

# SCHEDULES

## SCHEDULE 1

Regulation 5

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 [<sup>F1</sup>as defined in section 2(1)(a) of the Misuse of Drugs Act 1971], unless it is covered by a [<sup>F2</sup>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 [<sup>F3</sup>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 [<sup>F4</sup>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; <sup>F5</sup>...
  - (g) a product that—
    - (i) is not covered by a [<sup>F6</sup>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 <sup>M1</sup>[<sup>F7</sup>, <sup>F8</sup>...]
  - <sup>F9</sup>(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 [<sup>F10</sup>; and]]

- [<sup>F11</sup>(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(e)(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.

2. In this Part “cyanogenic substances” means preparations which—
- are presented for sale or supply under the name of, or as containing, amygdalin, laetrile or vitamin B17; or
  - contain more than 0.1 per cent by weight of any substance having the formula either—

- (i) alpha-Cyanobenzyl -6-O-Beta-d-glucopyranosyl -Beta-d-glucopyranoside, or
- (ii) alpha-Cyanobenzyl -Beta-d-glucopyranosiduronic acid.

## PART 2

Descriptions of certain medicinal products to be available only from a pharmacy

3. The following medicinal products shall be available only from a pharmacy—
- (a) a product comprising eye ointment;
  - (b) a product that contains Vitamin A, Vitamin A acetate or Vitamin A palmitate, in each case with a maximum daily dose equivalent to more than 7500 international units of Vitamin A or 2250 micrograms of retinol;
  - (c) a product that contains Vitamin D with a maximum daily dose of more than 400 units of antirachitic activity [<sup>F12</sup>, <sup>F13</sup>...]
  - [<sup>F14</sup>(d) 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, it is only to be available from a pharmacy [<sup>F15</sup>; and]]
  - [<sup>F16</sup>(e) 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, it is only to be available from a pharmacy.]

### Textual Amendments

- F12** Word in Sch. 1 para. 3(c) inserted (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), regs. 1(2), **31(3)(a)** and word in Sch. 1 para. 3(c) inserted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), regs. 1(2), **31(3)(a)**
- F13** Word in Sch. 1 para. 3(c) 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(3)(a)** (with reg. 19)
- F14** Sch. 1 para. 3(d) inserted (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.I. 2020/1125\)](#), regs. 1(2), **31(3)(b)** and Sch. 1 para. 3(d) inserted (N.I.) (6.11.2020) by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020 \(S.R. 2020/349\)](#), regs. 1(2), **31(3)(b)**
- F15** Word in Sch. 1 para. 3(d) 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(3)(b)** (with reg. 19)
- F16** Sch. 1 para. 3(e) 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(3)(c)** (with reg. 19)

4. The following medicinal products shall be available only from a pharmacy unless they are the subject of a [<sup>F17</sup>UK marketing authorisation, EU marketing authorisation, Article 126a authorisation, parallel import licence] or traditional herbal registration that classifies them as medicinal products subject to general sale—

- (a) a product that is for use as an anthelmintic;
- (b) a product that is for parenteral administration;
- (c) a product that is for use as an enema;
- (d) a product that is for use wholly or mainly for irrigation of—

**Changes to legislation:** There are currently no known outstanding effects for the The Human Medicines Regulations 2012, SCHEDULE 1. (See end of Document for details)

- (i) wounds, or
- (ii) the bladder, vagina or rectum;
- (e) a product that is for administration wholly or mainly to children being a preparation of aloxiprin or aspirin.

**Textual Amendments**

**F17** Words in Sch. 1 para. 4 substituted (31.12.2020) by [S.I. 2019/775, reg. 8\(b\)](#) (as substituted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1488\), reg. 1, Sch. 2 para. 5](#))

**5.** A medicinal product shall be available only from a pharmacy if it is a medicinal product of a kind specified in Schedule 15 but is not presented for sale in accordance with the requirements specified in that Schedule for a product of that kind to be subject to general sale.

**Changes to legislation:**

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