



Summary and purpose of statutory instruments

The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022

1. The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 extends existing defences to the criminal offences relating to inadvertent preparation or dispensing errors by registered pharmacy professionals to professionals working in hospitals and other pharmacy services (e.g. in prisons and care homes).
2. This aligns with provisions contained in an earlier Order entitled The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 (“Registered Pharmacies Order”), which entered into force on 16 April 2018, and introduced the initial defences for pharmacy professionals working at registered pharmacies – predominantly community pharmacies. This Order enables pharmacy professionals working in hospitals and other specified pharmacy services to make use of the defences already afforded to their colleagues working in registered pharmacies, and therefore ensures parity across the profession.
3. The aim of the policy is to remove the threat of criminal sanctions for inadvertent preparation and dispensing errors, incentivising an increase in the reporting of dispensing errors. Research suggests this should lead to more reporting and learning from errors, improving patient and consumer safety.
4. The Order has been developed on a UK wide basis, in collaboration with all four health departments, with the support of the Rebalancing Board, an expert stakeholder group and with full public consultation.

What does the Order do?

5. The Order outlines similar conditions as those under the existing Registered Pharmacies Order which must be met in order for the defences to be applicable:
 - a) The person who dispensed the product was a registrant, or was acting under the supervision of a registrant*
 - b) The medicine must be supplied in the course of the provision of a relevant pharmacy service (in essence, “relevant pharmacy services” are pharmacy services registered with or subject to inspection by relevant authorities such as the Care Quality Commission, Regulation and Quality Improvement Authority (NI), Healthcare Improvement Scotland or Healthcare Inspectorate Wales, this includes pharmacy services in hospitals, care homes, and places where people are lawfully detained (such as prisons)
 - c) The registrant was acting in course of their profession*
 - d) The medicine was a dispensed medicine, that is the sale or supply was in pursuance of a prescription or directions or was of a prescription only

medicine (POM) that was sold or supplied in circumstances where there is an immediate need or could not otherwise have been obtained without undue delay*

- e) At the time of the alleged contravention, the defendant did not know that the product had been adulterated/was not of the required nature or quality*
- f) The patient was promptly notified of the error, unless considered unnecessary*
- g) The relevant pharmacy service is overseen by a “Chief Pharmacist”.

* denotes commonality with the existing defence for registered pharmacies in the Registered Pharmacies Order.

- 6. The order also introduces a new statutory role of the “Chief Pharmacist”. This mirrors the statutory role of the “Superintendent Pharmacist” in registered pharmacies (general and commonplace in the retail pharmacy sector). This aims to strengthen the governance of pharmacy services by incentivising the creation of this role (if they do not already have one) in order to benefit from the defences.
- 7. The Chief Pharmacist must be both a registered pharmacist and have a senior management role with oversight of the pharmacy service, as part of which they must be responsible for ensuring the safe and effective running of the pharmacy service. Pharmacy services without a Chief Pharmacist will not be able to rely on the extended defences.
- 8. In recognition of the diverse governance arrangements across the UK and the need for flexibility, organisations do not need to adopt the statutory term “Chief Pharmacist” as a job title. However, they should ensure that the statutory functions of the Chief Pharmacist are included in the job responsibilities of the individual appointed to fulfil the role.
- 9. The Pharmacy Regulators – the General Pharmaceutical Council and Pharmaceutical Society of Northern Ireland – are given additional powers in relation to describing chief pharmacists’ responsibilities and setting standards of conduct and performance in relation to them.

Does the Order apply to the whole UK?

- 10. The Order extends to England, Wales, Scotland and Northern Ireland.

When do the new provisions apply?

- 11. Parts 2 and 3 of the Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022 come into force on 1 December 2022.

