2002 No. 269

MEDICINES

The Marketing Authorisations for Veterinary Medicinal Products (Amendment) Regulations 2002

Made - - - - -	*10th February 2002*
Laid before Parliament	*12th February 2002*
Coming into force - -	*10th March 2002*

The Secretary of State for Environment, Food and Rural Affairs, being designated(**a**) for the purposes of section 2(2) of the European Communities Act 1972(**b**), in relation to the Common Agricultural Policy of the European Community, in exercise of the powers conferred on her by that section, and of all other powers enabling her in that behalf, makes the following Regulations:

Title and commencement

1. These Regulations may be cited as the Marketing Authorisations for Veterinary Medicinal Products Regulations (Amendment) Regulations 2002 and come into force on 10th March 2002.

Amendment to the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994

2. The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994(**c**) are amended in accordance with these Regulations.

3. In regulation 1(1), for the list of Community instruments there is substituted—

"Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products(**d**)."

4. For paragraphs (2), (3) and (4) of regulation 1 there is substituted—

"(2) These Regulations shall apply in respect of products to which Directive 2001/82/EC applies by virtue of Article 2 and 3 of that Directive, they do not apply to products specified in Article 4.1 but they do apply to products intended for the uses set out in Article 4.2 of that Directive.

(3) These Regulations shall apply to homeopathic veterinary medicinal products other than those specified in Article 17.1 of Directive 2001/82/EC.

(4) In these Regulations, unless the context otherwise requires, any expressions used have the meaning they bear in Directive 2001/82/EC."

5. Regulation 1(6) is revoked.

(**a**) S.I. 1972/1811.
(**b**) 1972 c. 68.
(**c**) S.I. 1994/3142 as amended by S.I. 1997/654, S.I. 1998/1048, S.I. 1999/3142 and S.I. 2000/776.
(**d**) O.J. No. L311, 28.11.2001, p. 1.

6. For regulation 2(1) there is substituted—

"(1) These Regulations shall not apply to the placing on the market of veterinary medicinal products prepared extemporaneously in the circumstances described in Article 10(1)(c) of Directive 2001/82/EC.".

7. For regulation 3(1) there is substituted—

"(1) No person shall place on the market, or import for the purposes of placing on the market or have in his possession for those purposes, any veterinary medicinal product unless a marketing authorisation (or, in the circumstances described in Article 8 of Directive 2001/82/EC, an allowance within the terms of that Article) has been granted—

(a) by the Ministers; or

(b) in accordance with Council Regulation (EEC) No. 2309/93,

and it is placed on the market in accordance with such authorisation or allowance.".

8. For regulation 4 there is substituted—

"Form and manner of application

4.—(1) Every application for a marketing authorisation to the Ministers shall be made to them in accordance with this regulation.

(2) The application shall be in writing, in the English language and signed by the applicant.

(3) The applicant shall supply four copies of each application, and shall supply a further twenty two copies if the Ministers so direct.

(4) The application shall be—

(a) as specified in Articles 12, 13, 14 and 15 of Directive 2001/82/EC (or, in the case of an application for the authorisation of a product already authorised in another member State, in accordance with Article 32 of that Directive) and in accordance with the Introduction to Annex I to that Directive; or

(b) in the circumstances described in Article 26(3) of Directive 2001/82/EC, shall be accompanied by all relevant data available to the applicant.

(5) If the application is in respect of a product which is not an immunological product, the application shall in addition be in accordance with the requirements of Schedule 1 to these Regulations.

(6) If the application is in respect of an immunological product, the application shall in addition be in accordance with the requirements of Schedule 2 to these Regulations.

(7) In the case of a product that the applicant intends to import from outside the European Economic Area, the application shall in addition be in accordance with Article 45 of Directive 2001/82/EC.

(8) An applicant shall not be required, by virtue of Article 12(3)(j) of Directive 2001/82/EC, to provide the results of toxicological and pharmacological tests and clinical trials if he can demonstrate that he is entitled to the benefit of any of sub-paragraphs (a)(i) to (a)(iii) of Article 13.1(a) of that Directive.

(9) The preceding paragraph shall only apply where the applicant claims the benefit of Article 13.1(a)(iii) if the product authorised within the European Community to which the application refers has been so authorised for a period of not less than ten years before the making of the application."

9. For regulation 5 there is substituted—

"Grant of an authorisation

5. The Ministers shall consider an application for, and where appropriate grant, a marketing authorisation for a veterinary medicinal product—

(a) in accordance with Articles 6, 21, 22, 23, 24, 25, 26, 28, 30, 58(1) to (3), 71, the second paragraph of 83.1(e), 91 and 94, of, and Title I, Part 4, Chapter II, point 1, sixth paragraph of Annex I to, Directive 2001/82/EC;

(b) in the case of a product already authorised in another member State, in accordance with Articles 6, 7, 21, 22, 71 and 94 and Chapter 4 of Directive 2001/82/EC.".

