STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 13

Packaging and leaflets

CHAPTER 1

Requirements for packaging and package leaflets relating to medicinal products

Packaging requirements: general

257.—(1) The information specified in Part 1 of Schedule 24 must appear—

(a) on the outer packaging of a medicinal product; and

(b) on the immediate packaging of the product, unless paragraph (2) or (3) applies to the packaging.

(2) This paragraph applies to immediate packaging if the packaging is in the form of a blister pack and is placed in outer packaging which complies with the requirements of Part 1 of Schedule 24.

(3) This paragraph applies to immediate packaging if the packaging is too small to display the information required by Part 1 of Schedule 24.

(4) The information specified in Part 2 of Schedule 24 must appear on immediate packaging to which paragraph (2) applies.

(5) The information specified in Part 3 of Schedule 24 must appear on immediate packaging to which paragraph (3) applies.

(6) Information included on the packaging of a product in accordance with this regulation, **[**[F1]regulation 257C where the product is for sale or supply in Great Britain only,**]** regulation 261 and Schedule 24 must be easily legible, comprehensible and indelible.

(7) Nothing in this regulation or Schedule 24 applies to a registrable homoeopathic medicinal product.

[[F2](8) Nothing in this regulation applies to the outer or immediate packaging of an advanced therapy medicinal product for sale or supply in Great Britain only.**]**

F1 Words in reg. 257(6) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **198(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 152(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Reg. 257(8) inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **198(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 152(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 257.