

SCHEDULES

SCHEDULE 1

Section 5(2).

REGULATION OF MANUFACTURE OF AND OTHER MATTERS CONNECTED WITH VETERINARY THERAPEUTIC SUBSTANCES

Substances to which this Schedule applies

- 1 (1) Subject to the provisions of sub-paragraph (2) below, this Schedule applies—
- (a) to the therapeutic substances specified in paragraph 5 below ; and
 - (b) to any other therapeutic substances capable of being used for veterinary purposes which may from time to time be added to that paragraph as being substances the purity or potency of which cannot be adequately tested by chemical means.
- (2) In the case of any substance mentioned in sub-paragraph (1) above which is a substance to which the Therapeutic Substances Act 1956 applies, this Schedule applies to that substance in so far only as the substance is excluded from the operation of that Act, as being intended to be used solely for veterinary purposes, by regulations made under that Act.

Power to make orders as to substances to which this Schedule applies

- 2 (1) The Ministers may make orders for the following purposes—
- (a) for adding to paragraph 5 below any therapeutic substance capable of being used for veterinary purposes, the purity or potency of which cannot be adequately tested by chemical means;
 - (b) for prohibiting, except under a licence for the purpose issued by the appropriate Minister and in accordance with any conditions subject to which the licence is issued, the manufacture for sale or the importation, into Great Britain of any such substance to which this Schedule applies as may be specified in the order ;
 - (c) for prescribing the standard of strength, quality and purity of any substance in respect of which an order made for the purpose last mentioned is in force ;
 - (d) for prescribing the tests to be used for determining whether the standard prescribed as mentioned above has been attained;
 - (e) for prescribing units of standardisation ;
 - (f) for prescribing the form of licences and of applications for them, and of notices to be given in connection with them ;
 - (g) for prescribing the conditions subject to which licences may be issued, including, in the case of a licence to manufacture conditions that the manufacture shall be carried on only upon the premises specified in the licence and that the licensee shall allow any inspector authorised by the Minister in that behalf to enter any premises where the manufacture is carried on, and to inspect the premises and plant and the process of manufacture

- and the means employed for standardising and testing the manufactured substance and to take samples of it;
- (h) for prescribing any other matter which under this Schedule is to be prescribed.
- (2) The Ministers may make orders as respects any such substance to which this Schedule applies as may be specified in the order—
- (a) requiring that, if advertised or sold as a proprietary medicine or contained in such medicine, such accepted scientific name or name descriptive of the true nature or origin of the substance as may be prescribed shall appear on the label;
- (b) requiring that the date of the manufacture shall be stated in the prescribed manner on all vessels or other packages in which the substance is sold or offered for sale, and prohibiting the sale of the substance after the expiry of the prescribed period from the date of manufacture;
- (c) prohibiting the sale or the offering for sale or the importation of the substance otherwise than in a vessel or other container of such character as may be prescribed, and requiring that the prescribed label or other description shall be affixed to such vessel or container.

Licences to manufacture

- 3 (1) The following provisions shall have effect with respect to licences to manufacture for sale a substance the manufacture of which otherwise than under a licence is prohibited by an order—
- (a) the licence shall be issued subject to such conditions as may be prescribed, may extend to all such substances or to such one or more of them as may be specified in the licence, shall continue in force for such period as may be prescribed, but may from time to time be renewed for a like period;
- (b) an applicant for a licence or the renewal of a licence must satisfy the appropriate Minister that the conditions under which the substance is to be manufactured by him and the premises in which it is to be manufactured are such as to comply with any order in force for the purposes of paragraph 2 above, and an applicant who so satisfies the appropriate Minister shall be entitled to the grant or renewal of the licence;
- (c) the appropriate Minister may revoke a licence or suspend it for such period as he thinks fit, if in his opinion the licensee has failed to comply with the conditions subject to which the licence was issued or with any such order as is mentioned above as to the prescribed standards of strength, quality and purity, and such revocation or suspension may apply to all the substances to which the licence extends or to some one or more of them.
- (2) A person who is aggrieved by the revocation or suspension of his licence may, subject to rules of court, appeal to the court, whose decision shall be final.
- (3) Nothing in any order prohibiting or regulating the manufacture for sale of any substance to which this Schedule applies shall apply to the preparation by a registered veterinary surgeon or practitioner—
- (a) for the treatment of any animal under his care, or
- (b) for and at the request of another such surgeon or practitioner,
- of any such substance, if it is specially prepared with reference to the condition and for the treatment of an individual animal or bird.

(4) In this paragraph—

"the court" means, as respects England and Wales, the High Court and, as respects Scotland, the Court of Session, and

"registered" means, in relation to a veterinary surgeon, registered in pursuance of the Veterinary Surgeons Act 1966 in the register of veterinary surgeons and, in relation to a veterinary practitioner registered in pursuance of that Act in the Supplementary Veterinary Register.

Licences to import

4 The issue of a licence to import a substance the importation of which otherwise than under a licence is prohibited by an order shall be subject to such conditions, including conditions as to the strength, quality and purity of the substance and as to the suspension or revocation of the licence, as may be prescribed.

Therapeutic substances to which this Schedule applies

5 The therapeutic substances mentioned in paragraph 1(1)(a) above are—

- (1) The substances commonly known as vaccines, sera, toxins, antitoxins and antigens.
- (2) The substance commonly known as salvarsan (Dioxy-diamino-arseno-benzol-dihydrochloride), and analogous substances used for the specific treatment of infective disease.
- (3) Extract of the pituitary body.

Offences under this Schedule

6 A person who—

- (a) contravenes or fails to comply with any condition subject to which any such licence as is mentioned in this Schedule is issued,
- (b) sells or offers for sale or has in his possession for sale any substance to which this Schedule applies knowing it to have been manufactured or imported in contravention of an order in force for any of the purposes of paragraph 2 above,
- (c) contravenes or fails to comply with the provisions of any such order as is mentioned above,

is liable on summary conviction to a fine not exceeding £50 or, in the case of a second or subsequent conviction, to such a fine or to imprisonment for a term not exceeding 2 months, and in either case to forfeit any goods in connection with which the offence was committed, and without prejudice, if the offender is the holder of a licence, to the power of the appropriate Minister to revoke or suspend the licence.