Pharmacists' Defence Association Response to the Department of Health and Social Care's Consultation on the Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018 and the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

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About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for-profit organisation which aims to act upon and support the needs of individual pharmacists and, when necessary, defend their reputation. It currently has more than 28,000 members. The PDA Union was inaugurated in May 2008 and achieved independent certification in 2011.

The PDA is the largest pharmacist membership organisation and the PDA Union is the only independent Trade Union exclusively for Pharmacists, in the UK.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Arrange insurance cover for individual pharmacists to safeguard and defend their reputation.

Summary of the Department of Health and Social Care's (DHSC's) proposals

The DHSC is consulting from 19 June 2018 until 11 September 2018 on changes to the way registered pharmacies operate. Examples include permitting the GPhC and PSNI to bring about:

- Remote pharmacist responsibility for pharmacies (leading to remote supervision)
- Pharmacists being the Responsible Pharmacist for more than one pharmacy
- Making pharmacists responsible for following SOPs set by a superintendent, removing their power to write, set and maintain SOPs themselves

At the same time, the DHSC is consulting on extending the legal defences to prosecutions for inadvertent dispensing errors under section 63 or 64 of the Medicines Act 1968, to hospital pharmacists and pharmacists working in other areas of practice such as in care homes.

The PDA's recommendations are:

- Standard setting should be driven by professional leadership bodies, in pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland. If there is a role for professions in developing their own practice, and a role for professional leadership bodies in representing the collective ambitions of the profession, this cannot and should not be led by the regulator, whose job it is to regulate and enforce standards. This should be recognized by the Department of Health and Social Care when it decides on the future of regulation.

- The rebalancing board's approach should be changed to make it representative of the pharmacy profession, by ensuring organizations such as the PDA (the largest pharmacist membership organization in the UK), and the NPA – the independent contractors organization - are represented on the board. The approach should become an inclusive one which engages the wider profession in debate and involves it in developing reasonable proposals for its future and for the safety of the public.

- The rebalancing board ought to seek the introduction of guidance for state prosecutors, prompting local police forces to work to a programme where any offences related to inadvertent dispensing errors where gross negligence manslaughter has been excluded are referred to the regulator and are not subjected to criminal prosecution. At the same time, the board should conduct a broader review of medicines legislation

with a view to removing the threat of criminal sanction for inadvertent dispensing errors as far as possible as per the DHSC policy objective. It is fully understood that the prospect of gross negligence manslaughter prosecutions, and prosecution for crimes against the person (e.g. where harm occurs) cannot be removed.

- The threat of criminal sanctions under medicines laws for inadvertent dispensing errors made anywhere as part of a hospital pharmacy service should be removed.

- The threat of criminal sanctions under medicines laws for inadvertent dispensing errors, in so far as it relates to other relevant pharmacy services (e.g. those provided in prisons), should be removed.

- A Chief Pharmacist should be appointed to oversee all relevant pharmacy services; this requirement should be set out in legislation independently of the legislative changes proposed in this consultation in relation to inadvertent dispensing errors. Defences against criminal sanctions for inadvertent dispensing errors would then not need to specify that a Chief Pharmacist must be appointed in order for pharmacists to be able to use them (and nor should they; the appointment of a Chief Pharmacist or otherwise is a matter beyond the control of pharmacists who may need to be able to use them).

- Standard setting for Chief Pharmacists should be driven by the professional leadership bodies, in pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland. An advisory body should be established to scrutinize and evaluate the standards proposed before they are sent for approval by the regulator. This should comprise senior officials from the regulator and the professional leadership body. The role of the regulator should be to enforce the standards.

- The Department of Health should consider imposing restrictions on when a pharmacist can act as both the prescriber and supplier of a medicine in circumstances where there would be a vested financial interest in both, or where a business can profit from both activities. However, where it is appropriate or necessary for a pharmacist to both prescribe and dispense, the threat to those pharmacists of criminal sanctions under medicines laws for inadvertent dispensing errors should be removed.

- The threat of criminal sanctions under medicines laws for inadvertent dispensing errors made by pharmacists selling or supplying a medicine under a PGD should be removed. This must include amending the Human Medicines Regulations 2012 where necessary.

- The Department of Health and Social Care should commission a credible independent expert cost-benefit

analysis of its proposals. Error reporting is unlikely to increase as a result of the new Medicines Act defences (due to the uncertainty pharmacists will have as to whether the defences will apply) and indemnity insurance premiums are unlikely to be reduced by their implementation; more likely, they will increase. This is because the legal defence may take longer to manage and the associated costs are likely to increase if the proposals are implemented, due to the complexity of the new Medicines Act defences.

- A Superintendent Pharmacist's authority must not impair the Responsible Pharmacist's professional autonomy or his/her freedom to exercise professional judgement.

- A Superintendent Pharmacist must have sufficient authority within the business to ensure his/her views about how the business is run are adopted, so far as the concerns relate to the retail sale and supply of medicinal products and without impinging on the professional autonomy of the Responsible Pharmacist.

- The Superintendent Pharmacist should be a member of the board for all body corporates operating registered pharmacies. This is a patient safety measure which could help ensure the care and protection of patients and the public is taken in to account and given proper consideration by the board. The name of the most senior person accountable for the provision of pharmacy services must be clear and easily accessible to the public. Whether or not the company has "chemist" in its title is inconsequential to the level of protection that should be provided to the public.

- Superintendent Pharmacists (SPs) should able to be the SP for more than one business at any given time, provided that:
    - Provisions are put in place to ensure that SPs can effectively exercise the proposed duty to secure the safe and effective running of the retail pharmacy business(es) for which they are the SP
    - Limits are placed on the number of companies for which a pharmacist can act as the SP
    - Limits are placed on the number of pharmacies an SP can oversee where he/she is the SP for more than one business
    - There's a requirement for the SP to sit on the board of directors of each business
    - Provisions are put in place to manage conflicts of interest and vested interests, given that the SP will be in a position to influence the finances of more than one company.
    - The above matters are consulted upon separately to this consultation

- A discussion should be held within the profession, instigated by the professional leadership body, in

pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland to establish the minimum requirements for appointment as a Superintendent Pharmacist such as a minimum number of years qualified and the completion of a mandatory qualification. This could help instil quality in to the role, improve public protection and avoid situations where inexperienced pharmacists work as superintendents. A discussion should also be held within the profession to establish the maximum number of pharmacy businesses that one pharmacist could safely and properly be the superintendent for. A cap should then be agreed and enforced by the regulator.

- Standard setting for Superintendent Pharmacists and describing the role should be driven by the professional leadership body, in pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland. An advisory body should be established to scrutinize and evaluate the standards proposed before they are sent for approval by the regulator. This should comprise senior officials from the regulator and the professional leadership body. The role of the regulator should be to enforce the standards.

- The statutory duty of the Responsible Pharmacist (RP) should be engaged only for the time when the RP is actually designated the RP role for that pharmacy, is in charge and physically present in the pharmacy.

