# Medicines Act 1971

**1971 CHAPTER 69**

**1 Fees.**

(1) The Ministers may with the consent of the Treasury make regulations providing—

(a) for the payment and recovery of such fees as are prescribed by the regulations in connection with any application in pursuance of the [M1]Medicines Act 1968 (hereafter in this Act referred to as "the principal Act") for a licence, certificate or direction under Part II of that Act or for the variation or renewal of such a licence or certificate;

[F1](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;

(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;**]**

(b) for the payment of any such fee by instalments, and for the refund **[**F2, adjustment, set-off, waiver or reduction**]** of the whole or part of any such fee, in such cases as may be determined by or under the regulations;

and the regulations may include provision in respect of any such application made before the passing of this Act but after 30th June 1971.

**[**F3(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;

(b) F4...

" 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.**]**

(2) The Ministers may also make regulations—

(a) providing that subsection (5) or subsection (6) of section 27 of the principal Act (which among other things provides, in connection with an application for a licence of right, that that Act shall have effect in certain circumstances as if the licence had been granted), or either of those subsections as applied by any other provision of the principal Act, shall not apply in relation to an application while there remains unpaid a sum due by way of or on account of a fee payable by virtue of this section in respect of the application;

(b) providing for the suspension of any licence or certificate under Part II of the principal Act while there remains unpaid a sum due by way of or on account of a fee payable by virtue of this section in respect of the licence or certificate.

**[**F5(2A) In subsections (1) and (2)(b) above, any reference to a licence under Part II of the principal Act shall be taken to include a reference to a manufacturing authorisation under the Medicines for Human Use (Clinical Trials) Regulations 2004.**]**

(3) Expressions used in this section and the principal Act **[**F6(as amended) have the same meanings in this section as in that Act (as amended)**]**; and the following provisions of that Act, that is to say—

(a) subsections (1), (6) and (7) of section 128 (which among other things provide for the payment, out of money provided by Parliament and into the

Consolidated Fund respectively, of the expenses and receipts of the Ministers in consequence of that Act);

(b) subsections (2), (3)(c), (5) and (6) of section 129 (which provide for regulations under that Act to be subject to annulment and contain other supplementary provisions relating to such regulations); and

(c) paragraphs 6, 8 and 11 of Schedule 4 (which relates to Northern Ireland),

shall have effect as if any reference to that Act (except the second reference in the said paragraph 6) included a reference to this section.

(4) Subsection (3) of section 128 of the principal Act (which authorises the charging of fees in connection with applications under Part II of that Act) is hereby repealed; but any regulations in force by virtue of that subsection immediately before the passing of this Act shall have effect thereafter as if made under this section.

**Subordinate Legislation Made**

**P1** S.1: for previous exercises of this power see Index to Government Orders.

**P2** S.1: S.1(1)(2): power exercised by S.I. 1991/632.
S. 1: s. 1(1)(2) power exercised by S.I. 1991/1474

**P3** S. 1(1)(2): S. 1(1)(2) power exercised by S.I. 1991/2063

**Textual Amendments**

**F1** S. 1(1)(aa)–(ad) inserted by Health and Medicines Act 1988 (c. 49, SIF 113:2, 84), **s. 21(1)**

**F2** Words inserted by Health and Medicines Act 1988 (c. 49, SIF 113:2, 84), **s. 21(2)**

**F3** S. 1(1A) inserted by Health and Medicines Act 1988 (c. 49, SIF 113:2, 84), **s. 21(3)**

**F4** Words in s. 1(1A) omitted (1.10.2006) by virtue of The Veterinary Medicines Regulations 2006 (S.I. 2006/2407), reg. 1, **Sch. 8 para. 70** (with regs. 2(4), 3)

**F5** S. 1(2A) inserted (1.5.2004) by Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031), reg. 1, **Sch. 10 para. 20**

**F6** Words in s. 1(3) substituted (1.10.2008) by The Veterinary Medicines Regulations 2008 (S.I. 2008/2297), regs. 1, **45(2)**

**Modifications etc. (not altering text)**

**C1** Functions exercisable under this Act by Ministers jointly transferred to those Ministers and Secretary of State for Wales jointly: S.I. 1978/272, art. 2(3), **Sch. 1**

**C2** S. 1 applied (with modifications) (1.1.1995) by S.I. 1994/3144, **reg.9(12)**

**C3** S. 1 amendment to earlier affecting provision SI 1994/3144 reg. 9 (30.10.2005) by Medicines (Marketing Authorisations Etc.) Amendment Regulations 2005 (S.I. 2005/2759), regs. 1(a), **2(12)**

**C4** S. 1(1) modified (30.10.2005) by Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005 (S.I. 2005/2750), regs. 1(a), **10(6)** (with Sch. 6)

**C5** S. 1(1) modified (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), Sch. 34 para. 36(2)**Sch. 34 para. 36(3)** (with Sch. 32)

**C6** S. 1(2)(b) modified (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 36(2)(b)** (with Sch. 32)

**Marginal Citations**

**M1** 1968 c. 67.

**Changes to legislation:**
There are currently no known outstanding effects for the Medicines Act 1971, Section 1.