STATUTORY INSTRUMENTS

1971 No. 304

THERAPEUTIC SUBSTANCES

The Therapeutic Substances (Supply of Antibiotics and Chemotherapeutic Substances for Agricultural Purposes) Regulations 1971

Made - - - 24*th February* 1971

Laid before Parliament 26*th February* 1971

Coming into Operation

with respect to Flavomycin, Virginiamycin and substances 1 *to* 7 *in Schedule* 3 *and items* 12 *and* 13 *thereof in so far as they refer to items* 1 *to* 7 1*st March* 1971

for all other purposes 1*st September* 1971

The Secretary of State for Social Services, the Secretary of State for Wales, the Secretary of State for Scotland and the Minister of Health and Social Services for Northern Ireland, jointly in exercise of their powers under section 9 of the Therapeutic Substances Act 1956(**a**), as amended by the Transfer of Functions (Wales) Order 1969(**b**), and as having effect subject to the provisions of the Ministries (Transfer of Functions) (No. 2) Order (Northern Ireland) 1964(**c**) and of the Ministries (Transfer of Functions) (Northern Ireland) Order 1965(**d**), and of all other powers enabling them in that behalf, after consultation with the Medical Research Council and the Agricultural Research Council, hereby make the following regulations :—

Title and commencement

1. These regulations may be cited as the Therapeutic Substances (Supply of Antibiotics and Chemotherapeutic Substances for Agricultural Purposes) Regulations 1971, and shall come into operation on 1st September 1971 ; except that provisions relating to Flavomycin and Virginiamycin and substances 1 to 7 in Schedule 3 and items 12 and 13 thereof in so far as they refer to items 1 to 7 shall come into force on 1st March 1971.

Interpretation

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

"the appropriate Minister" means—

(*a*) as respects preparations sold or supplied in England and Wales, the Minister of Agriculture, Fisheries and Food,

(*b*) as respects preparations sold or supplied in Scotland, the Secretary of State concerned with agriculture in Scotland,

(*c*) as respects preparations sold or supplied in Northern Ireland, the Minister of Agriculture for Northern Ireland ;

(**a**) 1956 c. 25. (**b**) S.I. 1969/388 (1969 I, p. 1070).
(**c**) S.R. & O. (N.I.) 1964/205. (**d**) S.R. & O. (N.I.) 1965/13.

"approved" means—

(*a*) as respects preparations manufactured in England, or sold or supplied in England after importation into the United Kingdom, approved by the Secretary of State for Social Services,

(*b*) as respects preparations manufactured in Wales, or sold or supplied in Wales after importation into the United Kingdom, approved by the Secretary of State for Wales,

(*c*) as respects preparations manufactured in Scotland, or sold or supplied in Scotland after importation into the United Kingdom, approved by the Secretary of State for Scotland,

(*d*) as respects preparations manufactured in Northern Ireland, or sold or supplied in Northern Ireland after importation into the United Kingdom, approved by the Minister of Health and Social Services for Northern Ireland;

"virginiamycin" has the same meaning as in the Therapeutic Substances (Control of Sale and Supply) Regulations 1967(**a**);

"flavomycin" has the same meaning as in the Therapeutic Substances (Control of Sale and Supply) Regulations 1971(**b**);

"feeding stuffs containing virginiamycin" means poultry food to which virginiamycin supplement has been added;

"feeding stuffs containing flavomycin" means pig or poultry food to which flavomycin supplement has been added;

"feeding stuffs containing sulphaquinoxaline" means poultry food to which sulphaquinoxaline supplement has been added;

"feeding stuffs containing sulphanitran" means poultry food to which sulphanitran supplement has been added;

"poultry" means domestic fowls, turkeys, geese, ducks, guinea-fowls, pigeons, pheasants and partridges;

"sulphanilamide" means *p*-aminobenzenesulphonamide;

"sulphanitran" means N^4-acetyl-N^1-(4-nitrophenyl)sulphanilamide;

"sulphaquinoxaline" means N^1-quinoxalin-2-ylsulphanilamide;

"sulphanilamide powdered surface wound dressing" means a preparation containing sulphanilamide in the form of a powdered wound dressing for application to farm animals;

"flavomycin supplement", "virginiamycin supplement", "sulphanitran supplement" and "sulphaquinoxaline supplement" mean respectively dilute preparations of flavomycin, virginiamycin, sulphanitran or sulphaquinoxaline prepared by approved methods and with the use of approved diluents.

"a supplement" means flavomycin supplement, virginiamycin supplement, sulphanitran supplement, or sulphaquinoxaline supplement.

"zinc bacitracin" means the zinc complex of bacitracin.

