Transposition note for points 8, 9, 11 and 12 of Article 1 of Directive 2011/62/EU 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 amends Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of falsified medicinal products. The SI amends the Human Medicines Regulations 2012 in order to implement the final aspects of Directive 2011/62/EU which require two new safety features (a unique identifier and an anti-tampering device) to appear on the packaging of certain medicinal products.

Article of Directive 2011/62/EU	**Article of Directive 2001/83 affected**	**Objective**	**Implementation in the Regulations**
1(8)	47a(1)	This inserts new article 47a into Directive 2001/83. Paragraph 1 of article 47a provides that the safety features referred to in point (o) of Article 54 shall not be removed or covered, unless certain conditions are fulfilled. Paragraph 2 of article 47a provides that manufacturing authorisation holders, including those performing the activities referred to in paragraph 1 of this Article, shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in Directive 85/374/EEC.	Regulation 11 inserts regulation 257A into the 2012 Regulations to provide this requirement.
1(9)	51(1)	This inserts a subparagraph into Article 51(1) to provide that the qualified person under a manufacturing	Regulation 17 inserts this requirement into paragraph 12 of Schedule 7 of the 2012 Regulations.

		authorisation shall, in relation to medicinal products intended to be placed on the market in the Union, ensure that the safety features have been affixed on the packaging of certain medicinal products.	
1(11)	54(o)	This inserts point (o) into article 54 requiring safety features to appear on the packaging of certain medicinal products that would enable wholesale distributors and persons authorised to supply medicinal products to the public to authenticate, identify or otherwise establish if a medicinal product has been tampered with.	Regulation 19 inserts paragraph 18A into Schedule 24 of the 2012 Regulations to provide this requirement.
1(12)	54a(1)	This inserts article 54a into the Directive providing a requirement for medicinal products subject to prescription to bear the safety features, unless they have been listed in delegated acts made under the Directive.	Regulation 19 inserts paragraph 18A into Schedule 24 of the 2012 Regulations to provide this requirement.
1(12)	54a(2) and (3)	Paragraphs 2 and 3 of article 54a provides for the Commission to adopt delegated acts with the objective of establishing the detailed rules for the safety features.	No transposition needed.
1(12)	54a(4)	Paragraph 4 of article 54a provides for national competent authorities to notify the commission of	No transposition needed.

		prescription only medicinal products which they deem not to be at risk of falsification, and consequently should not be required to bear the safety features, as well as non-prescription medicinal products which they judge to be at risk of falsification and so should bear the safety features.	
1(12)	54a(5)	Paragraph 5 of article 54a allows member States to extend the scope of the safety features for the purposes of reimbursement, pharmacovigilance or patient safety.	No transposition needed.