spoke dispensing arrangements are not prevented from doing so and have the opportunity to operate on a 'level playing-field' basis.

That said; we are not aware of any appetite for this arrangement amongst independent pharmacies in Wales, who generally feel that the efficiency and financial benefits alluded to in the consultation are simply not realisable in practice. While CPW is supportive of taking the minimum steps necessary to facilitate a level playing field, the draft Regulations appear to propose sweeping changes to the section 10 of the Medicines Act 1968, wholesaler dealing exemptions and other changes which are over above what is necessary to achieve this aim.

Of significant concern to independent pharmacies in Wales is that allowing hub and spoke arrangements between different legal entities could, as an unintended consequence, open the market to the development of superhubs which have the potential to significantly distort the market as it currently operates. CPW would ask that; any changes to regulation that facilitates the operation of hub and spoke arrangements between independent pharmacies, is framed in such a way as to preclude the establishment of superhubs until a full impact assessment on the establishment of larger scale operations is carried out. CPW would expect any full impact assessment to include continuity of such models and their ability to ensure the uninterrupted, safe and efficient dispensing of medicines to the Welsh population, that the current arrangements deliver. In addition CPW would wish to see a full economic impact assessment carried out on effect of the establishment of a superhub in one country creating significant cross border flow of prescriptions. This impact assessment would need to include the effect on pharmacy funding and jobs in the sector. While the establishment of Superhubs may be an option for England, the Welsh Government sees a much more local pharmacy service ongoing and in the future, and Superhubs would not fit into this structure. Therefore any changes

made to Regulations need to carefully consider cross-border implications. It is not clear, from the consultation document, that these implications have been thought through and we would not want to see a change, designed for England, affecting the future of community pharmacy in Wales.

CPW is also concerned that the concentration of buying power into superhubs will affect the price of medicines in the market. CPW is concerned that there is a likelihood that high discount rates earned by superhubs could result in lower discount rates being available to standard dispensing pharmacies. As a statutory organisation with responsibility for the operation of the Community Pharmacy Contractual Framework as it applies to contractors in Wales, we are concerned that this very likely scenario has not been properly considered and could impact on pharmacy remuneration. At a UK level this could similarly have an influence on future PPRS agreements and at a devolved country level affect PPRS rebates which are currently based on dispensing data.

CPW would also expect any changes to Regulations to be clear about where the generation of a prescription charge occurs as we would not wish to see Welsh patients deprived of 'free prescription' arrangements because the prescription is 'dispensed' in a hub outside of Wales.

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: CPW would wish to see consideration of patient care, including the needs and accessibility requirements of patients, to be given prime importance in the development of supply models. We would want this override other factors, such as financial benefits, which are as yet unproven.

For this reason CPW believe that the Regulations should make it clear that the relationship with the patient remains at the spoke**.** Failure to do this could open up the market to 'direct to patient' supply. Direct to patient supply is not in the interests of our contractor network in Wales, or to the patients we care for, as Welsh Government investment in Choose Pharmacy services is predicated on face to face consultation with patients.

We also feel that is important that the terminology is clearly defined. Our understanding is that:-

- Hub and spoke dispensing occurs where a spoke pharmacy sends the prescription to a hub where it is assembled. The assembled medicines are then returned to the spoke for onward distribution to the patient.
- Centralised Dispensing has been defined as where prescriptions are dispensed at a central location and are sent either directly to the patient or to a remote collection point which may or may not be a pharmacy.

We believe that this second element, centralised dispensing, is very similar to the Distance Selling Pharmacy (DSP) situation and see no reason why centralised dispensing would be included in any consideration of hub-and-spoke arrangements. If any of the individual Health Departments or other organisations wishes to facilitate this form of arrangement then they should do so under the existing arrangements for DSPs.

CPW feels, most strongly, that if the intention of any legislative change is to introduce a level playing field, as alluded to in question 1, then centralised dispensing should not be allowed to slip in under the radar. CPW is concerned that should centralised dispensing be inadvertently facilitated, there is a real danger that commercial relationships develop between GPs and organisations providing centralised dispensing and prescription direction becomes widespread resulting in a curtailment of patient choice.

CPW is pleased to note that in recent communications, the Department of Health has signalled that Community Pharmacy has a bright clinical future ahead of it and it is keen to deliver more clinical services from the network. This desire is mirrored here in Wales and is founded on the relationships which develop between a pharmacy team and their patients. It is therefore essential that the Regulations are clear that the contact between the patient and the pharmacy network occurs at the spoke, if services based around face to face conversations with patients are to be protected. CPW are concerned at the possibility that the delivery of transformational Choose Pharmacy NHS Services, underpinned by the Welsh Government funded IT platform, which is already underway, could be put at risk. We hope that Welsh Government and The Department of Health can reassure us that this will not be the case.

