EXPLANATORY MEMORANDUM TO

THE PHARMACY (PREPARATION AND DISPENSING ERRORS – HOSPITAL AND OTHER PHARMACY SERVICES) ORDER 2022

2022 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2022 (the "Order") makes changes to the Medicines Act 1968, the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976.

2.2 The Order extends existing defences to the criminal offences of contravening sections 63 and 64 of the Medicines Act 1968 for inadvertent dispensing errors to registered pharmacy professionals working in hospital and other specified pharmacy services.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 Pharmacy regulation is a fully devolved matter as regards to Northern Ireland.

4.2 The territorial extent of this instrument is England, Wales, Scotland and Northern Ireland, except that where amendments are made to other legislation of more limited extent, those amendments have the same extent as the legislation being amended.

4.3 The territorial application of this instrument is England, Wales, Scotland and Northern Ireland, except that where amendments are made to other legislation of more limited application, those amendments have the same application as the legislation being amended.

4.4 Pharmacy technicians are not statutorily registered in Northern Ireland, and as so, with regard to Northern Ireland this Order only applies to preparation and dispensing errors by registered pharmacists and persons supervised by them. Pharmacy technicians are statutorily registered in England, Wales and Scotland and so for those countries the defences in this Order apply to dispensing and preparation errors by both pharmacists and pharmacy technicians, and by persons supervised by them.

5. European Convention on Human Rights

5.1 The Parliamentary Under-Secretary of State for Primary Care and Patient Safety, Maria Caulfield has made the following statement regarding Human Rights:

"In my view the provisions of The Pharmacy (Preparation and Dispensing Errors – Hospitals and Other Pharmacy Services) Order 2022 are compatible with the Convention rights."

6. Legislative Context

6.1 The Order will extend the existing defences to sections 63 (Adulteration of medicinal products) and 64 (Protection of purchasers of medicinal products) of the Medicines Act 1968, as introduced under the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 ('the 2018 Order'), which entered into force on 16 April 2018.

6.2 Section 63 of the Medicines Act 1968 (Adulteration of medicinal products) concerns the adulteration of medicinal products. Most dispensed medicines are manufactured away from the pharmacy, however pharmacists may have to make up (compound) a medicine from individual ingredients. Errors may occur if, for example, an ingredient is omitted or inadvertently added which 'adulterates' the medicines whether this is deliberate or inadvertent.

6.3 Section 64 of the Medicines Act 1968 (Protection of purchasers of medicinal products) concerns the protection for purchasers of medicinal products making provision for an offence where medicinal products are not of the nature or quality demanded by the purchaser, or as specified in a prescription given by an appropriate practitioner.

6.4 The role of the pharmacy regulators – the General Pharmaceutical Council (GPhC) as regards to Great Britain and the Pharmaceutical Society of Northern Ireland (PSNI) as regards to Northern Ireland – is key to safeguarding the public and, in particular, those who use or need the services of registered pharmacy professionals or the services provided by a registered pharmacy. As such, pharmacy regulators set and require compliance with standards and rules and have the ability to take action when these are not met.

6.5 Under section 67(2) of the Act, people who contravene sections 63 or 64 are guilty of an offence. Under section 67(4), the penalties for those found guilty can be a fine or imprisonment for up to two years or both.

6.6 Therefore, before the 2018 Order entered into force, pharmacy professions faced a 'triple' jeopardy where they commit a dispensing error, under the sanctions in section 63 and section 64 of the Medicines Act 1968, under general criminal law and under professional regulation, such as suspension or removal from the professional register.

6.7 The 2018 Order created defences to the offences for contravening sections 63 and 64 of the Medicines Act 1968, for registered pharmacy professionals working in registered pharmacies provided that certain conditions were met.

6.8 This Order extends those defences to registered pharmacy professionals working in hospitals and other specified pharmacy services, where there is a chief pharmacist. The result is that the combination of this Order and the 2018 Order, the vast majority of pharmacy professionals will be able to avail themselves of these defences, regardless of where they practice.

7. Policy background

What is being done and why?

