



Department
of Health

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

Frequently asked questions

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About this consultation

Pharmacy is changing. Today's pharmacies no longer simply dispense medicines. They provide clinical services such as medication reviews to help people get the most from their medicines, and they also deliver public health services such as stopping smoking, weight loss and flu vaccines. Encouraging pharmacy professionals to report, share and learn from mistakes improves patient safety through ensuring mistakes aren't repeated.

The rebalancing programme is about protecting, promoting and improving pharmacy services, and reducing and removing barriers to the responsible development of pharmacy practice and new services. This work is essential to enable the transformation of pharmacy.

Q - What is the Government consulting on?

This is a UK-wide consultation issued on behalf of the four countries.

At this stage we are consulting on proposals for changes to the legislation for (a) dispensing errors and (b) registered pharmacy standards.

Q - Why should I respond to this consultation?

It is important that you respond even where you agree with the changes proposed.

We are keen to have your views and to demonstrate that the changes proposed have the positive support, not just of representative bodies, but of individuals also.

Q - What does 'rebalancing' mean?

Rebalancing is about ensuring the right balance between Government legislation and professional regulation to ensure the safety of users of pharmacy services while encouraging responsible development in practice.

We also want to create a systematic approach to quality in pharmacy. Some sanctions and detailed provisions that are currently in medicines legislation will be better handled through the professional regulators, the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI).

Q - What are the consultation timescales?

The consultation runs from 12 February to 14 May 2015. After it closes, the Department of Health, with the other UK countries, will analyse and publish the results. Once any necessary changes are made, we will seek to take the legislation through parliament at the earliest possible opportunity in the new Government.

Q - How can I give my views?

Visit www.dh.gov.uk for further information, and to complete the consultation questionnaire. We are also holding online discussions, patients and public events and pharmacy representative organisations are holding consultation events.

About the rebalancing programme

Q - What does the programme cover?

It is looking to address recent changes in pharmacy practise to enable pharmacy professionals to do more for patients and the public. This includes:

- dispensing errors - reviewing the criminal offence in respect of dispensing errors;
- registered pharmacy standards - changing legislation to provide the pharmacy regulators with the appropriate powers to give effect to an outcomes based approach to the regulation of registered pharmacies
- the roles and responsibilities of the responsible pharmacist and the superintendent pharmacist - providing greater clarity of the roles, accountability and competence;
- hospital pharmacy - considering regulatory arrangements for hospital pharmacies;
- pharmacist supervision – reviewing legislation to identify restrictions that might impede the full use of the skills of the professional pharmacy workforce or restrict practice development and innovation.

Q - What will it achieve?

Key outcomes include:

- a continuous focus on safety for patients and the public through learning from dispensing errors as a result of increased reporting of errors;
- better use of the pharmacy workforce to support patients' health and wellbeing;
- legislative and regulatory arrangements that allow for progress in pharmacy practise and development of pharmacy professionals as well as more reliance on professional regulation standards.

These are significant areas for pharmacy professionals, government policy and patient and public safety.

Q - Where will the changes apply?

These changes are intended to cover the United Kingdom. However, there are constitutional, regulatory and operational differences in relation to pharmacy matters in the four countries in the UK, which will affect how changes are applied.

Q - Who has been involved in developing the proposals?

Key stakeholders, including the General Pharmaceutical Council (GPhC), Pharmaceutical Society of Northern Ireland (PSNI), Royal Pharmaceutical Society (RPS), Pharmacy Forum Northern Ireland (PF NI), the Association of Pharmacy Technicians (APTUK), Pharmacy Voice and representatives of other pharmacy organisations, patients and public have been directly involved by being part of the programme board, chaired by Ken Jarrold. There is also a Partners' Forum which acts as a sounding board to test out the board's proposals. Details, including membership and programme terms of reference is at www.dh.gov.uk.

Why is this happening, and what does it mean?

Q - What does this mean for pharmacists and pharmacy technicians?

Rebalancing aims to examine the respective scope of legislation and regulation and the interface between them with a view to delivering a modern approach to regulation and enable pharmacy practice development while maintaining and improving safety for the users of pharmacy. For example, some matters that are at present in legislation made by government are being examined to see whether they should instead be within the remit of the pharmacy regulators.

A priority for the programme board has been to examine medicines legislation relating to dispensing errors. It recognises that the fear of prosecution for inadvertent dispensing errors affects the level of reporting of such errors, by pharmacists and pharmacy technicians, and therefore the learning from these errors.

The programme also includes clarifying the roles and responsibilities of the pharmacy owner, responsible pharmacist, superintendent pharmacist and the pharmacy team.

Q - What does this mean for pharmacy customers and patients?

Pharmacists, pharmacy technicians and pharmacy teams will be able to better support patients health and wellbeing by optimising medicines use, or making public health interventions. Increased learning from dispensing errors will improve patient safety.

Q - Will proposals on dispensing errors and pharmacy standards put more pressure on independent pharmacies?

The proposals cover small and large pharmacies, and should not have any significantly different impacts on small firms relative to larger pharmacy businesses.

