SCHEDULES

SCHEDULE 24

Regulation 257

Packaging information requirements

PART 1

Outer and immediate packaging

1. The name of the medicinal product.

2. The strength and pharmaceutical form of the product.

3. Where appropriate, whether the product is intended for babies, children or adults.

4. Where the product contains up to three active substances, the common name of each active substance.

5. A statement of the active substances in the product, expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names.

6. The pharmaceutical form and the contents by weight, by volume or by number of doses of the product.

7. A list of—

(a) where the product is injectable or is a topical or eye preparation, all excipients; or

(b) in any other case, those excipients known to have a recognized action or effect and included in the guidance **[**[F1]published under regulation 257D in the case of products for sale or supply in Great Britain, or in the case of products for sale or supply in Northern Ireland, any guidance published pursuant to Article 65 of the 2001 Directive or under regulation 257D that is applicable to such products.**]**.

F1 Words in Sch. 24 para. 7(b) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

8. The method of administration of the product and if necessary the route of administration.

9. Where appropriate, space for the prescribed dose to be indicated.

10. A warning that the product must be stored out of the reach and sight of children.

11. Any special warning applicable to the product.

12. The product's expiry date (month and year), in clear terms.

13. Any special storage precautions relating to the product.

14. Any special precautions relating to the disposal of an unused product or part of a product, or waste derived from the product, and reference to any appropriate collection system in place.

15. The name and address of the holder of the **[**[F2]UK marketing authorisation, EU marketing authorisation**]** Article 126a authorisation or traditional herbal registration relating to the product and, where applicable, the name of the holder's representative.

F2 Words in Sch. 24 para. 15 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

16. The number of the **[**[F3]UK marketing authorisation, EU marketing authorisation**]** Article 126a authorisation or traditional herbal registration for placing the medicinal product on the market.

F3 Words in Sch. 24 para. 16 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

17. The manufacturer's batch number.

18. In the case of a product that is not a prescription only medicine, instructions for use.

[[F4]**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.**]**

F4 Sch. 24 para. 18A inserted (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.I. 2019/62), regs. 1, **19** and Sch. 24 para. 18A inserted (N.I.) (9.2.2019) by The Human Medicines (Amendment) Regulations 2019 (S.R. 2019/10), regs. 1, **19**

PART 2

Immediate packaging: blister packs

19. The name of the medicinal product.

20. The strength and pharmaceutical form of the product.

21. Where appropriate, whether the product is intended for babies, children or adults.

22. Where the product contains up to three active substances, the common name of each active substance.

23. The name of the holder of the **[**[F5]UK marketing authorisation, EU marketing authorisation**]**, Article 126a authorisation or traditional herbal registration relating to the product.

F5 Words in Sch. 24 para. 23 substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

24. The product's expiry date (month and year), in clear terms.

25. The manufacturer's batch number.

PART 3

Immediate packaging: small packages

26. The name of the medicinal product.

27. The strength and pharmaceutical form of the product.

28. Where appropriate, whether the product is intended for babies, children or adults.

29. Where the product contains up to three active substances, the common name of each active substance.

30. The method of administration of the product and if necessary the route of administration.

31. The product's expiry date (month and year), in clear terms.

32. The manufacturer's batch number.

33. The contents of the packaging by weight, by volume or by unit.

[F6PART 4

Outer and immediate packaging: advanced therapy medicinal products for sale or supply in Great Britain only

F6 Sch. 24 Pts. 4, 5 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **201(5)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 155(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

34. The name of the advanced therapy medicinal product which is the international non-proprietary name, or if none, the common name.

35. Where appropriate, whether the product is intended for babies, children or adults.

36. The expiry date in clear terms including the year and month and, if applicable, day.

37. A description of the active substance, expressed qualitatively and quantitatively.

38. Where the product contains tissues and cells of human or animal origin—

(a) a statement that the product contains such cells or tissues; and

(b) a short description of the cells or tissues and of their specific origin, including the species of animal in cases on non-human origin.

39. The pharmaceutical form and the contents by weight, volume or number of doses of the product.

40. A list of excipients, including preservative systems.

41. The method of use, application, administration or implantation and, if appropriate, the route of administration, with space provided for the prescribed dose to be indicated.

42. A special warning that the product is to be stored out of the sight and reach and children.

43. Any special warning necessary for the particular product.

44. Any special storage precautions.

45. Specific precautions relating to the disposal of the unused product or of waste derived from the product and, where appropriate, reference to any appropriate collection system.

46. The name and address of the holder of the UK marketing authorisation and, where applicable, the name of the representative appointed by the holder to represent him.

47. The UK marketing authorisation number.

48. The manufacturer's batch number.

49. The unique donation code assigned by a tissue establishment pursuant to—

(a) paragraph 1 of Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards human gametes and embryos; and

(b) paragraph 1 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other human tissues and cells.

50. Where the exempt advanced therapy medicinal product is for autologous use, the unique patient identifier and the words “for autologous use only”.

PART 5

Immediate packaging: blister packs and small packaging (advanced therapy medicinal products for sale or supply in Great Britain only)

51. The information specified in Part 2.

52. The unique donation code assigned by a tissue establishment pursuant to—

(a) paragraph 1 of Schedule 3A to the Human Fertilisation and Embryology Act 1990, as regards human gametes and embryos; and

(b) paragraph 1 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as regards other human tissues and cells.

53. Where the exempt advanced therapy medicinal product is for autologous use, the unique patient identifier and the words "for autologous use only".**]**

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, SCHEDULE 24.