7.1 Throughout the United Kingdom, we estimate that there are around 52 million items supplied a year in hospital and community care. Whilst the number of dispensing errors in UK hospital pharmacy services is relatively small, it is estimated that around

523,000 dispensing errors occur each year, but only 5% of these errors (26,132) are reported. Examples of preparation and dispensing errors include; where a medicine intended for a patient is dispensed to the wrong patient, the wrong medicine is dispensed, an ingredient is inadvertently omitted or added when making up a medicine, or an out of date medicine is supplied to a patient.

7.2 Before the 2018 Order came into force, pharmacy professionals were in an unusual position, compared to other healthcare professionals, of the triple threat of prosecution under the Medicines Act 1968, criminal law and professional regulation sanctions. The basis for the 2018 Order, and by extension this measure, is that the fear of prosecution deters the reporting of errors by pharmacy professionals (pharmacists and in Great Britain, pharmacy technicians) and pharmacies. This impacts on their willingness to record and report errors, which in turn impacts on the opportunity to learn from errors – a vitally important contributor to improving patient safety. As an analogy, the airline industry demonstrates the benefits of a culture of openness and transparency in learning from errors and ultimately enhancing public safety.

7.3 It is rationalised that the deterred reporting of dispensing errors could lead to risks for patients, as pharmacy professionals and pharmacies are not informed about errors and therefore cannot address and learn from their causes.

7.4 The purpose of the policy is to align with provisions contained in the 2018 Order, which introduced the initial defences for pharmacy professionals working at registered pharmacies, which tend to be retail pharmacy businesses. The Order enables pharmacy professionals working in hospitals and other specified pharmacy services (including care homes, and places where people are lawfully detained, such as prisons), not covered by the 2018 Order, to make use of the defences already afforded to their colleagues working at registered pharmacies, and therefore ensures parity across the profession.

7.5 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, which research suggests will afford greater learning opportunities – translating to a reduction in errors and increased patient safety. Indeed, a survey of pharmacy staff conducted by The Community Pharmacy Patient Safety Group a year after the 2018 Order came into force found that the new legal defence for dispensing errors, which came into law in April 2018, appears to have reduced the number of people who claimed fear of criminal prosecution might prevent them from reporting. This figure was 40% in 2016, compared with 22% (internal reporting) and 14% (external reporting) in the 2019 survey.

7.6 A key policy objective is to support safety for the users of pharmacy services while recognising that healthcare will always involve risks, but that these risks can be reduced through reporting, analysing, increasing awareness and tackling the causes of patient safety incidents.

7.7 The Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board ("the Board") was established to advise the Government and Devolved Administrations on changes to medicines legislation and pharmacy regulation to ensure that it is fit for purpose, reduce any unnecessary legislation and remove barriers to innovation and development of pharmacy practice. The Board in its discussions concerning this Order put patient safety at the heart of its deliberations and was clear that deliberate errors should continue to be subject to criminal sanction.

Proposing a change to the sanctions arrangements in the Medicines Act 1968 for inadvertent dispensing errors by pharmacy professionals at hospitals and other specified pharmacy services does not imply impunity for such errors. Instead such errors (should the relevant conditions of the defence be met) will be dealt with by the pharmacy regulators, who will continue to have responsibility in the context of the registration of individual pharmacy professionals to deal with such matters through professional misconduct sanctions.

7.8 In practice, prosecutions relating to dispensing errors are extremely uncommon. In the past 10 years, the MHRA has only prosecuted in one case concerning a death as a result of a dispensing error and involving a pharmacist. This does not include other cases where prosecution was not in the public interest.

7.9 It is believed that the Crown Prosecution Service (CPS) brought a similarly low level of prosecutions – with CPS usually only being alerted following referral from the police investigating a fatality.

7.10 In terms of what the Order will actually do, the key provisions provided for in Part 2 contain amendments to the Medicines Act 1968 that extend the existing defences to the offence of contravening sections 63 and 64 of that Act, and dealing with supplementary matters.

7.11 In order to qualify for the defences, certain conditions must be satisfied:

1. The person who dispensed the product was a registrant, or was acting under the supervision of a registrant*
2. 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)
3. The registrant was acting in course of their profession*
4. 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*
5. 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*
6. The patient was promptly notified of the error, unless considered unnecessary*
7. The relevant pharmacy service is overseen by a "Chief Pharmacist"

* denotes commonality with the existing defence for registered pharmacies in the 2018 Order.

