PDA Response to Consultation on:

Rebalancing Medicines Legislation and Pharmacy Regulation: draft Orders under section 60 of the Health Act 1999

May 2015

About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not for profit defence association and trade union for pharmacists. We are the only organisation that exclusively looks after the interests of employee and locum pharmacists across all sectors of pharmacy, and we currently have more than 24,000 individual pharmacists in membership. Most of these members are from the community and primary care sector, 5,000 are working in the hospital setting.

The PDA defends members should they find themselves involved in a critical incident situation, such incidents are common, in 2014 alone, they exceeded more than 4,000. The majority of these incidents are employment related and a significant proportion are caused by conflicts between the commercial imperatives of community pharmacy employers and the focus upon professionalism and patient safety exercised by individual pharmacists. Many of the defence episodes that we provide are caused by an involvement in a dispensing error.

In recent years, the PDA has been involved in the majority of the dispensing error prosecution situations and was the organisation behind the successful Elizabeth Lee appeal which clarified in the Royal Court of Appeal that individual employee and locum pharmacists could not be prosecuted for labelling offences under Section 85.5 of the Medicines Act.

The PDAs lawyers also attend to provide assistance to pharmacists who find themselves being interviewed in a police station following their involvement in a dispensing error; providing defence to pharmacists in the pre-prosecution phase of police investigations following serious dispensing errors.

This provides us with a rich vein of up to date experiences that have informed our policies. The answers to the questions being put in this Consultation are largely built upon this experience, they are overlaid onto the specialist advice from Queens Counsel, pharmacy law and pharmacy practice experts. They are also built upon the views of practicing pharmacists gathered through focus groups and other forms of consultation undertaken by the PDA.

The PDAs responses to this consultation are provided overleaf;

Question 1:

Do you agree with our overall approach, i.e. to retain the criminal offence in section 64 and to provide a new defence for pharmacy professionals against prosecution for inadvertent dispensing errors, subject to certain conditions?

The PDA believes that when a pharmacist makes an unintentional and inadvertent dispensing error, this should not constitute a criminal offence unless of course there are seriously aggravating factors such as gross negligence which leads to very serious harm or death. These proposals do not change the current position, inadvertent dispensing errors will still be criminal offences; these proposals merely offer some conditional defences for two of the offences under which pharmacists are exposed to the possibility prosecution. They also still leave pharmacists exposed to criminal proceedings in the event of a dispensing error.

We do not agree with the overall approach which needlessly embroils pharmacists in the need to mount a defence in criminal proceedings.

More importantly, the objective of this policy work is to amend the current legislative regime, such that pharmacy professionals do not experience a needless fear of prosecution and are not deterred from reporting errors, so that there is more reporting and learning from errors to improve patient and consumer safety.

We do not believe that what is on offer achieves that objective as it does not give pharmacists the reassurance that they have been waiting for.

We are also concerned that other areas of the medicines legislation that expose pharmacists to the prospect of criminal prosecution in the event of making an inadvertent dispensing error have not been addressed by the programme board.

The Programme board looked at 4 options when it considered the best way to proceed and it opted for option 3 which was to introduce an exemption from criminal liability where an inadvertent dispensing error occurs when a pharmacy professional is acting in the course of the profession.

The board discounted the other three options. We believe however that the programme board should have considered option 2 more closely, but instead of removing criminal sanctions concerning errors from the relevant statute altogether, it could have restricted the removal of criminal liability only to pharmacy professionals.

In our experience prosecutions of pharmacy professionals under section 64 for dispensing errors are pursued when there is a failure by the police to convict for more serious offences, Section 64 can then become a default prosecution that is then relied upon by the police.

The reason why section 64 was created was to protect the public from substandard medicines supplied by unscrupulous individuals often in the pursuit of profit. Pharmacists however are caught by the scope of Section 64 because it also applies to medicines that are dispensed according to a prescription or an order given by a practitioner. We, along with other pharmacy bodies have previously indicated to government in 2012 that removing references to dispensing of a medicine ordered via prescription or an order from a practitioner from the relevant part of Section 64 would remove the criminality associated with making an inadvertent dispensing error for pharmacists.

This approach could benefit pharmacists whether they are from the community or from the hospital sector. It would still leave as offences those situations where medicines are supplied erroneously by individuals not involved in dispensing activity and consequently would provide the solution that was sought for pharmacists without diluting down the protections for the public from the risks associated with the wider medicines supply pathway.

