SCHEDULE 6

Regulation 11

TRANSITIONAL PROVISIONS

1. If on 1st January 1995 there is in force in relation to a medicinal product for human use to which these Regulations apply a product licence granted under Part II of the Act, that product licence shall have effect from that date as if it were a marketing authorization granted under these Regulations.

2. Accordingly any right conferred or obligation imposed by these Regulations shall be conferred or imposed on the holder of such a product licence, except that the provisions of regulation 7(6) (which requires the holder of a marketing authorization to be established in the Community) and the provisions of Schedule 5 (labels) shall not apply.

3.—(1) Subject to sub-paragraph (2), any application for a product licence made before the date when these Regulations come into force but not then determined shall from that date be treated as an application for a marketing authorization, and the provisions of Schedule 2 shall apply accordingly.

(2) Where any act has been done in relation to an application to which sub-paragraph (1) applies before the date when these Regulations come into force, nothing in that sub-paragraph requires that act to be repeated.

4. The provisions of the Medicines (Labelling) Regulations 1976(**1**) and of the Medicines (Leaflets) Regulations 1977(**2**) (and subsequent regulations amending those Regulations) in so far as they relate to relevant medicinal products shall continue to have effect in relation to any relevant medicinal product in respect of which there is in force on the date these Regulations come into force a product licence under Part II of the Act, until the date when that licence is renewed.

5. Until 31st March 1995 the Medicines (Products for Human Use—Fees) Regulations 1991(**3**) shall have effect as if—

(a) any reference to a product licence or to licences under Part II of the Act included a reference to a United Kingdom marketing authorization;

(b) in regulation 2(1), the definition of "medicinal product" included a reference to a relevant medicinal product;

(c) in regulation 7, the reference to an application under section 30 of the Act to vary a product licence included a reference to an application under regulation 4 above to vary a United Kingdom marketing authorization; and

(d) in head 1(a)(i) in Column 1 of the Table in Part II of Schedule 1, paragraphs 2 and 2A of Part III of that Schedule and in the definition of "limited use drug" in paragraph 1 of Part I of Schedule 3, the references to paragraph 5 of Schedule 2 to the Applications Regulations included references to section G of Part 4 of the Annex to Council Directive 75/318/EEC(**4**).

(**1**) S.I. 1976/1726. The relevant amending instruments are S.I. 1977/996 and 2168, 1978/1140, 1981/1791, 1983/1729, 1985/1558 and 1992/3273.
(**2**) S.I. 1977/1055, amended by S.I. 1992/3274.
(**3**) S.I. 1991/1474. The relevant amending instruments are S.I. 1992/756 and 1994/691.
(**4**) The Annex to Council Directive 75/318/EEC was replaced by Council Directive 91/507/EEC.