

# Medicines Act 1968

## 1968 CHAPTER 67

An Act to make new provision with respect to medicinal products and related matters, and for purposes connected therewith.

[25th October 1968]

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

### PART I ADMINISTRATION

Ministers responsible for administration of Act.

**1.—**

(1) In this Act—

- (a) “the Health Ministers” means the following Ministers, that is to say, the Minister of Health, the Secretary of State concerned with health in Scotland and the Minister of Health and Social Services for Northern Ireland, and, in the case of anything falling to be done by the Health Ministers, means those Ministers acting jointly;
- (b) “the Agriculture Ministers” means the following Ministers, that is to say, the Minister of Agriculture, Fisheries and Food, the Secretary of State concerned with agriculture in Scotland and the Minister of Agriculture for Northern Ireland, and, in the case of anything falling to be done by the Agriculture Ministers, means those Ministers acting jointly,

and “to Ministers” means all the Ministers specified in paragraphs (a) and (b) of this subsection, and, in the case of anything falling to be done by the Ministers, means all those Ministers acting jointly.

[...]

**110.—**

[...]

(4) In relation to veterinary drugs and animal feeding stuffs in which medicinal products have been incorporated or in which any substance or article has been incorporated for a medicinal purpose, arrangements may be made between the Minister and the Minister of Agriculture for Northern Ireland, and by them varied or revoked, and fresh arrangements made by them, for the performance by the Minister of Agriculture for Northern Ireland of any function conferred or imposed by this section on the Minister; and where any such arrangements are for the time being in force this section shall have effect as if it conferred or imposed the function in question on the Minister of Agriculture for Northern Ireland.

(5) Subsections (9) and (10) of section 108 of this Act shall have effect in relation to Northern Ireland as if—

- (a) in the said subsection (9) the reference to subsections (2) to (8) of that section were a reference to subsections (2) and (3) of this section; and
- (b) in the said subsection (10) any reference to the appropriate Minister were a reference to the Minister within the meaning of this section, and for the words “the Pharmaceutical Society or any other body” there were substituted the words “any health authority” and the reference to subsections (4) to (8) of that section were a reference to subsection (3) of this section.

1946 c. 19 (N.I.).

(6) Functions conferred by or under this section on health authorities shall be deemed to have been conferred on them by the Public Health and Local Government (Administrative Provisions) Act (Northern Ireland) 1946, and the provisions of that Act shall have effect accordingly.

(7) Any expenses incurred by a health authority in consequence of this Act shall be defrayed as if those expenses had been incurred for the purposes of the Public Health and Local Government (Administrative Provisions) Act (Northern Ireland) 1946, and section 25 of that Act shall have effect accordingly.

(8) In this section “health authority” means a health authority constituted under the Public Health and Local Government (Administrative Provisions) Act (Northern Ireland) 1946.

Rights of entry.

### 111.—

(1) Subject to the following provisions of this section, any person duly authorised in writing by an enforcement authority shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises—

- (a) for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention of any provisions of this Act or of any regulations or order made under this Act which, by or under any provisions of sections 108 to 110 of this Act, that authority is required or empowered to enforce, or
- (b) generally for the purposes of the performance by the authority of their functions under this Act or under any such regulations or order.

(2) Any person duly authorised in writing by an enforcement authority shall, on production, if required, of his credentials, have a right at any reasonable time—

- (a) to enter any ship, aircraft or hover vehicle for the purpose of ascertaining whether there is in the ship, aircraft or vehicle any substance or article imported in contravention of any provisions of this Act or of any regulations or order made under this Act which, by or under any provisions of sections 108 to 110 of this Act, that authority is required or empowered to enforce;
- (b) to enter any vehicle other than a hover vehicle, any stall or place other than premises, or any home-going ship, for any purpose for which under subsection (1) of this section the person so authorised would have a right to enter any premises.