The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022

12. The order, the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 relates to the organisational governance arrangements for registered pharmacies (i.e. predominantly retail pharmacies), specifically in respect of two distinct roles to be undertaken by registered pharmacists in relation to retail pharmacy businesses:

- The responsible pharmacist (RP) – this is the person in charge of a particular registered pharmacy premises when it is open for business. However, their responsibility is taken up when the pharmacy opens and given up when the pharmacy closes. The responsible pharmacist can be a pharmacist employed by the business or could be a locum pharmacist.
- The superintendent pharmacist (SP) – this is the person who has oversight responsibilities across the whole of the retail pharmacy business, no matter how many retail pharmacy premises the business owns. The superintendent pharmacist has those responsibilities 24/7. The role only exists for businesses that are bodies corporate, and not for partnerships or sole traders.

13. The aim is to clarify and strengthen the organisational governance arrangements of registered pharmacies, specifically to define and clarify the core purpose of the RP and SP, and give powers to the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society of Northern Ireland (PSNI) to define in professional standards how those roles are fulfilled. In doing so, putting in place the necessary system governance framework to support maximising the potential of community pharmacy and make better use of the skill mix of pharmacy teams to deliver more clinical services in the community and support wider NHS/Health and Social Care capacity.

14. The Order has been developed on a UK wide basis, in collaboration with all four health departments with the support of the Rebalancing Board, an expert stakeholder group and with full public consultation.

What does the Order do?

15. The main aim of the Order is to:

- Ensure pharmacy practice standards are set and enforced by pharmacy regulators (GPhC and PSNI) and less by inflexible Government legislation and criminal courts.
- Clarify the relationship between pharmacy owners, SPs and RPs to ensure the safe and effective practice of pharmacy in a retail pharmacy context, making clear the accountability of each respective role.
- Introduce additional requirements of, and create a statutory general duty for, an SP within primary legislation in the Medicines Act 1968. It also clarifies the statutory general duty of the RP within the Medicines Act 1968.
- Take the powers to make provision about the RP's statutory responsibilities from Ministers under section 72A of the Medicines Act 1968 and give them to the pharmacy professional regulators (GPhC and PSNI) so that they can make rules or regulations in relation to this instead e.g. requirements on record keeping, absence of an RP etc.

- Put in place safeguards requiring the relevant pharmacy professional regulators to consult on any standards. It is proposed that before making rules under section 72A, the GPhC must publish draft rules and invite representations from Ministers and other appropriate persons to consult on those draft rules. In Great Britain, the resultant rules cannot enter into force until approved by the Privy Council and will then be subject to the “negative resolution” procedure in the UK Parliament. Separately, any regulations made under section 72A by the Council of the PSNI would require consultation of appropriate persons and consultation of and approval by the Department of Health in Northern Ireland.
- Revoke The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008, which will remain in force pending the first rules by the GPhC in respect to Great Britain and the first regulations of the Council of the PSNI as respects Northern Ireland.

16. The Pharmacy Regulators – the General Pharmaceutical Council and Pharmaceutical Society of Northern Ireland – are given additional powers to make rules/regulations in relation to the responsibilities of Responsible Pharmacists’ and Superintendent Pharmacists’.

Matters relating only to Northern Ireland

17. At the request of the Department of Health in Northern Ireland and the PSNI, there are also two technical changes that apply specifically to Northern Ireland. These aim to align the law in Northern Ireland with that of Great Britain:

- giving the Department of Health in Northern Ireland the power to appoint a deputy registrar, in respect of duties set out in the Pharmacy (Northern Ireland) Order 1976.
- extending the requirement that a Superintendent Pharmacist must inform the relevant pharmacy regulator when they stop holding the role in a pharmacy business to include Northern Ireland and the Pharmaceutical Society of Northern Ireland.

Does the Order apply to the whole UK?

18. The Order extends to England, Wales, Scotland and Northern Ireland.

When do the new provisions apply?

19. Parts 2 and 3 of, and the Schedules to, the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 come into force on 1 December 2022. This would mean, for example, the restriction on a Superintendent acting in this capacity for more than one body corporate, will be removed from this date.

20. One notable exception is that The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008, will remain in force pending the first rules by the GPhC in respect to Great Britain and the first regulations of the Council of the PSNI as respects Northern Ireland.