

## SCHEDULES

### SCHEDULE 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

### PART 13

Amendment of Part 14 (amendment of Part 13 (packaging and leaflets))

**164.** After regulation 208 (amendment of regulation 269 (offences relating to packaging and package leaflets: other persons)) insert—

**“Insertion of new regulation 269A (offences relating to packaging and package leaflets in Northern Ireland: other persons)**

**208A.** After regulation 269 insert—

**“Offences relating to packaging and package leaflets in Northern Ireland: other persons**

**269A.**—(1) This regulation applies to a person, other than the holder of a UKMA(UK), UKMA(NI), EU marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration for a medicinal product, who, in the course of a business carried on by that person, sells or supplies, or offers to sell or supply the product, or possesses the product for the purpose of sale or supply in Northern Ireland.

(2) A person to whom this regulation applies is guilty of an offence if the person sells or supplies, or offers to sell or supply, the product, or possesses the product for the purpose of sale or supply, in Northern Ireland knowing or having reasonable cause to believe—

- (a) that a package or package leaflet relating to the medicinal product does not comply with the applicable requirements of this Part, Article 9 of Commission Regulation 2016/161 or Article 28 or 32 of the Paediatric Regulation; or
- (b) that the product is not accompanied by a package leaflet when one is required by virtue of this Part.””.

#### Commencement Information

**11** Sch. 2 para. 164 in force at 31.12.2020 immediately before IP completion day, see [reg. 1](#)

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020, Paragraph 164.