STATUTORY RULES OF NORTHERN IRELAND

2019 No. 10

The Human Medicines (Amendment) Regulations 2019

Insertion of regulation 257A and 257B

11. After regulation 257 (packaging requirements: general), insert—

"**Packaging Requirements: medicinal products required to bear safety features**

257A.—(1) The information specified in paragraph 18A of Schedule 24 must not be removed or covered, either fully or partially, unless the following conditions are met—

(a) a person who is the holder of a manufacturer's licence verifies, prior to partially or fully removing or covering the features, that the medicinal product concerned is authentic and that it has not been tampered with;

(b) the holder of the manufacturer's licence replaces the features with ones which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product; and

(c) the replacement of the features is conducted in accordance with the applicable principles and guidelines for good manufacturing practice set out in the Good Manufacturing Practice Directive.

(2) For the purposes of paragraph (1)(b), the features shall be considered equivalent if they—

(a) comply with the requirements set out in Commission Regulation 2016/161; and

(b) are equally effective in enabling the verification of authenticity and identification of the medicinal product and in providing evidence of tampering with the medicinal product.

(3) In performing the activities referred to in paragraph (1), the holder of a manufacturer's licence shall be regarded as a producer for the purposes of the Consumer Protection Act 1987(**1**).

Transitional Arrangements

257B. The information specified in paragraph 18A of Schedule 24 does not need to appear on the packaging of a medicinal product released for sale or distribution before 9 February 2019, unless the product has been repackaged or relabelled after that date.".

(**1**) 1987 c.43.