The other option that the Programme Board should have considered in more detail in addition to Option 2, is Option 4. In its impact assessment under Policy option 4, the Board has incorrectly concluded that the current CPS guidance for the grounds under which prosecutions of pharmacists may occur is adequate – it is not. Indeed, even as recently as April 2015 a pharmacist received a police caution for a dispensing error.

As a defence association we use the CPS guidance as a working tool and we are frustrated by the lack of substance in the current version. Improved guidance would give us an increased likelihood to be able to persuade the police not to seek a prosecution. More favourable CPS guidance would give us a better chance of preventing pharmacists from being charged or cautioned in the first place.

We urge the programme board to consider these two alternative approaches as they will go a long way in achieving the policy objectives.

If however, it is accepted that these proposals will not achieve the policy objectives and support a much more productive approach to error log reporting by pharmacists and that they do no more than provide some helpful defences against prosecution in the limited area of Section 63 and 64, then we do give our support to the measures proposed as they are an improvement to the current position. We would consider this however, to have been a wasted opportunity to deliver the real changes that are needed.

Should this be the case, then we are further concerned that the proposed defences include one which requires the medicine to have been dispensed at / or from registered premises. This will exclude a large proportion of those pharmacists who work in the hospital sector where a large number of pharmacies are not registered premises. This leaves hospital pharmacists unable to take advantage of the defences that are to be made available.

Question 2:

Do you agree that, once a defendant has done enough to show that the relevant pharmacy professional might have been acting in the course of his or her profession, the prosecution should have to show, beyond a reasonable doubt, that the pharmacy professional was not "acting in the course of his or her profession" in order to secure a conviction?

We agree that the burden of proof should lie with the prosecution and that it should be at the level of "beyond reasonable doubt".

Paragraph 43 says "In the case of these new defences, the general position is that the defendant, most probably a pharmacy professional, will need to prove that they meet all the requirements of the defence, on a balance of probabilities". We believe that a pharmacy owner may be the defendant where he has not exercised his duty of candour. However we have difficulty in understanding in what other circumstances the defendant is not the healthcare professional and would welcome further clarification in this respect.

Question 3:

Do you agree the two proposed illustrative grounds that the prosecution could rely on to establish that the pharmacy professional was not acting in the course of their profession, if they were proven beyond reasonable doubt?

We agree with the illustrative grounds with one caveat; Paragraph 53 indicates that improper purpose includes monetary gain; we believe that it should also include avoiding monetary loss.

Although they have no statutory force, the guidance examples in paragraphs 52 to 54 might be helpful in a court if law, but they are somewhat limited. We would ask that more examples are provided. For greater protection, we would ask that the guidance examples should be contained in formal professional guidance in the Medicines Ethics and Practice guide issued by the Royal Pharmaceutical Society as they would then provide a useful reference tool when defending pharmacists in proceedings.

Question 4:

Do you agree that where a pharmacy professional does not follow procedures established for the pharmacy and an error takes place, this should not, on its own, constitute grounds for a decision in criminal proceedings that the pharmacy professional is not acting in the course of their profession?

Standard Operating Procedures are written to provide guidance to pharmacy teams on what actions they need to take for the majority of their activities when operating in an ideal situation. Non ideal situations in pharmacies are very common, brought about by staff shortages, heavy workloads or other developments. Furthermore, patients presenting to pharmacies can rarely be easily compartmentalised for SOP purposes. One of the greatest benefits of having a pharmacist present in a pharmacy is that they will know best when to abide by the strictures of an SOP or when to apply an alternative approach in the interests of patients; this is a great benefit and must not be considered to be a potential factor to support a prosecution.

The wider implications of paragraphs 55 to 57 are profound. The Responsible Pharmacist regulations are predicated on the need for SOP's. The PDA has consistently expressed the view that there is far too much emphasis and reliance placed on SOPs within the RP regulations and that this does not only lead to defensive practice, but it also has the effect of curtailing the right and duty of a pharmacist to exercise their professional judgement in the patients interest.

The RP regulations must be changed and we look forward to the next work stream and consultation on these changes.

The PDA believes that failing to follow established procedures should not be grounds for prosecution; we would go further and state that pharmacists following established procedures in an inappropriate situation expose both patients and themselves to risk. Consequently, we are of the view that the focus upon and the narrative surrounding SOP's within the context of these proposals is altogether unhelpful.

Question 5:

Do you agree that for the defence to apply, the sale or supply of the medicine must have been in pursuance of either a prescription or (in the case of sales) directions from an appropriate prescriber?