- Ministers should continue to set out Responsible Pharmacists' (RPs') statutory duties in legislation, such that the definition and duties of the RP role remain constant and are not subject to changes at the whim of a regulator; the role of the regulator is to regulate, rather than define the RP role and responsibilities in statute. Retaining ministerial control over the statutory responsibilities of the RP would help afford the appropriate public protections and help ensure any potential future changes to the role or its duties are subject to the appropriate public and parliamentary scrutiny. Ensuring that ministers continue to set statutory responsibilities for the RP would also help ensure common statutory responsibilities applied to both Great Britain and Northern Ireland; since there are two pharmacy regulators – the GPhC and the PSNI – the statutory responsibilities could diverge if pharmacy regulators are given this power.

- Section 72A of the Medicines Act should not be amended to allow either the GPhC or the PSNI to make exceptions to the general rule that a Responsible Pharmacist (RP) can only be in charge of one pharmacy at one time. Nor should it be amended to allow either the GPhC or the PSNI to make provisions about the RP's absence from the premises.

- The power to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time should be removed from legislation, since it is unnecessary and has not been used

thus far, but should not be given to pharmacy regulators. Should it become appropriate at some point in the future to reintroduce the ability for ministers to make such exceptions, the current provision must be accompanied by additional provisions to ensure the public is protected. In that event, the power to make exceptions should be given to ministers, but Section 72A (2) of the Medicines Act 1968 should be amended to strengthen the current provision such that ministers can only make provisions about RPs being responsible for more than one pharmacy provided that patient safety is not in any way compromised and is maintained at all times.

- The proposed provision in the draft legislation "In making any such provision, the General Pharmaceutical Council and the Council of the Pharmaceutical Society of Northern Ireland must have regard to the principle that the burdens imposed on businesses by rules or regulations should be the minimum necessary to secure the benefits, considered in general terms, which are expected to result from the rules or regulations" is inappropriate and must be removed. It is not appropriate for healthcare regulators to have to consider the interests of businesses in such a way, either as proposed or alongside other provisions, in their duties protecting patients and the public.

- The proposal to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time is not justified by the Department of Health and Social Care's reasoning that it would 'enable such developments as pharmacist controlled dispensing machines'. The meaning of 'pharmacist controlled dispensing machines' is unclear and the law already provides for this in some forms, and to that extent the change is unnecessary. A pharmacist should be present on the premises with such machines for various reasons – for example if it goes wrong, it may present a high risk to the safety of many patients and require a pharmacist's professional intervention on site to resolve the issues. In any case it could be argued that such 'dispensing machines' were not "pharmacist-controlled" if they were on different premises to the pharmacist. If the DHSC wishes to propose a clear, specific reason for the exception to the general rule, it should set out that exemption clearly and consult upon it with a view to setting out the exception in legislation.

- Establishing, maintaining and keeping procedures under review must be a shared, dual responsibility between Superintendent Pharmacists (SPs) and Responsible Pharmacists (RPs); a compact between the two. The SP must ensure that procedures are in place before the pharmacy opens, having agreed these with an RP in each pharmacy - who will be aware of the local situation day-to-day and able to ensure the procedures protect patient safety and work in patients' best interests.

- If Responsible Pharmacists are to have the responsibility to secure the safe and effective running of the individual registered pharmacy whilst the SP has the responsibility to secure the safe and effective running of the business, to maintain patient safety there must be requirements placed on SPs to:

    - Create, and be able to prove they have created, conditions which allow the RP and other pharmacy staff to follow those SOPs, including the provision of sufficient suitably qualified and trained staff
    - Deal appropriately with any concerns raised by the Responsible Pharmacist about the SOPs, such that the SOPs are amended to address those concerns

- If Responsible Pharmacists are to have the responsibility to secure the safe and effective running of the individual registered pharmacy whilst the SP has the responsibility to secure the safe and effective running of the business, to maintain patient safety and enable RPs to act in the best interests of patients, RPs must be able to amend the SOPs which are in place, or create additional ones, in order to meet the local and situational needs of that pharmacy.

- The requirement to keep and maintain records of Responsible Pharmacists should be preserved, but should be removed from legislation so that it is not a criminal offence, for example, to inadvertently make an inaccurate record. It should be a legal requirement for regulators to set out standards for record keeping.

- The wording of the question is poor. It could be taken to be asking whether the regulators should be given regulation-making powers about the Responsible Pharmacist and supervision. However, the issue of supervision has not been discussed in the consultation and the question is unclear, so it is essential that the Department of Health and Social Care does not take the responses to this question as providing any indication of respondents' views in that regard. That part of the question must be taken to pertain to the removal of the ministerial powers in section 72A (6) and (7) of the Medicines Act 1968, as explained and proposed in the consultation document.

- For the avoidance of doubt, the PDA opposes any UK pharmacy regulator being given any regulation-making powers about the supervision of pharmacies, the sale or supply of medicines including in relation to transactions, or the supervision of activities for which a pharmacist is not the RP. The PDA opposes remote supervision.

- Standard setting for Responsible Pharmacists and describing the role should be driven by the professional leadership body, in pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland. An advisory body should be established to scrutinize and evaluate the standards proposed before they are sent for approval by the regulator. This should comprise senior officials from the regulator and the professional leadership body. The role of the regulator should be to enforce the standards.

- The Department of Health and Social Care should factor in increased employment costs in to its proposals. We are opposed to the proposals as set out in our response to other questions, but if implemented, employment costs are likely to increase for various reasons, such as:
    - If the Responsible Pharmacist becomes responsible for services provided 'from' a registered pharmacy (as opposed to just 'at' a registered pharmacy as at present), the RP will likely have grounds to claim payment for being responsible for such services. This includes delivery services carried out outside of the pharmacy's normal operating hours
    - If an RP becomes responsible for more than one pharmacy, we expect his or her salary will increase in line with the additional responsibility.

Fundamental concerns of the PDA relating to this consultation which are not covered by formal consultation questions

The Rebalancing Medicines Legislation and Pharmacy Regulation programme board was established in 2013. Its objectives included:

1. **Replacing legislation with regulation.**

   The primary tactical approach being taken by the Rebalancing Medicines Legislation and Pharmacy Regulation programme board is alluded to in its title. The work of the board seeks to move the public protections and restrictions relating to pharmacy practice that are currently enshrined in legislation and transfer them to regulations that are controlled by the pharmacy regulators, the General Pharmaceutical Council (GPhC) and Pharmaceutical Society of Northern Ireland (PSNI). The effect of this would be that any changes to pharmacy practice could be made much more easily by pharmacy regulators in the future, and would not require changes in legislation - which require a lot more parliamentary attention. This transfer from legislation to regulation lies at the core of the rebalancing board's raison d'être.

2. **Developing pharmacy skill mix and removing legal constraints which are considered to be impediments to skill mix.**

   Address matters such as supervision, which the government considers to restrict full use of the skills of registered pharmacists and registered pharmacy technicians and impede the deployment of modern technologies.

3. **Removing the threat of criminal sanction for inadvertent dispensing errors.**

   To encourage error reporting and aid learning, leading to safer practice.

