

EXPLANATORY MEMORANDUM TO
THE PHARMACY (PREPARATION AND DISPENSING ERRORS – REGISTERED PHARMACIES) ORDER 2018

2018 No. [XXXX]

1. Introduction

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

2. Purpose of the instrument

- 2.1 This Order makes changes to the Medicines Act 1968 (“the Act”).
- 2.2 This Order creates new defences to the criminal offences of contravening sections 63 and 64 of the Act. The defences relate to preparation or dispensing errors by registered pharmacy professionals (registered pharmacists and registered pharmacy technicians) acting in the course of their profession in registered pharmacies, which predominantly are community pharmacies.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

Other matters of interest to the House of Commons

- 3.2 Disregarding minor or consequential changes, the territorial application of this instrument includes Scotland and Northern Ireland and it is not a financial instrument which relates exclusively to England, Wales and Northern Ireland.

4. Legislative Context

- 4.1 Part 3 of the Act contains two offences that may be used to prosecute inadvertent preparation or dispensing errors by registered pharmacy professionals working in registered pharmacies, although the offences also have much broader application: sections 63 (adulteration of medicinal products) and 64 (protection of purchasers of medicinal products). Registration of pharmacies is under Part 4 of the Act and is in respect of premises where a retail pharmacy business is carried on (predominantly community pharmacies).
- 4.2 Section 63 of the Act concerns changing the composition of a medicinal product in a way that is injurious to health. Most medicines dispensed at or from a registered pharmacy are manufactured away from the pharmacy. However there are circumstances when registered pharmacy professionals will 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 medicine.
- 4.3 Section 64 of the Act concerns sales or supplies on prescription of medicinal products that are not of the nature or quality ordered.

- 4.4 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.
- 4.5 The Act does not limit the categories of people who may be charged with breaching sections 63 and 64. For example, a prosecution for breach of section 64 would be possible in the case of ordinary retail sale of medicines that are on general sale, such as standard painkillers. In the most serious cases, for example where the potential breach is a dispensing error which leads to the death of a patient, prosecution is also and will continue to be possible under the general criminal law – for example for manslaughter.
- 4.6 In the case of a registered pharmacy professional who makes an error, if this is evidence that their fitness to practise is impaired, the matter may also be referred to one of the pharmacy regulators – the General Pharmaceutical Council (GPhC), whose functions in relation to professional conduct are principally set out in the Pharmacy Order 2010, and the Pharmaceutical Society of Northern Ireland (PSNI), whose functions relating to professional conduct are principally set out in the Pharmacy (Northern Ireland) Order 1976.
- 4.7 Therefore, currently, registered pharmacy professionals face a ‘triple’ jeopardy where they commit a preparation or dispensing error: possible breaches of section 63 and 64 of the Act, possible breaches of general criminal law, and possible professional regulation sanctions such as suspension or removal from the professional register.

5. Extent and Territorial Application

- 5.1 Pharmacy regulation is a fully devolved matter as regards to Northern Ireland.
- 5.2 This Order extends to England, Wales, Scotland and Northern Ireland. Retail pharmacy premises in England, Scotland and Wales are registered by the GPhC and in Northern Ireland by the PSNI.
- 5.3 Pharmacy technicians are not statutorily registered in Northern Ireland, and so, with regard to Northern Ireland, the new defences in this Order only apply to preparation and dispensing errors by registered pharmacists and persons supervised by them. Pharmacy technicians are however statutorily registered in England, Scotland and Wales and so for these countries the new defences in this Order apply to preparation and dispensing errors by both registered pharmacists and registered pharmacy technicians, and by persons supervised by them.

6. European Convention on Human Rights

- 6.1 Steve Brine MP, Parliamentary Under Secretary of State for Public Health and Primary Care has made the following statement regarding Human Rights:
- ‘In my view the provisions of The Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018 are compatible with the Convention rights.’

7. Policy background

What is being done and why

- 7.1 Throughout the United Kingdom, well over a billion prescription items were dispensed in 2015/16 (approximately 90% by community pharmacies). There has also been year-on-year growth in dispensing of 4-5% from 2005-12, falling to 2% in 2015.

