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STATUTORY INSTRUMENTS

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**1994 No. 3142**

**The Marketing Authorisations for Veterinary  
Medicinal Products Regulations 1994**

**Refusal, etc., of a marketing authorisation on grounds relating to safety, quality or efficacy**

12.—(1) If, in the circumstances where there will be no right of appeal under article 21.4 of Council Directive 81/851/EEC, 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, quality 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 for the time being 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; but this paragraph shall not apply if the Ministers are acting in accordance with article 11.3 or 36.3 of Council Directive 81/851/EEC.

(2) Such consultation shall take place before Ministers act except that when, in relation to paragraph (1)(b) above, Ministers consider urgent action necessary to protect human or animal health or the environment, it shall take place within three months of their acting.

(3) If the Ministers propose to determine the issue in a way which differs from the advice of the commission (or, where there has been no hearing before and no representations have been made or referred to the commission, the appropriate committee) they shall notify the applicant or authorisation holder accordingly, and, before determining the issue, shall afford him an opportunity of appearing before, and being heard by, a person appointed for the purpose by the Ministers, or of making representations in writing to the Ministers with respect to that proposal.

(4) Any notification given to the applicant or authorisation holder under the preceding paragraph shall state the advice of the commission or of the appropriate committee and the reasons stated by the commission or the committee for giving that advice, the proposals of the Ministers and the reasons for them.

(5) Where the applicant or authorisation holder avails himself of the opportunity of appearing before, and being heard by, a person appointed for the purpose—

- (a) the person so appointed shall not, except with the consent of the applicant or authorisation holder, be an officer or servant of any of the Ministers;
- (b) if the applicant or authorisation holder so requests, the hearing shall be in public; and
- (c) if the applicant or authorisation holder so requests, the Ministers shall furnish to him a copy of the report of the person so appointed.