



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 or of a clinical trial certificate or animal test certificate 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 or certificate 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 or of a clinical trial certificate or animal test certificate 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, or of a clinical trial certificate or animal test certificate applicable to them, and
 - (b) that the products were manufactured or assembled in accordance with that product licence or certificate.
- (3) Where a person is charged with an offence under the last preceding section in respect of a contravention of any provision of section 40 of this Act, in a case where he is

Status: This is the original version (as it was originally enacted).

not the holder of such a product licence or animal test certificate as is mentioned in subsection (1)(a) or subsection (3)(a) of the said section 40, it shall be a defence for him to prove that he believed, and had reasonable grounds for believing.—

- (a) that another person was the holder of such a licence or certificate, and
 - (b) that the substance or article to which the contravention relates was incorporated in the animal feeding stuff in accordance with that licence or certificate.
- (4) In the last preceding subsection any reference to section 40 of this Act shall be construed as including a reference to that section as extended by section 42 of this Act.