STATUTORY INSTRUMENTS

2019 No. 775

The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

PART 14

Amendment of Part 13 (packaging and leaflets)

Amendment of regulation 257 (packaging requirements: general)

198.—(1) Regulation 257 is amended as follows.

(2) In paragraph (6), after "this regulation," insert "regulation 257C,".

(3) After paragraph (7) insert—

"(8) Nothing in this regulation applies to the outer or immediate packaging of an advanced therapy medicinal product.".

Omission of regulations 257A and 257B (packaging requirements: medicinal products required to bear safety features and associated transitionals)

199. Omit regulations 257A and 257B(**1**).

Insertion of regulations 257C (packaging requirements: advanced therapy medicinal products) and 257D and 257E (guidance and regulations in relation to packing, leaflets and labelling)

200. After regulation 257, insert—

"**Packaging requirements: advanced therapy medicinal products**

257C.—(1) The information specified in Part 4 of Schedule 24 must appear—

(a) on the outer packaging of an advanced therapy medicinal product (other than an exempt advanced therapy 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 the 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 4 of Schedule 24.

(3) This paragraph applies to immediate packaging if the packaging is too small to display the information required by Part 4 of Schedule 24.

(4) The information specified in Part 5 of Schedule 24 must appear on immediate packaging to which paragraph (2) or (3) applies.

(**1**) Regulations 257A and 257B were inserted by S.I. 2019/62.

Guidance as to packaging and package leaflets

257D.—(1) The licensing authority may publish guidance on packaging and package leaflets which may, in particular, include—

(a) the wording of certain special warnings for certain categories of medicinal products;

(b) the particular information needs relating to products that are a pharmacy medicine;

(c) the legibility of particulars on the labelling and package leaflet;

(d) the methods of identification and authentication of medicinal products;

(e) the list of excipients which must feature on the labelling of medicinal products and the way in which these excipients must be indicated.

(2) Until such time as the licensing authority publishes guidance under paragraph (1), any guidance published by the Commission under Article 65 of the 2001 Directive, insofar as that guidance was in force immediately before exit day(**2**), continues to apply as if it had been published by the licensing authority under paragraph (1).

Regulation-making power as to certain forms of labelling

257E. The Ministers may by regulations require the use of certain forms of labelling of a medicinal product in order to make it possible to ascertain—

(a) the price of the medicinal product;

(b) any reimbursement conditions of the National Health Service;

(c) the legal status for supply to the patient in accordance with regulation 5 (classification), insofar as not already provided for in Schedule 25;

(d) authenticity and identification of the medicinal product in accordance with Article 54a(5) of the 2001 Directive.".

Amendment of Schedule 24 (packaging information requirements)

201.—(1) Schedule 24 is amended as follows.

(2) In paragraph 7(b), for "published pursuant to Article 65 of the 2001 Directive" substitute "published under regulation 257D".

(3) In paragraphs 15, 16 and 23, for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(4) Omit paragraph 18A(**3**).

(5) After Part 3 insert—

"PART 4

Outer and immediate packaging: advanced therapy medicinal products

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

(**2**) The guidance is available at: https://www.gov.uk/guidance/eu-guidance-documents-referred-to-in-the-human-medicines-regulations-2012 and a hard copy may be obtained from the Medicines and Healthcare products Regulatory Agency at the address given in the Explanatory Note.

(**3**) Paragraph (18A) was inserted by S.I. 2019/62.

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(**4**), 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(**5**), 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)

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

(**4**) 1990 c. 37. Schedule 3A was inserted by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007/1522, regulation 30.
(**5**) S.I. 2007/1523.

(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"."

Amendment of regulation 259 (packaging requirements: information for blind and partially sighted patients)

202. In regulation 259(2), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 260 (package leaflets)

203.—(1) Regulation 260 is amended as follows.

(2) After paragraph (1) insert—

"(1A) If the medicinal product is an advanced therapy medicinal product (other than an exempt advanced therapy medicinal product), the package leaflet must contain the information specified in Part 3 of Schedule 27 in the order specified in that Part.".

(3) In paragraph (2), after "Part 2 of that Schedule)" insert ", or where the product is an advanced therapy medicinal product, the information specified in Part 3 of that Schedule,".

(4) In paragraph (3), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of Schedule 27 (package leaflets)

204.—(1) Schedule 27(**6**) is amended as follows.

(2) In paragraph 8(c)(ii), for "Article 65 of the 2001 Directive", substitute "published under regulation 257D".

(3) In paragraph 11(f), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(4) Omit paragraph 12.

(5) In paragraph 13—

(a) for "Article 23 of Regulation (EC) No 726/2004" substitute "regulation 202A";

(b) before "statement", insert "symbol and"; and

(c) before "This", insert "▼".

