STATUTORY INSTRUMENTS

2000 No. 2386

MEDICINES

The Medicines (Data Sheets for Veterinary Drugs) Regulations 2000

Made - - - -	*4th September 2000*
Laid before Parliament	*8th September 2000*
Coming into force	*1st October 2000*

The Minister of Agriculture, Fisheries and Food and the Secretary of State concerned with health in England, the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, acting jointly in exercise of the powers conferred by sections 96(6) and 129(1) and (5) of the Medicines Act 1968**(a)** and now vested in them**(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 in accordance with section 129(6) of that Act, and the Minister of Agriculture, Fisheries and Food and the Secretary of State, being Ministers designated**(c)** for the purposes of section 2(2) of the European Communities Act 1972**(d)** in relation to medicinal products, acting jointly in exercise (so far as is required for cessation of application of previous Regulations) of the powers conferred on them by the said section 2(2), hereby make the following Regulations:

Title, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Data Sheets for Veterinary Drugs) Regulations 2000 and shall come into force on 1st October 2000.

(2) In these Regulations unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"approved name", in relation to a product, means a name approved in the licence or authorisation relating to the product;

"authorisation" means a marketing authorisation within the meaning of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994**(e)**;

(a) 1968 c. 67; see the definition of "prescribed" in section 132(1); "the Ministers" referred to in section 129(1) is defined in section 1 (see also the following footnote). Section 96 was applied to marketing authorisations by S.I. 1994/3142 and amended by S.I. 1995/232.

(b) In the case of the Minister of Agriculture, Fisheries and Food by virtue of articles 2(2) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999 (S.I. 1999/3142); in the case of the Secretary of State concerned with health in England by virtue of articles 2(1) and 5 of, and the Schedule to, the Transfer of Functions (Medicines and Poisons) Order 1999; and in the case of the Minister of Health, Social Services and Public Health and the Minister of Agriculture and Rural Development by virtue of section 95(5) of, and paragraph 10(1)(b) of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) and article 3(4) and (6) of the Departments (Northern Ireland) Order 1999 (S.I. 1999/283 (N.I. 1)).

(c) By S.I. 1972/1811.

(d) 1972 c. 68.

(e) S.I. 1994/3142, to which there are amendments not relevant to these Regulations.

"compendium" means a publication as described in regulation 2(1)(b);

"data sheet" means a data sheet relating to a medicinal product which is a veterinary drug and includes an SPC;

"Directive 81/851" means Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products**(a)** amended by Council Directives 90/676/EEC**(b)** and 93/40/EEC**(c)**;

"licence" means a product licence;

"medicinal product" includes—

(a) articles or substances specified in an order made under section 104 or 105 of the Act and which directs that section 96 of the Act shall have effect in relation to those articles or substances as it has in relation to medicinal products, and

(b) any product to which an authorisation relates;

"SPC" means a summary of the product characteristics, within the meaning of Articles 5.11 and 5a of Directive 81/851, to which an authorisation relates.

(3) Any reference in these Regulations to a numbered regulation or to the Schedule shall, unless the context otherwise requires, be construed as a reference to the regulation bearing that number in these Regulations or the Schedule to them.

Form of data sheets

2.—(1) Subject to the following provisions of these Regulations, every data sheet shall be in the form either of—

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

(b) a page or part of a page, containing those particulars and forming part of a compendium which—

(i) is published in book form, whether or not permanently bound (and whether or not also published in electronic form), and

(ii) complies with the requirements of paragraph (2) below,

and shall comply with the requirements of paragraphs (3) to (6) below.

(2) The requirements for a compendium are that—

(a) it contains entries relating to medicinal products which are all veterinary drugs,

(b) those entries are made with the consent of the holder of the licence or authorisation for each product the subject of the entry,

(c) it indicates prominently that it comprises data sheets and the date of publication and in the case of a compendium in book form such indication appears on its cover,

(d) it indicates the name and address of the printers and publishers,

(e) it contains no information other than that required or authorised by regulation 3, except that the compendium may contain an explanation of the contents and such information, both of a general and specific nature (other than in respect of medicinal products) which may be of use to the practitioner for the purposes of his practice,

(f) in the case of a compendium that is prepared by, or on behalf of, a commercially interested party it refers only to medicinal products in which such party is commercially interested,

(g) in the case of a compendium that is not prepared by or on behalf of a commercially interested party, it is a publication in which particular classes or groups of holders of licences or authorisations may participate, unless the products concerned do not fall within the scope of that compendium, and

(h) in the case of a compendium in electronic form, it contains sufficient safeguards to prevent changes being made to the text of a data sheet.

