

SCHEDULES

SCHEDULE 1

Further provisions for classification of medicinal products

PART 1

Descriptions of certain medicinal products to be available only on prescription

1. The following medicinal products shall be available only on prescription—
 - (a) a product for parenteral administration;
 - (b) a product that is a controlled drug [^{F1}as defined in section 2(1)(a) of the Misuse of Drugs Act 1971], unless it is covered by a [^{F2}UK] marketing authorisation in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale;
 - (c) cyanogenic substances, other than preparations for external use;
 - (d) medicinal substances that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used;
 - (e) a product that—
 - (i) is covered by a [^{F3}UK marketing authorisation, EU marketing authorisation, Article 126a authorisation or parallel import licence] in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale, and
 - (ii) consists of or contains aloxiprin, aspirin or paracetamol in the form of non-effervescent tablets or capsules;
 - (f) a product that—
 - (i) is covered by a [^{F4}UK marketing authorisation, EU marketing authorisation, Article 126a authorisation or parallel import licence] in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale, and
 - (ii) consists of or contains (in any pharmaceutical form) pseudoephedrine salts or ephedrine base or salts; ^{F5}...
 - (g) a product that—
 - (i) is not covered by a [^{F6}UK marketing authorisation, EU marketing authorisation, Article 126a authorisation or parallel import licence], and
 - (ii) is a prescription only medicine by virtue of articles 5 and 10 of, and Schedules 1 and 2 to, the Prescription Only Medicines (Human Use) Order 1997 ^{M1}[^{F7}, ^{F8}...]
 - ^{F9}(h) a product which is authorised by the licensing authority on a temporary basis under regulation 174, in circumstances where the licensing authority has attached a condition to that authorisation to the effect that, for the duration of the temporary authorisation, the product is classified as a prescription only medicine [^{F10}; and]]

- [^{F11}(i) an EAMS medicinal product, in circumstances where the licensing authority has attached a condition to the EAMS scientific opinion in respect of that product to the effect that, for the duration of that opinion, the product is classified as a prescription only medicine.]

Textual Amendments

- F1** Words in Sch. 1 para. 1(b) inserted (E.W.S.) (31.3.2014) by [The Human Medicines \(Amendment\) Regulations 2014 \(S.I. 2014/490\)](#), **regs. 1(2), 10** and words in Sch. 1 para. 1(b) inserted (N.I.) (31.3.2014) by [The Human Medicines \(Amendment\) Regulations 2014 \(S.R. 2014/323\)](#), **regs. 1(2), 10**
- F2** Word in Sch. 1 para. 1(b) inserted (31.12.2020) by [S.I. 2019/775](#), **reg. 8(a)(i)** (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), **reg. 1, Sch. 2 para. 5**)
- F3** Words in Sch. 1 para. 1(c)(i) substituted (31.12.2020) by [S.I. 2019/775](#), **reg. 8(a)(ii)** (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), **reg. 1, Sch. 2 para. 5**)
- F4** Words in Sch. 1 para. 1(f)(i) substituted (31.12.2020) by [S.I. 2019/775](#), **reg. 8(a)(ii)** (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), **reg. 1, Sch. 2 para. 5**)
- F5** Word in Sch. 1 para. 1(f) omitted (6.11.2020) by virtue of [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), **regs. 1(2), 31(2)(a)** and word in Sch. 1 para. 1(f) omitted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), **regs. 1(2), 31(2)(a)**
- F6** Words in Sch. 1 para. 1(g)(i) substituted (31.12.2020) by [S.I. 2019/775](#), **reg. 8(a)(ii)** (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\)](#), **reg. 1, Sch. 2 para. 5**)
- F7** Word in Sch. 1 para. 1(g) inserted (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), **regs. 1(2), 31(2)(b)** and word in Sch. 1 para. 1(g) inserted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), **regs. 1(2), 31(2)(b)**
- F8** Word in Sch. 1 para. 1(g) omitted (15.4.2022) by virtue of [The Human Medicines \(Amendments Relating to the Early Access to Medicines Scheme\) Regulations 2022 \(S.I. 2022/352\)](#), **regs. 1(2), 12(2)(a)** (with **reg. 19**)
- F9** Sch. 1 para. 1(h) inserted (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), **regs. 1(2), 31(2)(c)** and Sch. 1 para. 1(h) inserted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), **regs. 1(2), 31(2)(c)**
- F10** Word in Sch. 1 para. 1(h) inserted (15.4.2022) by [The Human Medicines \(Amendments Relating to the Early Access to Medicines Scheme\) Regulations 2022 \(S.I. 2022/352\)](#), **regs. 1(2), 12(2)(b)** (with **reg. 19**)
- F11** Sch. 1 para. 1(i) inserted (15.4.2022) by [The Human Medicines \(Amendments Relating to the Early Access to Medicines Scheme\) Regulations 2022 \(S.I. 2022/352\)](#), **regs. 1(2), 12(2)(c)** (with **reg. 19**)

Marginal Citations

- M1** [S.I. 1997/1830](#), as amended by [S.I. 1997/2044](#), [S.I. 1998/108](#), [S.I. 1998/1178](#), [S.I. 1998/2081](#), [S.I. 1999/1044](#), [S.I. 1999/3463](#), [S.I. 2000/1917](#), [S.I. 2000/2899](#), [S.I. 2000/3231](#), [S.I. 2001/2777](#), [S.I. 2001/3942](#), [S.I. 2003/696](#) and [S.I. 2006/915](#) and these Regulations. There are other amendments, but none is relevant.

Changes to legislation:

There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Paragraph 1.