STATUTORY INSTRUMENTS

1971 No. 1446

MEDICINES

The Medicines (Data Sheet) (Transitional) Regulations 1971

Made - - - -	*27th August* 1971
Laid before Parliament	*2nd September* 1971
Coming into Operation	*1st September* 1971

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Health and Social Services for Northern Ireland, the Minister of Agriculture, Fisheries and Food and the Minister of Agriculture for Northern Ireland, acting jointly, in exercise of their powers under sections 96(6) and 129(1) of the Medicines Act 1968(a) (as having effect subject to the provisions of article 2(2) of and Schedule 1 to the Transfer of Functions (Wales) Order 1969(b)) 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 the following regulations, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Data Sheet) (Transitional) Regulations 1971 and shall come into operation on 1st September 1971.

(2) In these regulations, unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"approved name" means the name which appears in the current edition (as defined in section 103(5) of the Act) of the list prepared and published under section 100 of the Act as in force at the date of the printing or last revision of the data sheet;

"data sheet" has the same meaning as in section 96(6) of the Act;

"medicinal product" includes articles or substances specified in orders made under section 104 or section 105 of the Act which are for the time being in force and which direct that Part VI of the Act shall have effect in relation to such articles or substances as that Part has in relation to medicinal products within the meaning of the Act;

"monograph" means a monograph in the current edition (as defined in section 103(5) of the Act) of the European Pharmacopoeia, of a com-

(a) 1968 c. 67. (b) S.I. 1969/388 (1969 I, p. 1070).

pendium published under section 99 of the Act, of the British Pharmacopoeia of the British Pharmaceutical Codex or of the British Veterinary Codex as in force at the date of the printing or last revision of the data sheet and a "monograph name" means in relation to an ingredient, the name which appears at the head of the relevant monograph ;

and other expressions have the same meaning as in the Act.

(3) Except in so far as the context otherwise requires, any reference in these regulations to any enactment or order shall be construed as a reference to that enactment or order, as the case may be as amended, extended or re-enacted by any other enactment or order.

(4) The Interpretation Act 1889(a) applies for the purpose of the interpretation of these regulations as it applies for the purpose of the interpretation of an Act of Parliament.

Particulars in data sheets

2.—(1) For the purposes of the Act every data sheet relating to a medicinal product to which neither subsection (2) nor subsection (3) of section 16 of the Act (transitional exemptions) is applicable shall contain the following particulars:—

(*a*) the name of the medicinal product to which the data sheet relates and, if the medicinal product has an approved name, the approved name ;

(*b*) therapeutic indications, dosage (if any), and method and routes of administration of the medicinal product to which the data sheet relates ;

(*c*) a list of the active ingredients contained in each unit or dose of the medicinal product to which the data sheet relates or where there are no active ingredients a statement indicating the material of which that medicinal product consists and in relation to each active ingredient (if any) the quantity and either the approved name or the monograph name, or where there is no approved name or monograph name, any other descriptive appellation ;

(*d*) details of any contra-indications or side-effects of the medicinal product to which the data sheet relates and of any precautions to be taken in relation thereto ;

(*e*) the name and address of the holder of the product licence in respect of the medicinal product to which the data sheet relates ; and

(*f*) the date of printing and of the last revision of the data sheet.

(2) Without prejudice to the preceding paragraph, any data sheet as aforesaid may in addition contain such information relating to the medicinal product to which the data sheet relates as may be necessary to assist the practitioner in the proper understanding, recognition, administration and use of that product.

(3) Where any of the particulars specified in paragraphs (1) and (2) of this regulation relate to matters specified in the provisions of the product licence in respect of the medicinal product to which the data sheet relates, any particulars contained in any data sheets in accordance with this regulation shall be consistent with those provisions.

(a) 1889 c. 63.

Signed by authority of the Secretary of State for Social Services.

Paul Dean,
Parliamentary Under Secretary of State,
Department of Health and Social Security.

11th August 1971.

Signed by authority of the Secretary of State for Wales.

David Gibson-Watt,
Minister of State,
Welsh Office.

27th August 1971.

Gordon Campbell,
Secretary of State for Scotland.

25th August 1971.

W. K. Fitzsimmons,
Minister of Health and Social Services
for Northern Ireland.

16th August 1971.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 24th August 1971.

(L.S.)

J. M. L. Prior,
Minister of Agriculture, Fisheries
and Food.

H. W. West,
Minister of Agriculture for Northern
Ireland.

17th August 1971.

EXPLANATORY NOTE

(*This Note is not part of the Regulations.*)

These Regulations prescribe particulars to be contained in data sheets which holders of product licences are required under the Medicines Act 1968 to send or deliver to practitioners in connection with any advertisements or representations. The regulations relate only to such medicinal products as are not exempt from the requirements of a product licence during the transitional exemptions period under sections 16 and 17 of the Act.