



Health and Medicines Act 1988

1988 CHAPTER 49

Medicines—licence fees

21 Fees for licences etc. under Part II of Medicines Act 1968.

- (1) The following paragraphs shall be inserted after paragraph (a) of subsection (1) of section 1 of the ^{M1}Medicines Act 1971—
- “(aa) for the payment and recovery of such fees as are prescribed by the regulations in respect of inspections made—
 - (i) in connection with applications for the grant, renewal or variation of any such licence; or
 - (ii) during the currency of any such licence;
 - (ab) for the payment and recovery of such annual or other periodic fees (in addition to fees payable by virtue of regulations made under paragraph (aa) above) as are prescribed by the regulations in connection with the holding of any such licence and for the payment and recovery of a penalty for failure to pay a fee so prescribed at the time at which it should have been paid;
 - (ac) for the calculation of the amount of any annual or other periodic fee payable by virtue of regulations made under paragraph (ab) above by reference to one or more of the following—
 - (i) the United Kingdom turnover of a medicinal product or a number of medicinal products to which the licence relates;
 - (ii) the United Kingdom turnover of all medicinal products to which licences held by the holder of the licence relate;
 - (iii) fees received by the holder of the licence in respect of a medicinal product or a number of medicinal products to which the licence relates;
 - (iv) fees received by the holder of the licence in respect of all medicinal products to which licences held by the holder of the licence relate;

Changes to legislation: Health and Medicines Act 1988, Cross Heading: Medicines—licence fees is up to date with all changes known to be in force on or before 26 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) View outstanding changes

- (ad) for the amount of any fee payable by virtue of regulations made under paragraph (ab) above to be calculated in such manner as may be specified in the regulations—
- (i) if insufficient evidence is submitted for the calculations that would be required by regulations made under paragraph (ac) above; or
 - (ii) if no evidence is submitted for those calculations;”.
- (2) In paragraph (b) of that subsection, after the word “refund” there shall be inserted the words “, adjustment, set-off, waiver or reduction”.
- (3) The following subsection shall be inserted after that subsection—
- “(1A) In subsection (1) above—
- “medicinal product” includes—
- (a) any article or substance in relation to which provisions of Part II of the principal Act have effect by virtue of an order under section 104 or 105 of that Act; and
 - (b) any medicated feeding stuff, as defined in subsection (3B) of section 130 of the principal Act, which by virtue of an order under subsection (3A) of that section is to be treated as a medicinal product for the purposes of that Act; and
- “United Kingdom turnover” means the value, as determined under the regulations, of the aggregate of all quantities of a medicinal product, other than quantities which the regulations direct to be excluded from the calculation, which, during a period specified in the regulations—
- (a) in the case of a product licence, are sold or supplied in the United Kingdom by the holder of the licence or such other person as may be prescribed by the regulations;
 - (b) in the case of a manufacturer’s licence, are manufactured or assembled by the holder of the licence in the United Kingdom;
 - (c) in the case of a wholesale dealer’s licence, are sold by the holder of the licence by way of wholesale dealing in the United Kingdom.”
- (4) Any regulations which purport to have been made under section 1 of the ^{M2}Medicines Act 1971—
- (a) if they purport to be in force on the day this Act is passed, shall have effect and be deemed always to have had effect; and
 - (b) if they do not purport to be in force on the day this Act is passed shall be deemed to have had effect at all times when they purported to be in force, as if this section had been in force when they were made.

Marginal Citations

M1 1971 c. 69.

M2 1971 c. 69.

Changes to legislation:

Health and Medicines Act 1988, Cross Heading: Medicines—licence fees is up to date with all changes known to be in force on or before 26 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.

[View outstanding changes](#)

Changes and effects yet to be applied to the whole Act associated Parts and Chapters:

Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- Sch. 11 words repealed by [2005 asp 13 sch. 3](#)