(3) Without prejudice to subsection (1) of this section, any person duly authorised in writing by the licensing authority shall, on production, if required, of his credentials, have a right at any reasonable time to enter any premises occupied by an applicant for a licence or certificate under Part II of this Act for the purpose of verifying any statement contained in the application for the licence or certificate.

(4) Admission to any premises used only as a private dwelling-house shall not be demanded as of right by virtue of the preceding provisions of this section unless twenty-four hours' notice of the intended entry has been given to the occupier.

(5) If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entering any premises for any purpose for which a person authorised by an enforcement authority has a right to enter them in accordance with the preceding provisions of this section, and is also satisfied—

- (a) that admission to the premises has been refused, or that a refusal is apprehended, and (in either case) that notice of the intention to apply for a warrant has been given to the occupier, or
- (b) that an application for admission, or the giving of such a notice, would defeat the object of the entry, or
- (c) that the case is one of urgency, or
- (d) that the premises are unoccupied or the occupier is temporarily absent,

the justice may by warrant under his hand authorise the enforcement authority, or any person duly authorised by them, to enter the premises, if need be by force.

(6) The last preceding subsection shall have effect in relation to entering any ship, aircraft, vehicle, stall or place which may be entered under subsection (2) of this section as it has effect in relation to entering any premises, as if in the last preceding subsection any reference to the occupier were a reference to the master, commander or other person in charge of the ship, aircraft, vehicle, stall or place.

(7) Any warrant granted under this section shall continue in force for a period of one month.

(8) In this section “home-going ship” means a ship plying exclusively in inland waters or engaged exclusively in coastal voyages; and for the purposes of this subsection “inland waters” means any canal, river, lake, loch, navigation or estuary and “coastal voyage” means a voyage which starts and ends in the United Kingdom and does not involve calling at any place outside the United Kingdom.

(9) In the application of this section to Scotland, references to a justice of the peace include references to the sheriff and a magistrate.

Power to inspect, take samples and seize goods and documents.

### 112.—

(1) For the purpose of ascertaining whether there is or has been a contravention of this Act or of any regulations or order made thereunder which, by or under any provisions of sections 108 to 110 of this Act an enforcement authority is required or empowered to enforce, any person duly authorised in writing by that authority shall have a right to inspect—

- (a) any substance or article appearing to him to be a medicinal product;
- (b) any article appearing to him to be a container or package used or intended to be used to contain any medicinal product or to be a label or leaflet used or intended to be used in connection with a medicinal product; or
- (c) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture or assembly of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the processes of manufacture or assembly, for testing the materials after they have been subjected to those processes.

(2) Where for the purpose specified in the preceding subsection a person authorised as mentioned in that subsection requires a sample of any substance or article appearing to him to be—

- (a) a medicinal product sold or supplied or intended to be sold or supplied, or
- (b) a substance or article used or intended to be used in the manufacture of a medicinal product,

he shall (if he does not obtain the sample by purchase) have a right to take a sample of that substance or article.

(3) For the purpose specified in subsection (1) of this section, any person authorised as mentioned in that subsection shall have a right—

- (a) to require any person carrying on a business which consists of or includes the manufacture, assembly, sale or supply of medicinal products, and any person employed in connection with such a business, to produce any books or documents relating to the business which are in his possession or under his control;
- (b) to take copies of, or of any entry in, any book or document produced in pursuance of the preceding paragraph.

(4) Any person so authorised shall have a right to seize and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under this Act is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under this Act.

(5) For the purpose of exercising any such right as is specified in subsection (4) of this section the person having that right may, so far as is reasonably necessary in order to secure that the provisions of this Act and any regulations or order made thereunder are duly observed, require any person having authority to do so to break open any container or package or open any vending machine, or to permit him to do so.

(6) Where a person seizes any substance or article (including any document) in the exercise of such a right as is specified in subsection (4) of this section, he shall inform the person from whom it is seized,

and, in the case of anything seized from a vending machine, the person whose name and address are stated on the machine as being those of the owner of the machine, or, if no name and address are so stated, the occupier of the premises on which the machine stands or to which it is affixed.