These are relatively complex and ambitious objectives aimed primarily at community pharmacy practice. They require expertise and a detailed knowledge of not just pharmacy practice, but in particular a detailed understanding of the operational and environmental conditions that operate in community pharmacy at scale. Changes made to the current established regime can result in unintended consequences, which can lead to a dramatic impact on the safety of the public. In light of this, the board needs to be able to rely on the expert knowledge from those organizations that have the experience of things that can and do go wrong in pharmacy practice at scale and the consequences this leads to, as well as expertise of defending pharmacists facing criminal prosecutions or regulatory sanctions for making inadvertent dispensing errors. In pursuing these objectives, however, despite formal representations, the rebalancing board has consistently refused to allow representation onto its board of the defence association and trades union for pharmacists: The Pharmacists' Defence Association (PDA), which, with more than 28,000 members, is now the largest representative body and defence union for pharmacists in the UK. Nor has it allowed into its membership the relevant representatives from the independent pharmacy contractor representative and indemnity organization, the National Pharmacy Association (NPA). Both of these organizations have detailed expertise of defending pharmacists who have found themselves facing prosecutions. The PDA has been involved in successfully challenging and consequently changing the interpretation of legislation related to the prosecution of pharmacists at the Royal Court of Appeal.

Instead, the rebalancing board is composed of individuals handpicked by civil servants, and meetings are held in relatively cloistered seclusion. There is a lack of transparency and wider engagement of pharmacists - who will be affected to a great extent by the board's deliberations. The rebalancing board argues that it makes use of wider expertise through a stakeholder ("partner's") forum, however this is not borne out by the facts. These meetings, typically lasting two and a half to three hours, are far too short to ever allow detailed representations to be made

by members of the stakeholder forum. What little time is left after senior representatives of the board describe their activities involves members of the stakeholder forum being separated out at various tables in a hall; they are allowed to contemplate a small discrete task which has been pre-selected for them by the meeting organizers and subsequently have to compete for a roving microphone if they are to make even the very briefest of interventions in a very short plenary session. These meetings are very heavily stage-managed and have only been held on a small number of occasions throughout the last five years. The result is that the rebalancing board lacks expertise and significantly lacks insight into the realities of pharmacy practice at scale; this becomes apparent in its deliberations. Examples include a five-year programme of work which was meant to remove the threat of criminal sanctions for pharmacists involved in making inadvertent dispensing errors, but which has failed to achieve this. Another example is to be found in this consultation where it suggests that a saving of £22,000 can be achieved by a reduction of £1 in the indemnity premiums paid by hospital pharmacists and pharmacy technicians to the NPA, because of the defences that have been proposed by the rebalancing board. Not all pharmacists and pharmacy technicians carry their own indemnity insurance and not all of those who do have their premiums with the NPA. The PDA, as the indemnity provider to more than half of the individual pharmacists in the profession, believes that the indemnity premiums are more likely to increase as a result of the complexity of the defences to inadvertent dispensing errors that have been proposed by the rebalancing board.

Yet another example is a secret proposal drafted by a sub group of the rebalancing board, which was to allow pharmacy technicians to supervise the sale and supply of medicines (including prescription only medicines) in a community pharmacy in the absence of a pharmacist. When this proposal was leaked to the wider profession, it caused such anxiety, outrage and consternation within the profession that the Minister of Health, when pressed in parliament about it, had to distance himself from it.

Despite these concerns, which are to do with the constitution of the board and the secrecy of its deliberations, at the heart of the reservations held by the PDA about this rebalancing process lie two much more fundamental, strategic and worrying concerns about public safety. Firstly, that currently the legislation protects the public insofar as it relates to the conditions which apply to the supply of medicines and the operation of pharmacy; this protection has been in place for more than fifty years largely by dint of the Medicines Act 1968. Although it is widely accepted that the legislation needs to be modernized, the government instead wants to move these public protections from the strictures of legislation and transfer them to the control of the pharmacy regulator. However, it has not first ensured that the pharmacy regulator is ready or fit for purpose to undertake this task. The current regulator in Great Britain, the General Pharmaceutical Council (GPhC), was established in 2010. We do not believe that it is ready to undertake the formidable task that has been outlined for it by the government in this rebalancing exercise, and nor do we believe that it will be ready any time soon.

As a relatively new organization, the GPhC has made significant progress in organizing the processes of regulating individual pharmacists, but it has struggled in the area of policy determination. Many pharmacists will recall the proposal made by the GPhC to allow P medicines to become available by self-selection, a proposition that caused so much bewilderment in the profession that eventually it was quietly abandoned by the regulator. [1] [2] The episode demonstrated a worrying lack of insight and expertise into the very profession that it sought to regulate. Added to this is the empirical evidence which shows that by August 2018, the GPhC will have taken 4,111 disciplinary sanctions against individual registrants since its inception in 2010. In the same period, it has issued none against pharmacy businesses, despite widely-publicized national scandals and having itself identified systemic ‘major risks to patient safety’ across hundreds of pharmacies. [3]

An even more fundamental and worrying concern about the transfer of legislation to regulation at

the hands of the GPhC however, is that the Department of Health consulted from October 2017 to January 2018 in its consultation 'Promoting Professionalism, Reforming Regulation' [4] on proposals to consolidate healthcare regulators and reduce the number from nine to three or four. It has not yet announced how it intends to move forward. It is possible that the GPhC and/or PSNI will be entirely consolidated in to a larger regulator overseeing more than one healthcare profession. The PDA supported such a proposal in its consultation response and especially supports the idea that pharmacy premises regulation should be given to a dedicated premises/systems regulator such as the CQC.

If concerns exist about the ability of the GPhC to undertake this 'rebalancing' exercise, then a brand new, much larger regulator will be even less well equipped to take on the additional responsibilities proposed in this consultation, such as determining the regime for supervision in community pharmacy; it could at best focus upon regulation, rather than the rebalancing ambition of the government, which is to set the detailed operational standards for pharmacy practice in the future.

Notwithstanding the PDA's concerns about the flawed rationale of this entire rebalancing exercise, particularly at this time, the PDA believes that fundamentally, the role of any regulator is to regulate and whether it is the current GPhC or the 'super regulator' of the future, it must be the profession that establishes the detailed practicing standards, as only the profession can ever hope to have the necessary expertise, insight and knowledge of the practice interface to do so. Our response to this consultation argues that it should be the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland that should be driving any standard setting agenda and not the pharmacy regulator. Once these standards have been established through a process of wide engagement of not only the profession but importantly the public and other relevant stakeholders, it then becomes the regulators' role to enforce these standards; they should do so fairly and even-handedly irrespective of whether this involves individual pharmacists or pharmacy

businesses.

The potential changes to regulation raise the question of whether it is appropriate to make the changes proposed in this consultation at all at this point, or even to consult upon them, without knowing what the future holds in this regard.

Recommendation

Standard setting should be driven by professional leadership bodies, in pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland. If there is a role for professions in developing their own practice, and a role for professional leadership bodies in representing the collective ambitions of the profession, this cannot and should not be led by the *regulator*, whose job it is to *regulate* and enforce standards. This should be recognized by the Department of Health and Social Care when it decides on the future of regulation.

