STATUTORY INSTRUMENTS

1992 No. 3271

MEDICINES

The Medicines Act 1968 (Amendment) (No. 2) Regulations 1992

Made - - - -	*22nd December 1992*
Laid before Parliament	*23rd December 1992*
Coming into force - -	*1st January 1993*

The Secretary of State and the Minister of Agriculture, Fisheries and Food, acting jointly in exercise of the powers conferred on them by section 2(2) of the European Communities Act 1972(**1**), being designated for the purposes of that section in relation to medicinal products(**2**), hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines Act 1968 (Amendment)(No. 2) Regulations 1992 and shall come into force on 1st January 1993.

(2) In these regulations "the Act" means the Medicines Act 1968(**3**).

Medicinal products on prescription only

2. After section 58 of the Act (medicinal products on prescription only) there is inserted—

"**Requirement to specify certain products for human use as prescription-only products.**

58A.—(1) The appropriate 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—

(a) in respect of which a product licence is granted;

(b) to which Chapters II to V of the 1965 Directive apply; and

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

falls within one of the descriptions or classes specified for the purposes of section 58.

(**1**) 1972 c. 68.
(**2**) S.I. 1972/1811.
(**3**) 1968 c. 67.

(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 appropriate 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 appropriate 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 and section 58B of this Act—

"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 Conven tion on Narcotic Drugs signed by the United Kingdom on 25th March 1972(**4**); and

"the Psychotropic Substances Convention" means the Conven tion on Psychotropic Substances signed by the United Kingdom on 21st February 1971(**5**).

Requirement to specify certain products for veterinary use as prescription-only products.

58B.—(1) The appropriate Ministers shall so exercise their powers under section 58(1) of this Act as to secure that every product—

(a) in respect of which a product licence is granted;

(b) to which the 1981 Directive applies; and

(c) to which subsection (2) or (3) of this section applies;

falls within one of the descriptions or classes specified for the purposes of section 58.

(2) This subsection applies to any product which—

(a) is subject to restrictions on supply or use resulting from the Narcotic Drugs Convention, the Psychotropic Substances Convention or any Community obligation (other than an obligation under the 1981 Directive); or

(b) is likely to cause unnecessary risk to the target species, humans or the environment unless special precautions are taken by a veterinary surgeon or veterinary practitioner; or

(c) is intended for a treatment or condition which requires a precise prior diagnosis; or

(d) may cause effects which impede or interfere with subsequent diagnosis or treatment.

(3) This subsection applies to any new product containing an active ingredient where a product licence for veterinary use was granted in respect of the ingredient less than five years prior to the relevant date in relation to the product unless, having regard to—

(a) the information and particulars provided by the applicant for the licence; or

(b) experience acquired in the use of the product;

the appropriate Ministers are satisfied that subsection (2) of this section does not apply to the product.

(4) For the purposes of subsection (3) of this section the relevant date in relation to a product is the date on which it falls to be determined by the appropriate Ministers whether subsection (3) applies to the product.

(5) Section 58A(5) of this Act applies for the purposes of this section.".

Interpretation of the Act

3. In section 132(1) of the Act (interpretation)(**6**) after the definition of "dentist" there is inserted—

""the 1965 Directive" means Council Directive 65/65/EEC(**7**) of 26th January 1965 on the aproximation of provisions laid down by law, regulation or administrative action relating

(**4**) The Convention, as amended by the Protocol, is published as Cmnd. 7466.
(**5**) Cmnd. 7330.
(**6**) There are amendments to section 132 which are not relevant.
(**7**) OJ No. 22, 9.2.65, p. 369/65 (OJ/SE 1965—66, p. 20).

to medicinal products (as amended by Council Directive 89/341/EEC(**8**) and as it applies in accordance with Council Directives 75/319/EEC(**9**), 89/342/EEC(**10**), 89/343/EEC(**11**) and 89/381/EEC(**12**));

"the 1981 Directive" means Council Directive 81/851/EEC(**13**) of 28th September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (as amended by Council Directive 90/676/EEC(**14**));".

Virginia Bottomley
22nd December 1992 — Secretary of State for Health

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 22nd December 1992.

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

(**8**) OJ No. L142, 25.5.89, p. 11.
(**9**) OJ No. L147, 9.6.75, p. 13.
(**10**) OJ No. L142, 25.5.89, p. 14.
(**11**) OJ No. L142, 25.5.89, p. 16.
(**12**) OJ No. L181, 28.6.89, p. 44.
(**13**) OJ No. L317, 6.11.81, p. 1.
(**14**) OJ No. L373, 31.12.90, p. 15.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines Act 1968 ("the Act") for the purpose of implementing Council Directive 92/26/EEC (OJ No. L113, 30.4.92, p. 5) ("the classification of human medicines directive") and Council Directive 90/676/EEC (OJ No. L373, 31.12.90, p. 15) which amends Council Directive 81/851/EEC (OJ No. L317, 6.11.81, p. 1) "the veterinary medicines directive").

The classification of human medicines directive lays down the criteria to be applied by member States in specifying which medicinal products for human use are to be supplied only upon medical prescription. These Regulations insert a new section 58A of the Medicines Act 1968 ("the 1968 Act") which specifies the relevant criteria according to which powers under section 58 of that Act must be exercised.

Similarly, these Regulations insert a new section 58B of the 1968 Act implementing the requirement of the veterinary medicines directive that certain veterinary medicinal products shall be supplied on prescription only (article 1.4 Directive 90/676/EEC which introduces a new article 4.3 into the veterinary medicines directive).

There are associated amendments to section 132 (interpretation) of the 1968 Act (regulation 3).