STATUTORY INSTRUMENTS

1983 No. 1724

MEDICINES

The Medicines (Medicines Act 1968 Amendment) Regulations 1983

Made - - - -	21*st November* 1983
Laid before Parliament	30*th November* 1983
Coming into Operation	21*st December* 1983

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

Title, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Medicines Act 1968 Amendment) Regulations 1983 and shall come into operation on 21st December 1983.

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

Amendment of section 7 of the Act

2.—(1) Section 7 of the Act (general provisions as to dealing with medicinal products)**(d)** shall be amended as follows.

(2) For subsection (5)(*b*) there shall be substituted—

"(*b*) if that product is a proprietary medicinal product or a ready-made veterinary drug, is responsible for the placing of the product on the market in the United Kingdom."

(3) For subsection (7) there shall be substituted—

"(7) In subsection (5) of this section—

(*a*) "proprietary medicinal product" means a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack; and for the purposes of this definition "medicinal product" does not include—

(i) vaccines, toxins or serums,

(ii) medicinal products based on human blood or blood constituents or radioactive isotopes,

(a) S.I. 1972/1811. **(b)** 1972 c. 68. **(c)** 1968 c. 67.
(d) Section 7 was amended by S.I. 1977/1050 and S.R. (N.I.) 1977 No. 170.

(iii) homoeopathic medicinal products, or

(iv) additives for animal feeding stuffs to which the provisions of Council Directive 70/524/EEC apply; OJ No. L270. 14.12.70, p. 1.

(*b*) "ready-made veterinary drug" means a ready-prepared veterinary drug placed on the market in the United Kingdom in a pharmaceutical form in which it may be used without further processing, not being a drug placed on the market under a special name and in a special pack; and for the purposes of this definition "veterinary drug" does not include—

(i) vaccines, toxins or serums,

(ii) veterinary drugs based on radioactive isotopes,

(iii) veterinary drugs specially prepared for administration by a veterinary surgeon or veterinary practitioner to a particular animal or herd which is under his care,

(iv) homoeopathic veterinary drugs, or

(v) additives for animal feeding stuffs to which the provisions of Council Directive 70/524/EEC apply." OJ No. L270. 14.12.70, p. 1.

Amendment of section 8 of the Act

3.—(1) Section 8 of the Act (provisions as to manufacture and wholesale dealing)**(a)** shall be amended as follows.

(2) In subsection (3)(*b*), after the words "proprietary medicinal product" there shall be inserted the words "or ready-made veterinary drug."

(3) For subsection (4) there shall be substituted—

"(4) Subsection (7) of section 7 of this Act shall apply for the purposes of subsection (3) of this section as it applies for the purposes of subsection (5) of that section."

Amendment of section 18 of the Act

4. For subsection (3) of section 18 of the Act (applications for licences)**(b)** there shall be substituted—

(a) Section 8 was amended by S.I. 1977/1050 and S.R. (N.I.) 1977 No. 170.

(b) Section 18 was amended by S.I. 1977/1050 and S.R. (N.I.) 1977 No. 170.

"(3) Where documents that constitute a dossier for the purposes of Article 9 of the Second Council Directive 75/319/EEC of 20 May 1975 are forwarded to the licensing authority under and in accordance with the said Article, or documents are forwarded to that authority under and in accordance with Article 17 of Council Directive 81/851/EEC of 28 September 1981, such forwarding shall be deemed to be an application for the grant of a product licence under this Part of this Act."

OJ No. L1 9.6.1975, p. 13.

OJ No. L3 6.11.81, p. 1.

Norman Fowler,
Secretary of State for Social Services.

21st November 1983.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 26th October 1983.

L.S.

Michael Jopling,
Minister of Agriculture,
Fisheries and Food.

EXPLANATORY NOTE

(*This Note is not part of the Regulations.*)

These Regulations amend the Medicines Act 1968 ("the Act") thereby implementing in part Council Directive 81/851/EEC (OJ No. L317, 6.11.81, p. 1) on the approximation of the laws of the Member States relating to veterinary medicinal products.

The Regulations—

(1) amend sections 7 and 8 of the Act so as to require persons responsible for placing on the market in the United Kingdom veterinary drugs which are proprietary medicinal products or ready-made veterinary drugs to hold licences and also to require distributors of such drugs imported from outside the European Communities to hold licences (Regulations 2 and 3); and

(2) amend section 18 of the Act so as to provide that documents forwarded to the licensing authority under Article 17 of Council Directive 81/851/EEC shall be treated as an application for the grant of a product licence under the Act (Regulation 4).

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