Skill mix in pharmacy

The civil servants involved in promoting the work of the rebalancing board seem determined to transfer the roles and responsibilities of community pharmacists to pharmacy technicians. If pharmacy and especially the community pharmacy service is to develop, then the development of the roles of pharmacy technicians becomes not only desirable, but essential. However, whilst a similar exercise was undertaken successfully in hospital pharmacy in the 1970s and 80s, this was achieved through the development of a comprehensive vision for hospital pharmacy practice which saw the aspirations of hospital pharmacists aligned with the ambitions of hospital pharmacy technicians. It was accompanied by a skills and salary escalator which was available to both

pharmacists and pharmacy technicians and it was supported by a comprehensive training programme. No such exercise has been undertaken in community pharmacy and the government in England has not been keen to accept the vision for community pharmacy proposed by numerous community pharmacy representative organizations. Instead, it has left the sector in limbo and unilaterally cut the annual community pharmacy budget by £170million. Worse still, unlike the governments in Scotland, Wales and Northern Ireland, the government in England has not been able to even articulate its own vision for community pharmacy. The only clue that has emerged has been the leaked proposal to allow pharmacy technicians to operate community pharmacies in the absence of a pharmacist.

Added to the concerns about a lack of developmental policy for community pharmacy is the fact that pharmacy technicians in the community pharmacy setting have not been engaged in this process. Research undertaken by the PDA shows that there are significant differences between hospital pharmacy technicians and those operating in the community pharmacy setting as observed across a wide range of factors. This is largely because of the longitudinal developmental programme that has been developed for the benefit of hospital pharmacists and pharmacy technicians over the last thirty years.

These structural issues are worrying as is the evident policy vacuum in so far as it relates to community pharmacy. Both of these factors must first be addressed if the transfer of roles from community pharmacists to community pharmacy technicians is to be undertaken.

Despite all of these significant fundamental and structural problems and potential risks for the public that they represent, the appetite of the government to proceed with this rebalancing initiative appears to be unabated. This is a worrying prospect.

Currently, it would appear that these matters are either not being considered by the government or they have been disregarded. However, they must be considered by pharmacists during this consultation process as ultimately, they are likely to lead to the detriment of the public, the practice of pharmacy and the profession.

Specific concerns about public safety by diluting the supervision by pharmacists

This consultation includes proposals from the DHSC to allow the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI) to set conditions in which a pharmacist can be responsible for more than one pharmacy and be the Responsible Pharmacist remotely. This is qualified by the condition that any "burden" on businesses is kept to a minimum. The business influence on the rebalancing board is evident and worrying and it appears to enjoy a greater emphasis than does the safety of the public.

The government has said that these legal changes will merely *allow* the regulators to make changes to pharmacists' roles. There would be no need to give the regulators these powers unless there was a plan to use them. All historical experience indicates that the provisions to allow an RP to supervise more than one pharmacy at a time, if implemented, will simply be used by some employers to derive the maximum possible profits through cost-cutting. The effect on patient safety and the ability of pharmacists to act professionally will become a secondary consideration. We believe this will enable further misuse of the regulations for Responsible Pharmacists. As an example of such misuse even under current regulations, one of the largest multiple pharmacies uses 'advance declarations' where the RP assumes responsibility for the pharmacy up to two hours before even arriving at work. The misuse of the "two hour" RP absence provision in the current legislation, whose purpose was to allow pharmacists to engage in clinical activities during the working day, allows this employer to maximize its profits by cutting its costs and operating the pharmacy without the pharmacist present.

Under the 'more than one pharmacy per RP' proposal, patients may no longer be able to rely on a pharmacist being there when they visit a pharmacy; the guaranteed access at the pharmacy to degree-level medicines expertise and clinical advice will be gone. And pharmacists, it seems – many of whom already report poor working conditions – will be expected to shoulder civil, regulatory and criminal responsibility for multiple pharmacies at the same time, where they are not physically present.

What is needed instead of the rebalancing board's proposals is an inclusive debate which engages with the profession widely as it seeks to determine its future strategy. The PDA has developed two policy documents which make such proposals:

- *Wider than Medicines*, which is a strategy for pharmacy designed to improve skill mix and encourage new ways of working for pharmacy technicians, pharmacists and ultimately GPs. [5]
- *Pharmacy Technicians: the Current UK Landscape and Community Pharmacy Skill Mix*, which makes proposals about future career frameworks, skills and salary escalators for pharmacists and pharmacy technicians in community pharmacy. [6] The report also makes proposals to improve the quality of pharmacy technician training and their capabilities.

Our view is that if these proposals were implemented (subject to receiving the support of the profession), and protections against criminal prosecution for inadvertent errors were improved appropriately, it might then be appropriate at that stage to consider some of the changes being proposed in this consultation, in order to release the pharmacist to fulfil a more clinically-orientated patient-facing role.

Recommendation

The rebalancing board's approach should be changed to make it representative of the pharmacy profession, by ensuring organizations such as the PDA (the largest pharmacist membership organization in the UK), and the NPA – the independent contractors organization - are represented on the board. The approach should become an inclusive one which engages the wider profession in debate and involves it in developing reasonable proposals for its future and for the safety of the public.

Timeline for dealing with consultation responses

Though the consultation finishes on 11 September, the Department of Health and Social Care said it plans to present a paper to the rebalancing board in October, and then lay the orders before parliament in December 2018 or January 2019, to come in to force no later than March 2019. We understand the effect of the UK's exit from the EU on parliamentary business, but any and all significant findings from the consultation will require the proper amount of time to be considered by the rebalancing board and the profession before they are implemented. As we have already set out, the existing defences to sections 63 and 64 of the Medicines Act 1968 (which were an output of the work of the rebalancing board) are flawed, and we believe it would be highly inappropriate to rush the implementation of the outputs of this consultation; it could lead to similar issues and unintended consequences. Our view is that the DHSC's timescale for implementation is far too short – perhaps even reckless given the importance of the subject in question, its impact and the lack of engagement with the profession resulting from the non-representative composition of the rebalancing board.

Questions

Part 1 – The draft Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2018

1. **Part 1 – Question 1: Do you agree with the approach to provide a defence for registered pharmacy professionals working in a hospital pharmacy, similar to that implemented for registered pharmacies (predominately community pharmacy)?**

Yes, subject to the caveats below.

From a legal defence perspective, the defences are better than nothing. However, it would have been better if the government had not made these proposals and taken a much more ambitious approach. Even though the PDA has demonstrated to senior representatives of the rebalancing board that the threat of criminal sanctions for inadvertent dispensing errors remains, the board and the government has continued to insist that a lot has been achieved and that the risks of prosecution are negligible. This stance has got in the way of making more ambitious progress. The consultation document states "*The aim of the legislation is to remove the threat of criminal sanctions for inadvertent dispensing errors…*", and yet the government knows that this is not what the legislation will achieve. It told the PDA that it knew this would not be achieved in a meeting just before the launch of this consultation. Another factor of concern is that senior representatives of the profession are expressing a view that the possibility of prosecutions due to inadvertent dispensing errors has been removed; this is patently not the case.

We are concerned that the extension of these defences to other areas of practice will lead to the same behaviours and that this will make it even more difficult to achieve more comprehensive changes to the prospect of prosecution; those providing real and more robust protections for pharmacists so as to improve patient safety through error reporting.

The defences have some serious flaws and will not protect hospital pharmacists against the threat of criminal prosecution under other areas of medicines legislation (such as the Human Medicines

Regulations 2012). Our position on the decriminalisation of inadvertent dispensing errors, and our view on the approach the government should take going forward, is set out in our response to the rebalancing board's work on decriminalisation. [7]

Recommendation

The rebalancing board ought to seek the introduction of guidance for state prosecutors, prompting local police forces to work to a programme where any offences related to inadvertent dispensing errors where gross negligence manslaughter has been excluded are referred to the regulator and are not subjected to criminal prosecution. At the same time, the board should conduct a broader review of medicines legislation with a view to removing the threat of criminal sanction for inadvertent dispensing errors as far as possible as per the DHSC policy objective. It is fully understood that the prospect of gross negligence manslaughter prosecutions, and prosecution for crimes against the person (e.g. where harm occurs) cannot be removed.

