EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations") in order to implement—

— points 8, 9, 11 and 12 of Article 1 of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products ("Directive 2011/62/EU");

— Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use ("the Delegated Regulation").

These regulations further amend the 2012 Regulations in order to widen the type of products containing naloxone hydrochloride that drug treatment services are able to supply for the purpose of saving life in an emergency and to introduce serious shortage protocols.

Regulations 3 to 8, 10 and 12 to 15 amend the 2012 Regulations in order to ensure that the provisions of the Delegated Regulation are enforceable in the United Kingdom.

Regulations 11, 17 and 19 amend the 2012 Regulations in order to transpose the changes made to Directive 2001/83 by points 8, 9, 11 and 12 of Article 1 of Directive 2011/62/EU.

Regulation 9 amends the 2012 Regulations in order to provide for the sale or supply of prescription only medicines by retail pharmacy businesses under a severe shortage protocol issued by the Ministers. The Ministers will have powers to issue such protocols where, in their opinion, the United Kingdom or part of the United Kingdom is experiencing or may experience a severe shortage of particular prescription only medicines. The protocols will allow for substitution, in restricted circumstances, of a different quantity of a prescription only medicine, or a different prescription only medicine, to that ordered by the prescriber.

Regulation 16 amends regulation 346 of the 2012 Regulations so that the new provisions are subject to review by the Secretary of State.

Regulation 18 amends Schedule 17 of the 2012 Regulations in order to allow naloxone hydrochloride that is for non-parenteral administration to be supplied by drug treatment services for the purpose of saving life in an emergency.

A transposition note is published with the Explanatory Memorandum alongside the instrument on www.legislation.gov.uk. Copies may also be obtained from the Department of Health and Social Care, 2E14 Quarry House, Leeds, LS2 7UE.