Medicines Act 1968

1968 CHAPTER 67

PART II

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

General provisions and exemptions

8 Provisions as to manufacture and wholesale dealing.

(1) The following provisions of this section shall have effect without prejudice to the operation of section 7 of this Act, but subject to the exemptions and provisions referred to in paragraphs (a) to (c) of subsection (1) of that section.

(2) **[**F1Subject to subsection (2A) of this section**]**No person shall, in the course of a business carried on by him, manufacture or assemble any medicinal product except in accordance with a licence granted for the purposes of this subsection (in this Act referred to as a "manufacturer's licence").

[F2(2A) In the case of a medicinal product that is an investigational medicinal product, the restrictions imposed by subsection (2) of this section only apply—

(a) if the product has a product licence or marketing authorization, and

(b) to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that licence or authorization.**]**

[F2(2B) In subsection (2A) of this section—

"investigational medicinal product" has the meaning given by the Clinical Trials Regulations; and

"marketing authorization" means—

(a) a marketing authorization issued by a competent authority in accordance with Directive 2001/83/EC, or

(c) a marketing authorization granted by the European Commission under Council Regulation (EEC) 2309/93.**]**

[F3(3) **[**F4Subject to **[**F5subsections (3C) and (3D)**]** of this section,**]** no person shall, in the course of a business carried on by him—

(a) sell, or offer for sale, any medicinal product by way of wholesale dealing, or

(b) distribute, otherwise than by way of sale, any proprietary medicinal product **[**F6, ready-made veterinary drug or industrially produced medicinal product other than a veterinary drug**]** which has been imported, but was not consigned from a member State,

except in accordance with a **[**F7wholesale dealer's licence**]**.**]**

[F8(3A) Without prejudice to the generality of subsection (3) of this section but subject to **[**F9subsections (3C) and (3D)**]**, no person shall, in the course of a business carried on by him, distribute by way of wholesale dealing a product to which **[**F10the 2001 Directive applies**]** apply except in accordance with a wholesale dealer's licence.

(3B) Distribution of such a product by way of wholesale dealing shall not be taken to be in accordance with a wholesale dealer's licence unless, in particular, it occurs in the course of a business which is carried on at a place or places specified in the licence.

(3C) The restrictions imposed by subsections (3) and (3A) of this section do not apply to anything done in relation to a product to which **[**F10the 2001 Directive applies**]** apply by the holder of a manufacturer's licence in respect of it.**]**

[F11(3D) The restrictions imposed by subsections (3) and (3A) of this section do not apply where the product concerned is an investigational medicinal product within the meaning given by the Clinical Trials Regulations.**]**

[F12(4) Where the product which a person distributes is not a veterinary drug, subsection (3)(b) of this section shall not apply if the product is—

(a) whole human blood, human blood plasma or blood cells of human origin, **[**F13or**]**

(b) a radiopharmaceutical in which the radionuclide is in the form of a sealed source, **[**F14. . .**]**

F14(c) . . .

(5) Where the product which a person distributes is a veterinary drug, subsection (3)(b) of this section shall not apply if the product is—

(a) a vaccine, toxin or serum,

(b) a product based on radioactive isotopes,

(c) a product specially prepared for administration by a veterinary surgeon or veterinary practitioner to a particular animal or herd which is under his care,

(d) a homoeopathic medicinal product, or

(e) an additive for animal feeding stuffs to which the provisions of Council Directive 70/524/EEC apply.

(6) In this section, **[**F15homoeopathic medicinal product,**]**"proprietary medicinal product", "radiopharmaceutical" and "ready-made veterinary drug" have the same meanings as in section 7 of this Act.**]**

[F16(7) In this section any reference to distribution of a product by way of wholesale dealing is a reference to—

(a) selling or supplying it, or

(b) procuring, holding or exporting it for the purposes of sale or supply,

to a person who receives it for the purposes of—

(i) selling or supplying it, or

(ii) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person.

(8) In this Act any reference to a wholesale dealer's licence is a reference to a licence granted for the purposes of subsection (3) or (3A) of this section.**]**

Textual Amendments

F1 Words in s. 8(2) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 4(2)**

F2 S. 8(2A)(2B) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 4(3)**

F3 S. 8(3)(4) substituted for s. 8(3) by (E.W.)(S.) S.I. 1977/1050, **art. 3(2)** and (N.I.) S.R. 1977 No. 170, **reg. 4**

F4 Words in s. 8(3) inserted (14.4.1993) by S.I. 1993/834, **reg. 2(2)**

F5 Words in s. 8(3) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 4(4)**

F6 Words in s. 8(3)(b) substituted (3.4.1992) by virtue of S.I.1992/604, **regs. 3(2)**, 4

F7 Words in s. 8(3) substituted (14.4.1993) by S.I. 1993/834, **reg. 2(3)**

F8 S. 8(3A)-(3C) inserted (14.4.1993) by S.I. 1993/834, **reg. 2(4)**

F9 Words in s. 8(3A) substituted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 4(4)**

F10 Words in s. 8(3A)(3C) substituted (28.2.2002) by S.I. 2002/236, **reg. 2(a)(i)**

F11 S. 8(3D) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 4(5)**

F12 S. 8(4)(5)(6) substituted (3.4.1992) for s. 8(4) by virtue of S.I. 1992/604, **regs. 3(3)**, 4

F13 Word in s. 8(4) inserted (13.2.1994) at the end of para.(a) by S.I. 1994/276, **reg. 4(2)(a)**(which S.I. revoked and replaced defective S.I. 1994/101, before the later S.I. came into force)

F14 In S. 8(4) paragraph (c) and words immediately preceeding it omitted (13.2.1994) by virtue of S.I. 1994/276, **reg. 4(2)(b)** (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)

F15 Words in s.8(6) inserted (13.2.1994) by S.I. 1994/276, **reg. 4(3)** (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)

F16 S. 8(7)(8) added (14.4.1993) by S.I. 1993/834, **reg. 2(5)**

Modifications etc. (not altering text)

C1 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**

C2 S. 8 excluded by S.I. 1989/2325, **art. 2(3)**

C3 S. 8(2) excluded by S.I. 1979/1114, **arts. 2**, 4 and by S.I. 1979/1585, **arts. 2**, 3

C4 S. 8(3) excluded by S.I. 1989/2322, **art. 2(1)**

C5 S. 8(3) excluded by S.I. 1990/566, **art. 2(1)**

C6 S. 8(3)(*b*) excluded by S.I. 1989/2322, **art. 2(3)**

C7 S. 8(3)(b) excluded by S.I. 1990/566, **art. 2(3)**

Status:
Point in time view as at 01/05/2004. This version of this provision has been superseded.

Changes to legislation:
Medicines Act 1968, Section 8 is up to date with all changes known to be in force on or before 30 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.