2. **Part 1 – Question 2: Do you agree that in the case of hospital pharmacy services, this should be extended to include dispensing errors by registered pharmacy professionals which are made anywhere as part of a hospital pharmacy service, and so including elsewhere in the hospital, for example on a ward or in a hospital facility that does not have a recognisable pharmacy but supplies dispensed medicines in accordance with the directions of a prescriber?**

Recommendation

The threat of criminal sanctions under medicines laws for inadvertent dispensing errors made anywhere as part of a hospital pharmacy service should be removed.

3. **Part 1 – Question 3: Do you agree in principle with the proposal to extend the defences for registered pharmacy professionals making an inadvertent dispensing error to include other relevant pharmacy services?**

Yes, subject to the caveats below.

Recommendation

The threat of criminal sanctions under medicines laws for inadvertent dispensing errors, in so far as it relates to other relevant pharmacy services (e.g. those provided in prisons), should be removed.

4. **Part 1 – Question 4: Are there any other pharmacy services that you feel should be included within the scope of the new defences as specified in article 8 of the draft Order, i.e. that are not mentioned in the consultation document, and meet the criteria?**

We have nothing further to add.

5. **Part 1 – Question 5: Do you agree with the proposals that a pharmacy service that potentially benefits from the extended defences must have a Chief Pharmacist in order to rely on the extended defences?**

No

Whilst we believe that a Chief Pharmacist should be appointed to oversee all relevant pharmacy services and this requirement should be set out in legislation, our view is that it is not appropriate to do this by making it a condition of the defences to inadvertent dispensing errors. It would further "make a mess" of the legislation, which, considering the objectives of the rebalancing board, could not be regarded as a good result. In addition, in terms of legislation for inadvertent dispensing errors, it sets a further unnecessary hurdle for the defences to apply which does not apply to errors made in registered pharmacies. The appointment of a Chief Pharmacist is beyond the control of pharmacists working in relevant pharmacy services, who may need access to the defences.

There are various circumstances where there may currently be no Chief Pharmacist appointed to oversee the provision of a "relevant pharmacy service", including:

- In care home settings (which is one of the areas the defences are intended to cover)
- If the Chief Pharmacist post is vacant and another has not been appointed

Recommendation

A Chief Pharmacist should be appointed to oversee all relevant pharmacy services; this requirement should be set out in legislation independently of the legislative changes proposed in this consultation in relation to inadvertent dispensing errors.

Defences against criminal sanctions for inadvertent dispensing errors would then not need to specify that a Chief Pharmacist must be appointed in order for pharmacists to be able to use them (and nor should they; the appointment of a Chief Pharmacist or otherwise is a matter beyond the control of pharmacists who may need to be able to use them).

6. **Part 1 – Question 6: Do you agree that the pharmacy regulators should be enabled to set standards in respect of pharmacists who are Chief Pharmacists (or who are designated the responsibilities of a Chief Pharmacist), including a description of the professional responsibilities of a Chief Pharmacist?**

Please see our recommendation below.

Recommendation

Standard setting for Chief Pharmacists should be driven by the professional leadership bodies, in pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland. An advisory body should be established to scrutinize and evaluate the standards proposed before they are sent for approval by the regulator. This should comprise senior officials from the regulator and the professional leadership body. The role of the regulator should be to enforce the standards.

7. **Part 1 – Question 7: Do you agree that the conditions of the defences for pharmacy professionals working in hospitals and other pharmacy services should broadly align with those required to be met by pharmacy professionals working in registered pharmacies?**

Yes, subject to the caveats below.

Whilst we take the view that the legal provisions for pharmacists working in hospitals and other pharmacy services should align with those applicable in registered pharmacies, the existing legal defences applicable to those in registered pharmacies are flawed, as outlined in our position statement. [7] The rebalancing board has proposed to introduce the same defences, without changing the original ones (which means retaining the flaws).

We set out our view on how the rebalancing board should remove the threat of criminal sanction for inadvertent dispensing errors in the recommendation we made in response to Part 1, Question 1.

8. **Part 1 – Question 8: Do you agree that the defences should apply where an inadvertent preparation or dispensing error is made in a situation where a pharmacist was both the prescriber and dispenser?**

Yes, subject to the caveats below.

We have concerns about the appropriateness and professionalism of arrangements where there might be vested financial interests for a pharmacist to act as both the prescriber and supplier of a medicine, or for a business to profit from both. Separate to this consultation, our view is that the government ought to consider imposing restrictions on such practices. However, we recognise that being both the prescriber and supplier may become more common with more pharmacists working in GP practices in prescribing roles, and we therefore make the following recommendation to apply to such circumstances.

Recommendation

The Department of Health should consider imposing restrictions on when a pharmacist can act as both the prescriber and supplier of a medicine in circumstances where there would be a vested financial interest in both, or where a business can profit from both activities. However, where it is appropriate or necessary for a pharmacist to both prescribe and dispense, the threat to those pharmacists of criminal sanctions under medicines laws for inadvertent dispensing errors should be removed.

9. **Part 1 – Question 9: Do you agree that the defences should apply where an inadvertent error is made in a situation where a pharmacist sells or supplies a medicine against any patient group direction?**

Yes, subject to the caveats below.

A pharmacist making a supply against a PGD could be prosecuted under section 233 of the Human Medicines Regulations 2012 – and the proposed defences would not be applicable in such cases.

Recommendation

The threat of criminal sanctions under medicines laws for inadvertent dispensing errors made by pharmacists selling or supplying a medicine under a PGD should be removed. This must include amending the Human Medicines Regulations 2012 where necessary.

10. **Part 1 – Question 10: Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.**

Yes

The cost savings in the DHSC's calculations include the assumption that the National Pharmacy Association (NPA) insures 22,000 hospital pharmacists and pharmacy technicians and will reduce its annual indemnity insurance premiums by £1 for each person. As far as we are aware, the NPA does not insure 22,000 hospital pharmacists and pharmacy technicians. Not all pharmacists and pharmacy technicians carry their own indemnity insurance and not all of those who do have their premiums with the NPA. We do not understand how this flawed statistic could ever have been arrived at.

That aside, the DHSC's logic appears to be that the *"[removal of] the threat of criminal sanctions for inadvertent dispensing errors*" will lead to more errors being reported, improve learning from those errors and ultimately result in fewer errors and improved patient safety. It remains to be seen whether there will be any reduction in the risk of criminal sanctions as a result of these proposals; we do not expect that the proposals, if implemented, will have the effect that has been anticipated. Nor do we anticipate a dramatic increase in error reporting as a result of the implementation of these proposals. By definition, pharmacists don't *decide* to make an inadvertent error, and so conditional defences which apply in one circumstance and not in others

will offer little comfort that they won't face prosecution. Consequently, we do not envisage any reduction in indemnity insurance premiums associated with these proposals. The PDA handles criminal prosecutions of pharmacists; indeed, it handled the Elizabeth Lee case. It is our belief that criminal defence cases will likely take longer to manage and the associated costs are likely to increase as a result of the complexity of the new defences, if these proposals are implemented.

