

Rebalancing Programme Board

Commencement of

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

Q&A

Key Points

1. The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 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. The new defences add to existing defences in the Medicines Act to section 63 and 64, for example where the contravention was due to the default of another person (section 121).
2. The Order, developed on a UK wide basis, has been debated and approved in both Houses of Parliament and by the Privy Council. The Pharmacy (Preparation and Dispensing Errors – Retail Pharmacies) Order 2018 (Commencement) Order of Council 2018 has been made by the Privy Council and commences the new defences on 16 April 2018.
3. Unlike other health professionals, pharmacy professionals are currently at risk of criminal prosecution for a strict liability offence (an offence where “intention” does not need to be proven for a successful prosecution) when inadvertent human error happens in the course of their routine professional practise. This Order aligns registered pharmacy professionals who are working in registered pharmacies with other health professions in this regard. 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. Department of Health and Social Care officials are 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 homes), and there are plans to consult on draft proposals shortly. This aims to ensure that pharmacy professionals working in other settings, such as hospitals (where the pharmacy is not registered), can make use of the new defences.

Legislative Process

1. What is the legislative process?

The legislative instrument creating the new defences is an Order under section 60 of the Health Act 1999. Section 60 Orders permit changes relating to the regulation of health care professionals to primary legislation (i.e. Acts of Parliament) through secondary legislation, by an affirmative procedure. The affirmative procedure means the Order had to be debated and approved by both Houses of Parliament before it could be presented for approval by the Queen at a meeting of the Privy Council. Following approval by the Queen, a further 'Commencement Order' was drafted to bring into force the new provisions in the four nations, and was made by the Privy Council on 21 March 2018 – bringing the provisions into effect from 16 April 2018.

Why is this happening, and what does it mean?

2. What does the Order do?

Currently, pharmacy professionals are at risk of prosecution under section 63 (adulteration of medicinal products) and section 64 (sale or supply in pursuance of a prescription 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 incorrectly.

This Order provides defences 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 in some cases 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.

3. Does the Order apply to the whole UK?

This Order extends to England, Wales, Scotland and Northern Ireland. The Order will come into effect in all four countries at the same time.

4. When will the Order come into force?

The Order was approved by the Queen on Thursday 8 February 2018. Following this, a Commencement Order was made by the Privy Council on 21 March 2018 - bringing into effect the new defences (Article 4 of the first Order) from 16 April 2018. This will apply to the whole of the UK.

5. Will the new legislation be reviewed?

Yes. As per Government guidance, the new provisions will be reviewed within 5 years of entering into force.

6. Why introduce these defences?

Unlike other health professionals, pharmacy professionals are currently at risk of criminal prosecution for a strict liability offence when inadvertent human error happens in the course of their routine professional practice. This Order aligns registered pharmacy professionals who are working in registered pharmacies with the other health professions in this regard. 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.

7. What other defences are available to offences under the Medicines Act in relation to section 63 and 64?

The new defences add to existing defences in the Medicines Act to section 63 (adulteration of medicinal products) and section 64 (sale or supply in pursuance of a prescription of any medicinal product which is not of the nature or quality demanded by the purchaser) in section 64 itself and in sections 121 and 122. In the past one of the key defences has been section 121(2), which exonerates a defendant where the contravention was due to the default of another person and the defendant themselves exercised all due diligence.

8. Why doesn't this Order cover pharmacy professionals making inadvertent dispensing errors in all settings, not just at or from registered pharmacies?

This Order applies only to registered 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 registered pharmacy professional in a hospital or other pharmacy service (e.g. in care homes and prisons) is needed, and there are plans to consult on draft proposals shortly.

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

9. What if a hospital operates its pharmacy service from a registered pharmacy for certain activities? When will the new defences for a registered pharmacy apply?

This will be very fact dependent. It is possible that some premises will operate both as a registered pharmacy and for other purposes – most obviously in a hospital setting, where premises or the part of a premises may need registering for retail functions. Operating as a retail pharmacy is however much more than about simply registering with the regulator and then supplying medicines. A separate system governance arrangement needs to be in place when a pharmacy is performing retail sales. In practice, we would expect it to be clear from the governance arrangements in place whether a pharmacy was in fact operating as a registered pharmacy or not, and generally a hospital pharmacy will not be.

It would have over-complicated this Order to deal with all the possible nuances, and there may be case specific anomalies. However, we always had in mind that 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 registered pharmacy professional in a hospital or other non-registered pharmacy services (e.g. in care homes and prisons) was needed, and there are plans to consult on draft proposals shortly. Any uncertainty should therefore only be short term.

10. What are preparation and dispensing errors?

Errors include for example:

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

11. If we are relaxing the rules, won't this negatively impact on patient safety?

We are not relaxing the rules. 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 improved patient safety.

It is important to recognise that pharmacy professionals may still be subject to prosecution, under the Medicines Act 1968, where the conditions of the defence are not fulfilled e.g. a pharmacist showing 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, pharmacy professionals may be prosecuted on the same basis as any other health care professional for the normal range of offences against the person and professional sanctions can also be administered, if warranted, by the General Pharmaceutical Council / the Pharmaceutical Society of Northern Ireland where errors occur. However, Professor Sir Norman Williams is currently undertaking a review of health care professionals and gross negligence manslaughter which is due to report at the end of spring 2018.

