STATUTORY RULES OF NORTHERN IRELAND

2019 No. 10

The Human Medicines (Amendment) Regulations 2019

Amendment of Schedule 24 (packaging information requirements)

19. In schedule 24, after paragraph 18 insert—

"**18A.** In the case of a medicinal product, other than a radiopharmaceutical, that is required by Article 54a of the 2001 Directive to bear safety features—

(a) a unique identifier which complies with the technical specifications set out in Chapter II of Commission Regulation 2016/161; and

(b) an anti-tampering device allowing verification of whether the packaging of the medicinal product has been tampered with.".