(a) OJ No. L317, 6.11.81, p.1.
(b) OJ No. L373, 31.12.90, p.15.
(c) OJ No L214, 24.8.93, p.31.

(3) Every data sheet that is in the form of a loose sheet shall be printed in black on a white background, except that the name of the product to which it relates or any name required by paragraph 10, column 2 of the Schedule may be printed in white on a black background when it is at the top or in the margins of the data sheet.

(4) Every data sheet which forms part of a compendium which is not in a permanently bound or electronic form shall comply with the requirements of paragraph (3) above.

(5) Every data sheet which forms part of a compendium which is in a permanently bound form shall be printed in black on a white background in type of uniform size and style, except that—

(a) headings and sub-headings may be in bold or in a different style of the type size used;

(b) the names of medicinal products may differ in style or type size, provided the same style or type size is used throughout the compendium for all such names; and

(c) the name and address required by paragraph 10, column 2 of the Schedule may differ in style or type size, provided the respective style or type is used throughout the compendium for all such names or addresses.

(6) Every data sheet which forms part of a compendium in electronic form shall be presented in type of uniform size, style, colour and background except that:—

(a) headings and sub-headings may be in bold or in a different style of the type size used;

(b) the names of medicinal products may differ in style or type size, provided the same style or type size is used throughout the compendium for all such names; and

(c) the name and address required by paragraph 10, column 2 of the Schedule may differ in style or type size, provided the respective style or type size is used throughout the compendium for all such names and addresses.

Particulars in data sheets—general

3.—(1) Every data sheet which is not a SPC shall in respect of the medicinal product to which it relates contain the particulars set out in column 2 of the Schedule, against the relevant headings set out in column 1 of the Schedule, following the order set out there, in the English language, but if any of the particulars are not relevant in respect of that product the heading in question shall be given followed by the word "Nil".

(2) Every data sheet which is a SPC shall in respect of the medicinal product to which it relates contain the particulars called for by paragraphs 1 to 6 of Article 5a of Directive 81/851, and the particulars required by paragraphs 7 (legal category), 8 (package quantities), 10 (licence or authorisation number and names and addresses) and 11 (date of preparation or last review) of column 2 of the Schedule, in the English language.

(3) A data sheet may additionally contain the device for the Queen's Award to Industry, a trade mark, with an indication that it is a trade mark, and a printer's mark.

(4) Any particulars required by these Regulations to be contained in any data sheet shall be consistent with the provisions of the licence or authorisation relating to the product in question, except that in the case of a data sheet which forms part of a compendium in a case where, since the compendium was published, the provisions in question have been altered, this requirement does not apply until the next edition or reprint of the compendium.

(5) Paragraphs (1) and (2) above are subject to regulation 5.

Particulars in data sheets—additional provisions for loose sheets

4.—(1) Every data sheet that is in the form of a loose sheet shall—

(a) if it is not a SPC, be marked clearly and prominently with the words "Data Sheet" at the top of the first side of the sheet, or

(b) if it is a SPC, be marked either with the words "Data Sheet" or "Summary of Product Characteristics" at the top of the first side of the sheet.

(2) Any data sheet that is in the form of a loose sheet shall not be regarded as failing to satisfy the provisions of regulation 3(1) or (2) by nature only of the additional appearance of the name of the medicinal product and any name required by paragraph 10, column 2 of the Schedule—

(a) 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 the required particulars and below the words "Data Sheet" or "Summary of Product Characteristics" as the case may be,

(b) in the side margins of the sheet, or

(c) in both such areas.

Particulars in data sheets—special provisions for compendia

5.—(1) Where a data sheet forms part of a compendium, the name and address referred to in paragraph 10, column 2 of the Schedule need not be included in the data sheet, if in the compendium data sheets are grouped together under a single name required by that paragraph, and the name and address appear either at the head of that group or in the first data sheet of that group.

(2) Where a data sheet forms part of a compendium, the date of preparation or last review referred to in paragraph 11, column 2 of the Schedule need not be included in the data sheet.

