Sheep Dipping

ORDER, DATED 28TH AUGUST, 1953, MADE BY THE MINISTRY OF AGRICULTURE UNDER THE DISEASES OF ANIMALS ACTS, 1894 TO 1948.

1953. No. 117.

This Order prescribing the dipping of sheep in the period from 5th October to 28th November, 1953, is of temporary effect and therefore is not printed at length in this Volume.

Therapeutic Substances

1953. No. 169

The Ministry of Agriculture for Northern Ireland by virtue and in exercise of the powers vested in it under the Diseases of Animals Acts (Northern Ireland) 1894 to 1948 and of every other power enabling it on that behalf, hereby makes the following Order :—

PART I — GENERAL

Short Title and Commencement

1. This Order, which may be cited as the Diseases of Animals (Therapeutic Substances) (Northern Ireland) Order, 1953 shall come into operation on the first day of January, nineteen hundred and fifty-four.

Interpretation

2.—(1) In this Order, unless the context otherwise requires, the following expressions have the meanings hereby respectively assigned to them :—

" Anaerobic vaccine " means a vaccine derived from or containing cultures of anaerobes.

" Antigen " means a suspension of an organism, or a solution or suspension of the special constituent or product of the organism, which is capable of inciting antibody production.

" Authorised Officer " means an officer duly authorised by the Ministry.

" Killed bacterial vaccine " means a sterile suspension of a killed culture of a micro-organism or micro-organisms.

" Living bacterial vaccine " means a vaccine containing micro-organisms which have not been treated by any method likely to kill them.

" Ministry " means the Ministry of Agriculture for Northern Ireland.

" Registered " means in relation to a veterinary surgeon, registered in pursuance of the Veterinary Surgeons Act, 1881 (a), in the

(a) 44 & 45 Vict. c.62.

Register of Veterinary Surgeons, and in relation to a veterinary practitioner, registered in pursuance of the Veterinary Surgeons Act, 1948 (a) in the Supplementary Veterinary Register.

" Relative Schedule " in relation to a therapeutic substance means such part of the Second, Third or Fourth Schedules to this Order as applies to that substance either specially or to the group of substances to which the substance belongs.

" Sera and antitoxins " means the sera or solutions of the purified proteins of sera separated from the blood of normal animals or of animals which have been artificially immunised against cultures of one or more organisms or against a soluble toxin or toxins produced by the organism or organism or against antigenic substances prepared from the organism or organisms.

" Therapeutic substance " means any of the following therapeutic substances which are for the time being excluded from the operation of the Therapeutic Substances Act, 1925 (b) as being intended *to be used solely for veterinary purposes*, by regulations made under paragraph (*g*) of subsection (1) of section 5 of that Act, that is to say —

(*a*) Sera and antitoxins, and antigens.
(*b*) Anaerobic vaccines.
(*c*) Killed bacterial vaccines.
(*d*) Living bacterial vaccines.
(*e*) Viral vaccines

(2) For the purposes of this Order the cubic centimetre may be used wherever the millilitre is indicated.

(3) The Interpretation Act, 1889 (c) shall apply to the interpretation of this Order as it applies to the interpretation of an Act of the Parliament.

Saving as to Therapeutic Substances Act, 1925 *etc.*

3. The provisions of this Order shall be in addition to, and not in substitution for the provisions of the Therapeutic Substances Act, 1925 (d) and of any Regulations made thereunder.

Revocation

4. The Diseases of Animals (Importation of Therapeutic Substances) (Northern Ireland) Order of 1936 (e) is hereby revoked.

Prohibition of Manufacture or Importation of Therapeutic Substances

5. No person shall, except under the authority of a licence issued by the Ministry and in accordance with any conditions subject to which the licence was issued, manufacture for sale, or land in Northern Ireland from any other country, any therapeutic substance :

Provided that no licence shall be issued under this Article for the manufacture or landing of any therapeutic substance the use of which

(a) 11 & 12 Geo. 6 c.52. (b) 15 & 16 Geo. 5 c.60. (c) 52 & 53 Vict. c.63.
(d) 15 & 16 Geo. 5 c.60. (e) S. R. & O. 1936/80.

in the opinion of the Ministry may spread any disease which is a disease for all or any of the purposes of the Diseases of Animals Acts.

6.—(1) Such of the forms set out in the First Schedule to this Order as may be applicable (or a form substantially to the like effect) shall be used whenever a licence under this Order is granted by the Ministry or an application for such a licence or for the renewal of a licence previously granted is made to the Ministry.

(2) Licences granted under this Order shall, unless sooner suspended or revoked, continue in force for a period of two years.

