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STATUTORY RULES OF NORTHERN IRELAND

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**2019 No. 10**

**The Human Medicines (Amendment) Regulations 2019**

**Insertion of regulation 43A (requirement for wholesale dealers to decommission the unique identifier)**

7. After regulation 43 (obligations of licence holder)(1), insert—

**“Requirement for wholesale dealers to decommission the unique identifier**

**43A.**—(1) This regulation applies only to medicinal products that are required to bear safety features pursuant to Article 54a of the 2001 Directive.

(2) Before supplying a medicinal product to a person in the United Kingdom who falls within one of the classes specified in paragraph (3), the licence holder must verify the safety features and decommission the unique identifier of that medicinal product in accordance with the requirements laid down in Commission Regulation 2016/161.

(3) The classes of person mentioned in paragraph (2) are—

- (a) persons authorised or entitled to supply medicinal products to the public who do not operate within a healthcare institution or within a pharmacy;
- (b) persons who receive the product for the purpose of selling, supplying or administering it as a veterinary medicinal product;
- (c) dentists;
- (d) registered optometrists or registered dispensing opticians;
- (e) registered paramedics;
- (f) persons who are members of Her Majesty’s armed forces;
- (g) a police force in England, Wales or Scotland or the Police Service of Northern Ireland;
- (h) government institutions maintaining stocks of medicinal products for the purposes of civil protection or disaster control;
- (i) universities or other institutions concerned with higher education or research, other than healthcare institutions;
- (j) a prison service;
- (k) persons carrying on the business of a school;
- (l) care homes;
- (m) hospices.”