STATUTORY INSTRUMENTS

1994 No. 3142

The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994

Title, commencement and interpretation

1.—(1) These Regulations, which implement parts of:

Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**1**);

Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products(**2**);

Council Directive 90/676/EEC amending Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**3**);

Council Directive 90/677/EEC extending the scope of Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products(**4**);

Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**5**);

Commission Directive 92/18/EEC modifying the Annex to Council Directive 81/852/EEC(**6**);

Council Directive 92/74/EEC widening the scope of Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homeopathic veterinary medicinal products(**7**);

Council Regulation 2309/93/EEC laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products(**8**); and

Council Directive 93/40/EEC amending Directives 81/851/EEC and 81/852/ EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**9**);

may be cited as the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 and shall come into force on 1st January 1995.

(2) These Regulations shall apply in respect of products to which Council Directive 81/851/EEC applies by virtue of article 2 of that directive, including products intended for the uses set out in

(**1**) OJNo. L317, 6.11.81, p.1.
(**2**) OJ No. L317, 6.11.81, p.16 as amended by Council Directive 87/20/EEC (OJ No. L15, 17.1.87, p.34) and Commission Directive 92/18/EEC (OJ No. L97, 10.4.92, p.1).
(**3**) OJ No. L373, 31.12.90, p.15.
(**4**) OJ No. L373, 31.12.90, p.26.
(**5**) OJ No. L228, 17.8.91, p.70.
(**6**) OJ No. L97, 10.4.92, p.1.
(**7**) OJ No. L297, 13.10.92, p.12.
(**8**) OJ No. L214, 24.8.93, p.1.
(**9**) OJ No. L214, 24.8.93, p.31.

article 3 of that directive, but do not apply to products specified in article 1.3 or 1.4 of Council Directive 90/677/EEC.

(3) These Regulations shall apply to homeopathic veterinary medicinal products other than those specified in article 7 of Council Directive 92/74/EEC.

(4) In these Regulations, unless the context otherwise requires, any expressions used have the meaning they bear in Council Directives 81/851/EEC and 90/677/EEC and Council Regulation 2309/93/EEC;

"the appropriate committee" has the meaning assigned by section 4(6) of the Medicines Act 1968(**10**);

"the commission" means the Medicines Commission established by the Medicines Act 1968;

"marketing authorisation" means an authorisation to place on the market a veterinary medicinal product to which these Regulations apply;

"the Ministers" means the Minister of Agriculture, Fisheries and Food, the Secretary of State concerned with health in England and the Secretaries of State for Wales and Scotland, the Department of Agriculture for Northern Ireland and the Department of Health and Social Services for Northern Ireland.

(5) Any function conferred on the Ministers under these Regulations may be performed by any one of those Ministers acting alone or by any two or more of them acting jointly.

(6) Any reference in these Regulations to a directive is to that directive as amended.

(**10**) 1968 c. 67.