



Medicines Act 1968

1968 CHAPTER 67

PART II

LICENCES AND CERTIFICATES RELATING TO MEDICINAL PRODUCTS

Supplementary provisions

46 Special defences under s. 45.

- (1) Where the holder of a product licence ^{F1}... is charged with an offence under the last preceding section in respect of any substance or article which has been manufactured (or, in the case of a medicinal product, manufactured or assembled) to his order by another person and has been so manufactured or assembled as not to comply with the provisions of that licence ^{F2}... which are applicable to it, it shall be a defence for him to prove—
 - (a) that he had communicated those provisions to that other person, and
 - (b) that he did not know, and could not by the exercise of reasonable care have discovered, that those provisions had not been complied with.
- (2) Where the holder of a manufacturer's licence is charged with an offence under the last preceding section in respect of any medicinal products which have been manufactured or assembled by him, in circumstances where he is not the holder of a product licence ^{F3}... which is applicable to those products, but the products were manufactured or assembled to the order of another person, it shall be a defence for him to prove that he believed, and had reasonable grounds for believing,—
 - (a) that the other person in question was the holder of a product licence applicable to those products, ^{F4}..., and
 - (b) that the products were manufactured or assembled in accordance with that product licence ^{F5}....
- (3) ^{F6}

Status: Point in time view as at 01/10/2006. This version of this provision has been superseded.

Changes to legislation: Medicines Act 1968, Section 46 is up to date with all changes known to be in force on or before 04 June 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. (See end of Document for details)

Textual Amendments

- F1** Words in s. 46(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 18(a)(i)** (with regs. 2(4), 3)
- F2** Words in s. 46(1) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 18(a)(ii)** (with regs. 2(4), 3)
- F3** Words in s. 46(2) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 18(b)(i)** (with regs. 2(4), 3)
- F4** Words in s. 46(2)(a) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 18(b)(ii)** (with regs. 2(4), 3)
- F5** Words in s. 46(2)(b) omitted (1.10.2006) by virtue of [The Veterinary Medicines Regulations 2006 \(S.I. 2006/2407\)](#), reg. 1, **Sch. 8 para. 18(b)(iii)** (with regs. 2(4), 3)
- F6** S. 46(3)(4) repealed by [Animal Health and Welfare Act 1984 \(c. 40, SIF 2:8\)](#), s. 16, Sch. 1 para. 3(3), **Sch. 2**

Modifications etc. (not altering text)

- C1** Pt. II(ss. 6–50) extended with modifications by [S.I. 1985/1403](#), **art. 3(1)**
- C2** S. 46 extended (with modifications) (14.2.1994) by [S.I. 1994/105](#), reg. 19, **Sch.4**
- C3** S. 46 amendment to earlier affecting provision [SI 1994/105 Sch. 4 \(30.10.2005\)](#) by [Medicines \(Homoeopathic Medicinal Products for Human Use\) Amendment Regulations 2005 \(S.I. 2005/2753\)](#), regs. 1(1), **19(2)**
- C4** S. 46(1) applied (with modifications)(3.4.1992) by [S.I. 1992/605](#), **reg. 2(1)(2)**,Sch.

Status:

Point in time view as at 01/10/2006. This version of this provision has been superseded.

Changes to legislation:

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