There has been some discussion regarding click and collect and remote collection points and their value in the medicines supply chain. We believe that these may be useful additions but it should be for the owner/ Superintendent to determine whether the appropriate security and regulatory framework exists for these facilities to be used and it should be for the pharmacist in the spoke in discussion with the patient to determine whether it is appropriate for that patient to make use of these facilities. Although 'click and collect' may be an innovative development in relation to retail supply, the philosophy is not necessarily transferrable to the supply of medicines and would be a significant backward step for patient care. Many pharmacies do not just aid patients in ordering their medicines (click) and rather than just asking patients to pick up their medicines from a central location (collect) they deliver their prescriptions directly to the patient's home. Unlike many retail customers, community pharmacy patients are often the most vulnerable in society and the least mobile, and will require a much better service than click and collect. Personal help in the ordering of prescriptions and free delivery to a patient's home is already provided by many community pharmacies (at no cost to the NHS).

CPW is concerned that given the rural location of many pharmacies allowing the development of larger superhub arrangements will reduce significantly the resilience of the supply chain particularly in periods of inclement weather. As spoke pharmacies will inevitably reduce stock levels following the establishment of hub and spoke dispensing arrangements, medicine supply from spoke pharmacies in remote locations cannot be guaranteed during these periods. In addition it is important that the Department of Health consider how the proposed changes to the supply chain could impact those pharmacies deemed to be essential and covered by the Essential Small Pharmacies Scheme in Wales, as continued involvement on the scheme is dependent on the achievement of minimum dispensing thresholds.

In addition CPW is most concerned about the environmental impact of long supply chain arrangements. The environmental impact of these changes again seems to have been downplayed in the impact assessment.

Overall there are clearly a number of areas which need considerably more thought, research and planning. There is a real danger that the DH has not properly considered the potential unintended consequences should these proposals go ahead and the very realistic risks to patient safety that could arise from a lack of due diligence.

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

Yes: CPW feel that the entire end to end dispensing process should take place in General Pharmaceutical Council (GPhC) registered premises. The primary role of the GPhC as a regulator is to protect patient safety. It does so through published standards and informed inspection. CPW therefore feel that hubs should be GPhC registered pharmacies and subject to the same GPhC standards and inspection regime as other pharmacy premises. It is totally inequitable for the dispensing of a medicine in a pharmacy to be subject to regulatory check and the same process in a hub to be subject to some other form of monitoring.

In addition the defence being proposed as part of the rebalancing changes to avoid prosecution for a simple dispensing error encompasses the following requirement:-

The medicine must have been dispensed at or from registered premises, i.e. premises entered in the premises register of the relevant pharmacy regulator (GPhC or PSNI). CPW is extremely concerned that the Draft Regulations refer to 'relevant clinical settings' and not registered premises. Allowing a hub to operate from a 'relevant clinical setting', as opposed to a 'registered' premise, would bring other facilities such as GP practices and hospital pharmacies into scope and it is important that this drafting anomaly is addressed.

If the hub is not a registered premise then all of the hard work undertaken to put this defence in place is in risk of being undone.

CPW notes that the question refers to whether the hub should be a registered pharmacy and appears to overlook the status of the spoke. CPW would wish to see it stated that spokes should also be registered premises otherwise the market could be opened up to direct to patient and other inappropriate models.

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

Yes: CPW feel that the hubs and spokes should be inspected as a single entity so that the entire dispensing chain from end-to-end is monitored and potential safety issues are exposed and addressed. As inter-pharmacy hub and spoke arrangements are complex, and data exchange is integral to the operation, there will be a need to ensure that the current inspectors have the skills to inspect arrangements of this nature.

As hub and spoke arrangements are different to standard dispensing arrangements and may, or may not, involve robotic picking, CPW believe that the regulator would need to issue a specific set of standards for hub and spoke dispensing so that informed regulation can take place.

CPW believe that the complexity of hub and spoke dispensing will require a clear definition of accountability and responsibility for all aspects of the dispensing supply chain and the patient safety elements within it. Any changes to the supervision arrangements being looked at by DH will need to be mindful of this type of arrangement, as a number of pharmacists and registered technicians are likely to be involved in the supply of any medicine under these circumstances. When errors occur, as they obviously will, liability needs to be clearly defined especially when the hub may have different liability arrangements in place to the spoke.