Additional requirements for data sheets which are not SPCs

6.—(1) Any data sheet which is not a SPC may relate to two or more medicinal products only if—

(a) the licence or authorisation for each product is held by the same person, and

(b) the products contain the same single active ingredient, or the same two or more active ingredients in the same proportion,

the licence or authorisation for each product expressly permits the products to be administered together with or following on from one another, and the products are or are to be sold, supplied or imported for administration in a package which contains some of each product.

(2) No data sheet which is not a SPC 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.

Cessation of application of previous Regulations

7. The Medicines (Data Sheet) Regulations 1972**(a)** shall cease to apply to veterinary drugs.

Hayman
Minister of State,
17th August 2000 Ministry of Agriculture, Fisheries and Food

Signed by authority of the Secretary of State for Health

Hunt
4th September 2000 Parliamentary Under Secretary of State for Health

Bairbre de Brún
30th August 2000 Minister of Health, Social Services and Public Safety

Bríd Rodgers
31st August 2000 Minister of Agriculture and Rural Development

(a) S.I. 1972/2076; relevant amending instruments are S.I. 1981/1633, 1989/1183, 1994/3142 (which was made under section 2(2) of the European Communities Act 1972 (c. 68)), 1996/2420.

SCHEDULE

Regulation 3(1) and (2)

PARTICULARS REQUIRED IN DATA SHEETS WHICH ARE NOT SPCS

	Column 1 *Headings*	Column 2 *Particulars*
1	Name of Product	Name of the medicinal product and, if the medicinal product has an approved name, the approved name.
2	Presentation	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 definitively identified— (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 (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; (b) where the medicinal product contains any active ingredient that cannot be definitively identified— (i) the information as required under (a) above in respect of each identifiable active ingredient (if any), and (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; (c) where there are no active ingredients in the medicinal product, a statement indicating the material of which that medicinal product consists.
3	Uses	Principal action (if any) of the medicinal product and the purposes for which it is recommended to be used.
4	Dosage and Administration	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.

Column 1 *Headings*		Column 2 *Particulars*
5	Contra-Indications, Warnings, etc.	Contra-indications, warnings, precautions, and action to be taken in the event of overdosage (including, where required in the interests of safety, antidote, emergency procedure or other appropriate action) relating to the medicinal product and main side effects and adverse reactions likely to be associated with the product and, where necessary, measures for the protection of— (a) operators, (b) consumers of the whole or any part of a carcase or any produce of an animal to which the medicinal product has been administered, including withdrawal periods, if any, and (c) livestock, wildlife and others, unless there are no such particulars to be given and there is a statement to that effect.
6	Pharmaceutical Precautions	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, unless there are — (a) no such requirements, or (b) no such precautions, and a statement to that effect is made.
7	Legal Category	References to statutory provisions relating to sale or supply of the medicinal product.
8	Package Quantities	Quantity or amount of the medicinal product in each size of package or container for retail sale, or for supply in circumstances corresponding to retail sale.
9	Further Information	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, such information not covering more than one-tenth of the total surface area of the data sheet.
10	Licence or Authorisation Numbers, Names and Addresses	Licence or authorisation number of the medicinal product and the name and address of the licence or authorisation holder.
11	Date of Preparation or Last Review	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.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations replace the Medicines (Data Sheet) Regulations 1972 as amended in so far as they relate to data sheets for veterinary drugs.

These Regulations prescribe the form of data sheets (regulation 2) and the particulars to be contained in them (regulations 3 to 6 and the Schedule) which the holder of a product licence or marketing authorisation is required under the Medicines Act 1968 to send or deliver to practitioners in connection with any advertisement or representation.

These Regulations enable documents which are summaries of the product characteristics to which a marketing authorisation relates, containing the particulars prescribed by Article 5a of Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (OJ No. L317, 6.11.81, p.1), to be used as data sheets for the purposes of advertisements and representations directed to practitioners in section 96 of the Medicines Act 1968. A "marketing authorisation" is defined as one to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (S.I. 1994/3142) apply, being one which is granted pursuant to Council Directive 81/851/EEC or one pursuant to Council Regulation (EEC) No. 2309/93 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ No. L214, 24.8.93, p.1).

The Medicines (Data Sheet) Regulations 1972, S.I. 1972/2076, as amended, cease to apply to veterinary drugs (regulation 7).

These Regulations have been notified to the European Commission and the other member states in accordance with Directive 98/34/EC of the European Parliament and of the Council (OJ No. L204, 21.7.98, p.37) as amended by Directive 98/48/EC of the European Parliament and of the Council (OJ No. L217, 5.8.98, p.18).

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