Q - If we are relaxing the rules, won't this lead to a fall in standards?

We are not relaxing the rules. By removing the threat of criminal sanctions for inadvertent dispensing errors, we are encouraging a culture which focuses on improving patient safety through more transparent reporting and learning from mistakes. Pharmacy professionals who are wilfully negligent or set out to cause deliberate harm will still face criminal prosecution, as is the case with all healthcare professionals.

Q – When will you address dispensing errors by pharmacy professionals in hospitals?

The programme board has started to look at the remainder of its programme. Work is underway to explore how the governance element of the defence for dispensing errors can be captured, in terms of relating it to a hospital pharmacy service which is under the direction of a pharmacist, rather than registration of pharmacy premises. The board is considering this matter further and will bring forward firmer proposals for discussion with stakeholders, followed by formal consultation.

Q - When will you consult on superintendent and responsible pharmacist proposals?

Proposals on the superintendent and responsible pharmacist will be put out for consultation once the necessary government clearances have been completed.

Q - When will you consult on supervision of the sale and supply of medicines by pharmacists?

Once the proposals are at a suitable stage, they will be discussed within the Partners' Forum and, in due course, there will be a formal public consultation.

About dispensing errors

Q - What do you mean by 'dispensing errors'?

A dispensing error is a discrepancy between a prescription and the medicine that is delivered to the patient, made in error by the person dispensing the medicine.

Q - Why are you removing the criminal offence for a dispensing error?

We are not removing the criminal offence. We are creating new defences that will set out the circumstances in which a criminal offence would not apply to inadvertent dispensing errors made by registered pharmacists and registered pharmacy technicians.

Q - Why can't the criminal sanction be removed completely?

This piece of legislation is used in many different situations, in addition to pharmacy, and cannot be removed completely. It has never been our intention to remove the criminal sanction completely because, as a matter of public protection, we need to retain the ability to prosecute in certain circumstances.

Q - How many dispensing errors take place each year?

Research into this is small scale, but studies show that of the 1 billion prescription items dispensed a year by community pharmacists, the vast majority are done without error.

Q - Why is criminal prosecution such a concern? Isn't it right to protect the public? Are you opening patients up to additional risk?

Knowing that a mistake can result in a criminal prosecution doesn't necessarily mean that patients and the public are better protected. It can lead the pharmacy professional to be wary to report dispensing errors because they would admit to a criminal offence by doing so. One of the aims of this work is to support the professional leadership in encouraging a culture of reporting mistakes, learning from them and sharing that learning. There is evidence that this approach is safer for patients and the public.

Q - If you know that errors are occurring why haven't you done something about this sooner?

There have been many attempts, including legislative proposals, to address the problem. The legislation governing dispensing errors is complex and agreement was needed from the many stakeholders affected by the legislation.

Q - Why are you only focussing on pharmacists and pharmacy technicians making dispensing errors? Surely other staff who dispense should be included?

Pharmacies are the major suppliers of medicines, and pharmacists have been prosecuted for apparent errors. There is an urgent need to address the fear among pharmacy professionals of criminal proceedings for dispensing errors. The aim is to encourage a culture of greater reporting and learning from errors, thereby improving patient safety.

Q - Do these proposals cover dispensing doctors?

No. They only relate to registered pharmacists in the UK and, in GB, registered pharmacy technicians where the medicine is sold or supplied from a registered pharmacy.

Q - What types of checks currently get done in a pharmacy?

Pharmacists and pharmacy technicians perform a number of checks on prescriptions and dispensed medicines before they are supplied to patients and the public. This includes a clinical check, by the pharmacist, to confirm that the treatment meets the needs of the patient and the prescription meets all the legal requirements.

An additional check where the person dispensing checks their own work and marks/initialises the dispensing label as appropriate, and a final accuracy check (generally by a qualified accuracy checking pharmacy technician or pharmacist) are undertaken. The items are then packed ready for supply to patients.

Q - If a dispensing error is made against a prescription issued by a supplementary or independent pharmacist prescriber, would that be a criminal offence on the part of the dispenser?

Yes, if the medicine is being supplied against a prescription in this situation, then the section 64 offence (supplying a medicinal product which is not of the nature or quality demanded by the purchaser) would apply, but there would now be a defence available provided the conditions were met.

Q - As a pharmacy technician, if I make an error on a delegated task, what would the proposals mean for me?

If you are registered with the General Pharmaceutical Council, then the proposals on defences will cover you as it does pharmacists.

Q - What sanctions will remain in criminal law?

The criminal offence provision within the medicines legislation will still be there. That is, dispensing errors that do not meet the conditions that provide for a defence will continue to be strict liability offences, i.e. they will be treated as criminal offences.

Q - I am a pharmacy owner - could I potentially be prosecuted for not notifying a patient of an error if the registered supervising pharmacist I employ knew about the error?

Yes, under your corporate duty of candour as a pharmacy owner, even if you do not know about the error but the registered supervising pharmacist does, you are, as the owner, potentially liable to prosecution. The intention of the corporate duty of candour is to create a powerful incentive for owners to remain on top of what is happening in their pharmacy businesses.