Recommendation

The Department of Health and Social Care should commission a credible independent expert cost-benefit analysis of its proposals. Error reporting is unlikely to increase as a result of the new Medicines Act defences (due to the uncertainty pharmacists will have as to whether the defences will apply) and indemnity insurance premiums are unlikely to be reduced by their implementation; more likely, they will increase. This is because the legal defence may take longer to manage and the associated costs are likely to increase if the proposals are implemented, due to the complexity of the new Medicines Act defences.

11. **Part 1 – Question 11: Do you have any additional evidence which we should consider in developing the assessment of the impact of this policy on equality?**

We have nothing further to add.

Part 2 – The draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2018

12. **Part 2 – Question 1: Do you agree that the Superintendent Pharmacist should be a senior manager of the retail pharmacy business (which may be just one part of the company for which they work) with the authority to make decisions that affect the running of the retail pharmacy business so far as concerns the retail sale of medicinal products and the**

supply of such products?

Yes, subject to the caveats below.

Recommendation

A Superintendent Pharmacist's authority must not impair the Responsible Pharmacist's professional autonomy or his/her freedom to exercise professional judgement.

Recommendation

A Superintendent Pharmacist must have sufficient authority within the business to ensure his/her views about how the business is run are adopted, so far as the concerns relate to the retail sale and supply of medicinal products and without impinging on the professional autonomy of the Responsible Pharmacist.

13. **Part 2 – Question 2: Do you agree with the removal of the restriction for companies with "chemist" in their title such that the Superintendent Pharmacist no longer has to be a member of the board of the body corporate?**

No

Having the Superintendent Pharmacist on the board of a body corporate would help to ensure that the discussions and decisions of the board include a senior pharmacist's perspective. We view this as an important patient safety measure.

Having the Superintendent Pharmacist on the board could also ensure that patient safety and care

was always properly considered by the company. This is important in the context of other decisions the board may make and could help ensure it gives sufficient priority to pharmacy. The importance of this principle has been illustrated in other sectors; in the 2007/8 global financial crisis, the risks inherent in the system were missed and the controls were inadequate. An analysis of the eight most prominent US financial institutions revealed that more than two-thirds of the occupants of those board seats had no significant recent experience in the banking business and fewer than half had any financial services industry experience at all. The Financial Times said "*one of the main charges levelled at directors of financial groups is that they do not know enough about the industry their companies are in. Even Wall Street executives admit that, although day-to-day-affairs are the realm of management, greater financial literacy could have helped directors challenge management's appetite for risk.*" [8]

Recommendation

The Superintendent Pharmacist should be a member of the board for all body corporates operating registered pharmacies. This is a patient safety measure which could help ensure the care and protection of patients and the public is taken in to account and given proper consideration by the board. The name of the most senior person accountable for the provision of pharmacy services must be clear and easily accessible to the public. Whether or not the company has "chemist" in its title is inconsequential to the level of protection that should be provided to the public.

14. Part 2 – Question 3: Do you agree with the proposed general duty for the role of the Superintendent Pharmacist?

Yes – subject to the caveats within our response to Part 2, Question 14.

In answering this question, we have taken the general duty to mean a duty for *"securing the safe and effective running of the pharmacy business so far as concerns the retail sale and supply of*

medicinal products".

15. **Part 2 – Question 4: Do you agree that the Superintendent Pharmacist general duty should extend to all medicines – general sale list (GSL) medicines, as well as prescription only medicines (POM) and pharmacy (P) medicines?**

Yes

16. **Part 2 – Question 5: Do you agree that the role of the Superintendent Pharmacist should extend to other services, such as clinical and public health services?**

Yes

17. **Part 2 – Question 6: Do you agree that the restriction whereby a Superintendent Pharmacist can only be a Superintendent Pharmacist for one business at any given time should be removed from primary legislation and the issue be left to the pharmacy regulators?**

Yes, subject to the caveats set out in our recommendations below and not until these have been implemented. In principle this could help create a career pathway for pharmacists to work as 'professional or career' superintendents and instil quality through the experience these individuals bring to the role as they take on roles in progressively larger businesses. By helping to create such a pathway, it could also help avoid situations where inexperienced pharmacists are asked to work as superintendents. However, our support for this proposal is tempered by the need to restrict the number of pharmacy businesses that one SP could serve. Such a decision should only be made once a debate has been held within the profession.

Recommendation

Superintendent Pharmacists (SPs) should able to be the SP for more than one business at any given time, provided that:

- Provisions are put in place to ensure that SPs can effectively exercise the proposed duty to secure the safe and effective running of the retail pharmacy business(es) for which they are the SP
- Limits are placed on the number of companies for which a pharmacist can act as the SP
- Limits are placed on the number of pharmacies an SP can oversee where he/she is the SP for more than one business
- There's a requirement for the SP to sit on the board of directors of each business
- Provisions are put in place to manage conflicts of interest and vested interests, given that the SP will be in a position to influence the finances of more than one company.
- The above matters are consulted upon separately to this consultation

Recommendation

A discussion should be held within the profession, instigated by the professional leadership body, in pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland to establish the minimum requirements for appointment as a Superintendent Pharmacist such as a minimum number of years qualified and the completion of a mandatory qualification. This could help instil quality in to the role, improve public protection and avoid situations where inexperienced pharmacists work as superintendents.

A discussion should also be held within the profession to establish the maximum number of pharmacy businesses that one pharmacist could safely and properly be the superintendent for. A cap should then be agreed and enforced by the regulator.

18. **Part 2 – Question 7: Do you agree with the proposal to retain the requirement for Superintendent Pharmacists to notify the General Pharmaceutical Council when they stop being Superintendent Pharmacist for a particular pharmacy and to extend the requirement to Northern Ireland and the Pharmaceutical Society of Northern Ireland?**

Yes

19. **Part 2 – Question 8: Do you agree with the proposal to provide the pharmacy regulators with power to set professional standards for Superintendent Pharmacists and describe their role?**

No

Recommendation

Standard setting for Superintendent Pharmacists and describing the role should be driven by the professional leadership body, in pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland. An advisory body should be established to scrutinize and evaluate the standards proposed before they are sent for approval by the regulator. This should comprise senior officials from the regulator and the professional leadership body. The role of the regulator should be to enforce the standards.

20. **Part 2 – Question 9: Do you agree that the statutory duty of the Responsible Pharmacist should be engaged only for the time when the Responsible Pharmacist is actually designated the RP role for that pharmacy, and is therefore in charge?**

Yes

Recommendation

The statutory duty of the Responsible Pharmacist (RP) should be engaged only for the time when the RP is actually designated the RP role for that pharmacy, is in charge and physically present in the pharmacy.

