EXPLANATORY NOTE

(This note is not part of the Order)

This Order makes provision relating to preparation errors and dispensing errors by registered pharmacists and registered pharmacy technicians, or persons supervised by them, in the course of the provision of certain pharmacy services. Pharmacy technicians are not statutorily registered in Northern Ireland, and so, as regards Northern Ireland, this Order only makes provision relating to preparation errors and dispensing errors by registered pharmacists and persons supervised by them.

Part 1 contains general provisions, including powers to make commencement orders and transitional provisions orders – and the procedural requirements relating to them.

Part 2 contains amendments to the Medicines Act 1968 ("the 1968 Act") which modify the defences to offences of contravening sections 63 and 64 of the 1968 Act that were inserted by the Pharmacy (Preparation and Dispensing Errors – Registered Pharmacies) Order 2018(**1**) ("the 2018 Order"). The 2018 Order inserted defences that were only available in respect of preparation or dispensing errors in respect of medicinal products for human use prepared or dispensed at registered pharmacies, which generally are retail pharmacy premises. In summary, these defences are modified so that they are now also available in respect of medicinal products for human use prepared or dispensed in certain other settings.

The offences of contravening section 63 of the 1968 Act relate to adulteration of medicinal products for human use. If the product is not sold or supplied, in order to benefit from the defence in section 67A of the 1968 Act in relation to contravening section 63, the defendant is already required to show firstly that the person who adulterated the product was either a registered pharmacist or a registered pharmacy technician who was acting in the course of his or her profession, or was someone acting under the supervision of such a registrant – and secondly that he or she did not know that the product was being or had been adulterated. The third element of the defence, that the adulteration must have taken place at a registered pharmacy, has been broadened (article 5) so that it is now also available if the adulteration took place in the course of the provision of a relevant pharmacy service.

What is meant by a "relevant pharmacy service" is set out in section 67F of the 1968 Act (article 9). Pharmacy services are "relevant pharmacy services" if two conditions are met. Firstly, the pharmacy service has to be the pharmacy service for a facility where certain regulated activities are carried on – hospitals, care homes, places where people are lawfully detained (such as prisons and pre-departure accommodation for people facing deportation) and other similar facilities. Secondly, the pharmacy service must have a chief pharmacist. Some of the requirements of the role of the chief pharmacist are specified, but amendments are also made, in Part 3, to 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 (article 10).

Essentially, the approach taken to modification of the defence in section 67A of the 1968 Act is also applied in relation to the other defences in respect of errors inserted into the 1968 Act by the 2018 Order. If an adulterated product is sold or supplied, the defence in relation to contravening section 63 that was inserted by the 2018 Order is in section 67B of the 1968 Act. As was the case in relation to section 67A, the section 67B defence, as originally inserted, was only available if the adulteration by or under the supervision of a registered pharmacist or pharmacy technician took

(**1**) S.I. 2018/181.

place at a registered pharmacy. However, section 67B has been modified so that the defence is also available if the adulteration takes place in the course of the provision of a relevant pharmacy service (article 6).

In cases where the product is sold or supplied, in order to benefit from the section 67B defence, the defendant must also show that the product is a dispensed medicinal product and that if an appropriate person (such as the dispenser) becomes aware of the error, all reasonable steps are taken to ensure that the patient is notified of the error, unless the appropriate person forms the view that it is neither necessary nor appropriate to do so. These conditions, which were in the defence as originally inserted, also apply in the new circumstances in which the defence now applies.

The offence of contravening section 64 of the 1968 Act relates to the sale, or supply in pursuance of a prescription, of medicinal products for human use which are not of the nature or quality demanded by the purchaser or as specified in a prescription. The defence in relation to contravening section 64 in section 67C of the 1968 Act, which functions along similar lines to the defence in relation to contravening section 63 that is in section 67B of the 1968 Act, has been modified in a similar way. Previously the section 67C defence was only available if the medicinal product was dispensed at a registered pharmacy, but it has been modified so that it is also available if the medicinal product was dispensed from a registered pharmacy or in the course of the provision of a relevant pharmacy service (article 7).

A consequential amendment is also made to a rule of evidence relating to standard operating procedures (article 8).

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sectors is foreseen.