SCHEDULES

SCHEDULE 27 Regulation 260

Package leaflets

PART 1

General requirements

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

6. The product's therapeutic indications.

7. A list of—

(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; and

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

8. The list mentioned in paragraph 7 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 to 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 pursuant to **[**[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.**]**

Textual Amendments

F1 Words in Sch. 27 para. 8(c)(ii) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(2)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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

(a) the dosage;

(b) the method and, if necessary, route of administration;

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

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

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

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

(g) an indication, if necessary, of the risk of withdrawal effects; and

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

10. 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.

11. 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 composition (in active substances and excipients), and the quantitative composition in active substances, using common names, of each presentation of the medicinal product;

(e) for each presentation of the product, the pharmaceutical form and content in weight, volume or units of dosage;

(f) 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, if applicable, the name of the holder's appointed representative; and

(g) the name and address of the manufacturer of the product.

Textual Amendments

F2 Words in Sch. 27 para. 11(f) substituted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **reg. 204(3)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

12. Where the product **[**[F3]is authorised for sale or supply in Northern Ireland and**]** is authorised under different names in different member States in accordance with Articles 28 to 39 of the 2001 Directive, a list of the names authorised in each member State.

Textual Amendments

F3 Words in Sch. 27 para. 12 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(4)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

13. For medicinal products included in the list referred to in Article 23 of Regulation (EC) No 726/2004**[**[F4]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,**]** the **[**[F5]symbol and **]** statement: "**[**[F6]▼**]** This medicinal product is subject to additional [F7]... monitoring".

Textual Amendments

F4 Words in Sch. 27 para. 13 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(5)(a)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Words in Sch. 27 para. 13 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

F6 Symbol in Sch. 27 para. 13 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(5)(c)**; 2020 c. 1, Sch. 5 para. 1(1)

F7 Word in Sch. 27 para. 13 omitted (E.W.S.) (1.10.2014) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **28(2)** and word in Sch. 27 para. 13 omitted (N.I.) (1.10.2014) by virtue of The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **28(2)**

[[F8]**14.** A standardised text relating to adverse event reporting in accordance with the third sub-paragraph of Article 59(1) of the 2001 Directive.**]**

Textual Amendments

F8 Sch. 27 para. 14 substituted (E.W.S.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.I. 2014/1878), regs. 1, **28(3)** and Sch. 27 para. 14 substituted (N.I.) (1.10.2014) by The Human Medicines (Amendment) (No. 2) Regulations 2014 (S.R. 2014/324), regs. 1(1), **28(3)**

15. The date on which the package leaflet was last revised.

PART 2

Paracetamol

16. If a medicinal product contains paracetamol, unless the product is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage".

17. If a medicinal product contains paracetamol and is wholly or mainly intended for children twelve years old or younger, the words "Talk to a doctor at once if your child takes too much of this medicine even if they seem well. This is because too much paracetamol can cause delayed, serious liver damage".

[F9 Part 3

Advanced therapy medicinal products for sale or supply in Great Britain only

Textual Amendments

F9 Sch. 27 Pt. 3 inserted (31.12.2020) by The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775), regs. 1, **204(6)** (as amended by S.I. 2020/1488, reg. 1, **Sch. 2 para. 158(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

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.**]**

Changes to legislation:
The Human Medicines Regulations 2012, SCHEDULE 27 is up to date with all changes known to be in force on or before 27 September 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

- Sch. 27 para. 12 omitted by S.I. 2019/775 reg. 204(4) (This amendment not applied to legislation.gov.uk. Reg. 204(4) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 158(c))
- Sch. 27 para. 8(c)(ii) words omitted by S.I. 2024/832 reg. 143(a)
- Sch. 27 para. 11(f) words omitted by S.I. 2024/832 reg. 143(b)
- Sch. 27 Pt. 3 heading words omitted by S.I. 2024/832 reg. 143(c)
- Sch. 27 para. 11(f) words substituted by S.I. 2019/775 reg. 204(3) (This amendment not applied to legislation.gov.uk. Reg. 204(3) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 158(b))
- Sch. 27 para. 13 words substituted by S.I. 2019/775 reg. 204(5)(a) (This amendment not applied to legislation.gov.uk. Reg. 204(5)(a) amended immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 158(d))