(2) Unless the context otherwise requires, references to a substance in Schedule 3 by name shall be construed as references to the substance for which such name is shown in the list of names published under section 100 of the Medicines Act 1968(**c**).

(**a**) S.I. 1967/1851 (1967 III, p. 4969). (**b**) S.I. 1971/303(1971 I, p. 1021).
(**c**) 1968 c. 67.

(3) References in these regulations to a numbered regulation or to a numbered schedule shall be construed as references to the regulation or schedule bearing that number in these regulations.

(4) The Interpretation Act 1889(a) shall apply to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

Sale or supply without prescription

3. Section 9(1) of the Therapeutic Substances Act 1956 (which controls the sale and supply of substances to which Part II of the Act applies) shall not apply to the sale or supply of animal feeding stuffs containing flavomycin, virginiamycin, sulphanitran and sulphaquinoxaline, or to flavomycin supplement, virginiamycin supplement, sulphanitran supplement, sulphaquinoxaline supplement or to sulphanilamide powdered surface wound dressing when sold or supplied in accordance with the conditions set out in regulations 4 and 5.

4.—(1) The number of parts of a substance mentioned in column 1 of Schedule 1 to one million parts of animal feeding stuff shall not exceed the number shown in column 2 of that Schedule relative to the substance shown in column 1 thereof, and in the case of flavomycin the number shown in column 2 shall apply in relation to the type of animal shown in column 3 thereof.

(2) When a concentrated animal feeding stuff is mixed with another animal feeding stuff before being fed the concentrated animal feeding stuff shall not contain a greater number of parts of a substance mentioned in column 1 of Schedule 1 to one million parts than that found by the formula $n\left(\frac{f}{c}+1\right)$ where c represents the number of units of weight of a concentrated feeding stuff, f represents the number of units of weight of the other feeding stuff and n represents the number shown in column 2 of Schedule 1 relative to the substance mentioned in column 1 of that Schedule, provided that $\frac{f}{c}+1$ in the foregoing formula shall not exceed 20. In the case of flavomycin the figures in column 2 of Schedule 1 shall apply respectively to the types of animal shown in column 3 of that Schedule.

(3) The number of parts of a substance mentioned in column 1 of Schedule 2 to one thousand parts of a supplement shall not exceed the number shown in column 2 of that Schedule relative to the substance shown in column 1 thereof.

(4) Sulphanilamide powdered wound dressing shall not contain more than five per cent of sulphanilamide.

(5) Nothing in this section shall have the effect of permitting the sale or supply of feeding stuffs or supplements containing mixtures of zinc bacitracin or virginiamycin or flavomycin either with one another or with any other antibiotic, or containing mixtures of sulphaquinoxaline or sulphanitran either with one another or with sulphanilamide or any of its derivatives having any of the hydrogen atoms of either or both nitrogen atoms substituted by an equal number of univalent atoms or radicals.

5.—(1) Any feeding stuff containing a substance mentioned in Schedules 1 or 2 shall have printed on the container or have affixed thereto, or inserted therein, or the container shall be accompanied by a label showing in such manner as the appropriate Minister may require, such particulars as the appropriate Minister may require with respect to—

(a) 1889 c. 63.

(*a*) the name of the scheduled substance contained in the feeding stuff,

(*b*) if appropriate, the number of units of the substance added in a given weight of feeding stuff, or

(*c*) quantity of the substance incorporated in a given weight of feeding stuff,

(*d*) conditions of storage and use of the feeding stuff,

(*e*) considerations of safety ; and

if the feeding stuff is a concentrated feeding stuff,

(*f*) gross or net weight of the feeding stuff, and

(*g*) amounts of such concentrated feeding stuff to be added to other feeding stuffs for different purposes :

Provided that when the feeding stuff is supplied unpackaged in bulk the supplier shall furnish the purchaser, on delivery, with a statement in writing containing the particulars referred to in (*a*) to (*g*) of this paragraph.

(2) (*a*) Supplements shall be packed in containers suitable for preserving the potency of the contents up to the expiry date ; and

(*b*) every container containing supplements shall have printed thereon or have affixed thereto or inserted therein or shall be accompanied by a label showing in such manner as the appropriate Minister may require such particulars as the appropriate Minister may require with respect to—

(i) name of the supplement,

(ii) weight of the contents, and if appropriate the number of units or the quantity of the therapeutic substance added in a given weight of supplement,

(iii) nature of the diluent,

(iv) conditions of storage and use of the supplement, including the amounts to be added to feeding stuffs for different purposes,

(v) date up to which the contents may be expected to retain potency,

(vi) considerations of safety.

