STATUTORY INSTRUMENTS

1994 No. 2852

MEDICINES

The Medicines (Standard Provisions for Manufacturer's Licences for Veterinary Medicinal Products) Regulations 1994

Made - - - -	*26th October 1994*
Laid before Parliament	*8th November 1994*
Coming into force - -	*1st December 1994*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland, and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of the powers conferred by sections 47(1) and 129(5) of the Medicines Act 1968(**1**) and now vested in them(**2**), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations in accordance with section 129(6) of the said Act, hereby make the following Regulations:

Title and commencement

1. These Regulations may be cited as the Medicines (Standard Provisions for Manufacturer's Licences for Veterinary Medicinal Products) Regulations 1994 and shall come into force on 1st December 1994.

Interpretation

2.—(1) In these Regulations—

"Directive 81/851/EEC" means Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**3**) as amended by Council Directive 90/676/EEC(**4**) and Council Directive 93/40/ EEC(**5**);

(**1**) 1968 c. 67. "The Ministers" is defined in section 1(1) (see also the following footnote).
(**2**) In the case of the Secretaries of State concerned with health in England and Wales by virtue of S.I. 1969/388, in the case of the Secretary of State concerned with agriculture in Wales by virtue of S.I. 1978/272 and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).
(**3**) OJ No. L317, 6.11.81, p.1.
(**4**) OJ No. L373, 31.12.90, p.15.
(**5**) OJ No. L214, 24.8.93, p.31.

"Directive 91/412/EEC" means Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**6**); and

"veterinary medicinal product" has the meaning given by Article 1.2 of Directive 81/ 851/EEC, and shall mean a veterinary medicinal product to which Article 2.1 of that Directive applies.

(2) For the purposes of these Regulations the term "competent authority" used in Directives 81/851/EEC and 91/412/EEC means the licensing authority under section 6 of the Medicines Act 1968.

(3) Unless the context otherwise requires, expressions used both in these Regulations and in Directive 81/851/EEC or 91/412/EEC shall be interpreted in accordance with the Directive in which they are used.

(4) References in regulations 4 to 7 below to a numbered Article are references to that Article in Directive 81/851/EEC.

Standard provisions for manufacturer's licences for veterinary medicinal products

3. The standard provisions for manufacturer's licences for veterinary medicinal products for the purposes of Part II of the Medicines Act 1968 shall be the provisions set out in regulations 4 to 8 below.

Standard provisions: Directive 81/851/EEC

4. The licence holder shall comply with the provisions of paragraphs (a) to (g) of Article 27, and in the case of paragraph (c), the words "the particulars supplied pursuant to Article 25" shall mean the particulars corresponding to those set out in that Article submitted to the licensing authority as part of the holder's application for the relevant licence pursuant to the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971(**7**).

5.—(1) The licence holder shall have permanently and continuously at his disposal the services of at least one Qualified Person, who satisfies the requirements as to qualifications and experience set out in Article 31, or who is permitted to act as a Qualified Person by virtue of the provisions of Article 32.

(2) The licence holder may himself undertake the duties of the Qualified Person if he satisfies the provisions of Article 31 or 32 as the case may be.

(3) The Qualified Person shall be responsible in particular for carrying out the duties specified in Article 30.1(a) and (b) and 30.2.

(4) Where, after the licence holder and the person acting as a Qualified Person have been given the opportunity to make written or oral representations, the licensing authority have served written notice on the licence holder stating that the person so acting does not satisfy the provisions of Article 31 or 32, or that that person has failed to carry out the duties required by paragraph (3) above, which notice has not been withdrawn, the licence holder shall not permit that person to act as a Qualified Person.

6. The licence holder shall give to the licensing authority on request details of the control tests carried out on the finished product and on the constituents and intermediate products of the manufacturing process, which have been carried out in accordance with the methods approved for the purposes of the relevant product licence granted in respect of the product.

7. Where the licensing authority have given the licence holder written notice that one or more of the grounds set out in Article 37.1(a) to (e) applies in respect of a product, or any batch thereof, to

(**6**) OJ No. L228, 17.8.91, p.70.
(**7**) S.I. 1971/974, relevant amending instruments are S.I. 1977/1052 and 1983/1725.

which his licence relates, the licence holder shall comply with any direction in the notice to withhold that product or batch from sale or supply and to withdraw the product or batch from the market.

Standard provisions: Directive 91/412/EEC

8.—(1) Subject to paragraph (2) below, the licence holder shall comply with the principles and guidelines of good manufacturing practice as set out in Articles 4 to 14 of Directive 91/412/EEC, and such principles and guidelines shall be interpreted in accordance with Article 3, second paragraph, of that Directive.

(2) In order to comply with the provisions of Article 12 of that Directive (Work contracted out), the licence holder shall ensure that the terms of the contract require that the contractor complies with the requirements of Article 12.3 and 12.4.

Disapplication

9. The standard provisions for manufacturer's licences prescribed by regulation 3(4) of and Schedule 2 to the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**8**) shall be superseded by these Regulations in so far as those provisions apply to manufacturer's licences for veterinary medicinal products.

Tom Sackville
Parliamentary Under Secretary of State,
21st October 1994 Department of Health

Hector Monro
Parliamentary Under Secretary of State, Scottish
19th October 1994 Office

Signed by authority of the Secretary of State for Wales,

Gwilym Jones
Parliamentary Under Secretary of State, Welsh
21st October 1994 Office

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 26th October 1994.

L.S.

William Waldegrave
Minister of Agriculture, Fisheries and Food

(**8**) S.I. 1971/972, relevant amending instruments are S.I. 1972/1226, 1983/1730, 1992/2846.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 18th day of October 1994.

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 17th day of October 1994.

L.S.

J. Murray
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Articles 27, 29 to 33, 35 and 37 of Council Directive 81/ 851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (OJNo. L317, 6.11.81, p.1), amended by Council Directive 90/676/ EEC (OJ No. L373, 31.12.90, p.15) and Council Directive 93/40/EEC (OJ No. L214, 24.8.93, p.31), and implement Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ No. L228, 17.8.91, p.70).

They prescribe by standard provisions for manufacturer's licences for veterinary medicinal products the requirements of Council Directive 81/851/EEC including the requirements in connection with the Qualified Person (regulations 4 to 7), and the provisions as to good manufacturing practice set out in Commission Directive 91/412/ EEC (regulation 8).

The standard provisions for manufacturer's licences prescribed by the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 (S.I.1971/972), as amended, are superseded by these Regulations in so far as those provisions apply to manufacturer's licences for veterinary medicinal products (regulation 9).

A Compliance Cost Assessment has been prepared and a copy has been placed in the library of each House of Parliament.