
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

[^{F1}Offences relating to the safety features appearing on the packaging of medicinal products]

[^{F1}Offences relating to Commission Regulation 2016/161]

94A.—[^{F2}(1) A person who is—

- (a) the holder of a UKMA(NI), UKMA(UK) or parallel import licence, or
- (b) a parallel distributor,

is guilty of an offence if the holder fails to comply with a requirement or obligation contained in a provision of Commission Regulation 2016/161 listed in paragraph (2).]

(2) The provisions mentioned in paragraph (1) are—

- (a) Article 33 (uploading of information in the repositories system);
- (b) Article 40 (products recalled, withdrawn or stolen);
- (c) Article 41 (products to be supplied as free samples); and
- (d) Article 42 (removal of unique identifiers from the repositories system).

[^{F3}(3) In this regulation “parallel distributor” means a person who imports into Northern Ireland from an EEA state a product which has been granted a marketing authorisation under Regulation (EC) No 726/2004 and in relation to which that person is not the holder of a UKMA(NI), UKMA(UK), Article 126a authorisation, COR(NI), COR(UK), THR(NI) or THR(UK).]]

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| F1 | Reg. 94A and cross-heading inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62) , regs. 1, 8 and reg. 94A and cross-heading inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10) , regs. 1, 8 |
| F2 | Reg. 94A(1) substituted (31.12.2020) by S.I. 2019/775 , reg. 91(a) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488) , reg. 1 , Sch. 2 para. 68) |
| F3 | Reg. 94A(3) substituted (31.12.2020) by S.I. 2019/775 , reg. 91(b) (as substituted by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488) , reg. 1 , Sch. 2 para. 68) |

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 94A.