
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 Schedule 27 (package leaflets)

204.—(1) Schedule 27^{M1} is amended as follows.

(2) In paragraph 8(c)(ii), for “Article 65 of the 2001 Directive”, substitute “ published under regulation 257D [^{F1}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.] ”.

(3) In paragraph 11(f), [^{F2}for “marketing authorisation,” substitute “UK marketing authorisation, EU marketing authorisation”.]

(4) [^{F3}In] paragraph 12 [^{F4} after “ Where the product ” insert "is authorised for sale or supply in Northern Ireland and".]

(5) In paragraph 13—

(a) [^{F5}after] “Article 23 of Regulation (EC) No 726/2004” [^{F6}insert “in the case of products for sale or supply in Northern Ireland, or the list referred to in regulation 202A, in the case of products for sale or supply in Great Britain.”];

(b) before “statement”, insert “ symbol and ”; and

(c) before “This”, insert “ ▼ ”.

(6) At the end insert—

“Part 3

Advanced therapy medicinal products [^{F7}for sale or supply in Great Britain only]

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.

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.”.

Textual Amendments

- F1** Words in reg. 204(2) inserted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 158(a)**
- F2** Words in reg. 204(3) substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 158(b)**
- F3** Word in reg. 204(4) substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 158(c)(i)**
- F4** Words in reg. 204(4) inserted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 158(c)(ii)**
- F5** Word in reg. 204(5)(a) substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 158(d)(i)**
- F6** Words in reg. 204(5)(a) substituted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 158(d)(ii)**
- F7** Words in reg. 204(6) inserted (31.12.2020 immediately before IP completion day) by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), reg. 1, **Sch. 2 para. 158(e)**

Commencement Information

- I1** Reg. 204 in force at 31.12.2020 on IP completion day (in accordance with [2020 c. 1](#), **Sch. 5 para. 1(1)**), see [reg. 1](#)

Marginal Citations

- M1** Schedule 27 was amended by [S.I. 2014/1878](#).

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, Section 204.