
STATUTORY INSTRUMENTS

1997 No. 1830

The Prescription Only Medicines (Human Use) Order 1997

Exempt medicinal products

5.—(1) [^{F1}A medicinal product that is not the subject of a marketing authorisation is a prescription only medicine for the purposes of the Human Medicines Regulations 2012 if it, or a substance in it, is listed in column 1 of Schedule 1, unless there] –

- (a) is an entry in column 2, 3, 4 or 5 of that Schedule which contains a condition and that condition is satisfied in accordance with the following provisions of this article; or
- (b) there is more than one such condition which applies where that substance is used in that product and each of those conditions is so satisfied.

[^{F2}(1A) In paragraph (1) “marketing authorisation” means—

- (a) in relation to medicinal products for sale or supply in Great Britain, a UKMA(GB) or UKMA(UK);
- (b) in relation to medicinal products for sale or supply in Northern Ireland, a UKMA(NI) or UKMA(UK), an EU marketing authorisation or a parallel import licence.]

(2) Where a maximum strength is specified in column 2 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where the maximum strength of that substance in that medicinal product, or where specified in that column the maximum strength of a medicinal product which contains that substance, does not exceed that specified maximum or, where the medicinal product consists of more than one of the substances sodium fluoride, sodium monofluorophosphate or stannous fluoride combined in a dentifrice, where the maximum strength of that combination of substances in a product does not exceed the equivalent of 0.15 per cent of fluorine.

(3) Where a route of administration is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for administration only by that route.

(4) Where a use is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition in respect of use where it is sold or supplied only for use—

- (a) where a purpose for which it may be used is so specified, for that purpose;
- (b) where the class of persons in whom it may be used is so specified, in persons of that class [^{F3},

provided that, where the entry in column 3 contains a condition to the effect that the product is to be wholly or mainly for use in a specified class of persons, the product satisfies that condition where it is sold or supplied wholly or mainly for use in persons of that class].

(5) Where a pharmaceutical form is specified in column 3 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied in that pharmaceutical form.

(6) Where a maximum dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum dose which does not exceed that specified maximum dose.

(7) Subject to paragraph (8), where a maximum daily dose is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use at a maximum daily dose which does not exceed that specified maximum daily dose.

(8) A medicinal product which contains more than one of the substances–

Atropine
 Atropine Methobromide
 Atropine Methonitrate
 Atropine Oxide Hydrochloride
 Atropine Sulphate
 Hyoscine
 Hyoscine Butylbromide
 Hyoscine Hydrobromide
 Hyoscine Methobromide
 Hyoscine Methonitrate
 Hyoscyamine
 Hyoscyamine Hydrobromide
 Hyoscyamine Sulphate,

satisfies the condition only where it is sold or supplied for use at a maximum daily dose which does not exceed 1 milligram in total of the alkaloids derived from belladonna, hyoscyamus, stramonium or other solanaceous plant which are contained in that medicinal product.

(9) Where a maximum period of use or a maximum frequency of use is specified in column 4 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it is sold or supplied for use for a maximum period or frequency, as the case may be, which does not exceed the maximum period of use or the maximum frequency of use which is so specified.

(10) Where a maximum quantity is specified in column 5 in relation to a substance, a medicinal product which consists of or contains that substance satisfies the condition where it, or where so specified in that column, the medicinal product which contains that substance is sold or supplied in a quantity which does not exceed that specified maximum quantity.

(11) In paragraphs (2) to (7) and (9) and (10) a reference to a numbered column is a reference to the column bearing that number in Schedule 1.

Textual Amendments

- F1** Words in art. 5(1) substituted (14.8.2012) by [The Human Medicines Regulations 2012 \(S.I. 2012/1916\)](#), reg. 1(2), **Sch. 34 para. 71(3)** (with Sch. 32)
- F2** Art. 5(1A) inserted by [The Human Medicines \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/775\)](#), reg. 1, **Sch. 8 para. 4** (as amended by S.I. 2020/1488, reg. 1, Sch. 2 para. 194(a)); 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in art. 5(4) added (16.11.2000) by [The Prescription Only Medicines \(Human Use\) Amendment \(No. 2\) Order 2000 \(S.I. 2000/2899\)](#), arts. 1(1), 2

Changes to legislation:

There are currently no known outstanding effects for the The Prescription Only Medicines (Human Use) Order 1997, Section 5.