Q - I am a pharmacy owner - could I potentially be prosecuted for not notifying a patient of an error even if the registered supervising pharmacist I employ did not know about the error?

A pharmacy owner in this situation is unlikely to be prosecuted if they, nor the registered supervising pharmacist they employ, did not know of the error.

Q - I am a registered pharmacist, could I potentially fail to meet the candour element of the defence, for not notifying a patient of an error made by a member of staff I am supervising even if I did not know about the error, but they did?

A registered pharmacist in this situation could be liable for prosecution if the dispenser does nothing about the error as the pharmacist cannot rely on their own ignorance of the problem as a way of avoiding liability. The intention of the professional duty of candour is to create a powerful incentive for pharmacists who are supervising non-registrants (which, in Northern Ireland would include pharmacy technicians) to remain on top of the activities they are supervising.

Q - Where a patient ends up in hospital as a result of the dispensing error, and the clinician treating them is aware of the error, does the pharmacist still have a duty to notify the patient of the error if they know about it?

If the clinician was aware of the dispensing error, it would be up to the clinician treating the patient to consider whether or not to notify the patient.

Q - Elizabeth Lee, a locum pharmacist, successfully appealed against her conviction for a labelling offence as she was not supplying a medicine “in the course of a business carried on by him or her”. Does regulation 269 of the Human Medicines Regulations make equivalent provision as was in section 85(5)(b) of the Medicines Act 1968?

There was an error in the transposition of section 85(5) when the Human Medicines legislation was consolidated in 2012. It is the intention of the Medicines and Healthcare Products Regulatory Agency (MHRA) to amend the legislation, at an early opportunity, to restore the original position.

About pharmacy regulation

Q - How is pharmacy regulated?

Pharmacy professionals are registered in a similar way to other health professionals, such as doctors, nurses and dentists. In order to practise as a pharmacist in the UK, individuals must be registered with the professional regulator. In Great Britain (GB), this is the General Pharmaceutical Council (GPhC), and in Northern Ireland, it is the Pharmaceutical Society of Northern Ireland (PSNI). Pharmacy technicians in GB are registered with the GPhC.

Pharmacy premises (where pharmacy medicines are sold, and where prescription only medicines are dispensed against a prescription) are registered with the GPhC in GB, and the PSNI in Northern Ireland

Hospital pharmacy

Q - Do these proposals cover unregistered premises such as medicines dispensed on hospital wards?

No. These defences only relate to medicines sold or supplied from a registered pharmacy premises.

Hospital pharmacies are not required to be registered in the way community pharmacies are. We do want those working in unregistered hospital pharmacies to have the right to the same defence as those working in registered community pharmacies. The Board is looking at proposals for this now and is fully committed to addressing the dispensing error offences for hospital pharmacy professionals at the earliest opportunity.

Q - Why is this proposal just about community pharmacy?

The Board is developing proposals to mitigate the criminal sanctions for inadvertent dispensing errors by hospital pharmacy professionals.

A large proportion of medicine transactions in hospitals are a supply against the direction of a doctor. Section 64, which concerns the nature or quality of the medicine demanded, is silent on this type of transaction and so no criminal offence is committed if a dispensing error is made when a medicine is supplied against the direction of a doctor or other appropriate practitioner, in hospitals or elsewhere. However, if a dispensing error was made when a medicine is supplied against a prescription or sold the section 64 offence would apply.

Also the section 63 offence, concerning the adulteration of medicines, applies to all dispensing transactions, including sale or supply against a prescription or the directions of doctor or other appropriate practitioner.

The current proposals to mitigate the criminal offences in section 63 and 64 for dispensing errors, aimed at community pharmacies, as part of the conditions of the defence require the medicine to have been sold or supplied from a registered pharmacy. Hospital pharmacies are not required to be registered, so many are not and thus would not be able to make out the defence currently being proposed for community pharmacies.

Work is already underway to explore how the governance element of the defence can be captured, in terms of relating it to a hospital pharmacy service which is under the direction of a pharmacist, rather than registration of pharmacy premises.

Q - What changes are being reviewed in hospital pharmacy?

The board, through the Chief Pharmaceutical Officers of the four countries, has commissioned a review, by an Expert Advisory Group, of the regulatory arrangements for all hospital pharmacies, including how hospital pharmacy can be included in the proposals to address the criminal sanctions for dispensing errors.

Q - What is the timetable for the hospital pharmacy project?

An Expert Advisory Group was set up to consider the regulatory arrangements for hospital pharmacies. It has concluded its work, reported to the four chief Pharmaceutical Officers (CPhOs), and made a presentation to the programme board. The Board discussed the recommendations and accompanying advice from the CPhOs. They welcomed the report and in particular the proposal for a defence for hospital pharmacy professionals who have made an inadvertent dispensing error. Further discussions will be held to progress this, which is a priority matter for the Board. The CPhOs are currently considering how to take forward the Group's other findings.