STATUTORY INSTRUMENTS

1995 No. 2321

MEDICINES

The Medicines Act 1968 (Amendment) Regulations 1995

Made - - - -	*5th September 1995*
Laid before Parliament	*6th September 1995*
Coming into force - -	*29th September 1995*

The Secretary of State and the Minister of Agriculture, Fisheries and Food, acting jointly in exercise of the powers conferred on them by section 2(2) of the European Communities Act 1972(**1**), being designated for the purposes of that section in relation to medicinal products(**2**), hereby make the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines Act 1968 (Amendment) Regulations 1995 and shall come into force on 29th September 1995.

Amendment

2. In section 96 of the Medicines Act 1968 (advertisements and representations directed to practitioners)(**3**), after subsection (6) there is inserted the following subsection—

> "(7) Nothing in this section applies in relation to a relevant medicinal product, as defined by paragraph (1) of regulation 2 of the Medicines (Advertising) Regulations 1994(**4**), in respect of which there is required to exist a summary of product characteristics as defined by that paragraph."

Stephen Dorrell
One of Her Majesty's Principal Secretaries of State

5th September 1995

(**1**) 1972 c. 68.
(**2**) S.I. 1972/1811.
(**3**) 1968 c. 67.
(**4**) S.I. 1994/1932, amended by S.I. 1994/3144.

Angela Browning
Parliamentary Secretary Ministry of Agriculture, Fisheries and Food

4th September 1995

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, made under powers contained in section 2(2) of the European Communities Act 1972, deal with matters related to the implementation of Council Directive 92/28/EEC (OJNo. L113, 30.4.92, p.13) ("the Advertising Directive"). The Advertising Directive, which was implemented principally by the Medicines (Advertising) Regulations 1994 (S.I.1994/1932), provides that advertising of a relevant medicinal product must be based on the provisions of that product's summary of product characteristics. Requirements for the contents of summaries of product characteristics are set out in Article 4a of Directive 65/65/EEC (OJ No. L22, 9.2.65, p.369/65; relevant amending Directives are 83/570/EEC (OJ No. L332, 28.11.83, p.1) and 89/341/EEC (OJ No. L142, 25.05.89, p.11)). The Advertising Directive also sets out the circumstances in which summaries of product characteristics are to be made available to health professionals. These provisions differ from those contained in the Medicines Act 1968.

Regulation 2 adds subsection (7) to section 96 of the Medicines Act 1968 (which deals with advertisements and representations directed to practitioners), so that that section does not apply in relation to any medicinal product governed by the provisions of the Medicines (Advertising) Regulations 1994 and which is required to have a summary of product characteristics.