Rebalancing Medicines Legislation and Pharmacy regulation: draft Orders under section 60 of the Health Act 1999
Royal Pharmaceutical Society (RPS) Response

General comments:

The Royal Pharmaceutical Society (RPS) believes that patient safety will be improved if the threat of criminal prosecution is removed from dispensing errors because more pharmacy professionals will report, share and learn from mistakes. The changes suggested in this consultation will enable pharmacy professionals to move away from a culture of fear and to encourage them to be more innovative in their practice. We encourage all pharmacy professionals to do this through our existing professional standards and this will be reinforced by the legislation outlined in the consultation.

The RPS strongly believes that we need to create the right environment for pharmacy professionals to carry out their practice but we must also continue to protect patients and the public. The changes proposed in this consultation will support pharmacy professionals to do this. We assume that the Regulator response will be proportionate and in the spirit of balancing public safety with enabling a culture of improvement through reporting without fear

We are concerned that this solution does not apply to the whole profession, but we do however understand the complexities of different healthcare settings and the requirement to remove the long standing anomalies in the legislation for as many pharmacists as possible, as quickly as possible. Pharmacists, wherever they are working are bound by the same regulatory and professional standards and we believe that the conditions proposed should apply to the individual professional and not the premises in relation to the hospital situation.

It is therefore imperative that a solution be found for pharmacists working in hospitals as quickly as possible and that discussion in this area continues at pace until a solution is agreed. Hospital pharmacists were very appreciative of the commitment the board made to the next stage of the workstream during the consultation events and should be kept informed of any progress and expected timelines relating to their situation.

The role of the profession is becoming more and more clinical with many of the profession undertaking roles that are more patient facing, in pharmacies and elsewhere in the healthcare system. Clarity is required as to how GPhC will be assessing these roles as section 63 relates to supply only and not clinical advice. In addition the term ‘associated premises’ needs to be defined and clarified as there is concern as to how the proposed changes would affect care homes and pharmacists working in a ‘hub and spoke model’.

We understand that as the new regulatory environment evolves checks and balance will be available to provide challenge to change.

Questions:

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 Royal Pharmaceutical Society supports the approach taken in this consultation. We have been campaigning for a number of years to remove the threat of criminalisation due to inadvertent dispensing errors. We believe that the approach taken will enable pharmacists to share and report errors increasing the learning from such errors and thereby improving patient safety.

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?
Yes, we believe that this is the correct approach to take. It should be the responsibility of the prosecution to demonstrate that the pharmacy professional was not acting in the course of their profession. We would expect the Departments of Health to issue supporting guidance to clarify what is considered 'acting in the course of his or her profession', or what is considered as acting outside of this.

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 two illustrative grounds laid out in the consultation and these should form the basis of guidance to support pharmacy professionals in understanding the new legislation.

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?
We completely agree with this. Sometimes a pharmacy professional may work outside of an established procedure for the best interest of the patient. This does not mean they are working in an unprofessional manner, just that they are using their professional judgement. Professional autonomy must be valued and encouraged at all times.

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 RPS agrees with this.

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?
We agree that efforts should be made to contact the patient if an appropriate person at the pharmacy knew about the problem. The consultation clearly states that as long as reasonable steps are taken to notify the patient, the patient does not actually have to be located for the defence to be made out. However, we would suggest to the Rebalancing Programme Board that they reconsider the need to include this requirement within legislation. The General Pharmaceutical Council (GPhC) requires that pharmacists and pharmacy technicians need to be open and transparent at all times, and states that candour is an essential duty for all professionals

(http://www.pharmacyregulation.org/news/gphc-highlights-requirement-openness-and-honesty-amongst-pharmacy-professionals-signing-joint). Given that the concept of rebalancing is to use regulation rather than legislation we believe the GPhC regulatory stance is sufficient.

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?
We agree that other members of the pharmacy team should also be able to use the defence outlined in this consultation. Members of the pharmacy team are often involved in the supply of medicines and can also make inadvertent errors so should be subject to the same conditions as the pharmacy professionals.