Yes

The defence should also operate in situations where a pharmacist independent prescriber writes the prescription and is also involved in dispensing it. It should also apply to situations where non independent prescriber pharmacists make a supply under a minor ailments scheme (or other similar system).

Question 6:

In your view, should it be part of a defence where someone is charged with a dispensing error that if an appropriate person at the pharmacy knew about the problem before the defendant was charged, all reasonable attempts were made to contact the patient unless it was reasonably decided not to do so?

Yes – and we would add to the guidance presented.

The only person who is in a position to judge whether an error is significant and can make a decision on whether the patient needs to be contacted is the pharmacist on duty at the time the error is discovered. This is partly a clinical decision and partly one that is also based on experience leading to a risk vs benefit analysis. The pharmacist is the only person in the team who has the necessary skill and knowledge to make such a decision; the pharmacist must be made aware of all errors.

We fully support the concept of the owner of a pharmacy having a duty of candour and by extension having processes in place to ensure that all errors are reported and acted upon. However we believe that due to conflicts brought about by discrepancies in Medicines legislation circumstances exist which mitigate against owners putting such systems in place or to fostering the exercising of the duty of candour.

Following the case of Elizabeth Lee in the Royal Court of Appeal, pharmacist pharmacy owners may still face prosecution for labelling offences under the Human Medicines Regulations 2012 for which there is no defence. Systems for gathering information on dispensing errors could bring forward cases where labelling errors have been made by owner pharmacists and this will lead to an increase in the risk of prosecution of owners.

If it has already been accepted by government that error reporting is currently being inhibited through the fear of prosecution and that there is a need to remove the possibility of self-incrimination, then surely it must also recognise that pharmacist employers must not end up exposed.

The prospect of a prosecution for which there is no defence for owner pharmacists would also be in conflict with the duty of candour. Keeping the potential prosecution for labelling errors creates conflict and tension with this section 60 order introducing conflicts of interest between pharmacy owners and pharmacists.

We urge the government to remedy this situation by removing these risks for pharmacist owners by amending the Human Medicines Regulations accordingly.

Question 7:

Do you agree that the unregistered staff involved in the sale or supply of a medicine (including, for example pharmacy assistants who hand over medicines that have been dispensed or van drivers who deliver medicines to patients) or the owner of the pharmacy where a dispensing error occurs should potentially be able to benefit from the new defences?

Yes, but in respect of non-pharmacist pharmacy owners we do not see how the regulations apply. Virtually all pharmacies, whether independent or part of a chain, are registered as limited companies; this includes some of the largest corporate pharmacy employers in the UK. A limited company is not a person and in the context of a limited company what "person" might be facing a prosecution that would need to rely on this defence?

Question 8:

Do you agree that the defence should not apply in cases where unregistered staff involved in sale or supply of medicine deliberately interfere with the medicine being sold or supplied at or from the pharmacy?

Yes.

Question 9:

Do you agree with the overall approach to the new defence in section 67B in relation to the offence in section 63, i.e. to retain the criminal offence and provide a new defence subject to essentially the same conditions as will apply in relation to section 64? If you think different, additional or fewer conditions should apply, could you explain what, if any, conditions you think should apply.

We do not agree with the overall approach which needlessly embroils pharmacists in the need to mount a defence in criminal proceedings.

However, subject to the caveats described in response to question 1 above we agree that the approach to section 63 should be the same as section 64.

Question 10

Do you agree that in relation to GPhC, the obligation to set standards in rules should be removed?

That the GPhC will be given greater flexibility to allow it to work more rapidly is to be welcomed. However, under current arrangements which are to be changed, the GPhC is required to undertake a detailed consultation.

When the Law Commission made its recommendations, it is unclear to what extent it considered the fact that the GPhC is relatively new to pharmacy regulation and that it is still undergoing its formative experiences. Additionally, as an organisation that is no longer run and operated by pharmacists it has a limited insight of the realities of pharmacy practice. In the interests of public safety, if the obligation to set standards in the rules is removed then the GPhC must be statutorily required to consult with the appropriate stakeholders on any of its proposals in the future.

Question 11

Are you content to place a statutory duty on PSNI to set standards for registered pharmacies?

We would need to understand first any proposals on how the current joint role of regulation and representation is to be managed by the PSNI going forward.

Question 12

Do you agree with the approach we are taking to breaches of registered pharmacy standards by pharmacy owners?

That the approach to premises standards is to be moved from the current position of prosecution and put on a disciplinary footing is to be welcomed.