21. **Part 2 – Question 10: Do you agree that the trigger for when there needs to be an RP in charge of the premises is when medicines are being sold or supplied, or handled, assembled prepared or dispensed at or from the premises with a view to sale or supply?**

Yes

22. **Part 2 – Question 11: Do you agree that Responsible Pharmacist's duties should be clarified so that it is clear these are related to the operation of the pharmacy business "at or from" the particular premises (e.g. including home deliveries of medicines)?**

Yes

23. **Part 2 – Question 12: Do you agree that the pharmacy regulators rather than Ministers should set out the detail of the Responsible Pharmacist's statutory responsibilities?**

No

The GPhC has issued 4,111 sanctions against individual registrants since its inception in 2010. In August 2018 the PDA learned, through an FOI request, that during that time it has not brought a single sanction against a pharmacy owner or superintendent on the basis of a failure to comply with the standards for registered pharmacies. [9] By its own admission, it regards itself as a "peripheral player" in tackling workplace pressure. [10] We take the view that the GPhC has not demonstrated an appetite to be a pharmacy premises regulator, and it appears to have an attitude towards premises regulation which ultimately leads to questions over the adequacy of the protection being afforded to the public. As such, it seems inappropriate to us to allow the GPhC to ascribe the statutory responsibilities of Responsible Pharmacists, who currently work in conditions that it has difficulties in regulating. In any event, the role of the GPhC should be to regulate rather than to define the statutory responsibilities (which help define the role) or set standards.

Recommendation

Ministers should continue to set out Responsible Pharmacists' (RPs') statutory duties in legislation, such that the definition and duties of the RP role remain constant and are not subject to changes at the whim of a regulator; the role of the regulator is to regulate, rather than define the RP role and responsibilities in statute. Retaining ministerial control over the statutory responsibilities of the RP would help afford the appropriate public protections and help ensure any potential future changes to the role or its duties are subject to the appropriate public and parliamentary scrutiny. Ensuring that ministers continue to set statutory responsibilities for the RP would also help ensure common statutory responsibilities applied to both Great Britain and Northern Ireland; since there are two pharmacy regulators – the GPhC and the PSNI – the statutory responsibilities could diverge if pharmacy regulators are given this power.

24. Part 2 – Question 13: Do you agree that the pharmacy regulators should have the power to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time?

No

This is not an appropriate change to make, for the reasons set out at the start of this submission. It would create an unacceptable risk to patient safety and expose pharmacists unfairly to criminal and civil prosecution and regulatory sanctions, in working conditions that at present are poorly regulated.

Recommendation

Section 72A of the Medicines Act should **not** be amended to allow either the GPhC or the PSNI to make exceptions to the general rule that a Responsible Pharmacist (RP) can only be in charge of one pharmacy at one time. Nor should it be amended to allow either the GPhC or the PSNI to make provisions about the RP's absence from the premises.

Recommendation

The power to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time should be removed from legislation, since it is unnecessary and has not been used thus far, but should not be given to pharmacy regulators. Should it become appropriate at some point in the future to reintroduce the ability for ministers to make such exceptions, the current provision must be accompanied by additional provisions to ensure the public is protected. In that event, the power to make exceptions should be given to ministers, but Section 72A (2) of the Medicines Act 1968 should be amended to strengthen the current provision such that ministers can only make provisions about RPs being responsible for more than one pharmacy provided that patient safety is not in any way compromised and is maintained at all times.

Whilst opposed to these proposals, we also found it extraordinary that the government would draft legislation requiring the regulators to have regard to the interests of businesses if they are to implement such changes.

Recommendation

The proposed provision in the draft legislation "*In making any such provision, the General Pharmaceutical Council and the Council of the Pharmaceutical Society of Northern Ireland must have regard to the principle that the burdens imposed on businesses by rules or regulations should be the minimum necessary to secure the benefits, considered in general terms, which are expected to result from the rules or regulations*" is inappropriate and must be removed. It is not appropriate for healthcare regulators to have to consider the interests of businesses in such a way, either as proposed or alongside other provisions, in their duties protecting patients and the public.

A further point is that the consultation document states "*Current powers allow for an exception to the general rule that a RP can only be in charge of one pharmacy at one time, for example, to enable such developments as pharmacist controlled dispensing machines. The proposal is to replace the Ministerial regulation making power to make an exception with a pharmacy regulator rule/regulation making power to do this instead."* We were concerned by this statement. It is not clear what is meant by "to enable such developments as pharmacist controlled dispensing machines":

- If this is a reference to vending machines, the proposed changes would be unnecessary since such machines are already lawful and in operation (according to the GPhC). GPhC council papers from July 2017 state: "*Claire Bryce-Smith (CBS) explained that where vending machines had been used to dispense prescriptions, that part of the premises had been de-registered so that it was lawful. This was because in registered premises the responsible pharmacist must be present in order to dispense.*" [11]
- If this is a reference to large automated dispensing facilities, such as that used by large multiples, such dispensing machines are accompanied by a substantial amount of manual dispensing to

prepare split packs and other medicines for supply to patients, since the process cannot be entirely automated and will likely not be for the foreseeable future.

If a 'pharmacist controlled dispensing machine' goes wrong, it may present a high risk to the safety of many patients. There are good reasons why a pharmacist should be present on the same premises as such machines, which remain only as accurate as the human input. In any event, a legal challenge may find that such 'dispensing machines' were not "pharmacist-controlled" if they were on different premises to the pharmacist.

Recommendation

The proposal to make an exception to the general rule that a Responsible Pharmacist can only be in charge of one pharmacy at one time is not justified by the Department of Health and Social Care's reasoning that it would '*enable such developments as pharmacist controlled dispensing machines'*. The meaning of 'pharmacist controlled dispensing machines' is unclear and the law already provides for this in some forms, and to that extent the change is unnecessary. A pharmacist should be present on the premises with such machines for various reasons – for example if it goes wrong, it may present a high risk to the safety of many patients and require a pharmacist's professional intervention on site to resolve the issues. In any case it could be argued that such 'dispensing machines' were not "pharmacist-controlled" if they were on different premises to the pharmacist. If the DHSC wishes to propose a clear, specific reason for the exception to the general rule, it should set out that exemption clearly and consult upon it with a view to setting out the exception in legislation.

25. Part 2 – Question 14: Do you agree that the duty on the Responsible Pharmacist to establish, maintain and keep procedures under review is removed and instead is subsumed into the general duties of Superintendent Pharmacists?

No

The consultation document states: *"In general, it is expected that SOPs should be the responsibility of the SP. However, that should not inhibit the RP from their responsibility to contribute to the development and operation of SOPs and to act in the best interests of the patients, notwithstanding the SOP."*

We have various concerns about this proposal as it stands. If implemented without any restrictions or simultaneous provisions (none are mentioned in this consultation), it could expose pharmacists to increased and unfair civil, regulatory and criminal liability and take away the professional decision-making capacity of the pharmacist, putting patients at risk. Our view is that many corporate SOPs set unrealistic expectations of staff (either due to the level of detail or the wording) and are set up primarily to protect the company and senior management rather than patients. For example, some SOPs may take an inappropriate broad-brush approach such as "ensure there are no errors", without explaining the steps needed to avoid those errors.

Recommendation

Establishing, maintaining and keeping procedures under review must be a shared, dual responsibility between Superintendent Pharmacists (SPs) and Responsible Pharmacists (RPs); a compact between the two. The SP must ensure that procedures are in place before the pharmacy opens, having agreed these with an RP in each pharmacy - who will be aware of the local situation day-to-day and able to ensure the procedures protect patient safety and work in patients' best interests.