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Sch. 11 para. 1(1)(d)-(f) inserted by S.I. 2019/775 reg. 63(2)(a)(ii) (This amendment not applied to legislation.gov.uk. Reg. 63(2)(a)(ii) substituted immediately before IP completion day by S.I. 2019/1385, reg. 1, Sch. 1 para. 7(2))
- Sch. 24 para. 18B inserted by S.I. 2024/832 reg. 142(e)
- Sch. 24 Pt. 1 para. 23 words omitted by S.I. 2024/832 reg. 142(f)
- Sch. 33A para. 57A inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(4) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(3) substituted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(b) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33A para. 57(2) words inserted by S.I. 2019/775, Sch. 7 (as amended) by S.I. 2019/1385 Sch. 1 para. 10(3)(a) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 10(3)(4) omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(c))
- Sch. 33B inserted by S.I. 2024/832 reg. 146
- reg. 3(12)(d)(ia) omitted by S.I. 2024/832 reg. 4(a)
- reg. 4(4)(d)(ia) omitted by S.I. 2024/832 reg. 5
- reg. 43(7)(b)(ii)(bb) words omitted by S.I. 2024/832 reg. 18(b)
- reg. 49(1ZA)-(1ZD) inserted by S.I. 2024/832 reg. 26(a)
- reg. 49(3ZA) inserted by S.I. 2024/832 reg. 26(d)
- reg. 51(9) words inserted by S.I. 2019/775, reg. 56 (as amended) by S.I. 2019/1385 Sch. 1 para. 5 (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 52(1)(a)(i)(ii) and words substituted by S.I. 2019/775 reg. 57(2) (This amendment not applied to legislation.gov.uk. Reg. 57 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 42)

- reg. 53(2)-(2C) substituted for reg. 53(2) by S.I. 2019/775 reg. 58(3) (This amendment not applied to legislation.gov.uk. Reg. 58 substituted immediately before IP completion day by S.I. 2020/1488, reg. 1, Sch. 2 para. 43)
- reg. 53(2)(a) substituted by S.I. 2019/775, reg. 58(3) (as amended) by S.I. 2019/1385 Sch. 1 para. 6(2) (This amendment not applied to legislation.gov.uk. Sch. 1 paras. 2-6 omitted immediately before IP completion day by virtue of S.I. 2020/1488, reg. 1, Sch. 3 para. 1(a))
- reg. 55(1)(b)(iii)(bb) substituted by S.I. 2024/832 reg. 43(a)(ii)
- reg. 60A(10A) inserted by S.I. 2024/832 reg. 49(e)
- reg. 68(11H)-(A12) inserted by S.I. 2024/832 reg. 56(b)
- reg. 173(e) inserted by S.I. 2017/1322 Sch. 4 para. 2(2)(b) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(i).)
- reg. 240(2A) words inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(c) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 240(6A) inserted by S.I. 2017/1322 Sch. 4 para. 2(3)(g) (This amendment not applied to legislation.gov.uk: superseded by S.I. 2018/121, reg. 2(4)(b)(ii).)
- reg. 257(9) inserted by S.I. 2024/832 reg. 110(c)
- reg. 257AA257AB inserted by S.I. 2024/832 reg. 111
- reg. 327(1)(c)(va) omitted by S.I. 2024/832 reg. 128(a)
- reg. 346(2)(c)(iia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iiia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(iva) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xviia) omitted by S.I. 2024/832 reg. 132(b)
- reg. 346(2)(c)(xxviiij) omitted by S.I. 2024/832 reg. 132(b)
- reg. 347B inserted by S.I. 2024/832 reg. 133