Medicines Act 1968

1968 CHAPTER 67

PART II

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

General provisions and exemptions

7 General provisions as to dealing with medicinal products.

(1) The following provisions of this section shall have effect subject to—

(a) any exemption conferred by or under this Part of this Act;

(b) the provisions of this Part of this Act relating to clinical trials and medicinal tests on animals; and

(c) the provisions of section 48 of this Act.

(2) Except in accordance with a licence granted for the purposes of this section (in this Act referred to as a "product licence") no person shall, in the course of a business carried on by him, and in circumstances to which this subsection applies,—

(a) sell, supply or export any medicinal product, or

(b) procure the sale, supply or exportation of any medicinal product, or

(c) procure the manufacture or assembly of any medicinal product for sale, supply or exportation.

[F1(2A) The restrictions imposed by subsection (2) of this section shall not apply where the medicinal product concerned is a homoeopathic medicinal product in respect of which a certificate of registration has been granted.

(2B) In relation to a homoeopathic medicinal product to which the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 F2 apply but in respect of which no certificate of registration has been granted, the references in subsection (2) of this section to the activities of sale or supply and of procuring the sale or supply respectively shall be taken to include references to any activity which amounts to placing such a product on the market within the meaning of Council Directive 92/73/EEC F3 of 22 September 1992.**]**

(3) No person shall import any medicinal product except in accordance with a product licence.

[F4(3A) The restrictions imposed by subsections (2) and (3) of this section shall not apply where the medicinal product concerned is an investigational medicinal product within the meaning of the Clinical Trials Regulations.**]**

(4) In relation to an imported medicinal product, subsection (2) of this section applies to circumstances in which the person selling, supplying or exporting the medicinal product in question, or procuring the sale, supply or exportation or the manufacture or assembly for sale, supply or exportation of that product, has himself imported the product or procured its importation.

(5) In relation to any medicinal product which has not been imported, subsection (2) of this section applies to any circumstances in which the person selling, supplying or exporting the medicinal product in question, or procuring the sale, supply or exportation or the manufacture or assembly for sale, supply or exportation of that product,

[F5(a) is responsible for the composition of the product, or

[F6(b) if that product is a proprietary medicinal product **[**F7, a ready-made veterinary drug or an industrially produced medicinal product other than a veterinary drug**]**, is responsible for the placing of the product on the market in the United Kingdom.**]]**

(6) For the purposes of subsection (5) of this section a person shall be taken to be responsible for the composition of a medicinal product if (but only if) in the course of a business carried on by him—

(a) he procures the manufacture of the product to his order by another person, where the order specifies, or incorporates by reference to some other document, particulars of the composition of the product ordered, whether those particulars amount to a complete specification or not, or

(b) he manufactures the product otherwise than in pursuance of an order which fulfils the conditions specified in the preceding paragraph.

[F8(6A) Where the product which a person is responsible for placing on the market in the United Kingdom is not a veterinary drug, subsection (5)(b) of this section shall not apply if the product is—

(a) whole human blood, human blood plasma or blood cells of human origin, **[**F9or**]**

(b) a radiopharmaceutical in which the radionuclide is in the form of a sealed source, F10. . .

F10(c) . . .

(6B) Where the product which a person is responsible for placing on the market in the United Kingdom is a veterinary drug, subsection (5)(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.**]**

[F11(7) **[**F12In this section—

[F13"certificate of registration" means a certificate granted under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994;

"homoeopathic medicinal product" means any medicinal product (which may contain a number of principles) prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State;**]**

"proprietary medicinal product" means a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack;

"radiopharmaceutical" means a medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose; and**]**
" ready-made veterinary drug " means a ready-prepared veterinary drug placed on the market in the United Kingdom in a pharmaceutical form in which it may be used without further processing, not being a drug placed on the market under a special name and in a special pack; F14 . . . **]**

Textual Amendments

F1 S. 7(2A)(2B) inserted (13.2.1994) by S.I. 1994/276, **reg. 3(2)** (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)
F2 S.I. 1994/105.
F3 OJ No. L 297, 13.10.92, p. 8.
F4 S. 7(3A) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 3**
F5 Words substituted by (E.W.)(S.) S.I. 1977/1050, **art. 2(2)** and (N.I.) S.R. 1977 No. 170, **reg. 3**
F6 S. 7(5)(*b*) substituted by S.I. 1983/1724, **art. 2(2)**
F7 Words in S. 7(5)(b) substituted (3.4.1992) by S.I. 1992/604, **regs. 2(2)**, 4
F8 S. 7(6A)(6B) inserted (3.4.1992) by S.I. 1992/604, **regs. 2(3)**, 4
F9 Word inserted (13.2.1994) in s. 7(6A) at the end of (a) by S.I. 1994/276, **reg. 3(3)(a)** (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)
F10 In s. 7(6A) para.(c) and word "or"omitted (13.2.1994) by S.I.1994/276, **reg.3(3)(b)** (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)
F11 S. 7(7) substituted by S.I. 1983/1724, **art. 2(3)**
F12 Words in s. 7(7) substituted (3.4.1992) by S.I. 1992/604, **regs. 2(4)**, 4
F13 Definitions in s. 7(7) inserted (13.2.1994) by S.I. 1994/276, **reg. 3(4)** (which S.I. revoked and replaced defective S.I. 1994/101 before the latter S.I. came into force)
F14 Words in s. 7(7) repealed (3.4.1992) by S.I. 1992/604, **regs. 2(5)**, 4

Modifications etc. (not altering text)

C1 Pt. II(ss. 6–50) extended with modifications by S.I. 1985/1403, **art. 3(1)**
C2 S. 7 excluded by S.I. 1989/2325, **art. 2(1)**
C3 S. 7 excluded (11.12.1992) by S.I. 1992/2844, **art. 2**
S. 7 excluded (31.12.1994) by S.I. 1994/2986, **reg.3(1)**
S. 7 excluded (1.1.1995) by S.I. 1994/3142, **reg. 18(1)**

S. 7 excluded (1.1.1995) by S.I. 1994/3144, **reg.9(2)**

C4 S.7 excluded by S.I. 1981/164, **art. 3**

C5 S. 7(1)(a)(2)(4)(5)(6) applied (with modifications) (3.4.1992) by S.I. 1992/605, reg. 2(1)(2), **Sch.**

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 7 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.