Special enforcement and sampling provisions relating to animal feeding stuffs.

**117.—**

(1) For the purposes of the application of the provisions of sections 112, 113 and 115 of this Act in relation to animal feeding stuffs, regulations made by the Agriculture Ministers may provide that any of those provisions specified in the regulations shall have effect subject to such modifications as may be so specified.

(2) Regulations made by the Agriculture Ministers—

(a) may make provision as to the manner in which samples may be taken by virtue of the provisions of section 112 of this Act as modified by any regulations made under the preceding subsection, as to the manner in which samples may be set aside, or substances or articles may be treated as samples, by virtue of the provisions of section 113 of this Act as so modified, or as to the manner in which samples may be submitted for analysis by virtue of the provisions of section 115 of this Act as so modified, and

(b) in relation to samples so taken, set aside or submitted for analysis, or substances or articles so treated as samples, may make provision (either in substitution for, or by way of modification of or addition to, any of the provisions of Schedule 3 to this Act) as to the manner in which such samples, substances and articles are to be dealt with.

(3) For the purposes of proceedings for such offences under this Act relating to animal feeding stuffs as may be prescribed by regulations made under subsection (2) of this section, the regulations may—

(a) prescribe a method of analysis to be used in analysing samples of animal feeding stuffs in order to determine what quantity or proportion (if any) of a substance or article of a description or class specified in the regulations has been incorporated in them, and

(b) provide that, on production in the proceedings of such evidence as may be so prescribed of the results of an analysis of a sample performed by the method so prescribed, evidence of the results of any analysis of any part of the sample performed by any other method shall not be admissible in those proceedings.

(4) In relation to the incorporation in animal feeding stuffs of substances or articles of any description or class specified in an order made under this subsection by the Agriculture Ministers, so much of any licence granted or animal test certificate issued under Part II of this Act as imposes any restriction or requirement by reference to the quantity to be incorporated, or the proportion in which any substance or article may be incorporated, in any animal feeding stuff shall not be taken to be contravened in any particular case if the discrepancy does not exceed such limit as may be specified by the order in relation to substances or articles of that description or class.

(5) Where a label or mark on a container or package containing any animal feeding stuff, or a leaflet supplied or to be supplied with any animal feeding stuff, specifies a quantity or proportion of a medicinal product of a particular description as being incorporated in the animal feeding stuff, section 90(2) of this Act shall not be taken to be contravened by reason only that the quantity or proportion actually incorporated in the animal feeding stuff is greater or less than that so specified, if the discrepancy does not exceed such limit as the Agriculture Ministers may by order specify in relation to medicinal products of that description, or in relation to a class of medicinal products which includes medicinal products of that description.

(6) In section 114(2)(b) of this Act the reference to section 112 of this Act shall be construed as including a reference to the provisions of that section as modified by any regulations made under this section.

(7) The powers conferred by subsection (2) of this section shall be exercisable in addition to any power exercisable by virtue of paragraph 27 of Schedule 3 to this Act.

Restrictions on disclosure of information.

**118.—**

(1) If any person discloses to any other person—

- (a) any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered by virtue of section 111 of this Act, or
- (b) any information obtained by or furnished to him in pursuance of this Act,

he shall, unless the disclosure was made in the performance of his duty, be guilty of an offence.

(2) Any person guilty of an offence under this section shall be liable—

- (a) on summary conviction, to a fine not exceeding £400;
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

Protection for officers of enforcement authorities.

**119.—**

(1) An officer of an enforcement authority shall not be personally liable in respect of any act done by him in the execution or purported execution of this Act and within the scope of his employment if he did it in the honest belief that his duty under this Act required or entitled him to do it.

(2) Where an action has been brought against an officer of an enforcement authority in respect of an act done by him in ...

[...]