(3) Containers in which sulphanilamide powdered wound dressing is packed shall have printed thereon or have affixed thereto or inserted therein a label showing in such manner as the appropriate Minister may require such particulars as the appropriate Minister may require with respect to—

(*a*) storage and use,

(*b*) name of the preparation,

(*c*) weight or volume of the contents and the quantity of sulphanilamide contained therein,

(*d*) nature of other ingredients of the preparation.

(*e*) considerations of safety.

Sale or supply of animal feeding stuffs and diluents against a written direction of a registered veterinary surgeon or practitioner

6. Section 9(1) of the Therapeutic Substances Act 1956 shall not apply to the sale and supply of animal feeding stuffs or diluents containing any of the substances mentioned in Schedule 3, which are sold or supplied in accordance with the conditions set out in regulation 7.

7.—(1) The substance to be sold or supplied shall be mixed with an animal feeding stuff or diluent and sold or supplied in accordance with a written direction addressed to the supplier and which may be used once only and within a period of one month from the date of the direction and which otherwise complies with the requirements specified in paragraph 2 of this regulation.

(2) A direction mentioned in the foregoing paragraph shall—

(*a*) be given, signed and dated by a registered veterinary surgeon or a registered veterinary practitioner,

(*b*) specify the quantity of the substance with which a stated quantity of animal feeding stuff or diluent is to be mixed,

(*c*) authorise the quantity of animal feeding stuff or diluent that has been mixed with the substance that may be sold or supplied to a person, firm, company or organisation named in the direction,

(*d*) contain a statement that the animal feeding stuff or diluent that has been mixed with the substance to which the direction relates is for administration to animals under the care of the registered veterinary surgeon or registered veterinary practitioner by whom the direction is given.

SCHEDULE 1

Regulations 4(1), (2) and 5.

Substance	*Number of parts of substance to one million parts of feeding stuff*	*Kind of animal*
(1)	(2)	(3)
Virginiamycin	7	For poultry
Flavomycin	25	For poultry
	63	For pigs
Sulphaquinoxaline	75	For poultry
Sulphanitran	375	For poultry

SCHEDULE 2

Regulations 4(3) and 5.

Substance	*Number of parts of substance to one thousand parts of supplement*
(1)	(2)
Virginiamycin	11
Flavomycin	5
Sulphaquinoxaline	108
Sulphanitran	300

SCHEDULE 3

Regulation 6.

1. Chlortetracycline, an antimicrobial organic base produced by *Streptomyces aureofaciens* and having the chemical structure 7-chloro-4-dimethylamino-1, 4, 4a, 5, 5a, 6, 11, 12a-octahydro-3, 6, 10, 12, 12a-pentahydroxy-6-methyl-1 11-dioxonaphthacene-2-carboxyamide. The expression includes any salt or derivative of the said base which contains chlorine in the 7-position.

2. Erythromycin.

3. Neomycin.

4. Nystatin.

5. Oxytetracycline.

6. Penicillin, any antimicrobial acid, any salt thereof, or any derivative which is obtained therefrom, which may be shown on chemical and physical examination to contain in its structure a fused thiazolidine β-lactam nucleus.

7. Framycetin.

8. Furazolidone.

9. Nitrofurazone.

10. Sulphanilamide, and any of its derivatives having any of the hydrogen atoms of either or both nitrogen atoms substituted by an equal number of univalent atoms or radicals.

11. Tylosin, that is to say the antimicrobial substance with a macrolide structure produced by strains of *Streptomyces fradiae*.

12. any substance the chemical and biological properties of which are identical with or similar to those of any of the substances specified in items 1 to 7 and 11 of this Schedule but which are not produced by living organisms.

13. to any ester or salt of any of the substances specified in items 1 to 7, 11 and 12 of this Schedule or to any salt of any such ester.

14. to any ester or salt of either of the substances specified in items 8 and 9 of this Schedule or to any salt of any such ester.

Keith Joseph,
Secretary of State for Social Services.

22nd February 1971.

Given under my hand on 22nd February 1971.

Peter Thomas,
Secretary of State for Wales.

Given under the seal of the Secretary of State for Scotland on 23rd February 1971.

(L.S.)

Gordon Campbell,
Secretary of State for Scotland.

Given under my hand on 24th February 1971.

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

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations made under section 9(1) of the Therapeutic Substances Act 1956 legalise in regulations 3 to 5 the sale or supply without prescription of animal feeding stuffs, supplements and an animal wound dressing containing certain therapeutic substances in accordance with conditions contained in these regulations : they also legalise in regulations 6 and 7 the sale and supply of animal feeding stuffs and diluents containing other therapeutic substances against a written direction of a registered veterinary surgeon or practitioner.