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 **[**F1as defined in section 2(1)(a) of the Misuse of Drugs Act 1971**]**, unless it is covered by a **[**F2UK**]** 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 **[**F3UK 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 **[**F4UK 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 **[**F6UK 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(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—

(a) are presented for sale or supply under the name of, or as containing, amygdalin, laetrile or vitamin B17; or

(b) 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 **[**F12; F13...**]**

[F14(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 **[**F15; and**]]**

[F16(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 **[**F17UK 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—

(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.