PART II — LICENCES FOR MANUFACTURE OF THERAPEUTIC SUBSTANCES

7. A licence to manufacture a therapeutic substance for sale (hereinafter referred to as a " manufacturing licence ") shall be issued subject to the special conditions, if any, set out in the relative Schedule and to the following general conditions :—

(*a*) manufacture shall be carried on only upon the premises specified in the licence ;

(*b*) the licensee shall at all times provide an adequate staff and plant and maintain the premises aforesaid in a suitable condition for the proper manufacture of the substance in respect of which the licence is issued ;

(*c*) without prejudice to the generality of the foregoing requirement, every holder of a licence to manufacture a therapeutic substance, who for any purpose engages in the culture or manipulation of pathogenic spore-bearing micro-organisms, shall provide to the satisfaction of the Ministry separate laboratories and utensils and apparatus for the culture or manipulation of such micro-organisms, and the laboratories and utensils and apparatus so provided shall not be used for the manufacture of any other therapeutic substance :

Provided that in any particular case the Ministry may, if it thinks fit, dispense with the requirements of this paragraph either wholly or in part ;

(*d*) the licensee shall either —

(i) provide and maintain an adequate staff and adequate premises and plant for carrying out such tests of the substance as, pursuant to Part V of this Order, may be required to be carried out by him, including proper housing for animals used for the purpose of such tests, or

(ii) make arrangements approved by the Ministry for such tests to be regularly carried out on behalf of the licensee ;

(*e*) the licensee shall not sell or offer for sale a therapeutic substance manufactured by him unless it has been subjected by the manufacturer, or on the manufacturer's behalf in

accordance with arrangements approved by the Ministry for the purpose of carrying out tests, to the tests prescribed in Article 16 of this Order, and has attained the standard of purity prescribed in that Article :

Provided that the Ministry may, in the case of any particular therapeutic substance, dispense with this condition either wholly or in part ;

(*f*) when the therapeutic substance is intended for sale in liquid form in containers which are sealed in such a manner that portions of the contents can be withdrawn for use on different occasions, the liquid shall contain a sufficient proportion of a suitable bacteriostatic to prevent the growth of any organism which may be accidentally introduced in the process of removing a portion of the contents of the container :

Provided that the Ministry may, in the case of any particular preparation of any therapeutic substance, dispense with this condition ;

(*g*) The following particulars shall be printed or written in indelible ink either on the label borne by the container of any therapeutic substance or on a label or wrapper affixed to any package in which any such container is issued for sale :—

(i) the name and address of the manufacturer of the final product ;

(ii) where a bacteriostatic has been added, the nature and percentage proportion of the bacteriostatic in the substance as prepared for use ;

(iii) the precautions necessary for preserving the properties of the contents to the date referred to in sub-paragraph (*d*) of paragraph (1) of Article 13 of this Order as the date to which the substance, if kept under suitable conditions, may reasonably be expected to retain its potency.

No label or wrapper shall be used for the purposes of this paragraph unless the general form of such label or wrapper has been approved by the Ministry ;

(*h*) the licensee shall keep permanent records of the details of manufacture of each batch of the substance which is issued for sale and of the application of the tests thereto in such form as to be available for inspection and to be easily identified by reference to the number of the batch as shown on the label of each container ;

(*i*) the licensee shall allow any inspector authorised by the Ministry in that behalf to enter, at all reasonable times, any premises where the manufacture is carried on and to inspect the premises and plant and any animals on the premises and

the process of manufacture and the means employed for testing the substance in accordance with the provisions of this Order and to take samples of the substance ;

(*j*) the licensee shall report immediately to the Ministry any changes in the expert staff responsible for the manufacture or testing of the substance and any material alterations in the premises or plant used for that purpose ;

(*k*) the licensee shall on request furnish to the Ministry from every batch of the substance or from such batch or batches as the Ministry may from time to time specify a sample of such amount as the Ministry may consider adequate for any examination required to be made ; and the licensee shall, if so required, furnish full protocols of the tests which have been applied ;

(*l*) if the Ministry so directs, the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under the last preceding sub-paragraph until a certificate authorising the sale of the batch has been issued to him by the Ministry ;

(*m*) the licensee shall, on being informed by the Ministry that any part of any batch of the substance has been found by the Ministry not to conform with the standards specified in this Order and on being directed so to do, withdraw the remainder of the batch from sale, and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch ;

(*n*) the licensee shall comply with all the relevant provisions of the Diseases of Animals (Therapeutic Substances) Act (Northern Ireland) 1935, and of this Order and with such further requirements, if any, as may be specified in any subsequent Act or Order relating to therapeutic substances.

PART III—LICENCES FOR IMPORT OF THERAPEUTIC SUBSTANCES

8. An applicant for a licence to land in Northern Ireland from any country other than Great Britain, a therapeutic substance for purposes other than those of scientific research (in this Part of this Order referred to as an " import licence ") shall furnish to the Ministry a written undertaking in a form approved by the Ministry signed by or on behalf of the person who manufactures the therapeutic substance to which the application relates (hereinafter referred to as the " manufacturer "), that for the duration of the licence —

(*a*) the applicant shall be the sole accredited agent of the manufacturer for the import of the substance ;

(*b*) the manufacturer will comply with the conditions imposed on a licensee by paragraphs (*b*) to (*j*) inclusive of Article 7 of this Order ;