10. For regulation 6(1) there is substituted—

"6.—(1) After a marketing authorisation has been issued, the holder of that authorisation shall comply with—

(a) Articles 12.3.m, second paragraph, 26, 27, 28, 58 to 61, 74, 75, 81.1, 81.2, second paragraph and 91.2, of Directive 2001/82/EC, the third paragraph of the introduction of Annex I to that Directive, and, if appropriate, the final paragraph of Title I, Part 4, Chapter II.1 and the final paragraph of Title I, Part 4, Chapter III.2.1 of that Directive;

(b) any directions given by the Ministers in accordance with Article 84 of Directive 2001/82/EC;

(c) the requirement in Article 81 of Directive 2001/82/EC to provide the information specified there;

(d) paragraph C.a of Title I, Part 2 (for veterinary medicinal products other than immunological veterinary medicinal products) or paragraph C.a of Title II, Part 6 (for immunological medicinal products) of Annex I to Directive 2001/82/EC.".

11. For regulations 7 and 8 there is substituted—

"Products manufactured outside the European Economic Area

7.—(1) Where a product to which a marketing authorisation relates is imported from outside the European Economic Area, the holder of that marketing authorisation shall comply with Article 50(c) of Directive 2001/82/EC and shall obtain an undertaking from the manufacturer that the manufacturer will comply with the provisions of this regulation.

(2) The manufacturer shall comply with any conditions attached to the authorisation.

(3) The manufacturer shall comply with the provisions of paragraphs (a), (b), (d) and (e) of Article 50 of Directive 2001/82/EC.

(4) In accordance with Article 81(1) of Directive 2001/82/EC, the manufacturer shall give to the Ministers on request the data specified in that Article.

(5) Subject to the following paragraph, the manufacturer shall comply with the principles and guidelines of good manufacturing practice as set out in Articles 4 to 14 of Commission Directive 91/412/EEC(**a**), and such principles and guidelines shall be interpreted in accordance with Article 3, second paragraph of that Directive.

(6) In order to comply with the provisions of Article 12 of Commission Directive 91/412/EEC, the manufacturer shall ensure that the terms of the contract require that the contractor complies with the requirements of Article 12.3 and 12.4 of that Directive.

Duties on an importer who holds a marketing authorisation

8.—(1) Where the holder of a marketing authorisation imports the products to which the authorisation relates from outside the European Economic Area he shall comply with the provisions of this regulation.

(2) He shall have permanently and continuously at his disposal the services of at least one Qualified Person who satisfies the requirements on qualifications set out in Article 53 of Directive 2001/82/EC, or who is permitted to act as a Qualified Person by virtue of the provisions of Article 54 of that Directive.

(3) He may himself undertake the duties of a Qualified Person if he satisfies the provisions of Article 53 or 54 of that Directive.

(4) The Qualified Person shall carry out the duties in Article 55 of that Directive.

(5) Where, after the holder of a marketing authorisation and the person acting as Qualified Person have been given the opportunity to make written or oral representations, the Ministers have served written notice on the holder of the marketing authorisation stating that the person acting as the Qualified Person does

(**a**) O.J. No. L228, 17.8.1991, p. 70.

not satisfy the requirements of Article 53 or 54 of that Directive, or that the person has failed to carry out the duties required by this regulation, the holder of the marketing authorisation shall not permit that person to act as a Qualified Person for him unless that notice is withdrawn.".

12. For paragraphs (2) and (3) of regulation 10 there is substituted—

"(2) The application shall be in accordance with Articles 26(3) and 28 of Directive 2001/82/EC, and shall be submitted not earlier than five months before the expiry of the existing authorisation.

(3) The application shall include any information required under Articles 12, 13, 14 and 15 of Directive 2001/82/EC, and the relevant parts of Annex I to that Directive, not previously submitted to the Ministers.".

13. For regulation 11 there is substituted—

"Suspension and revocation

11. The Ministers may suspend or revoke a marketing authorisation in accordance with Articles 62, 78, 83, 84, 85 and 94 of Directive 2001/82/EC".

14. For regulation 12(1) there is substituted—

"(1) If, in the circumstances where there will be no right of appeal under Article 36.4 of Directive 2001/82/EC, the Ministers propose—

(a) acting in accordance with regulation 5(a) above to refuse to grant a marketing authorisation on any grounds relating to safety, qualify or efficacy, or

(b) acting in accordance with regulation 11 above to suspend or revoke an authorisation on those grounds,

they shall consult the appropriate committee or, if there is no such committee, with the Commission in accordance with Schedule 3, and shall take account of their advice in coming to a decision.".