As some prescriptions, received from the hub, may require the addition of a fridge line or other medicine before handing to a patient, liability issues have the potential to become more complex and, if accountability and responsibility are not clearly defined, this could result in legal disputes between liability providers while the patient, who may have suffered harm, is left to await the outcome.

In addition to the need for clarity as to whom in the dispensing supply chain holds the responsibility for what element, the water becomes muddier at a higher level where there may well be a different Pharmacy Superintendents for the hub and the spoke. For example: who in these circumstances is responsible for the quality of the premises from which the medicine was supplied and who is responsible for the appropriateness of the standard

operating procedure. CPW would also recommend that unrestricted wholesaler dealing between different legal entities should not be permitted as part of hub and spoke dispensing arrangements.

Any arrangements established will also need to cover repeat dispensing processes using batch prescriptions and the planned future operation of electronic authentication checks at the point of dispensing that will arise as a result of the requirements of the European Falsified Medicines Directive.

It is clear that hub and spoke dispensing has the potential to introduce significant additional complexity into medicines supply arrangements. As there is no room for any 'lack of clarity' where the supply of medicines is concerned, given the patient safety implications, CPW remains to be convinced that the ends justify the means.

When a patient brings in a prescription to a pharmacy there is an understanding that the patient has provided consent (implied/informed consent) for the prescription to be dispensed in the pharmacy and the necessary records of the dispending made. It is important to clarify that this remains the case if the medication is dispensed off site in a location that the patient will most likely not be aware of, to a pharmacy owned and operated by a separate legal entity to the pharmacy they presented their prescription at.

In light of the work on rebalancing, we are concerned that the proposed statutory defence for dispensing errors may not be applicable in the hub and spoke arrangements and request that further consideration is given to this. The proposed defence applies if:-

- The sale or supply is of a medicine dispensed by a registrant, i.e. a registered pharmacist or registered pharmacy technician, or by someone acting under their supervision (but see paragraphs 46 and 47 concerning "supervision");
- The registrant was acting in the course of their profession;
- The medicine must have been dispensed at or from registered premises, i.e. premises entered in the premises register of the relevant pharmacy regulator (GPhC or PSNI);
- The sale or supply must have been in pursuance of a prescription or directions; and
- If the error is discovered before the defendant is charged, there was prompt notification of the error.

While the consultation signals and intention to work with regulators in developing guidance, we would have expected the two consultations to run in parallel given the importance of ensuring that the two pieces of work dovetail together. CPW feel most strongly that there is a responsibility on the Department of Health, acting on behalf of the devolved countries, to fully

address the issues raised above, before any changes to the Regulations are enacted.

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: CPW fully recognise that there are many unknown elements around the establishment of inter-company hub and spoke arrangements, however as already stated, we do not believe that the impact assessment is sufficiently robust and could well have been the victim of compacted time scales.

There are aspects of the impact assessment that we have particular concerns about and feel have not received due consideration.

- The majority of pharmacies operate with a single pharmacist. As a pharmacy must be under the control of a pharmacist, the cost of the pharmacist is essentially a fixed cost. Given that community pharmacists, and their teams, will play an increasing role in the delivery of frontline care and services to the people of Wales, to divert activity away from more costly GP and A&E services, we do not see that the savings, identified in the impact assessment, can be realised.

- We accept that there could some limited savings in dispensing staff in the spoke, although, given that minimum staffing levels are governed by current contractual arrangements, any savings will not be as high as has been estimated. As dispensing operations will continue in the spoke, albeit to a lesser extent, a number of dispensary operations such as cleaning, date checking, record keeping, medicines recalls, waste management etc. together with delivery of Essential Services such as disposal of unwanted medicines, promotion of healthy lifestyles, signposting and support for self care, will still need to be carried out as these are not volume dependent activities. As the supply of medicines for self care will not be affected by any proposed savings there will be no savings from other staff members.

- As the operation of hub and spoke dispensing is significantly more complex, it will require significant investment in IT systems, at both the hub and the spoke, which will negate many of the estimated savings elsewhere in the process.

- As we have explained, increased complexity comes hand in hand with increased risk. As a result it is likely that the cost of liability cover will increase for the combined operation and this has not been built into the impact assessment.

- The clearest and most obvious omission from the impact assessment is fuel and transport costs. As medicines will need to be delivered to the spoke and medicines supplied in error returned to the hub, the cost of transport, including driver time, between the hub and the spoke is entirely an additional cost which will be borne by the supply system as a whole. As some of the spokes will be in remote locations these costs could well be significant. In addition the environmental impact of this has similarly not been captured. In practice CPW would expect to see the same degree of 'cherry picking', as occurs in the delivery of mail, where commercially operated hubs choose not to deliver to remote locations and the end result is anything but a level playing field.