7.12 A key element of the governance that underpins the defence, is the creation of the statutory role of 'chief pharmacist' in the Medicines Act 1968. Article 9 of the Order, amends the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976 to give the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland additional powers in relation to describing chief pharmacists' responsibilities

and setting standards of conduct and performance in relation to them. It is proposed that the introduction of the statutory term of 'chief pharmacist', together with a statutory duty in respect of the safe and effective running of the pharmacy service, for which they are responsible, will provide the certainty and clarity necessary for the defences to be relied upon. Pharmacy services without a chief pharmacist will not be able to rely on the defences. We recognise the diversity of governance arrangements across the UK and the need for flexibility. As such, organisations do not need a specific chief pharmacist role, but should ensure that statutory functions of a chief pharmacist are included in the relevant individual's job responsibilities, if they do want to benefit from the defences.

7.13 The policy behind this approach, which is inherited from the 2018 Order, is to create a powerful incentive for chief pharmacists and supervisors to remain on top of what is happening in their pharmacy service or under their supervision. If any appropriate person knows of the error but does nothing about it, the new defence is lost to all the potential defendants.

7.14 As is the case under the 2018 Order, the notification of the patient builds on the "duty of candour" of health care professionals where they make a mistake. This is a key part of the new thinking. Registered pharmacy professionals, in particular, will move from a position of having a reason not to report their errors (fear of prosecution) to a position of having a clear additional reason to report them (helping to make out a possible defence to a prosecution).

7.15 The Explanatory Memorandum for the 2018 Order, sets out examples to illustrate how these notification obligations will work in practice, and are reproduced here for ease of the reader.

7.16 The following examples illustrate how these notification obligations will work in practice.

7.17 A pharmacist dispenses the wrong dose of a medicine with the potential to cause serious harm on a Friday afternoon. On his/her/their way home the pharmacist realises he/she/they made an error, telephones the pharmacy service to see if anyone is still there, finds that everyone has gone home or can't talk to a colleague, and then leaves the matter until Monday. The patient is admitted to intensive care over the weekend. In these circumstances, the pharmacist has not discharged their duty of candour "promptly" and so cannot benefit from the defence, even if on the Monday he/she/they tries to contact the patient before he/she/they becomes aware of the hospitalisation. Once the new defences are implemented the pharmacist will have a clear incentive to return to the pharmacy on the Friday and take all reasonable steps to contact the patient.

7.18 Altering the facts slightly but with the same risk of serious harm, the pharmacist is not sure whether or not an error was made and leaves the matter until the Monday. Arguably, because he/she/they does not "know" an error has been made, he/she could still potentially benefit from the defence, albeit that he/she/they has clearly behaved unprofessionally. However, if a court determines that he/she/they has "deliberately failed to have due regard to patient safety" (section 67D(3)(b)), the court will find that he/she was not "acting in the course of his or her profession" and so the defence will not be available. Again, even if the pharmacist is unsure, he/she will have a clear incentive to return to the pharmacy to make sure he/she discharges his/her professional responsibilities.

7.19 Altering the facts slightly again, but still with the same risk of serious harm, this time the error is made by a pharmacy student, who is acting under the supervision of a pharmacist. On his/her/their way home, the student realises that he/she/they has made an error, and contacts the pharmacy service. The pharmacist is still there. If the pharmacist fails to act, neither of the two – the student or the pharmacist – will be able to benefit from the defence. This may initially seem unfair on the student, albeit that he/she/they were the error maker, but if the student has exercised all due diligence to avoid the commission of the offence and the offence is actually due to the default of another person, he/she/they has a defence under section 121(2) (Contravention due to default of other person) of the Act and the other person can still be prosecuted by virtue of section 121(1). Thus, all the main protagonists with "duty of candour" obligations will have a clear incentive to ensure that the patient is notified.

7.20 Many more permutations of these basic facts are of course possible, but this illustrates how the provisions have been designed to incentivise reporting – and not just by the error maker.

7.21 The impact assessment of the 2018 Order estimated that 62% of errors can be corrected by increased information and learning and estimates over a four year period a 30% decrease in errors, if learning is enabled. The evidence base therefore suggests very considerable patient benefits from these proposals, as well as very significant improvement of the services provided by registered pharmacy professionals.

