STATUTORY RULES OF NORTHERN IRELAND

# 2019 No. 10

# The Human Medicines (Amendment) Regulations 2019

**Insertion of regulation 94A (offences relating to Commission Regulation 2016/161)**

**8.** After regulation 94 (failure to submit report to EMA), insert—

*"Offences relating to the safety features appearing on the packaging of medicinal products*

**Offences relating to Commission Regulation 2016/161**

**94A.**—(1) The holder of a marketing authorisation or parallel import licence, or 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(b) Article 40 (products recalled, withdrawn or stolen);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).

(3) In this regulation "parallel distributor" means a person who imports from another 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 marketing authorisation, Article 126a authorisation, certificate of registration or a traditional herbal registration.".