- Following soundings with our elected members we believe that the appetite for inter-company hub and spoke dispensing has been significantly over-estimated. The owners of many smaller independent businesses will be reluctant to hand over control of their dispensing process to others and to place themselves and their patients at risk of transport or system breakdowns.

- We have also been advised that unless there is a commitment at national level to move to original pack dispensing, we will be left with considerable built in inefficiencies that would result in the estimated savings being unrealisable.

- It appears that there is an assumption in the impact assessment that all hubs will be automated and this is clearly not the case. We are aware of companies that operate hubs without automated systems and we are similarly aware of many pharmacies that have introduced automated processes for standard dispensing. It is therefore a rather simplistic assumption that there are savings associated with the introduction of automation across the board.

- We are concerned that the salary costs used in the impact assessment are understated as they do not reflect the market rates paid by pharmacy owners and somewhat surprisingly do not appear to contain the usual employment on-costs associated with employment such as NI or pension contributions. The impact of the recently introduced National Living Wage should similarly be factored into the analysis.

- We concur that there is an opportunity to reduce stock-holding in the spokes, however this will be offset to a significant extent by increased stock holding at the hub. In addition we believe that as the spokes will seek to maintain a full breadth of stock it will only be the stockholding of the highest turnover lines, many of which are lower value generic medicines, where stock levels will be able to be decreased.

- We most strongly believe that direct supply to a patient from a hub is inappropriate – see our response to question 2.

- The impact assessment does not cover the social or economic impact on jobs in one country being lost to another. Similarly the impact assessment does not look at impact on Welsh Government policies on high street regeneration and support of businesses in predominately Welsh speaking areas.

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: As hubs will be isolated from many of the pressures that are felt in community pharmacies there are likely to be fewer distractions and interruptions to the dispensing process. In standard dispensing operations many of these 'interruptions' to the dispensing process convert to face to face interactions with patients enabling the delivery of essential services, providing help to solve patient problems and signposting to health and social care support. Many issues addressed in this manner are not directly related to the dispensing process. We do not have any evidence of the impact of this and we have no direct evidence that hub and spoke operations contribute any cost savings to the dispensing operation as a whole. Taking into account the high set up costs and the additional investment in IT, which itself has new annual costs attached, it is likely that there will be additional costs rather than savings in the short to medium term and any savings will only be realisable in the longer term.

Board members, that have experience of hub and spoke operations, have confirmed that they do not in themselves generate efficiency savings. Where they do add value to the business is in providing some 'head-room' for the pharmacists in the spoke to undertake clinical services. However, as the commissioning of enhanced services in Wales varies from LHB to LHB and also often within LHB areas, it is not appropriate to assign a particular value to this or to build this into the impact assessment to any significant extent. The converse is in reality may well be the case, where the release of pharmacist time in the spoke becomes an additional cost to the business if this time cannot be used to provide additional NHS services.

On balance we do not agree that the use of a hub, at this stage, represents any cost saving and may, in fact, increase costs. Furthermore, any efficiency gain will invariably come at the expense of staff numbers at a time when GP practices are struggling with capacity issues. CPW feel that if any capacity is released in the spokes then this additional capacity should be used to move workload from GP practices to pharmacies in accord with the strategy of Choose Pharmacy in Wales.

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: CPW would ask that the Department of Health, working on behalf of the devolved administrations, first recognise the extremely low level of dispensing errors that occur in the current model and that any changes to error rates will therefore be very marginal.

CPW recognise that the introduction of automation, especially when combined with bar code medicine authentication, has the potential to reduce picking errors. Any pharmacy introducing both of these elements is likely to reduce its picking error rate. CPW is however of the opinion that considerably more research needs to be carried out in this area to gather robust evidence. The only safety gain we can see, as the result of moving to hub and spoke dispensing, is as a result of fewer interruptions to the dispensing process.

We again, raise the issue of system resilience and business continuity as a key risk with the widespread adoption of hub and spoke and the impact that these factors may have on patient safety.

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: We accept that it is appropriate to make changes to regulation to allow additional information to be displayed on dispensed medicines, if that is the will of the individual health department. CPW have concerns around this proposed policy and its ability to be implemented and seek reassurance that any move to add additional information to medicine labels is subjected to the rigour of a full and separate consultation process.

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: We are not aware of the outcomes of any research into this issue; however we understand that some research is being conducted by Cardiff School of Pharmacy in partnership with the National Pharmacy Association.