Responses to the Government's consultation on this measure highlighted considerable support from patient and service-user groups and recognition of the potential for increased learning to help prevent dispensing errors and improve patient safety.

12. What is being done to increase learning from preparation and 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:

- i. Published professional standards to support increased reporting, learning, changing practice and sharing learning from dispensing errors and near misses
- ii. Run patient safety and quality roadshows and medicines safety conferences to promote the standards and engage the professions.
- iii. 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 to support learning and improvement at a local, regional and national level and help to better identify and address system errors. For example, in England there has been the introduction of medication safety officers and improvement of reporting systems (the National Reporting and Learning System – also in Wales).

13. Why did it take so long for these defences to become available?

Multiple factors led to this Order being delayed in being laid before Parliament, including the General Election and EU referendum.

14. Registered pharmacy professionals are covered by the defence, but what about unregulated individuals such as counter assistants and delivery drivers?

This Order provides a defence for registered pharmacy professionals (and those being supervised by them) working in a registered pharmacy only. Other individuals, such as herbalists or retail outlets selling medicines, like shops and garages, cannot take advantage of this defence as they are not subject to professional or system regulation.

If a medicine is dispensed from a registered pharmacy, unregulated individuals involved will also benefit from the defence. For example, pre-registration trainee pharmacists and pharmacy technicians, dispensers, counter assistants and pharmacy delivery drivers. However, if they knowingly make a change, for example switching the medicine for a different medicine, the defence would no longer apply to them and the supervising pharmacist could make out a defence under section 121(2) of the Medicines Act i.e. they had exercised all due diligence to avoid the offence and the offence was due to the fault of another person.

15. Will these defences apply to hub and spoke models?

The defences afforded by this Order will apply to hub and spoke models of pharmacy, where both the 'hub' and 'spokes' are registered pharmacies.

16. How frequent are dispensing errors in community pharmacy?

Dispensing errors fortunately only occur in a small proportion of cases.

There are over a billion prescription items dispensed by community pharmacies every year and it is testament to the professionalism of pharmacy staff that the error rate is so low.

17. Why do dispensing errors occur?

Pharmacy professionals have listed multiple explanations for the occurrence of dispensing errors, including;

- Similar medicine names and the same branding on packaging for different products;
- Poorly written prescriptions;
- Workload, interruptions and distractions;
- Physical environment, e.g. lighting.

18. What is being done to tackle medication errors more generally?

In February 2018, at the Patient Safety Movement Foundation Summit, the Secretary of State for Health and Social Care outlined the results of a recent

evidence base review that indicated the prevalence, scale and economic burden of medication errors in the NHS. New research estimates that some 237 million medication errors occur in England per annum. He also set out a number of areas where we could do better to tackle prescribing and medication errors: from improving how we use technology, such as electronic prescribing and medicines administration systems, to understanding how best to educate and inform patients about their medicines.

19. **When a dispensing error occurs, patients should be told about it. How does this Order address this?**

It is a requirement of the defence for prompt notification of the patient. This builds on the “duty of candour” of health care professionals where they make a mistake, and the corporate “duty of candour” of pharmacy owners.

This is a key part of the new thinking, and registered pharmacy professionals working at or from registered pharmacies are expected to move from a position of having a reason not to report their errors - fear of prosecution - to a position of having a clear incentive to report them - helping to make out a possible defence to a prosecution.

The Explanatory Memorandum, a summary document published alongside the Order on the legislation.gov.uk website, contains examples to illustrate how these notification obligations will work in practice.

20. **A condition of the defence is that the patient was promptly notified of an error, what constitutes ‘promptly’?**

A pharmacy professional should take all reasonable steps to notify a patient as soon as possible if an error has occurred. Depending on the severity of the error, the expected response of a pharmacy professional may differ.

Often, it is the patient themselves who recognise the error and inform the pharmacy professional. In this case, there is clearly no requirement to inform the patient – as they already know.

21. **The burden of proof for acting promptly to notify the patient is in the wrong place?**

We have put the burden of proof on the prosecution to show that the defendant did not act “promptly” in notifying the patient of an error.

On balance, we have opted in favour of making prosecutions difficult to bring rather than making it difficult for defendants to show they come within the defence. The benefit of doubt should be with the defendant – which is a general presumption in criminal law.

22. “Acting in the course of his or her profession” is a condition of the defences. How will it be judged whether a registered pharmacy professional is “acting in the course of his or her profession”?

The burden of proof will be for the prosecution to show otherwise beyond reasonable doubt.

In general, if a registered pharmacy professional is dispensing a medicine as part of normal practice, it would be difficult to reach a view that they were not acting in the course of their profession.

Illustrative grounds of what is not considered as “acting in the course of his or her profession” are provided for in the Medicines Act 1968, and were inserted by the Order. The illustrative grounds are, a registrant “misusing his or her professional skills for an improper purpose” and “acting in a manner that showed deliberate disregard for patient safety”.