However, whereas action currently taken under fitness to practice procedures is taken against individual pharmacists who are natural persons, it is difficult to understand how fitness to practice proceedings can be taken against a body corporate who is not a natural person. The vast majority of pharmacies are owned by limited companies and some of these are large corporate entities. If the ultimate sanction for an individual professional is to be struck off from the register of pharmacists, then the ultimate sanction for a limited company with one pharmacy could be a removal of that pharmacy from the register of pharmacies. However, we need to understand more about how the GPhC would apply the ultimate sanction of removing a large corporate multiple from the register in the event that it was unprepared to make any changes required of it by the regulator in the style of its operations. The corollary to this, is that if the GPhC cannot see a situation where it would remove from the register an entire corporate chain, then this would represent an imbalance in its approach to the way that it deals with independent and corporate pharmacies and ultimately to its important duty of protecting the public through regulation.

Question 13

Do you agree with the changes to provide for publication of GPhC reports and outcomes from pharmacy inspections?

That the public is to be allowed to see the reports and outcomes of GPhC inspections is to be welcomed. However, the initial pilot phase of the GPhC's inspections has shown that it is vital first to get both the inspection process and the inspection outcome grading process right. The initial pilot graded both highly performing pharmacies and less well performing pharmacies as satisfactory demonstrating that the GPhC grading process was flawed. Had this information been published it would have created a misleading perception amongst the public and had the potential to damage the image of pharmacy.

The GPhC must engage with stakeholders so as to arrive at a position that enjoys the support of the profession before it embarks on any programme to publish its reports. The thrust of this point is further embellished in the Answer to Question 10.

Question 14

Do you agree with the changes to the GPhC powers to obtain information from pharmacy owners?

Yes

Question 15

An IA has been prepared covering the costs and benefits of the dispensing error proposals. Do you agree with our assessment? If not, pleased provide details and estimates of any impacts and costs that you consider are not relevant, or alternatively have not been taken into account.

The Impact assessment works on an assumption that providing defences to prosecutions for offences under Section 63 and 64 will bring an end to prosecutions of pharmacists in the event of inadvertent dispensing errors, it then assumes that this will result in a 400% increase in error reporting. We do not agree with this assumption. Once the police have completed any gross negligence manslaughter investigations and a prosecution under this charge has been excluded, they have historically defaulted to any other offences that they can find to prosecute pharmacists. The emphasis has tended to be upon offences under which there is a likelihood of a successful prosecution. In the past, the police have focussed upon Section 64 offences although labelling offences (Section 85.5) have also been relied upon. In the event that the defences offered in this consultation are made available and hence the likelihood of a successful prosecution under Section 64 is reduced, the police instead are likely to seek alternative offences under which to secure a successful prosecution. Pharmacists are still exposed to other offences when making a dispensing error for which the work of the Rebalancing Programme board has not considered as it has stated that it has no remit to do so. Furthermore, the consultation is clearly built upon the belief that pharmacists will now become much more involved in error reporting since the fear of criminal prosecution will have receded and this will lead to the benefits of learning. In light of the fact that the approach taken by the Rebalancing Programme Board has not removed criminality, nor has it provided defences for other areas of the legislation for which exposure to prosecutions still remains, we cannot see how the benefits of a greater involvement in error reporting and learning will be enjoyed.

Question 16.

Do you consider there are any additional significant impacts or benefits on any sector involved that we have not yet identified? Please provide details and estimates.

The impact assessment (page 14. 32) suggests that benefits would accrue for the police force from a reduced need to undertake investigations, we disagree.

This would only be the case if Option 2 and Option 4 were to be pursued and CPS guidance was to be strengthened to mitigate against prosecutions for inadvertent dispensing errors.

In the event that these proposals were to proceed, the police would have to establish whether or not the pharmacist could rely upon the defences now being proposed as the burden of proof has been placed upon the prosecution. This would involve the police in significant additional costs that currently they would not incur. Furthermore, in the event that the police could not successfully prosecute for Section 64 offences, because the defences to Section 64 offences were viable, time would then need to be spent in preparing to pursue alternative avenues available in the legislation under which to prosecute.

Question 17

As part of preparing the IA we have asked business representatives whether, if the new defences were introduced, they would have a downward impact on employee cost pressures (for instance, any reduction in the risk of being prosecuted could slightly reduce legal or insurance costs). No significant cost impacts have so far been identified. Are there any specific impacts on small and micro businesses that we need to take into account?

PDA arranges insurance for more than 24,000 pharmacists and consequently, it is routinely in discussions with underwriters and actuaries in relation to the assessment of risks. For reasons that have already been described in Question 15, there will be no downward impact upon the costs of insurance because it is not felt that the risk of a prosecution for dispensing errors has been reduced by these proposals.

