

Draft Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018

Affirmative Order Debates: 4 December 2017 (HoC) and 6 December 2017 (HoL)

Key points

1. The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 has now been laid before Parliament. The Order introduces defences to the criminal offences relating to inadvertent preparation or dispensing errors by registered pharmacy professionals (registered pharmacists and registered pharmacy technicians) acting in the course of their profession in registered pharmacies - predominantly community pharmacies.
2. The Order, developed on a UK wide basis, will now be debated in both houses before being signed by Privy Council and coming into force next year.
3. Unlike other health professionals, pharmacists and pharmacy technicians are currently at risk of criminal prosecution for a strict liability offence when inadvertent human error happens in the course of their professional practise. This order aligns pharmacists and registered pharmacy technicians who are working in registered pharmacies with other health professions. It supports increased reporting of errors, without the fear of prosecution, and allows for individual and shared learning from those mistakes, leading to improved patient safety.
4. The Department of Health, is working with the Health Departments in Scotland, Wales and Northern Ireland, to develop similar measures for hospitals and other specified pharmacy settings (e.g. pharmacy services for prisons and care home), and plans to consult on draft proposals in the New Year. This aims to ensure that pharmacy professionals working in other settings, such as hospitals (where the pharmacy is not registered), can make use of this defence.

What does the Order do?

Currently, pharmacy professionals are at risk of prosecution under section 63 (adulteration of medicinal products) and section 64 (sale of any medicinal product which is not of the nature or quality demanded by the purchaser) of the Medicines Act 1968 in the event that they prepare or dispense medicines erroneously.

This Order offers a defence to these criminal offences, if certain conditions are satisfied –

- the error must have been made by a registered pharmacy professional, working in a pharmacy registered with the General Pharmaceutical Council (GPhC) or Pharmaceutical Society of Northern Ireland (PSNI) and have been acting in the course of their profession;
- The sale or supply must have been in pursuance of a prescription or directions; and
- They or another responsible person must also have taken prompt steps to notify any affected patients when the error came to light, unless they reasonably formed the view that this was not necessary (for example they know the patient already knows), for this defence to apply.

What are preparation and dispensing errors?

Errors include for example:

- a medicine intended for another patient being dispensed to the wrong patient
- the wrong medicine being dispensed
- an ingredient is omitted or inadvertently added when making up a medicine
- the medicine being dispensed at the wrong strength or in the wrong dosage form

Will this Order negatively impact on patient safety?

We expect that this Order will have a positive impact because of an increase in the reporting of dispensing errors, which will afford greater learning opportunities – translating to increased patient safety.

It is important to recognise that pharmacy professionals may still be subject to prosecution, under the Medicines Act where the conditions of the defence are not met e.g. a deliberate disregard for patient safety would not benefit from the defence, as such a person would not be “acting in the course of his or her profession”. In addition under general criminal law, where patient harm occurs or where there is pre-meditated criminal intent, pharmacy professionals may be prosecuted on the same basis as any other health care professional and also there are professional sanctions that can be administered, if warranted, by the GPhC/PSNI where errors occur.

During consultation on this measure, there was considerable support from patient and consumer groups and recognition of the potential for increased learning to help prevent dispensing errors and improve patient safety.

Why does the Order not apply to hospitals and other pharmacy service providers?

This Order applies only to pharmacy professionals making inadvertent preparation and dispensing errors in registered pharmacies. Hospital pharmacies are generally not registered and do not have the same governance arrangements. A separate order providing defences to section 63 and section 64 of the Medicines Act 1968, in the case of an error made by a pharmacy professional in a hospital or other care setting (e.g. pharmacy services for care homes and prisons), is being developed separately.

Whilst this Order does not provide a legal defence to preparation and dispensing errors occurring outside of a registered pharmacy, prosecutors will be advised as to plans to consult on an Order in respect to this.

What is being done to increase learning from dispensing errors?

Government, regulatory and professional bodies expect pharmacy teams to be pro-active and engaged in improving patient safety.

To encourage and foster a culture of learning and improvement in registered pharmacies, the regulatory and professional pharmacy bodies across the UK have:

- Published professional standards to support increased reporting, learning, changing practice and sharing learning from dispensing errors and near misses
- Run patient safety and quality roadshows and medicines safety conferences to promote the standards and engage the professions.
- Published a range of tools and resources to support the further improvement to systems and procedures

In each of the four nations, there are also a number of system wide initiatives for example the introduction of medication safety officers/champions and reporting systems (National Reporting and Learning Systems), supporting learning and improvement at local, regional and national level and helping to better identify and address system errors.

Does the Order apply to the whole UK?

This Order extends to England, Wales, Scotland and Northern Ireland.

When will the Order come into force?

Pending agreement by Parliament, the Order will need to be made by the Privy Council in early 2018. Once made the order will enter into force 28 days later.

A further ‘commencement’ order is required to bring into force the defences in Article 4 of the draft Order. This will be progressed as soon as practically possible.