STATUTORY INSTRUMENTS

1996 No. 2420

MEDICINES

The Medicines (Data Sheet) Amendment Regulations 1996

Made - - - -	*18th September 1996*
Laid before Parliament	*19th September 1996*
Coming into force - -	*10th October 1996*

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and with agriculture in Wales and in Scotland respectively, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 96(6) and 129(1) and (5) of the Medicines Act 1968(**1**) and now vested in them(**2**) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations(**3**) hereby make the following Regulations:—

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Data Sheet) Amendment Regulations 1996 and subject to paragraph (2) of this regulation shall come into force on 10th October 1996.

(2) Regulation 4 shall come into force immediately after regulation 3(b).

(3) In these Regulations, "the principal Regulations" means the Medicines (Data Sheet) Regulations 1972(**4**).

Amendment of regulation 1 of the principal Regulations

2. Regulation 1 of the principal Regulations shall be amended so that—

(**1**) 1968 c. 67 ("the Act"). The expression" the Ministers" used in section 129 of the Act is defined in section 1(1) of the Act as amended by S.I.1969/388, Schedule 1. The word" prescribed" in section 96(6) is defined in section 132(1).

(**2**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388); in the case of the Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272); in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36) and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(**3**) *See* section 129(6) of the Act.

(**4**) S.I. 1972/2076 as amended by S.I. 1979/1760, S.I. 1981/1633, S.I. 1989/1183 and S.I. 1994/3142.

(a) in paragraph (2) after the definition of "monograph" the following definitions are inserted—

""product information compendium" has the meaning it bears in regulation 2A(1)(b);

"summary of product characteristics" has the meaning it bears in regulation 2(1) of the Medicines (Advertising) Regulations 1994(**5**);", and

(b) after paragraph (2) the following paragraph is inserted—

"(2A) In these Regulations unless the context otherwise requires "product licence" includes a marketing authorisation in respect of medicinal products intended for use by being administered to human beings and granted under Council Regulation (EEC) No. 2309/93(**6**) or under the Medicines for Human Use (Marketing Authorisations, Etc.) Regulations 1994(**7**);".

Amendment of regulation 2 of the principal Regulations

3. Regulation 2 of the principal Regulations (form of data sheets) shall be amended so that—

(a) in paragraph (1) after the words "for the purposes of the Act, every data sheet" the words "in respect of medicinal products for use by being administered to animals" are inserted, and

(b) in paragraphs (2) and (3) for the words "regulations 3 and 4" there are substituted the words "regulation 4".

Insertion of regulation 2A in the principal Regulations

4. After regulation 2 of the principal Regulations there shall be inserted the following regulation—

"**Data Sheets for medicinal products for human use**

2A.—(1) Subject to the following provisions of these Regulations, for the purposes of the Act every data sheet in respect of medicinal products for use by being administered to human beings shall be either in the form of—

(a) a loose sheet containing the particulars specified in these Regulations, or

(b) a page or part of a page, containing such particulars and forming part of a publication (in these Regulations referred to as a "product information compendium") consisting of a list of entries in respect of such medicinal products (whether or not it also consists of summaries of product characteristics, or other explanatory material which may be of use to the practitioner).

(2) The provisions of paragraphs (2) and (5) of regulation 2 shall apply in respect of data sheets to which paragraph (1) of this regulation applies as they apply in respect of data sheets to which regulation 2 applies but as if in paragraph (2) for the words "regulation 4" there were substituted "regulation 3"."

(**5**) S.I. 1994/1932.
(**6**) OJ no. L214, 24.8.93, p. 1.
(**7**) S.I. 1994/3144.

Amendment of regulation 3 of the principal Regulations

5. In regulation 3(8) and (9) of the principal Regulations (particulars in data sheets relating to medicinal products for human use) for the words "data sheet compendium" wherever they appear there shall be substituted the words "product information compendium".

Amendment of Schedule 1 to the principal Regulations

6. Schedule 1 to the principal Regulations shall be amended so that—

(a) at the beginning for the reference to "Regulation 2(2) and 3" a reference to "Regulations 2(2) and (3) and 2A(2)" is substituted, and

(b) at the end of the heading of Part II after the word "REQUIREMENTS" the words "IN RESPECT OF MEDICINAL PRODUCTS FOR USE BY BEING ADMINISTERED TO ANIMALS" are added.

Amendment of Schedule 2 to the principal Regulations

7. In paragraph 10 of column 2 (particulars) of Schedule 2 (particulars required in data sheets relating to medicinal products for human use) for the words "data sheet compendium" there shall be substituted the words "product information compendium".

Revocation

8. Regulation 6 (temporary provisions) of the principal Regulations shall be revoked.

Stephen Dorrell
12th September 1996 — Secretary of State for Health

Gwilym Jones
Parliamentary Under-Secretary of State, Welsh
17th September 1996 — Office

James Douglas Hamilton
17th September 1996 — Minister of State, The Scottish Office

Tim Boswell
Parliamentary Secretary, Ministry of Agriculture,
12th September 1996 — Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 17th September 1996

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 18th September 1996

L.S.

J. Murray
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

Regulation 2 of the Medicines (Data Sheet) Regulations 1972 ("the principal Regulations") prescribes the form of data sheets falling within section 96 of the Medicines Act 1968.

These Regulations remove certain requirements relating to the compilation of data sheets for medicinal products for human use by inserting a new regulation 2A into the principal Regulations (regulation 4). They also revoke transitional provisions in the principal Regulations (regulation 8).