STATUTORY INSTRUMENTS

# 2023 No. 437

# The Human Medicines (Amendment) Regulations 2023

**Amendment of regulation 17 (manufacturing of medicinal products)**

**3.**—(1) Regulation 17(**1**) is amended as follows.

(2) In paragraph (2), for "paragraphs (3) to (5)" substitute "paragraphs (3) to (9)".

(3) After paragraph (8) insert—

"(9) Paragraph (1)(d) does not apply to the importation of a medicinal product into Northern Ireland from Great Britain by the holder of a wholesale dealer's licence, where the following conditions are met—

(a) the medicinal product has undergone—

(i) in an EEA State, the quality control testing provided for by Article 51 of the 2001 Directive, or

(ii) in the United Kingdom, checks in accordance with these Regulations and the requirements of the marketing authorisation relating to the product and that these are appropriately certified;

(b) the batch release of the medicinal product has been undertaken—

(i) in Northern Ireland or an EEA State, by a qualified person in accordance with Article 51(1) of the 2001 Directive, and it is accompanied by the appropriate control reports, or

(ii) in Great Britain, by a qualified person applying equivalent standards;

(c) the medicinal product has a UKMA(UK) or UKMA(NI);

(d) the importation of the medicinal product is with a view to its sale or supply in Northern Ireland only; and

(e) in the case of medicinal products, other than radiopharmaceuticals, that are required to bear safety features pursuant to Article 54a of the 2001 Directive, that the features specified in paragraph 18A of Schedule 24 are affixed on the packaging.".

(**1**) Regulation 17 was amended by S.I. 2019/775, as amended by S.I. 2020/1488.