
STATUTORY INSTRUMENTS

1994 No. 276

**The Medicines Act 1968 (Amendment)
(No. 2) Regulations 1994**

Section 28 of the Act — suspension etc. of the licence

- 6.—(1) Section 28(1) (general power to suspend, revoke or vary licences) is amended as follows.
- (2) In subsection (3)—
- (a) at the beginning there is inserted “Subject to subsection (3A) of this section”; and
 - (b) in paragraph (j) after “relates” there is inserted “(other than products to which Chapters II to V of the 1965 Directive apply)”.
- (3) After subsection (3) there is inserted—
- “(3A) Where a product licence relates to a product to which Chapters II to V of the 1965 Directive apply, the power conferred by this section to suspend a licence shall be exercisable in relation to the licence on the ground that—
- (a) any of the provisions contained in regulations made under section 85 (labelling and marking of containers and packages) or 86 (leaflets) of this Act, or
 - (b) section 86(4),
- has to a material extent been contravened in relation to the product by the holder of the licence or by a person procured by him to manufacture or assemble the product.”.
- (4) The amendments made by this regulation have effect only in relation to licences granted or renewed after the coming into force of these Regulations.

(1) Section 28 was amended by regulation 2(2) of the Medicines (Medicines Act 1968 Amendment) Regulations 1975 (S.I.1975/1169), S.R. & (N.I.) 1975/197, regulation 4(5) of S.I. 1977/1050, regulation 5(5) of (N.I.) S.R. 1977 No.170 and by paragraph 3(2) of Schedule 1 to the Animal Health and Welfare Act 1984 (c. 40). See also the Medicines Act (Application to Radiopharmaceutical-associated Products) Regulations 1992 (S.I. 1992/605).