8. European Union Withdrawal and Future Relationship

8.1 This Order does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 There are no plans to consolidate the legislation.

10. Consultation outcome

10.1 A UK-wide public consultation ran from 19 June 2018 until 11 September 2018. The consultation was separated into two parts: Part 1 being in respect of the draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022, and Part 2 being in respect of the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022.

10.2 To encourage responses to the consultation, officials from the Department of Health and Social Care and the Devolved Administrations supported a number of engagement events across the United Kingdom during the consultation period. The aim was to ensure that stakeholders understood the proposals fully and had an opportunity to raise their comments and concerns for clarification. A number of post-consultation stakeholder events were also held to discuss the outcome of the consultation and proposed government response.

10.3 In total, 632 responses were received to the consultation. Responses were received from a mix of pharmacy professionals, representative groups, organisations and public-sector bodies. Of the total respondents, 473 answered questions on Part 1. The overwhelming majority of respondents responding to Part 1 of the consultation supported the proposals in relation to extending preparation and dispensing error defences to pharmacy professionals working in hospital and other pharmacy services.

10.4 The changes will apply to Great Britain and Northern Ireland. Officials from the Department of Health and Social Care have engaged with officials in the Devolved Administrations to develop the policy and agreed that the consultation should be taken forward on a UK-wide basis.

10.5 Full details of the consultation and the Government's response can be found at: Pharmacy legislation on dispensing errors and organisational governance - GOV.UK (www.gov.uk).

11. Guidance

11.1 The Department of Health and Social Care does not propose to issue any guidance in relation to this Order. Standards for registered pharmacy professionals are a matter for consideration by the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland. They develop guidance on specific issues where they consider this to be necessary.

12. Impact

12.1 The impact on business, charities or voluntary bodies is positive. In summary, the costs to business are estimated to be £258,000 in cost savings over a 10 year period. A summary breakdown is provided below:

- One off familiarisation costs are estimated at £14,300
- The cost of increased error reports is estimated at £11,600
- Cost savings resulting from the reducing in processing of errors is estimated at £226,000
- Cost savings resulting from avoidance of dispensing errors is estimated at £41,000
- Cost savings resulting from the reduction in insurance costs is estimated at £17,000

12.2 The cost savings estimated for the National Health Service as a result of this instrument is estimated to be £4,111,000 over a 10 year period.

12.3 There is no negative impact on charities or voluntary bodies.

12.4 The impact on the public sector is likely to be minimal. The Order shifts the balance from dealing with matters in criminal law to doing so in professional regulation, by the pharmacy regulators, including, as necessary, through registration sanctions rather than the criminal courts. The proposals are likely to reduce the volume of cases going through the courts though the difference is expected to be minimal given the low number of prosecutions in recent years.

12.5 It has not been possible to quantify the costs of prosecutions because very few have taken place in recent years and those that have concerned very different types of errors and defendants. We anticipate that the impact upon Courts or Tribunals will be minimal.

12.6 An Impact Assessment has not been prepared for this instrument because government rules dictate that an Impact Assessment does not need to be produced if the equivalent Annual Net Direct Cost to Business is less than +/- £5m. It is estimated that the proposed Order will fall below this threshold. Instead, a summary cost-benefit analysis has been undertaken and is summarised in 12.1.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is that the Department of Health and Social Care has committed itself to undertaking a review of the measures introduced by this Order within five years of it being made and a report of the review will be published.

14.2 The draft Order does not include a statutory review provision and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015 the Parliamentary Under-Secretary of State for Primary Care and Patient Safety, Maria Caulfield, has made the following statement:

"In my view it is not appropriate to include a statutory review provision in the Order because there is no significant annualised net impact on business expected".

15. Contact

15.1 Stephen Knight at the Department of Health and Social Care (telephone: 020 7972 4155 or email: Stephen.Knight@dhsc.gov.uk) can be contacted with any queries regarding the instrument.

15.2 Alette Addison, Deputy Director for Pharmacy, Dentistry and Eyecare, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Maria Caulfield, Parliamentary Under-Secretary of State for Primary Care and Patient Safety at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.