Medicines Act 1968

1968 CHAPTER 67

PART III

FURTHER PROVISIONS RELATING TO DEALINGS WITH MEDICINAL PRODUCTS

Additional provisions

[F1 58A [F2Requirement to specify certain products as prescription-only products]

(1) The F3 ... Ministers shall, subject to subsection (4) of this section, so exercise their powers under section 58(1) of this Act as to secure that every product—

F4(a) . . . . . .

F4(b) . . . . . .

(c) to which subsection (2) of this section applies;

[F5is specified as a prescription only medicine**]**.

(2) This subsection applies to any product which—

(a) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist; or

(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health; or

(c) contains substances or preparations of substances of which the activity requires, or the side-effects require, further investigation; or

(d) is normally prescribed by a doctor or dentist for parenteral administration.

(3) In considering whether subsection (2) of this section applies to a product the F6 ... Ministers shall take into account whether the product—

(a) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention); or

(b) contains a substance which is listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the pro duct is not a preparation

which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention); or

(c) is likely, if incorrectly used—

(i) to present a substantial risk of medicinal abuse, or

(ii) to lead to addiction, or

(iii) to be used for illegal purposes; or

(d) contains a substance which, by reason of its novelty or properties, might fall within paragraph (c) above, but as to which there is insufficient information available to determine whether it does so fall; or

(e) by reason of its pharmaceutical characteristics or novelty, or in the interests of public health, is reserved for treatments which can only be followed in a hospital; or

(f) is used in the treatment of conditions which must be diagnosed in a hospital or in an institution with special diagnostic facilities (although administration and subsequent supervision may be carried out elsewhere); or

(g) is intended for outpatients but may produce very serious sideeffects which would require a prescription drawn up as required by a specialist and special supervision throughout the treatment.

(4) Subsection (1) of this section shall not apply in relation to any product if the [F7] ... Ministers so determine having regard to—

(a) the maximum single dose;

(b) the maximum daily dose;

(c) the strength of the product;

(d) its pharmaceutical form;

(e) its packaging; or

(f) such other circumstances relating to its use as may be specified in the determination.

(5) In this section [F8] ...—

"the Narcotic Drugs Convention" means the Single Convention on Narcotic Drugs signed by the United Kingdom on 30th March 1961 as amended by the Protocol Amending the Single Convention on Narcotic Drugs signed by the United Kingdom on 25th March 1972 [X1] ; and

"the Psychotropic Substances Convention" means the Convention on Psychotropic Substances signed by the United Kingdom on 21st February 1971 [X2] . **]**

Editorial Information

X1 The Convention, as amended by the Protocol, is published as Cmnd. 7466.

X2 Cmnd. 7330.

Textual Amendments

F1 S. 58A inserted (1.1.1993) by S.I. 1992/3271 , **regs. 1(1)** , 2

F2 Words in s. 58A heading substituted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30**

F3 Word in s. 58A(1) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30(a)** (with regs. 2(4), 3)

F4 S. 58A(1)(a)(b) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 6(a)** (with Sch. 32)

F5 Words in s. 58A(1) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 6(b)** (with Sch. 32)

F6 Word in s. 58A(3) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30(b)** (with regs. 2(4), 3)

F7 Word in s. 58A(4) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30(c)** (with regs. 2(4), 3)

F8 Words in s. 58A(5) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 30(d)** (with regs. 2(4), 3)

Modifications etc. (not altering text)

C1 Ss. 58 58A amendment to earlier affecting provision SI 1994/3144 reg. 9 (30.10.2005) by Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759) , regs. 1(a) , **2(12)**

C2 S. 58A extended (with modifications) (14.2.1994) by S.I. 1994/105 , reg. 19 , **Sch. 4**

C3 S. 58A modified (1.1.1995) by S.I. 1994/3144 , **reg. 9(4)(10)**
S. 58A applied (1.1.1995) by 1994/3142, reg. 18

Status:
Point in time view as at 14/08/2012.

Changes to legislation:
Medicines Act 1968, Section 58A is up to date with all changes known to be in force on or before 10 June 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.