

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

Member briefing

Why is this important?

The threat of criminal prosecution for dispensing errors has long been a key concern for pharmacists. The RPS recognises this and has been working with government and other pharmacy organisations as part of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board to change the law with regard to dispensing errors and criminal prosecution. We also believe that patient safety will be improved if the threat of criminal prosecution is removed from dispensing errors because more people will report, share and learn from mistakes

What is the Government proposing?

This UK wide consultation proposes two significant changes in law that will have an impact on pharmacists and pharmacy practice

- Changes to the way criminal law is applied to dispensing errors
- Changes to the way the pharmacy regulator, The General Pharmaceutical Council (GPhC), sets, monitors and enforces standards for registered pharmacies

What's the background to these changes?

These changes are part of wider changes for “rebalancing” between professional regulation and criminal law. The government is seeking to address the balance between legal requirements, regulatory requirements and professional practice so that professional practice is enforced by registration sanctions rather than the criminal courts. The rebalancing programme for pharmacy is about improving pharmacy services for patients and the public, and reducing and removing barriers to the development of pharmacy practice and new pharmacy services. This work is essential to enable the transformation of pharmacy services and the further development of pharmacists' roles. More information on the work of the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board can be found at <https://www.gov.uk/government/groups/pharmacy-regulation-programme-board>

How is the law around dispensing errors changing?

The proposals in this consultation will remove the threat of criminal prosecution for pharmacists who make a dispensing error. A new legal defence is proposed and a number of conditions will apply, you must be a registered pharmacy professional, working in a registered premises, in the course of your professional duty, dispensing a medicine from a prescription or from the directions of a prescriber and if you have knowledge of the error you must have notified the patient of the error. If these conditions apply then you would have a robust defence against any criminal sanctions.

If there was intention to cause harm, or if criminal negligence was suspected, then criminal sanctions would still apply.

More information on the new legal defence can be found at

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404797/pharmacy-consult-faq.pdf

What else is in these proposals?

This consultation is also seeking changes to legislation which will remove the requirement for the GPhC to set standards for registered pharmacy premises in legislative rules. This allows more flexibility (as changes to the standards will not need legislative change) and enables the regulator to deal with any breaches in standards through

regulatory processes rather than enforcement notices (which could lead to criminal proceedings). Other changes will be enabled including changes which will allow the GPhC to publish inspection reports.

More information can be found here

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/404797/pharmacy-consult-faq.pdf

What about future proposals?

The work of the Programme Board on dispensing errors and registered pharmacy premises has been identified as a high priority and these proposals are both included in the current consultation. However there are a number of other areas of work which are also underway and further proposals will follow. These include

- Pharmacy owners, Superintendent Pharmacists and Responsible Pharmacists – proposals to clarify the roles, accountability and competence of pharmacy owners and superintendents, and the roles of Responsible Pharmacists
- Supervision – reviewing the medicines legislation and developing new proposals to remove legislative barriers to the development of new models of pharmacy service whilst still ensuring patient and public safety.
- Hospital pharmacy - currently not all hospital pharmacies are registered pharmacies in the same way that community pharmacies are. One of the conditions of the new defence against criminal prosecution for dispensing errors is that the dispensing took place in registered pharmacy premises. This means that pharmacy professionals working in a hospital pharmacy which is not registered with the GPhC would be unable to use the new defence. The programme board has recognised this issue and is considering new regulatory arrangements for hospitals which will be discussed with stakeholders and followed by formal consultation.

Events to find out more:

The Departments of Health across England, Wales, Scotland and Northern Ireland are holding a series of events for patients and the public to explain the changes to them and seek their views. RPS is hosting similar events for pharmacists and pharmacy technicians, in partnership with DH, GPhC and APTUK, to explain the changes and seek the views of the pharmacy profession. These events are being held on the following dates and times and more information can be found http://www.rpharms.com/what-s-happening-news_show.asp?id=2476

Additional information.

This consultation is UK wide so covers England, Scotland Wales and Northern Ireland. It was published on 12 February and responses can be submitted until 14 May 2015.

You can find the consultation documents at <https://www.gov.uk/government/consultations/pharmacy-legislation-on-dispensing-errors-and-standards>

What does the RPS think about this?

Ash Soni, RPS President, welcomed the publication of the [Rebalancing Medicines Legislation and Pharmacy Regulation consultation](#), saying:

"The threat of criminal prosecution for reporting dispensing errors has weighed heavy on the profession for too long. The knock on effect has been a reduction in the potential reporting sharing and learning from errors that will ultimately improve safety for patients and the public. I believe that the proposals and programme outlined in [today's announcement](#) offer an opportunity to improve this situation substantially.

"The RPS has been fully involved in the Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board where the professional views of the RPS boards in England, Wales and Scotland have been helpful and influential in shaping the consultation and that has been published today.

"The fact the Rebalancing Board is made up of the full range of stakeholders including community and hospital pharmacy practitioners, and most importantly patients, means there is already a consensus around the way forward.

"I am confident that exactly the same provisions will be made for pharmacists working in hospitals, ending the automatic criminalisation of dispensing errors made by hospital pharmacists.

"I am aware that it will be frustrating for pharmacists in hospitals that these proposals will take longer to put into place. Hospital pharmacists have my complete assurance that my colleagues on the Rebalancing Board will not rest until this happens and it remains the Royal Pharmaceutical Society's number one focus. I hope the announcement today proves that change can and will happen if pharmacy works together to provide a united voice

We will be responding to the consultation in full in the coming weeks and welcome the views and comments of our members to ensure we can submit a response which is informed by your views.