23. Can a pharmacy professional benefit from the defences if they have not followed Standard Operating Procedures (SOPs)?

Yes. This is because occasionally a pharmacy professional must use their professional judgement to put the benefit of a patient above strictly following an SOP. This is why not following a SOP does not in itself contribute proof that the pharmacy professional was not “acting in the course of their profession”. The prosecution still has to prove that beyond a reasonable doubt.

24. Why are only some types of supply mentioned in the defences, and what about for example an emergency supply on the NHS (e.g. the NHS Urgent Medicines Supply Advanced Service (NUMSAS) in England)?

Defendants can avail themselves of the defences in any case of a preparation or dispensing error at a registered pharmacy, where the preparation or dispensing is by, or under the supervision of, a registered pharmacy professional. However, not all acts of sale or supply are caught by sections 63 and 64 and therefore in these cases a defence will not be required as no offences have been made.

Where a medicine is supplied to a patient, the Order provides a defence when this supply is against a prescription or certain types of direction. Supplies as part of the NHS are not covered by Section 64 of the Medicines Act unless they are supplies on prescription – and so, it is likely that in most cases of NHS supply against patient group directions or under minor ailment schemes at registered pharmacies, an offence has not potentially occurred and a defence is

therefore not required. Such supplies would be covered by the adulteration offence under section 63 – but the new defence is broad enough to include supplies under a Patient Group Direction or directions of a relevant prescriber.

The emergency supply of medicines, such as via the NHS Urgent Medicines Supply Advanced Service (NUMSAS) in England, usually requires a medicine to be supplied without a prescription, rather than sold – meaning it also does not contravene section 64 of the Medicines Act 1968 – but again, if there was instead a contravention of section 63 (adulteration), this would be covered by the new defence. Essentially, if an emergency supply is lawful within the terms of the Human Medicines Regulations 2012, the new defences pick up dispensing errors in relation to it because of alignment of the language of the various provisions.

25. Will the defences provided by this Order apply when a prescription only medicine is sold in an emergency?

Yes. Where a medicine is sold in an emergency, for example, a patient requests an asthma inhaler whilst on holiday and pays for the medicine, registered pharmacy professionals would be able to use the defences in the event that an inadvertent error is made.

26. Will the defences provided by this Order apply if the pharmacist that dispenses the medicine also prescribed it?

Yes. However, it is currently exceptional for a situation like this to occur, usually arising in situations where it is felt that patient need surpasses normal practice.

27. This Order makes it more difficult for prosecution services like the Crown Prosecution Service to bring successful prosecutions?

This is true and deliberate. As regards mistakes by pharmacy professionals at registered pharmacies, the prosecution services will no longer be able to bring a relatively simple prosecution for a strict liability offence. This is necessary to help remove the “fear factor” of an easy to prove prosecution.

28. The Order does not go far enough and should have removed the offence altogether.

The offences should be retained because they apply to all sales of medicines or supplies on prescription, not just to those by pharmacy professionals in community pharmacies – for example they apply to over the counter sales in shops and sales by herbalists. There is no mandate to sweep away the offence in these other contexts.

There are also still circumstances where pharmacy professionals in community pharmacies should not benefit from a defence, for example where they have shown a deliberate disregard for patient safety or have not discharged their professional “duty of candour”.

We are looking to extend the defence to pharmacy professionals working in other settings, but that will be the subject of further consultation.

29. This Order does not go far enough and should mandate the reporting of errors?

The defences have been drafted to incentivise the reporting of errors – and not just by the error maker. In addition, pharmacy professionals are already subject to professional standards set out by the pharmacy regulators – the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland.

These standards include a “duty of candour”, which includes an obligation to be open and honest when things go wrong and report and raise concerns. This is in line with other healthcare professionals.

30. Is there a reason why the law change is just about pharmacy professionals and not other health care professionals – such as GPs? The Dr Bawa-Garba case has prompted the Government to look at use of criminal law more generally: will dispensing errors be part of that?

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

Unlike other health professionals, pharmacy professionals are currently at risk of criminal prosecution for a strict liability offence when inadvertent human error occurs in the course of their routine professional practise. This Order aligns registered pharmacy professionals who are working in registered pharmacies with other health professions in this regard. The Order 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.

There is a separate piece of work being taken forward by Professor Sir Norman Williams to look at gross negligence manslaughter in medicine across healthcare. The review will aim to report at the end of spring 2018.

31. Why is the Government considering on changing the structure of professional regulation as regards pharmacy professionals at a time when this Order is putting increased reliance on professional Regulators?

The UK's model of professional regulation for healthcare professionals has become increasingly complex and outdated. It needs to change to protect patients better, to support our health services and to help the workforce meet future challenges. Government is committed to a flexible model of professional regulation which secures public trust, fosters professionalism and improved clinical practice, while also being able to adapt swiftly to future developments in health care. This needs to be complemented by a culture that enables professionals to learn from their experiences, including from their mistakes

The changes this Order makes are fully in line with the Government's proposals on professional regulation, on which it recently consulted.