As has been identified in Answer 16, the legal defence costs are likely to increase since there is already considerable legal cost associated with the area of police station representation which the new defences would likely exacerbate. Furthermore, the condition requiring the owner to take responsibility for a situation where a pharmacist has not made contact with a patient is one that introduces potential conflict and is likely to result in further increases in legal activity.

Question 18

At this stage, we do not consider it feasible to estimate a 'typical' cost of prosecutions for dispensing errors on individual professionals or pharmacy businesses because of the small numbers involved over the last decade. Do you agree with this? If not, do you have any relevant information which we can consider?

We agree that there is no such thing as a typical prosecution, but this question presupposes that the costs are limited to prosecutions. In reality, significant costs are spent in trying to defend a pharmacist in the early stages of police investigations so as to prevent a case from progressing to prosecution stage, a process that often takes many months or even a year.

Typically, these pre-prosecution costs will cost in the region of £15,000 to £25,000 per case.

From the narrative contained in the consultation and also in the question itself, it is apparent that the Rebalancing Board has not considered these pre-prosecution episodes in its analysis of the wider problem.

In the event that a prosecution cannot be avoided then the additional costs of a prosecution, involving legal and counsel representation and often more than a year of preparation, will be in the region of £120,000 and may be more in complex cases. In the event of an appeal, these costs will increase to beyond £175,000.

Beyond these costs are also the costs associated with defending pharmacists in employer disciplinary processes and also providing defence in regulatory disciplinary episodes when dispensing errors occur where the commission of a criminal offence is cited. Whilst it may not have been the remit of the Rebalancing Programme Board to seek to avoid these processes, the board should be aware the extent to which the exposure to these additional and highly worrying exposures contribute to the reluctance of pharmacists to report errors.

Question 19.

We have provided an estimate of the magnitude of the costs and benefits that may arise from the potential implementation of the introduction of the change in approach to dispensing errors. These estimates rely on a number of general assumptions – summarised in Annex B of IA. These include the length of time it takes a pharmacist to deal with different types of dispensing errors. In addition, we have also made assumptions regarding the potential benefits from learning and from a lower risk of prosecution. Do you think that the assumptions we have made are proportionate and realistic? Please provide an estimate of the cost of such assumptions.

In our answer to Question 15, we have already expressed the view that in light of the fact that the approach taken by the Rebalancing Programme Board has not removed criminality, nor has it provided defences for other areas of the legislation for which exposure to prosecutions still remains, we cannot see how the benefits of a greater involvement in error reporting and learning will be enjoyed.

However, if we assume that the IA prediction is correct and there will be an increase of error reporting rates by approximately 400% and that this leads to greater learning, we disagree that this would lead to a 30% reduction in dispensing errors after four years. This may be the case if the lessons learned were to be acted upon. However, in the experience of the PDA, in supporting our members through a large number of dispensing error episodes every year, it is clear that excessive workloads and staffing shortages are the single largest cause of dispensing errors. That an increase in learning will simply tell us what is already known, that staffing levels need to be increased, will not in itself reduce dispensing errors. Only a significant increase in the quality and quantity of staff in the pharmacy and/or a much greater reliance on technology will result in a reduction in dispensing errors.

Question 20

We have prepared an IA covering the costs and benefits of the premises standards proposals. Do you agree with our proposals? If not, please provide additional information (with estimates) regarding other costs or benefits that you think have not been considered in the IA.

We have no further information to add.

Question 21

Our initial analysis of the proposed changes to pharmacy premises standards suggests that our preferred option, Option 2, has no significant transition or ongoing costs relative to the current framework. This is based on assumptions in Annex A of the IA. Are our assumptions valid? If not, please identify what other costs and assumptions have not been identified and provide examples and estimates that will help us quantify and monetise the costs.

We have no further information to add.

Question 22

We do not consider that there will be any specific adverse impacts from this proposal on small or micro businesses. Do you agree? If not, please identify what these impacts are and their likely costs and explain why they are specific to small and microbusinesses. Also provide evidence on how small and micro businesses would be affected by an alternative prescriptive rules based approach compared to an outcome based system. Please say i) what assumptions we should use ii) identify the impacts iii) estimate their likely costs and explain why they are relevant to small and micro-businesses.

We have no further information to add.

Question 23.

Do you have any additional evidence which we should consider in developing the assessment of the impact in equality?

We have no further information to add.