Recommendation

If Responsible Pharmacists are to have the responsibility to secure the safe and effective running of the individual registered pharmacy whilst the SP has the responsibility to secure the safe and effective running of the business, to maintain patient safety there must be requirements placed on SPs to:

- Create, and be able to prove they have created, conditions which allow the RP and other pharmacy staff to follow those SOPs, including the provision of sufficient suitably qualified and trained staff
- Deal appropriately with any concerns raised by the Responsible Pharmacist about the SOPs, such that the SOPs are amended to address those concerns

Recommendation

If Responsible Pharmacists are to have the responsibility to secure the safe and effective running of the individual registered pharmacy whilst the SP has the responsibility to secure the safe and effective running of the business, to maintain patient safety and enable RPs to act in the best interests of patients, RPs must be able to amend the SOPs which are in place, or create additional ones, in order to meet the local and situational needs of that pharmacy.

26. Part 2 – Question 15: Do you agree that the duties relating to record keeping should be set out by the pharmacy regulators, rather than in Ministerial legislation, and be enforced where appropriate via fitness to practice procedures?

Yes

Recommendation

The requirement to keep and maintain records of Responsible Pharmacists should be preserved, but should be removed from legislation so that it is not a criminal offence, for example, to inadvertently make an inaccurate record. It should be a legal requirement for regulators to set out standards for record keeping.

27. **Part 2 – Question 16: Do you agree that the pharmacy regulators should be provided with a new general rule/regulation making power in respect to the Responsible Pharmacist and remove the specific Ministerial regulation making powers in respect of:**
    (a) the qualification and experience of Responsible Pharmacists;
    (b) the Responsible Pharmacist and supervision;
    (c) procedures; and
    (d) the record-keeping of the Responsible Pharmacist

No

Please refer to our responses to Part 2, Questions 12, 14 and 15 and consider them as the rationale for our response to this question. This includes our recommendations that:

- The statutory duties of responsible pharmacists should continue to be set by ministers in legislation and not by pharmacy regulators
- Standard setting for Responsible Pharmacists should be driven by the professional leadership body; an advisory body should evaluate the standards and the regulator should regulate and enforce them
- Regulators should set out the standards for Responsible Pharmacist record keeping.

Recommendation

The wording of the question is poor. It could be taken to be asking whether the regulators should be given regulation-making powers about the Responsible Pharmacist and supervision. However, the issue of supervision has not been discussed in the consultation and the question is unclear, so it is essential that the Department of Health and Social Care does not take the responses to this question as providing any indication of respondents' views in that regard. That part of the question must be taken to pertain to the removal of the ministerial powers in section 72A (6) and (7) of the Medicines Act 1968, as explained and proposed in the consultation document.

Recommendation

For the avoidance of doubt, the PDA opposes any UK pharmacy regulator being given any regulation-making powers about the supervision of pharmacies, the sale or supply of medicines including in relation to transactions, or the supervision of activities for which a pharmacist is not the RP.

The PDA opposes remote supervision.

28. Part 2 – Question 17: Do you agree that the pharmacy regulators should be given new powers to set professional standards for Responsible Pharmacists and describe their role?

No

Recommendation

Standard setting for Responsible Pharmacists and describing the role should be driven by the professional leadership body, in pharmacy's case the Royal Pharmaceutical Society and the Pharmacy Forum of Northern Ireland. An advisory body should be established to scrutinize and evaluate the standards proposed before they are sent for approval by the regulator. This should comprise senior officials from the regulator and the professional leadership body. The role of the regulator should be to enforce the standards.

29. **Part 2 – Question 18: Do you agree that the Pharmacy (Northern Ireland) Order 1976 should be amended to provide for the appointment of a Deputy Registrar and to provide that the Deputy Registrar may be authorised by the Registrar to act on their behalf in any matter?**

Yes

30. **Part 2 – Question 19: Views are invited on each of the assumptions in the cost benefit analysis. Do you consider there are any additional significant impacts or benefits that we have not yet identified? Please provide evidence and estimates.**

Yes

Legal defence costs for pharmacists may increase if these proposals are implemented. Professional indemnity costs are unlikely to change. Please refer to our response to Part 2, Question 14 for the rationale.

Recommendation

The Department of Health and Social Care should factor in increased employment costs in to its proposals. We are opposed to the proposals as set out in our response to other questions, but if implemented, employment costs are likely to increase for various reasons, such as:

- If the Responsible Pharmacist becomes responsible for services provided 'from' a registered pharmacy (as opposed to just 'at' a registered pharmacy as at present), the RP will likely have grounds to claim payment for being responsible for such services. This includes delivery services carried out outside of the pharmacy's normal operating hours
- If an RP becomes responsible for more than one pharmacy, we expect his or her salary will increase in line with the additional responsibility.

31. Part 2 – Question 20: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?

We have nothing further to add.

References

[1] "Consultation report - Modernising pharmacy regulation: A consultation on the draft standards for registered pharmacies," General Pharmaceutical Council, December 2012. [Online]. Available: https://www.pharmacyregulation.org/sites/default/files/GPhC%20Registered%20Pharmacies%20consultation%20report%20Dec%202012.pdf.

[2] "P meds on self-selection. GPhC decision must be challenged," The Pharmacists' Defence Association, 17 September 2012. [Online]. Available: https://www.the-pda.org/p-meds-on-self-selection-gphc-decision-must-be-challenged/.

[3] The Pharmacists' Defence Association, "The GPhC identified major patient safety concerns in 667 pharmacies across Great Britain," 27 July 2018. [Online]. Available: https://www.the-pda.org/the-gphc-identified-major-patient-safety-concerns-in-667-pharmacies-across-great-britain/.

[4] Department of Health, "Promoting professionalism, reforming regulation consultation," [Online]. Available: https://www.gov.uk/government/consultations/promoting-professionalism-reforming-regulation. [Accessed 2018 July 26].

[5] "Wider than Medicines - A Pharmacy perspective on creating an integrated health system - Road Map 2," May 2018. [Online]. Available: https://www.the-pda.org/wp-content/uploads/634_A4-PDA-12pg_Wider-Than-Medicine_V8_LRES.pdf.

[6] The Pharmacists' Defence Association, "The Role of Pharmacy Technicians," June 2018. [Online]. Available: https://www.the-pda.org/pharmacy-technicians/.

[7] "Decriminalisation of Inadvertent Dispensing Errors - Position Statement (to be published)," The Pharmacists' Defence Association, 11 September 2018. [Online].

[8] F. Guerrera and P. T. Larsen, "Gone by the board? Why bank directors did not spot credit risks," Financial Times, 25 June 2008. [Online]. Available:

https://www.ft.com/content/6e66fe18-42e8-11dd-81d0-0000779fd2ac.

[9] The Pharmacists' Defence Association, "PDA concerned about GPhC lack of action," 18 December 2017. [Online]. Available: https://www.the-pda.org/gphc_lack_of_action/ .

[10] "GPhC: We should be 'peripheral player' in tackling pressure," Chemist and Druggist, 25 October 2016. [Online]. Available: https://www.chemistanddruggist.co.uk/news/gphc-we-should-be-%E2%80%98peripheral-player%E2%80%99-tackling-pressure .

[11] "GPhC Council Meeting Papers," 12 July 2018. [Online]. Available: https://www.pharmacyregulation.org/sites/default/files/document/2018-07-12_combined_papers_for_website.pdf.