

EXPLANATORY NOTE

(This note is not part of the Order)

This Order includes new defences relating to preparation errors and dispensing errors by registered pharmacists and registered pharmacy technicians, or persons supervised by them, at retail pharmacy premises. Retail pharmacy premises in the United Kingdom have to be registered by either the General Pharmaceutical Council or the Pharmaceutical Society of Northern Ireland – by virtue of provisions of Part 4 of the Medicines Act 1968. Pharmacy technicians are not statutorily registered in Northern Ireland, and so, as regards Northern Ireland, the new defences only apply to preparation errors and dispensing errors by registered pharmacists and persons supervised by them.

Articles 1 to 3 contain general provisions, including powers to make commencement orders and transitional provisions orders – and the procedural requirements relating to them.

Article 4 contains amendments to the Medicines Act 1968 creating new defences to offences of contravening sections 63 and 64 of that Act, and dealing with supplementary matters.

The offences in section 63 relate to adulteration of medicinal products for human use. If the product is not sold or supplied, in order to benefit from the new defence in section 67A, the defendant must prove three things. Firstly, the person who adulterated the product either was a registered pharmacist or registered pharmacy technician who was acting in the course of his or her profession, or was acting under the supervision of such a registrant. Secondly, the adulteration took place at a registered pharmacy. Thirdly, the defendant did not know that the product was being – or (if it was being offered or exposed for sale or supply) had been – adulterated.

If the product is actually sold or supplied, in order to benefit from the new defence in section 67B, in most cases the defendant must prove four things. Firstly, the person who adulterated the product either must have been a registered pharmacist or registered pharmacy technician who was acting in the course of his or her profession, or must have been acting under the supervision of such a registrant. Secondly, the adulteration must have taken place at a registered pharmacy. Thirdly, the product must have been sold or supplied in pursuance of a prescription or directions, or be an emergency sale or supply of a prescription only medicine in circumstances where a prescription could not be obtained without undue delay. Fourthly, if an appropriate person (such as the dispenser) becomes aware of the mistake, all reasonable steps must be taken to ensure that the patient is notified of the mistake, unless the appropriate person reasonably forms the view that it is neither necessary nor appropriate to do so.

The offence in section 64 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 elements of the new defence in section 67C which apply in most cases are similar to those in the new section 67B. Firstly, the person who dispensed the product either must have been a registered pharmacist or registered pharmacy technician who was acting in the course of his or her profession, or must have been acting under the supervision of such a registrant. Secondly, the dispensing of the product must have taken place at a registered pharmacy. Thirdly, the sale or supply must have been in pursuance of a prescription – or possibly directions, in the case of a sale – or be an emergency supply of a prescription only medicine in circumstances where a prescription could not be obtained without undue delay. Fourthly, if an appropriate person (such as the dispenser) becomes aware of the mistake, all reasonable steps must be taken to ensure that the patient is notified of the mistake, unless the appropriate person reasonably forms the view that it is neither necessary nor appropriate to do so.

There are also new provisions in section 67D and 67E relating to rules of evidence and interpretation in respect of the new defences, and these include a rule that a registered pharmacist or registered pharmacy technician is not to be considered as acting in the course of his or her profession for the purposes of the new defences if he or she either misuses his or her professional skills for an improper purpose or deliberately fails to have due regard for patient safety.

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health, Wellington House, 133-155 Waterloo Road, London SE1 8UG. It is also available alongside this instrument on www.legislation.gov.uk.