STATUTORY INSTRUMENTS

2019 No. 000

MEDICINES

The Human Medicines (Amendment) Regulations 2019

Made - - - -	*2019*
Laid before Parliament	*2019*
Coming into force - -	*March 2019*

The Secretary of State and the Minister of Health, Social Services and Public Safety, in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**a**), and the Secretary of State, in exercise of the powers conferred by section 8 of the European Union (Withdrawal) Act 2018(**b**), make the following Regulations.

The Secretary of State and the Minister of Health, Social Services and Public Safety, have been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to medicinal products(**c**).

Citation, commencement and interpretation

1. These Regulations may be cited as the Human Medicines (Amendment) Regulations 2019 and come into force on [March 2019].

Amendment of the Human Medicines Regulations 2012

2.—(1) The Human Medicines Regulations 2012(**d**) are amended as follows.

(2) After regulation 226 (emergency sale etc by pharmacists: pandemic disease), insert—

"Sale etc by a pharmacist in accordance with a serious shortage protocol

226A.—(1) Regulation 214(1) does not apply to the sale or supply of a prescription only medicine by a person lawfully conducting a retail pharmacy business if conditions A, B and C are met.

(2) Condition A is that the prescription only medicine is sold or supplied for the purpose of being administered to a person in accordance with a serious shortage protocol (SSP).

(3) Condition B is that the requirements of the SSP in respect of to whom the prescription only medicine may be sold or supplied for the purpose of being administered, and subject to what conditions, are satisfied.

(**a**) 1972 c. 68. Section 2(2)…
(**b**) 2018 c. 16.
(**c**) S.I. 1972/1811.
(**d**) S.I. 2012/1916.

(4) Condition C is that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is of the opinion, in the exercise of his or her professional skill and judgment, that—

(a) in a case to which paragraph (5)(b)(i) applies, selling or supplying a different quantity or dosage form of the prescription only medicine to the quantity or dosage form of the prescription only medicine ordered by the prescriber is reasonable and appropriate; or

(b) in a case to which paragraph (5)(b)(ii) applies—

(i) selling or supplying a prescription only medicine other than the prescription only medicine ordered by the prescriber is reasonable, and

(ii) sale or supply of the substituted prescription only medicine, in accordance with the directions for use that he or she specifies, is appropriate.

(5) For the purposes of this regulation, a SSP is a written protocol that—

(a) is issued on behalf of the Ministers (either of them acting alone or both of them acting jointly) in circumstances where the United Kingdom or any part of the United Kingdom is experiencing or may experience a serious shortage of a prescription only medicine or prescription only medicines of a specified description;

(b) provides for the sale or supply by or under the supervision of a pharmacist and subject to such conditions as may be specified in the SSP—

(i) of a different quantity or dosage form of the prescription only medicine to the quantity or dosage form ordered by the prescriber, or

(ii) of a prescription only medicine other than the prescription only medicine ordered by the prescriber;

(c) provides, in a case to which sub-paragraph (b)(ii) applies, that the other prescription only medicine is to be—

(i) a generic version of the prescription only medicine being substituted, or that both products are generic versions of another prescription only medicine,

(ii) in the case of a biological medicinal product, a similar medicinal product to the prescription only medicine being substituted, or that both products are similar medicinal products to another biological medicinal product, or

(iii) a prescription only medicine that has a similar therapeutic effect to the prescription only medicine being substituted; and

(d) specifies the period for which, and the parts of the United Kingdom (which may be all of the United Kingdom) in which, the protocol is to have effect.".

(3) After regulation 344A, insert—

"**Modifications to deal with serious shortages**

344B.—(1) The Ministers may by regulations modify the application of any of the specified provisions in circumstances where the United Kingdom, or any part of the United Kingdom, is experiencing or may experience a serious shortage of medicinal products, or of medicinal products of a specified description, arising from the withdrawal of the United Kingdom from the European Union.

(2) Regulations may only be made under paragraph (1) for the purposes of preventing, remedying or mitigating the serious shortage that is being or may be experienced.

(3) For the purposes of paragraph (1), the "specified provisions" are the provisions of Parts 1, 3 to 5, 10 to 13 and 16, and of the associated Schedules.

(4) The reference in paragraph (1) to a serious shortage arising from the withdrawal of the United Kingdom from the European Union includes reference to a serious shortage where

one but not the only significant factor contributing to the shortage is the withdrawal of the United Kingdom from the European Union.

(5) No regulations may be made under paragraph (1) after the end of, or that have effect after the end of, the period of two years beginning with exit day.

(6) The power to make regulations under paragraph (1) is exercisable by statutory instrument.

(7) Regulations made under paragraph (1) are subject to annulment by resolution of either House of Parliament.".

Signed by authority of the Secretary of State for Health

Name
Parliamentary Under Secretary of State
Department of Health

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations…