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 STATUTORY INSTRUMENTS
 

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1972 No. 2076

## MEDICINES

## The Medicines (Data Sheet) Regulations 1972

Made - - - 30th December 1972

Laid before Parliament 12th January 1973

Coming into Operation 1st February 1973

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 Secretary of State for Northern Ireland and the Minister of Agriculture, Fisheries and Food, acting jointly, in exercise of their powers under sections 96(6) and 129(1) and (5) 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 section 1(1)(a) of the Northern Ireland (Temporary Provisions) Act 1972(c) 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 and after taking into account the advice of the Medicines Commission, hereby make the following regulations:—

*Citation, commencement and interpretation*

1.—(1) These regulations may be cited as the Medicines (Data Sheet) Regulations 1972 and shall come into operation on 1st February 1973.

(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 preparation or last review or revision of the data sheet;

“business name” means the name or style under which any business is being carried on being a name or style required to be registered under the Registration of Business Names Act 1916(d);

“commercially interested party” has the same meaning as in section 92(4) of the Act and “party is commercially interested” shall be construed accordingly;

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

“data sheet compendium” has the meaning assigned to it by regulation 2(1)(b) of these regulations;

“finally disposed of” has the same meaning as in section 27(7) of the Act;

“mark” includes a device, brand, name, signature, word, letter, numeral, or any combination thereof;

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(a) 1968 c. 67.

(b) S.I. 1969/388 (1969 I, p. 1070).

(c) 1972 c. 22.

(d) 6 & 7 Geo. 5. c. 58.

“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 section 96 of the Act shall have effect in relation to such articles or substances as that section 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 compendium 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;

“trade mark” means a mark used or proposed to be used in relation to the medicinal product to which the data sheet relates for the purpose of indicating, or so as to indicate, a connection in the course of trade between that medicinal product and some person having the right either as a proprietor or as a person authorised by a proprietor to use the mark;

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

(3) For the purpose of these regulations medicinal products are of the same category if (but only if) they are all medicinal products for use by being administered to animals or, as the case may be, are all medicinal products for use by being administered to human beings.

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

(5) 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.

#### *Form of data sheets*

2.—(1) Subject to the following provisions of these regulations, for the purposes of the Act every data sheet 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 consisting of a list of entries in respect of medicinal products (which publication is in these regulations referred to as a “data sheet compendium”) provided that such page or part of a page shall not be treated as a data sheet—

(i) unless the data sheet compendium contains only entries relating to medicinal products that are of the same category and only entries made with the consent of the holder of the product licence relating thereto and, where such entries are not data sheets, they likewise conform to the particulars and requirements specified in these regulations for data sheets, excepting that such data sheet compendium shall indicate in a prominent manner on its cover that it comprises data sheets and may contain an explanation of the contents and such information, both of a general and specific nature

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(a) 1889 c. 63.

(other than in respect of medicinal products) which may be of use to the practitioner for the purposes of his practice together with the name and address of the printers and publishers,

- (ii) in the case of a data sheet compendium that is prepared by, or on behalf of, a commercially interested party unless such data sheet compendium refers only to medicinal products in which such party is commercially interested, and
- (iii) where, in the case of a data sheet compendium that is not prepared by or on behalf of a commercially interested party, such data sheet compendium is a publication in which particular classes, or groups of holders of product licences, are precluded from participating other than by reason of the fact that the products concerned do not fall within the scope of that compendium.

(2) Without prejudice to regulations 3 and 4 of these regulations, every data sheet that is in the form of a loose sheet shall comply with the requirements as to dimensions, shape, weight, colour and typesetting set out in Part I of Schedule 1 to these regulations.

(3) Without prejudice to regulations 3 and 4 of these regulations and, except as provided in the following paragraph of this regulation, every data sheet that is in the form of a page or part of a page of a data sheet compendium shall comply with the requirements as to dimensions, colour and typesetting set out in Part II of Schedule 1 to these regulations.

(4) The requirements as to dimensions, colour and typesetting as set out in Part II of Schedule 1 to these regulations shall not apply to a data sheet compendium that is prepared by or on behalf of a commercially interested party until after 31st December 1973 and such requirements shall not, in any event, apply to a data sheet which forms part of such compendium (not being a permanently bound publication) if such data sheet complies with the requirements as to dimensions, colour and typesetting set out in Part I of Schedule 1 to these regulations (which relate to loose sheet data sheets).

(5) Where a data sheet relates to two or more medicinal products whether having the same or different pharmaceutical forms such medicinal products shall—

- (a) be medicinal products with respect to which the product licences are held by the same person, and
- (b) be of the same category, and
- (c) contain the same single active ingredient, or the same two or more active ingredients in the same proportion or, if the licensing authority allows, different proportions, or
- (d) be medicinal products with respect to which the product licences expressly permit the medicinal products to be administered concomitantly with or sequentially upon one another and such medicinal products are or are to be sold, supplied or imported for such administration in a container which contains some of each such medicinal product or in a package which contains such a container.

*Particulars in data sheets relating to medicinal products for human use*

3.—(1) Subject to the following provisions of these regulations, every data sheet relating to a medicinal product for use by being administered to human beings shall in respect of the medicinal product to which the data sheet relates contain the particulars set out in column 2 of Schedule 2 to these regulations

in the order therein set out, provided that this provision shall be regarded as having been satisfied if, in lieu of any such particulars, the relevant heading as set out in column 1 of that Schedule, followed by the word "Nil" is given where it is not appropriate to give such particulars.

(2) Any data sheet as aforesaid that is in the form of a loose sheet shall in addition be marked in a clear and prominent manner with the words "Data Sheet" at the top of the first side of the sheet or, in the case of a folded sheet, at the top of the first side of the first fold of the sheet.

(3) Any data sheet as aforesaid may further contain the device for the Queen's Award to Industry, a trade mark together with an indication that such trade mark is a trade mark and a printer's mark and, in relation to any of the particulars given, the relevant heading set out in column 1 of Schedule 2 to these regulations.

(4) No data sheet as aforesaid shall contain any reference relating to a substance or article other than the medicinal product to which the data sheet relates, except in so far as such reference is necessary to—

(a) explain the contra-indications or precautions or the action to be taken in the event of overdosage, of the medicinal product to which the data sheet relates, or

(b) assist the practitioner in the proper understanding, recognition, administration and use of the medicinal product to which the data sheet relates.

(5) Except as aforesaid no data sheet shall contain any information relating to a substance or article other than the medicinal product to which the data sheet relates except in so far as such information is necessary to assist the practitioner in the proper understanding, administration and use of that substance or article, being a substance or article which forms part of or is necessary for the administration of the medicinal product.

(6) Where any of the particulars set out in column 2 of Schedule 2 to these regulations relate to matters specified in any application for, or 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 the matters specified in such application and those provisions, provided that, in the event of any conflict between the matters specified in such application and those provisions, such particulars shall be consistent with those provisions.

(7) A data sheet as aforesaid that is in the form of a loose sheet shall be regarded as satisfying the provisions of this regulation if, in addition to the name of the medicinal product and such name as is required by paragraph (10) of column 2 of Schedule 2 to these regulations being given as part of the particulars required, such names also appear in the space at the top of the first side of the sheet or in the case of a folded sheet at the top of the first side of the first fold of the sheet immediately above the first of such particulars and below the words "Data Sheet" or in the side margins of the sheet or in both such areas.

(8) A data sheet that is in the form of a page or part of a page of a data sheet compendium shall be regarded as satisfying the preceding provisions of this regulation (except as to the name and approved name, if any, of the medicinal product) if in that data sheet there is a reference to another data sheet in the same publication relating to the same medicinal product being a data sheet which contains the particulars required by this regulation.

(9) Where a data sheet is in the form of a page or part of a page of a data sheet compendium, the particulars required by paragraph (11) of column 2 of Schedule 2 need not be included in such data sheet but may be stated in the title page of the data sheet compendium provided that the holder of the product licence for the medicinal product to which the data sheet relates reviews and, where necessary, revises such data sheet prior to publication of each edition or reprint of the data sheet compendium.

*Particulars in data sheets relating to medicinal products for use by being administered to animals*

4.—(1) Without prejudice to regulation 3 of these regulations and subject to the following provisions of these regulations, every data sheet relating to a medicinal product for use by being administered to animals shall in respect of the medicinal product to which the data sheet relates contain the particulars set out in column 2 of Schedule 3 to these regulations in the order therein set out, provided that this provision shall be regarded as having been satisfied if, in lieu of any such particulars, the relevant heading as set out in column 1 of that Schedule followed by the word “Nil” is given where it is not appropriate to give such particulars.

(2) Any data sheet as aforesaid that is in the form of a loose sheet shall in addition be marked in a clear and prominent manner with the words “Data Sheet” at the top of the first side of the sheet or, in the case of a folded sheet, at the top of the first side of the first fold of the sheet and with the letter “V” at the top right hand side of the first such side.

(3) Any data sheet as aforesaid may further contain the device for the Queen’s Award to Industry, a trade mark together with an indication that such trade mark is a trade mark and a printer’s mark and, in relation to any of the particulars given, the relevant heading set out in column 1 of Schedule 3 to these regulations.

(4) No data sheet as aforesaid shall contain any reference relating to a substance or article other than the medicinal product to which the data sheet relates, except in so far as such reference is necessary to—

- (a) explain the contra-indications or precautions or the action to be taken in the event of overdose, of the medicinal product to which the data sheet relates, or
- (b) assist the practitioner in the proper understanding, recognition, administration and use of the medicinal product to which the data sheet relates.

(5) Except as aforesaid no data sheet shall contain any information relating to a substance or article other than the medicinal product to which the data sheet relates except in so far as such information is necessary to assist the practitioner in the proper understanding, administration and use of that substance or article, being a substance or article which forms part of or is necessary for the administration of the medicinal product.

(6) Where any of the particulars set out in column 2 of Schedule 3 to these regulations relate to matters specified in any application for, or 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 the matters specified in such application and those provisions, provided that, in the event of any conflict

between the matters specified in such application and those provisions, such particulars shall be consistent with those provisions.

(7) A data sheet as aforesaid that is in the form of a loose sheet shall be regarded as satisfying the provisions of this regulation if, in addition to the name of the medicinal product and such name as is required by paragraph (10) of column 2 of Schedule 3 to these regulations being given as part of the particulars required, such names also appear in the space at the top of the first side of the sheet or in the case of a folded sheet at the top of the first side of the first fold of the sheet immediately above the first of such particulars and below the words "Data Sheet" or in the side margins of the sheet or in both such areas.

(8) A data sheet as aforesaid that is in the form of a page or part of a page of a data sheet compendium shall be regarded as satisfying the preceding provisions of this regulation (except as to the name and approved name, if any, of the medicinal product) if in that data sheet there is a reference to another data sheet in the same publication relating to the same medicinal product being a data sheet which contains the particulars required by this regulation.

(9) Where a data sheet is in the form of a page or part of a page of a data sheet compendium, the particulars required by paragraph (11) of column 2 of Schedule 3 need not be included in such data sheet but may be stated in the title page of the data sheet compendium provided that the holder of the product licence for the medicinal product to which the data sheet relates reviews and, where necessary, revises such data sheet prior to publication of each edition or reprint of the data sheet compendium.

#### *Revocation and existing data sheets*

5.—(1) The Medicines (Data Sheet) (Transitional) Regulations 1971(a) are hereby revoked.

(2) Any document which has been prepared on or before the day these regulations came into operation and which but for the above revocation would have been a data sheet for the purposes of the Act may, during the period until 1st January 1974, be used as a data sheet for the purposes of the Act, and, if so used, shall be regarded as complying with the preceding provisions of these regulations provided that the person who so prepared such data sheet or on whose behalf it was so prepared is on that day the holder of a product licence in respect of the medicinal product in question, or has made an application which has not been finally disposed of, for such a licence.

#### *Temporary provisions*

6.—(1) Without prejudice to the other provisions of these regulations, in relation to a medicinal product of any description to which the Medicines (Termination of Transitional Exemptions) (No. 1) Order 1972(b) is applicable, and in respect of which the conditions specified in paragraphs (2) or (3) of this regulation are fulfilled, for the purposes of the Act and during the respective periods stated in those paragraphs, a data sheet may be in the form of a loose sheet or may form part of some other document or publication whether in the form of a leaflet or otherwise and may contain any one or more of the particulars that are required by these regulations, provided that it shall contain the following particulars, that is to say—

(a) the name of the medicinal product,

(b) the pharmaceutical form or description of the appearance of the medicinal product and a list of the active ingredients,

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(a) S.I. 1971/1446 (1971 III, p. 4082).

(b) S.I. 1972/1198 (1972 II, p. 3546).

- (c) the purposes for which the medicinal product is recommended to be used, and
- (d) the name and address of the holder of the product licence for the medicinal product, or the business name and address of the part of his business that is responsible for its sale and supply, or the name and address of a person named in the product licence as being responsible for, or permitted to participate in, its sale and supply, or the name and address of the person to whom the provisions of Article 3 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971(a) are applicable, unless any such name and address is specified in some other part of the document or publication of which the data sheet forms part:

Provided that where any such particulars relate to matters specified in any application for, or in the provisions of, the relevant product licence, any particulars contained in such data sheet shall be consistent with matters specified in such application or provisions.

(2) With respect to the period until 1st January 1974 or until the data sheet compendium referred to in (a) below is published, whichever is the first in time, the conditions referred to in paragraph (1) of this regulation are—

- (a) that on or before 1st March 1973 the holder of a product licence has made arrangements, in respect of the medicinal product to which this regulation applies, to participate in a data sheet compendium and that data sheet compendium has not been published by that date, and
- (b) that before that date the licensing authority has been notified of the arrangements specified in (a) above and has been furnished with a copy of the data sheet which is in accordance with paragraph (1) of this regulation.

(3) Without prejudice to the provisions of paragraph (2) of this regulation, with respect to the period until 1st June 1973 the conditions referred to in paragraph (1) of this regulation are—

- (a) that data sheets in respect of a medicinal product to which this regulation applies which comply with the requirements of regulation 2 of these regulations are not available and that arrangements for the preparation and subsequent distribution to practitioners of such data sheets have been or are being made, and
- (b) that the licensing authority—
  - (i) has been notified of the factors and arrangements specified in (a) of this paragraph,
  - (ii) has been furnished with a copy of the data sheet which is in accordance with paragraph (1) of this regulation, and
  - (iii) has consented (such consent to be regarded as having been given if the licensing authority has not, within 14 days of such copy being furnished, objected to its use), and has not withdrawn its consent, to the use of such data sheet as a data sheet for the purposes of the Act under this regulation, prior to such data sheet being sent or delivered to a practitioner in accordance with section 96(3) of the Act.

(4) Where a data sheet relating to a medicinal product of a particular description which is in accordance with paragraph (1) of this regulation has been sent or delivered to a practitioner by virtue of the conditions in paragraph (2)

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(a) S.I. 1971/1450 (1971 III, p. 4118).

of this regulation being satisfied, then during the period of twelve months after the relevant data sheet compendium has been published, a data sheet in respect of that medicinal product shall be either—

- (a) in the form of a page or part of a page of that data sheet compendium,  
or
- (b) in the form of a loose sheet that is in accordance with regulation 2(1)(a) of these regulations provided that that data sheet compendium contains an entry in respect of that medicinal product.

(5) Where a data sheet relating to a medicinal product of a particular description which is in accordance with paragraph (1) of this regulation has been sent or delivered to a practitioner by virtue of the conditions in paragraph (3) of this regulation being satisfied, then, until a data sheet that satisfies the requirements of regulation 2 of these regulations has been sent or delivered to that practitioner in respect of that medicinal product, any loose sheet, which but for this paragraph would have been a data sheet for the purposes of the Act, shall not be treated as a data sheet, if that loose sheet relates to a medicinal product in respect of which an advertisement was issued or a representation was made on or after 1st June 1973 and the same person is the holder of the product licence in respect of both medicinal products.

(6) In this regulation, unless the context otherwise requires—

- (a) “published” shall mean generally distributed to doctors or to doctors and dentists in the United Kingdom or, where the relevant data sheet compendium includes only data sheets relating to medicinal products for use by being administered to animals, to veterinary surgeons and veterinary practitioners in the United Kingdom,
- (b) any reference to a data sheet compendium shall not include a data sheet compendium which is prepared by or on behalf of a commercially interested party, or a data sheet compendium which includes medicinal products that are not of the same category.

*English Language*

7. Any particulars that are required to be contained in any data sheet shall, except with respect to numerals, be given in the English language.

*Keith Joseph,*

Secretary of State for Social Services.

21st December 1972.

*Peter Thomas,*

Secretary of State for Wales.

29th December 1972.



*Gordon Campbell,*  
Secretary of State for Scotland.

30th December 1972.

*W. S. I. Whitelaw,*  
Secretary of State for Northern Ireland.

28th December 1972.

In witness whereof the official seal of the Minister of Agriculture, Fisheries  
and Food is hereunto affixed on 28th December 1972.

(L.S.)

*Joseph Godber,*  
Minister of Agriculture, Fisheries and Food.

Regulation 2(2) and (3)

## SCHEDULE 1

## PART I

## LOOSE SHEET DATA SHEET REQUIREMENTS

DIMENSIONS AND SHAPE	<p>Unfolded sheet ... 203 millimetres by 127 millimetres without any protrusion by way of filing tabs or otherwise.</p> <p>Folded sheet ... 203 millimetres by the appropriate multiple of 127 millimetres without any protrusion by way of filing tabs or otherwise, each fold having the same dimension as an unfolded sheet.</p>
WEIGHT	Not less than 150 grams per square metre.
COLOUR	White background with printing in black, except that the name of the medicinal product or such name as is required by paragraph (10) of column 2 of Schedule 2 or 3 to these regulations may be printed in white on a black background when appearing at the top or in the margins of a data sheet.
TYPESETTING	<ol style="list-style-type: none"> <li>1. All printing to be at right angles to the side of the sheet measuring 203 millimetres, except that the name of the medicinal product or such name as is required by paragraph (10) of column 2 of Schedule 2 or 3 to these regulations, may be parallel to that side where any such name appears in the side margins.</li> <li>2. In the case of a folded sheet, no line of printing on any one side of any fold shall be in excess of 127 millimetres.</li> <li>3. The words "Data Sheet" at the top of the sheet to be in capitals in bold in not less than the largest typesetting used in the text other than that used for the name of the medicinal product.</li> <li>4. The letter "V" at the top right hand side of the first page or fold of the sheet to be in 18 Didot Univers bold or equivalent.</li> <li>5. The name of the medicinal product to be not greater than 18 Didot Univers bold or equivalent.</li> <li>6. All other printing to which 3, 4 or 5 above does not relate, to be in uniform size in not less than 8 Didot Univers or equivalent with headings and sub-headings in bold of the typesetting used.</li> </ol>

PART II  
DATA SHEET COMPENDIUM REQUIREMENTS

DIMENSIONS	A 5 paper	
COLOUR	White background with printing in black.	
TYPESETTING	Name of medicinal product and such name as is required under paragraph (10) of column 2 of Schedule 2 or 3 to these Regulations.	
	<table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none;">All other printing</td> <td style="border: none;">not greater than 18 Didot Unvers bold or equivalent.  not less than 6 Didot Unvers or equivalent with headings and subheadings in bold of the typesetting used in the text to which the heading or subheading relates.</td> </tr> </table>	All other printing
All other printing	not greater than 18 Didot Unvers bold or equivalent.  not less than 6 Didot Unvers or equivalent with headings and subheadings in bold of the typesetting used in the text to which the heading or subheading relates.	

Regulation 3(1)

## SCHEDULE 2

PARTICULARS REQUIRED IN DATA SHEETS RELATING TO  
MEDICINAL PRODUCTS FOR HUMAN USE

Column 1 <i>Headings</i>	Column 2 <i>Particulars</i>
Name of Product	(1.) Name of the medicinal product and, if the medicinal product has an approved name, the approved name.
Presentation	<p>(2.) Description of appearance and pharmaceutical form of the medicinal product together with the following information that is to say—</p> <p>(a) where the medicinal product contains active ingredients all of which can be definitively identified—</p> <p style="margin-left: 20px;">(i) a list of such ingredients, each described by its approved name or monograph name or, where it has no approved name or monograph name, any other descriptive appellation, and</p> <p style="margin-left: 20px;">(ii) the quantity of each such ingredient contained in each unit or dose of the medicinal product or, where there is no such unit or dose, the percentage of each such ingredient contained in the medicinal product;</p> <p>(b) where the medicinal product contains any active ingredient that cannot be definitively identified—</p> <p style="margin-left: 20px;">(i) the information as required under (a)</p>

<i>Column 1</i>	<i>Column 2</i>
	<p>above in respect of each identifiable active ingredient (if any), and</p> <p>(ii) a description of the material to which the activity of any other ingredient is ascribed and, where appropriate, a statement of the activity or potency of the medicinal product;</p> <p>(c) where there are no active ingredients in the medicinal product, a statement indicating the material of which that medicinal product consists.</p>
Uses	(3.) Principal action (if any) of the medicinal product and the purposes for which it is recommended to be used.
Dosage and Administration	(4.) Where the medicinal product is recommended for administration only to adults, the dosage (if any) for adults stating, unless it is otherwise apparent, that the medicinal product is not recommended for administration to children and, where the medicinal product is recommended for administration only to children, the dosage (if any) for children stating, unless it is otherwise apparent, that it is not recommended for administration to adults and, where it is recommended for administration to both adults and children, both such dosages (if any) and in each case the methods and routes of administration and, where appropriate, recommendations as to diluents.
Contra-Indications, Warnings, etc.	(5.) Contra-indications, warnings, precautions and action to be taken in the event of overdose, relating to the medicinal product and main side effects and adverse reactions likely to be associated therewith and, where there are no such particulars to be given, a statement to that effect shall be made; where required in the interests of safety, the antidote or other appropriate action to be taken.
Pharmaceutical Precautions	(6.) Special requirements for the storage of medicinal products and, where appropriate, pharmaceutical precautions including recommendations as to excipients, diluents and other additives and as to suitable containers, or, where there are no such requirements or no such precautions, a statement to that effect shall be made.
Legal Category	(7.) References to statutory provisions relating to sale or supply of the medicinal product.
Package Quantities	(8.) Quantity or amount of the medicinal product in each size of package or container for retail sale, or supply in circumstances corresponding to retail sale.

<i>Column 1</i>	<i>Column 2</i>
Further Information	(9.) Such further information (if any) as may be necessary to assist the practitioner in the proper understanding, recognition, administration and use of the medicinal product provided that such information shall not cover more than one-tenth of the total surface area of the data sheet.
Product Licence Numbers, Names and Addresses	(10.) Product licence number of the medicinal product and (a) name and address of the holder of the product licence, or (b) the business name and address of the part of his business that is responsible for its sale and supply, or (c) the name and address of a person named in the product licence as being responsible for, or permitted to participate in, its sale and supply, or (d) the name and address of a person to whom the provisions of Article 3 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 are applicable unless, as respects the name and address in the case of a data sheet compendium, data sheets are grouped together by reference to any name falling within either (a), (b), (c) or (d) of this paragraph and the name and address appears either at the head of that group or in the first data sheet of that group.
Date of Preparation or Last Review	(11.) Date of preparation of the data sheet or where since such preparation there has been a review or revision of the data sheet, the date of the last such review or revision.

## SCHEDULE 3

Regulation 4(1)

PARTICULARS REQUIRED IN DATA SHEETS RELATING TO  
MEDICINAL PRODUCTS FOR USE BY BEING ADMINISTERED TO ANIMALS

<i>Column 1 Headings</i>	<i>Column 2 Particulars</i>
Name of Product	(1.) Name of the medicinal product and, if the medicinal product has an approved name, the approved name.
Presentation	(2.) Description of appearance and pharmaceutical form of the medicinal product together with the following information that is to say— (a) where the medicinal product contains active ingredients all of which can be

Column 1	Column 2
	<p>definitively identified—</p> <ul style="list-style-type: none"> <li>(i) a list of such ingredients, each described by its approved name or monograph name or, where it has no approved name or monograph name, any other descriptive appellation, and</li> <li>(ii) the quantity of each such ingredient contained in each unit or dose of the medicinal product or, where there is no such unit or dose, the percentage of each such ingredient contained in the medicinal product;</li> </ul> <p>(b) where the medicinal product contains any active ingredient that cannot be definitively identified—</p> <ul style="list-style-type: none"> <li>(i) the information as required under (a) above in respect of each identifiable active ingredient (if any), and</li> <li>(ii) a description of the material to which the activity of any other ingredient is ascribed and, where appropriate, a statement of the activity or potency of the medicinal product;</li> <li>(c) where there are no active ingredients in the medicinal product, a statement indicating the material of which that medicinal product consists.</li> </ul>
Uses	(3.) Principal action (if any) of the medicinal product and the purposes for which it is recommended to be used.
Dosage and Administration	(4.) Dosage, (if any) for the medicinal product together with methods and routes of administration according to species and categories within species and, where appropriate, recommendations as to diluents.
Contra-Indications, Warnings, etc.	<p>(5.) Contra-indications, warnings, precautions, and action to be taken in the event of overdose, relating to the medicinal product and main side effects and adverse reactions likely to be associated therewith including, where necessary, measures for the protection of—</p> <ul style="list-style-type: none"> <li>(a) operators, and</li> <li>(b) consumers of the whole or any part of a carcass or any produce of an animal to which the medicinal product has been administered, including withdrawal periods, if any, and</li> <li>(c) livestock, wildlife and others, and</li> </ul> <p>where there are no such particulars to be given a statement to that effect shall be made; where required in the interests of safety, the antidote or other appropriate action to be taken.</p>

<i>Column 1</i>	<i>Column 2</i>
Pharmaceutical Precautions	(6.) Special requirements for the storage of medicinal products and, where appropriate, pharmaceutical precautions including recommendations as to excipients, diluents and other additives and as to suitable containers, or, where there are no such requirements or no such precautions, a statement to that effect shall be made.
Legal Category	(7.) References to statutory provisions relating to sale or supply of the medicinal product.
Package Quantities	(8.) Quantity or amount of the medicinal product in each size of package or container for retail sale, or supply in circumstances corresponding to retail sale.
Further Information	(9.) Such further information (if any) as may be necessary to assist the practitioner in the proper understanding, recognition, administration and use of the medicinal product provided that such information shall not cover more than one-tenth of the total surface area of the data sheet.
Product Licence Numbers, Names and Addresses	(10.) Product licence number of the medicinal product and (a) name and address of the holder of the product licence, or (b) the business name and address of the part of his business that is responsible for its sale and supply, or (c) the name and address of a person named in the product licence as being responsible for, or permitted to participate in, its sale and supply, or (d) the name and address of a person to whom the provisions of Article 3 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971 are applicable unless, as respects the name and address in the case of a data sheet compendium, data sheets are grouped together by reference to any name falling within either (a), (b), (c) or (d) of this paragraph and the name and address appears either at the head of that group or in the first data sheet of that group.
Date of Preparation or Last Review	(11.) Date of preparation of the data sheet or, where since such preparation there has been a re-review or revision of the data sheet, the date of the last such review or revision.

## EXPLANATORY NOTE

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

These Regulations revoke the Medicines (Data Sheet) (Transitional) Regulations 1971 and replace them by these regulations which prescribe the form of data sheets and the particulars to be contained in them which holders of product licences are required under the Medicines Act 1968 to send or deliver to practitioners in connection with any advertisement or representation. Regulation 5 provides for certain documents conforming to the transitional regulations being regarded until 1st January 1974 as complying with these regulations. Regulation 6 makes temporary provisions for the use of informal data sheets during certain limited periods.

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