(6) At the end insert—

"Part 3

Advanced therapy medicinal products

18. The name of the advanced therapy medicinal product.

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

20. The common name of the advanced therapy medicinal product.

(**6**) Schedule 27 was amended by S.I. 2014/1878.

21. The therapeutic group, or type of activity, of the product, in terms easily comprehensible for the patient.

22. Where the product contains cells or tissues, a description of those cells or tissues and of their specific origin, including the species of animal in cases of non-human origin.

23. Where the product contains medical devices or active implantable medical devices, a description of those devices and their specific origin.

24. The product's therapeutic indications.

25. A list of information which is necessary before the medicinal product is taken or used, including—

(a) contra-indications;

(b) appropriate precautions for use;

(c) interactions with other medicinal products which may affect the action of the product;

(d) interactions with other substances, including alcohol, tobacco and foodstuffs which may affect the action of the product;

(e) special warnings; if any, relating to the product.

26. The list mentioned in paragraph 25 must—

(a) take into account the special requirements of particular categories of users (including, in particular, children, pregnant or breastfeeding women, the elderly and persons with specific pathological conditions);

(b) mention, if appropriate, possible effects on the ability to drive vehicles or operate machinery; and

(c) list any excipients—

(i) if knowledge of the excipients is important for the safe and effective use of the product; and

(ii) the excipients are included in the guidance published under regulation 257D.

27. Instructions for proper use of the product including in particular—

(a) the dosage;

(b) the method of use, application, administration or implantation and, if necessary, the route of administration;

(c) the frequency of administration (including, if necessary, specifying the times at which the product may or must be administered);

(d) the duration of treatment if this is to be time limited;

(e) symptoms of an overdose and the action, if any, to be taken in the case of an overdose;

(f) what to do if one or more doses have not been taken;

(g) a specific recommendation to consult a doctor or pharmacist, as appropriate, for further explanation of the use of the product.

28. A description of the adverse reactions which may occur in normal use of the medicinal product and, if necessary, the action to be taken in such a case.

29. A reference to the expiry date printed on the packaging of the product with—

(a) a warning against using the product after that date;

(b) if appropriate, details of special storage precautions to be taken;

(c) if necessary, a warning concerning visible signs of deterioration;

(d) the full qualitative and quantitative composition;

(e) the name and address of the UK marketing authorisation holder and, if applicable, the name of the holder's appointed representative; and

(f) the name and address of the manufacturer.

30. The date on which the package leaflet was last revised.".

Amendment of regulation 266 (language requirements etc)

205.—(1) Regulation 266 is amended as follows.

(2) In paragraph (1), omit "unless either or both of paragraphs (2) and (3) applies".

(3) Omit paragraphs (2) and (3).

Amendment of regulation 267 (submission of mock-ups of packaging and leaflets to licensing authority)

206. In regulation 267, in each place where it occurs, for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

Amendment of regulation 268 (offence relating to packaging and package leaflets)

207.—(1) Regulation 268(**7**) is amended as follows.

(2) In paragraph (1), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(3) In paragraph (2)(a)—

(a) for "Article 28 or 32 of the Paediatric Regulation" substitute "regulation 50C(4), 50D(8) or 58A(2)(b)"; and

(b) omit ", Article 9 of Commission Regulation 2016/161".

Amendment of regulation 269 (offences relating to packaging and package leaflets: other persons)

208.—(1) Regulation 269(**8**) is amended as follows.

(2) In paragraph (1), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(3) In paragraph (2)(a)—

(a) for "Article 28 or 32 of the Paediatric Regulation" substitute "regulation 50C(4), 50D(8) or 58A(2)(b)"; and

(b) omit ", Article 9 of Commission Regulation 2016/161".

Amendment of regulation 270 (non-compliance with requirements of this Part)

209. In regulation 270(1) and (2), for "marketing authorisation, Article 126a authorisation" substitute "UK marketing authorisation".

(**7**) Regulation 268 was amended by S.I. 2019/62.
(**8**) Regulation 269 was amended by S.I. 2015/903 and 2019/62.

Amendment of regulation 273 (child resistant containers for regulated medicinal products)

210.—(1) Regulation 273 is amended as follows.

(2) In paragraph (2), for sub-paragraph (b) substitute—

"(b) any specification for non-reclosable child resistant packaging that the licensing authority is satisfied is of an equivalent or higher technical specification to that specified in sub-paragraph (a).".

(3) In paragraph (3), for sub-paragraph (b) substitute—

"(b) any specification for reclosable child resistant packaging that the licensing authority is satisfied is of an equivalent or higher technical specification to that specified in sub-paragraph (a).".