

1979 No. 899

MEDICINES

The Medicines (Fees) Amendment Regulations 1979

<i>Made</i> - - - -	26th July 1979
<i>Laid before Parliament</i>	3rd August 1979
<i>Coming into Operation</i>	1st September 1979

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, with the consent of the Treasury, in exercise of powers conferred by section 1(1) and (2) of the Medicines Act 1971(a) and now vested in them (b) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations, hereby make the following regulations:—

Citation and commencement

1. These regulations, which amend the Medicines (Fees) Regulations 1978(c) (hereinafter referred to as “the principal regulations”), shall come into operation on 1st September 1979 and may be cited as the Medicines (Fees) Amendment Regulations 1979.

Amendment to regulation 6 of the principal regulations

2. For paragraph (7) of regulation 6 of the principal regulations there shall be substituted the following paragraph—

“(7) If an application is for the variation of a manufacturer’s licence so as to authorise the manufacture of categories of products additional to those to which the licence relates, there shall be payable by the applicant a capital fee of £25”.

Amendment to Table A of Part I of Schedule 1 to the principal regulations

3. In column 3 of paragraphs 1 and 2 of Table A of Part I of Schedule 1 to the principal regulations under the heading Standard percentage for “0·24” there shall be substituted “0·28”.

(a) 1971 c. 69.

(b) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388), in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272), and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36), and section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(c) S.I. 1978/1121.

Amendment of Part VI of Schedule 1 to the principal regulations

4.—(1) In paragraph 1(1) of Part VI of Schedule 1 to the principal regulations after the words “the standard percentage” there shall be inserted the words “of turnover”.

(2) For paragraph 1(2) of Part VI of Schedule 1 to the principal regulations there shall be substituted the following paragraph—

“Where the circumstances set out in sub-paragraph 1(a) or (b) apply, annual fees shall be payable at the basic rate or the alternative percentage of turnover set out in column 3 of Table A, whichever is the greater”.

Amendment to paragraph 6 of Part VI of Schedule 1 to the principal regulations

5. In paragraph 6 of Part VI of Schedule 1 to the principal regulations for “£25 million”, in each place where it appears, there shall be substituted “£30 million”.

Patrick Jenkin,
Secretary of State for Social Services.

12th July 1979.

Nicholas Edwards,
Secretary of State for Wales.

13th July 1979.

George Younger,
Secretary of State for Scotland.

17th July 1979.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed this 20th day of July 1979.

(L.S.)

Peter Walker,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 23rd day of July 1979.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 23rd day of July 1979.

(L.S.)

J. A. Young,
Permanent Secretary.

We consent,

26th July 1979.

John MacGregor,
J. A. Douglas-Hamilton,
Two of the Lords Commissioners of
Her Majesty's Treasury.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations amend the Medicines (Fees) Regulations 1978 which provide for the fees payable in connection with licences granted and certificates issued under the Medicines Act 1968.

The changes introduced by these Regulations are—

- (a) to provide for a fixed rate of £25 as the capital fee payable upon an application for the variation of a manufacturer's licence to authorise the manufacture of additional categories of products;
- (b) to increase the annual fees payable in respect of product licences for both human and veterinary medicinal products by raising the standard percentages to 0.28 of turnover;
- (c) to clarify, for the removal of any doubt, that annual fees are calculated upon the standard percentage of the licence holder's turnover for the calendar year in question;
- (d) to raise the figure from which holders of product licences with large turnovers may offset half of their turnover for the purpose of calculating annual fees.

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