15. For regulation 13(1) there is substituted—

"(1) If, in the circumstances where there will be no right of appeal under Article 36.4 of Directive 2001/82/EC, the Ministers propose—

(a) acting in accordance with regulation 5(a) above to refuse to grant a marketing authorisation on any grounds not relating to safety, quality or efficacy; or

(b) acting in accordance with regulation 11 above to suspend or revoke an authorisation on grounds not relating to safety, quality or efficacy,

then before doing so they shall serve a notice on the applicant or authorisation holder stating their proposals and the reasons for them and specifying a time within which he may apply to a person appointed by the Ministers under this regulation; but this paragraph shall not apply if the Ministers are acting in accordance with Article 30(e), first or second paragraphs, or Article 83(e), first or second paragraphs.".

16. Regulation 15 is revoked.

17. Schedules 1 and 2 are replaced with the Schedule to these Regulations.

Whitty
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

10th February 2002

SCHEDULE

Regulation 17

Replacement Schedules

SCHEDULE 1

Regulation 4(5)

Requirements in respect of products other than immunological products

1. The applicant shall comply with all the requirements set out in Parts 1 and 4 of Title I of Annex I to Directive 2001/82/EC.

2 (1) Subject to sub-paragraphs (2) and (3) below, the applicant shall comply with the requirements set out in Part 2 of Title I of Annex I to Directive 2001/82/EC.

(2) Where at the request of the applicant a manufacturer of an active ingredient of the product submits details concerning the method of manufacture, quality control during manufacture and process validation directly to the Ministers, the applicant shall obtain from the manufacturer, and submit to the Ministers—

(a) all the data necessary for him to take responsibility for the product,

(b) written confirmation that the manufacturer will ensure batch consistency and inform the applicant before he modifies the manufacturing process; and

(c) written confirmation that the manufacturer will supply to the Ministers all documents and particulars which may be required by them relating to any such modification.

(3) Where the applicant refers to a specification in a monograph in a pharmacopoeia but the Ministers consider that such specification is insufficient to ensure the quality of the product, the applicant shall submit to the Ministers on request a more appropriate specification.

3. The applicant shall comply with the requirements set out in Part 3 of Title I of Annex I to Directive 2001/82/EC, and shall supply a copy of any certificate issued by a laboratory which carries out such test certifying that the test was carried out in conformity with the principles of good laboratory practice.

SCHEDULE 2

Regulation 4(6)

Requirements in respect of immunological products

1. The applicant shall comply with the requirements set out in Parts 5, 7, 8 and 9 of Title II of Annex I to Directive 2001/82/EC and shall supply a copy of any certificate issued by a laboratory which carries out a safety test certifying that the test was carried out in conformity with the principles of good laboratory practice.

2(1) Subject to sub-paragraphs (2) and (3) below, the applicant shall comply with the requirements set out in Part 6 of Title II of Annex I to Directive 2001/82/EC.

(2) Where at the request of the applicant a manufacturer of an active ingredient of the product submits details concerning the method of manufacture, quality control during manufacture and process validation directly to the Ministers, the applicant shall obtain from the manufacturer, and submit to the Ministers—

(a) all the data necessary for him to take responsibility for the product,

(b) written confirmation that the manufacturer will ensure batch consistency and inform the applicant before he modifies the manufacturing process or specifications; and

(c) written confirmation that the manufacturer will supply to the Ministers all documents and particulars which may be required by them relating to any such modification.

(3) Where the applicant refers to a specification in a monograph in a pharmacopoeia but the Ministers consider that such specification is insufficient to ensure the quality of the product, the applicant shall submit to the Ministers on request a more appropriate specification.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, S.I. 1994/3142. They implement parts of Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products (O.J. No. L311, 28.11.2001, p. 1). The Directive consolidates—

— Council Directive 81/851/EEC (O.J. No. L317, 6.11.1981, p.1) as last amended by Commission Directive 2000/37/EC (O.J. No. L139, 10.6.2000, p. 25).

— Council Directive 81/852/EEC (O.J. No. L317, 6.11.1981, p. 16) as last amended by Commission Directive 1999/104/EC (O.J. No. L3, 6.1.2000, p. 18).

— Council Directive 90/677/EEC (O.J. No. L373, 31.12.1990, p. 26).

— Council Directive 92/74 EEC (O.J. No. L287, 13.10.1992, p. 12).

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