We would be concerned that some patients may choose not to take their medicines if they feel that the price of the medicine is too high to be borne by a financially constrained NHS and that this could in itself pass higher costs down the line. We also believe it is wrong to assume that just because the price is on the label the patient will remember to take the medicine; as any impact is likely

to be realised at the first dispensing only after which the price could well simply becomes 'background noise'.

We would also be concerned that reducing font size to squeeze additional wording on to the dispensing label could lead to patients not reading their dosage instructions correctly with the result that they may take their medication incorrectly. Any changes to font size would also have significant impact on the visually impaired patient.

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

NO: As the question refers to proposed implementation in NHS England it would not be appropriate for an organisation whose remit covers pharmacies in Wales to respond to this question.

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

YES: CPW feel that the proposed changes are to be welcomed and are supportive in nature. We would suggest that, despite the examples given in the consultation document, there is a need to clarify further the type of MDS. Any Regulations supporting this change will also need to anticipate likely changes to the nature of MDS such as direct printing on to the blister.

We would also suggest that changes take account of working practices so that facilitative regulation does not become restrictive in nature. For example, in the case of MDS, consideration should be given to the date of supply. It is established practice across the sector that once the dispensing label is created it may be a number of days before the medicines are dispensed into the MDS which may be a number of days before the medicines are then supplied to the patient. As a consequence, the strict date of sale or supply may be different to that which appears on the dispensing label.

In relation to PGDs, it is important to recognise that not all medicines are taken away with the patient e.g. the administration of a vaccine under PGD. It would therefore be a waste of scarce resources to have pharmacy teams label a vaccine so that it can be almost immediately placed in the waste bin. CPW would therefore be supportive of the labelling of a medicine provided under a PGD, only if the medicine is given to the patient to take away from the pharmacy.

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

NO: Given that the proposal is enabling in nature, apart from the issue raised above, CPW do not envisage contractors having any operational difficulties with this change, other than any software development which may be needed.

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?

NO: CPW are supportive of the proposal.

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: Some pharmacies create MDS pre-packs for other pharmacies (although this is usually within the same legal entity). We therefore believe that the changes to the Regulations should not prevent this efficient practice from occurring.

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: We agree that the use of Chemist's Nostrums is rare. The only situation which may fall into this category that we are aware of is the preparation of methadone liquid from methadone powder and green syrup. However this is obviously for supply against a prescription and may not be applicable.

Overall the current exemptions in section 10 of the Medicines Act 1968, including Chemist's Nostrums, serves patients and are a valuable discretion for pharmacy. They remain in use by some pharmacies and CPW is not aware of any difficulties with them.

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

NO: We have no other comments

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: As there are a greater proportion of female workers in the community pharmacy sector, CPW agrees with the equality assessment that female technicians will be affected disproportionally. In addition reductions in pharmacist hours are similarly likely to affect female pharmacists disproportionately.

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

NO: We have no comment to make on the amendments.

Part 3: Conclusion

CPW recognise that the proposed amendments to the Human Medicines Regulations are primarily being driven by a change agenda in NHS England, and, while we would not wish to interfere with this agenda, we are keen to ensure that there is nothing in the proposed amendments that would interfere with, or restrict the strategic development of, the community pharmacy network in Wales. Where we feel there are concerns these have been covered in our response.

While we feel it is appropriate to provide for a level playing field for independent pharmacies that may wish to enter into hub and spoke dispensing arrangements, we are not aware of any appetite to do so. Wile CPW is supportive of taking the minimum steps necessary to achieve this; many of the proposals set out in the consultation go beyond this objective.

CPW's main concern, that we would ask the Department to take on board, is that, as an unintended consequence of changes to regulation, the path will be open to the establishment of 'superhub' type arrangements by organisations such as wholesalers, NHS Trusts or 'Amazon like' companies. The establishment of superhubs on one side of the border has the potential to significantly affect the community pharmacy market on the other side and CPW feel that the Department has a responsibility to ensure that their proposed changes to the Regulations do not result in a migration of community pharmacy remuneration and/or skilled jobs across the Wales-England border. It is clear to CPW that insufficient thought has been given to the potential impact of these proposals on devolved countries and to the differing pharmacy structures and strategies in each nation.

CPW are fully supportive of the Welsh Government's desire to develop the community pharmacy network in Wales to deliver a key set of NHS Services outside of hospitals. The delivery of these services will require significant behavioural change, for pharmacies and patients, and we would not want to see this England driven development resulting in any barriers to delivery.

CPW agree that the content of this response can be made public. A copy of this consultation response will be sent separately to the Chief Pharmaceutical Officer in Wales

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CPW welcomes communication in either English or Welsh.

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