Further statistical information is given in the Impact Assessment submitted with and published alongside this Explanatory Memorandum.

- 7.2 The Impact Assessment notes that there were an estimated 20,820 estimated reported dispensing errors in the UK in 2016 (paragraph 66) but the number of unreported dispensing errors for that year was around 499,651 (paragraph 69). A number of factors are likely to contribute to this under-reporting, but the estimate given in the Impact Assessment is that 20% of the under-reporting is because of fear of prosecution.
- 7.3 That fear of prosecution is in part a result of the relative ease with which prosecutions can be brought. Breaches of sections 63 and 64 are what are known as “strict liability” offences, notwithstanding that they are already subject to limited defences in sections 64(3) and (4), 121 and 122 of the Act). This means that the prosecution does not have to prove a “mental element” – intention, recklessness or negligence – on the part of the defendant for the prosecution to succeed. This means in turn that prosecutions are relatively easy to bring, resulting in a “fear factor” amongst pharmacy professionals, who are reluctant to admit errors as it may mean that they will face prosecution.
- 7.4 In fact, prosecutions have to date been rare and have only been brought in the most serious cases, where the error has resulted in death. It is probable that recourse has only been made to section 64 in these cases because of the difficulty in proving beyond reasonable doubt the “mental element” that might need to be proven for another offence, for example a manslaughter offence.
- 7.5 Despite the rarity, the evidence included in the Impact Assessment demonstrates that the “fear factor” persists. The fundamental premise on which this Order is based is that reduction in the risk of prosecution will increase the number of reported errors. Over time, learning from increased numbers of error reports should lead to improvements in training and practices, which should reduce the number of errors made. The consultation responses have confirmed that this logic (i.e. a virtuous cycle of reporting, learning and improving) and the assumptions underlying it are realistic.
- 7.6 The new defences are drafted in similar terms and take a similar approach in relation to both sections. In relation to breaches of section 63 (adulteration of medicinal products), the defendant is required to show that:
- The person who adulterated the product is or was supervised by a registered pharmacy professional who was acting in the course of his or her profession (so, for example, a registered pharmacy professional showing 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”), and
 - The adulteration must have taken place at the registered pharmacy, and
 - If the product has been sold or supplied, it must have been sold or supplied in pursuance of a prescription or direction or under arrangements for the emergency supply of prescription only medicines, and
 - If an appropriate person becomes aware of the problem, they promptly take all reasonable steps to ensure the patient is notified.
- 7.7 In relation to breaches of section 64 (protection of purchasers of medicinal products) of the Act , the defendant is required to show:

- The product was dispensed by or under the supervision of a registered pharmacy professional who was acting in the course of his or her profession, and
- The dispensing must have taken place at the registered pharmacy, and
- The sale or supply must have been in pursuance of a prescription, or directions in the case of a sale, or be an emergency supply of prescription only medicines in circumstances where a prescription could not be obtained without undue delay (there is an added layer of complexity because supplies that are not sales but are in pursuance of directions are not caught by the offence); and
- If an appropriate person becomes aware of the problem, they promptly take all reasonable steps to ensure the patient is notified.

7.8 In both cases, the final element of the defence – notification of the patient – 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. 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).

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

7.10 A pharmacist dispenses the wrong dose of a medicine with the potential to cause serious harm on a Friday afternoon. On his/her way home the pharmacist realises he/she has made an error, telephones the pharmacy to see if anyone is still there, finds that everyone has gone home, and then leaves the matter until Monday. The patient is hospitalised 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 tries to contact the patient before he/she 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.

7.11 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 does not “know” an error has been made, he/she could still potentially benefit from the defence, albeit that he/she has clearly behaved unprofessionally. However, if a court determines that he/she has “deliberately failed to have due regard to patient safety” (section 67E(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.

7.12 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 way home, the student realises that he/she has made an error, and contacts the pharmacy. The pharmacist or the pharmacy owner is still there. If the pharmacist or the pharmacy owner fails to act, none of the three – the student, the pharmacist or the pharmacy owner – will be able to benefit from the defence. This may initially seem unfair on the student, albeit that he/she was 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 has a defence under section 121(2) 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.

