STATUTORY INSTRUMENTS

1994 No. 3144

The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994

Revocation, suspension or variation of a United Kingdom marketing authorization or the suspension of the use or marketing of medicinal products.

6.—(1) The licensing authority may and, where appropriate shall, subject to and in accordance with the relevant Community provisions, revoke, suspend or vary a marketing authorization for a relevant medicinal product.

(2) The licensing authority may and, where appropriate, shall, subject to paragraph (3) and subject to and in accordance with the relevant Community provisions, by notice in writing to the holder of a marketing authorization for a relevant medicinal product, forthwith or from a date specified in the notice, suspend the use, supply or marketing within the United Kingdom of the product to which the authorization relates for a period specified in the notice.

(3) In any case where the relevant Community provisions permit or require the suspension of the use, supply or marketing of a product until some decision or similar action is taken by the Community, the licensing authority may, instead of specifying a period in the notice, provide that the suspension is to apply until further notice.

(4) Where the licensing authority, in accordance with paragraph (3) include a provision that the suspension is to apply until further notice, they shall, where the effect of the Community decision or action is that the product may continue to be used or, as the case may be, marketed, in the United Kingdom, promptly give the holder of the authorization written notice revoking the suspension forthwith or from such date specified in the notice as to comply with that decision or action.

(5) Where, under the preceding provisions of this regulation or the provisions of Council Regulation (EEC) No. 2309/93, the licensing authority or the European Commission revoke or suspend a marketing authorization, or where the licensing authority suspend the use, supply or marketing of a product, or where the relevant Community provisions so permit or require, the licensing authority may and, where appropriate, shall give written notice to the person who is or, immediately before its revocation or suspension, was the holder of the authorization, requiring him to take all reasonably practicable steps to—

(a) inform wholesalers, retailers, medical practitioners, patients and others who may be in possession of relevant products of the revocation or suspension, the reasons for it, and the action (if any) to be taken to restrict or prevent further use, supply or marketing;

(b) withdraw from the market in the United Kingdom and recover possession of such products within the time and for the period specified in the notice.

(6) The licensing authority may require the holder of the marketing authorization to withdraw from the market in the United Kingdom specified batches only of a product to which a notice under paragraph (5) applies.

(7) Schedule 2 shall have effect to regulate the procedure for receiving advice and representations before revocation, variation (otherwise than on the application of the holder) or suspension of a marketing authorization, and for notifying the holder of that authorization in accordance with the preceding provisions of this regulation.

(8) The licensing authority shall publish in the Gazette notice of every decision by them to revoke an authorization.