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?
Obviously if a member of the pharmacy team deliberately interferes with the medicine then they should be subject to the legal consequences that result from such action.

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 agree with this.

Question 10: Do you agree that in relation to GPhC, the obligation to set standards in rules should be removed?
Yes, we agree with this.

Question 11: (for respondents in Northern Ireland): Are you content to place a statutory duty on PSNI to set standards for registered pharmacies?
NA

Question 12: Do you agree with the approach we are taking to breaches of premises standards by pharmacy owners?
Yes, we agree with this approach assuming that an appeals process will be established for registrants to appeal against a GPhC decision.

Question 13: Do you agree with the changes to provide for publication of GPhC reports and outcomes from pharmacy inspections?
Yes, we agree with this. Patients and the public should be able to access the outcomes of GPhC inspections of pharmacies that they use.

Question 14: Do you agree with the changes to the GPhC powers to obtain information from pharmacy owners?
Yes, we agree with this. We welcome the safeguards that will be established to ensure the rules do not impose disproportionate burdens.

Question 15: An IA has been prepared covering the costs and benefits of the dispensing error proposals. Do you agree our assessment? If not, please provide details and estimates of any

impacts and costs that you consider are not relevant or, alternatively, have not been taken into account.
Yes, we agree with the assessment and are not aware of any additional impacts or costs that could be included.

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.
We believe that all of the significant impacts and benefits have been included in the impact assessment.

Question 17: As part of preparing this IA we have asked business representatives whether, if the new defence were introduced, it 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 specific impacts on small and micro-businesses that we need to take into account?
We believe that you have taken all of the impacts into account already.

Question 18: At this stage, we do not consider it is 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, the small number of prosecutions over the last decade make it difficult to estimate such a cost.

Question 19: We have provided an estimate of the magnitude of the cost 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 the IA. These include the length of time it takes a pharmacist to deal with different types of dispensing errors. In addition, we have made assumptions regarding the potential benefits from learning and from a lower risk of prosecution. Do you think the assumptions we have made are proportionate and realistic? If not, what assumptions should we use? Please provide an estimate of the cost of such assumption.
We believe that the assumptions that have been made are proportionate and realistic.

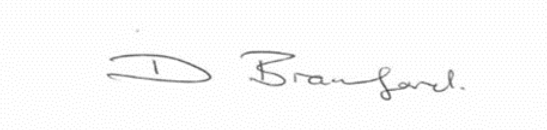
Question 20: We have prepared an IA covering costs and benefits of the premises standards proposals. Do you agree our assessment? If not, please provide additional information (with estimates) regarding other costs or benefits that you think have not been considered in the IA.
Yes, we agree with your assessment.

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 believe the assumptions are valid.

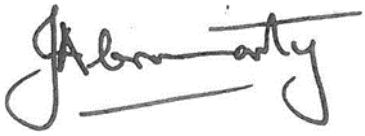
Question 22: We do not consider there will be any specific adverse impacts from this proposal on small or micro businesses. Do you agree? If not, please identify what these impacts are and their likely costs and explain why they are specific to small and micro businesses. Also, please provide evidence 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 and (iii) estimate their likely costs and explain why they are relevant to small and micro businesses.
Yes, we agree

Question 23: Do you have any additional evidence which we should consider in developing the assessment of the impact on equality?
We do not have any additional evidence to be considered.



Dr David Branford PhD, FRPharmS, FCMHP
Chairman, English Pharmacy Board



Professor John Cromarty FRPharmS
Chairman, Scottish Pharmacy Board

Mair Davies. FFRPS, FRPharmS, FHEA.
Consultant in Pharmacy Education & Training
Chair, Welsh Pharmacy Board

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

About us

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

The RPS leads and supports the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science, practice, education and knowledge in pharmacy and the provision of professional standards and guidance to

promote and deliver excellence. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

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

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

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