- 7.13 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.
- 7.14 The Impact Assessment estimates that 62% of errors can be corrected by increased information and learning (paragraph 74) and estimates over a four year period a 30% decrease in errors, if learning is enabled (paragraph 79). 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.
- 7.15 Powers have been included in the Order to make transitional provisions, but this has been done essentially on a precautionary basis. Although prosecutions are rare, the possibility exists that investigations or proceedings will be ongoing at the time that the amendments to the Act are brought into force. When investigations do happen, the issues they may throw up are inherently unpredictable and it is possible that they will not be dealt with adequately by the general criminal law. In these circumstances, a transitional provision dealing with the issues may be desirable. Before the defences are brought into force, prosecuting authorities will be contacted to see if there are any issues of this sort, but the expectation is that no transitional provisions will in fact be needed.

Consolidation

- 7.16 There are no plans to consolidate the legislation.

8. Consultation outcome

- 8.1 A number of public and patient engagement events were held about the proposed legislative changes in order to inform participants and to seek their views. These events were held in Belfast, Cardiff, Edinburgh and London and were hosted by Department of Health personnel and devolved administration colleagues.
- 8.2 Professional bodies (Royal Pharmaceutical Society, Pharmaceutical Society of Northern Ireland – Pharmacy Forum and the Association of Pharmacy Technicians United Kingdom) also hosted events for their members across the UK. Department of Health personnel and devolved administration colleagues attended and contributed to these events.
- 8.3 A public consultation ran from 12 February 2015 until 14 May 2015. In total 159 responses were received from a variety of respondents including from pharmacy professionals, patients, representative groups and organisations and the public. A Consultation Report is submitted with and published alongside this Memorandum.
- 8.4 The key message is that there was widespread support to introduce a defence from criminal liability where an inadvertent dispensing error is made by a pharmacy professional whilst acting in the course of their profession, with 78% of respondents indicating agreement to the proposals. Of the remaining respondents most argued for

the criminal sanctions to be removed for inadvertent dispensing errors or complete removal of the Section 64 criminal offence.

- 8.5 Full details of the consultation and the Government's response can be found at: <https://www.gov.uk/government/consultations/pharmacy-legislation-on-dispensing-errors-and-standards>

9. Guidance

- 9.1 The Department of Health does not propose to issue any guidance in relation to this Order. Standards for registered pharmacy professionals are a matter for consideration by GPhC and PSNI. They develop guidance on specific issues where they consider this to be necessary.

10. Impact

- 10.1 The impact on business, charities or voluntary bodies is positive. In summary, the costs to business are estimated to be £871,000 in cost savings over a ten year period. A summary breakdown is provided below:
- One off familiarisation costs are estimated at £392,000
 - The net cost of impact of changes in error reports £4,707,000
 - Cost savings resulting from reductions in the handling of dispensing errors £5,404,000
 - Net cost savings from reduced risk of criminal prosecution £566,000
- 10.2 There is no impact on charities or voluntary bodies.
- 10.3 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.
- 10.4 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.
- 10.5 Those registered pharmacies in the public sector will also benefit proportionately from cost savings as set out above for the business sector.
- 10.6 An Impact Assessment is submitted with this Memorandum and will be published alongside the Explanatory Memorandum on the legislation.gov.uk website.

11. Regulating small business

- 11.1 The legislation applies to activities that are undertaken by small businesses.
- 11.2 It is an existing requirement for all registered pharmacy professionals to be familiar with the legislative provisions affecting their professions and to keep informed of significant changes to those provisions which affect the standards of professional behaviour. Pharmacy and criminal law does not differentiate between pharmacies in terms of their overall business size, nor does criminal law or the requirements for premises or professional registration. We do not expect this policy to disproportionately adversely impact on small and medium size businesses.

12. Monitoring & review

- 12.1 The Department of Health 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.

13. Contact

- 13.1 Stephen Knight at the Department of Health (Telephone: 020 7972 4155 or email: Stephen.Knight@dh.gsi.gov.uk) can answer any queries regarding the instrument.