
STATUTORY INSTRUMENTS

1995 No. 1116

MEDICINES

The Medicines (Products for Human
Use — Fees) Regulations 1995

<i>Made</i>	- - - -	<i>20th April 1995</i>
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THE MEDICINES (PRODUCTS FOR
HUMAN USE — FEES) REGULATIONS 1995

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SCHEDULE 1 — CAPITAL FEES FOR APPLICATIONS FOR, AND VARIATIONS
TO, MARKETING AUTHORIZATIONS, LICENCES AND
CERTIFICATES

PART I — INTERPRETATION

1. In this Schedule— “active ingredient” means an ingredient of a...

PART II — CAPITAL FEES FOR APPLICATIONS FOR AUTHORIZATIONS,
LICENCES AND CERTIFICATES

1. Marketing authorizations
2. Where a major application is made by a person who...
3. (1) In this paragraph— “joint development” means the development by...

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4. (1) Subject to sub-paragraphs (2) and (3), where an application...
5. Manufacturer's licences
6. Wholesale dealer's licences
7. Clinical trial certificates

PART III — CAPITAL FEES FOR APPLICATIONS FOR VARIATIONS OF
AUTHORIZATIONS, LICENCES AND CERTIFICATES

1. Marketing authorizations
2. Subject to paragraphs 3 to 6 and 13 and 14,...
3. Where, for the purposes of Commission Regulation (EC) No. 541/95,...
4. Subject to paragraph 5, where a marketing authorization has been...
5. Paragraph 4 shall not apply where the first application for...
6. The fee payable under regulation 7(1) in connection with an...
7. Manufacturer's licences
8. The fee payable under regulation 7(1)(b) in connection with an...
9. Wholesale dealer's licences
10. The fee payable under regulation 7(1)(b) in connection with an...
11. Clinical trial certificates
12. Where an application is made for a variation to a...
13. Identical variations
14. Where more than one application for a Type II complex...

SCHEDULE 2 — FEES FOR INSPECTIONS

1. Interpretation
2. Fees
3. (1) Where any inspection at a site would be a...
4. (1) Subject to sub-paragraph (2), unless the applicant or, as...
5. (1) In the case of an inspection of a site...
6. The fee payable in respect of an inspection at a...

SCHEDULE 3 — PERIODIC FEES FOR LICENCES

PART I — INTERPRETATION

1. In this Schedule— “anthroposophic product” means a medicinal product prepared...

PART II — CALCULATION OF TURNOVER

1. (1) Subject to sub-paragraph (2), “turnover” means, for the purposes...
2. For the purposes of paragraph 1, manufacturer's prices are the...
3. (1) For the purpose of satisfying the licensing authority for...

PART III — PERIODIC FEES FOR MARKETING AUTHORIZATIONS AND
LICENCES

1. Marketing authorizations
2. Notwithstanding the provisions of paragraph 1, in the case of...
3. Subject to paragraph 4, where a marketing authorization is held...
4. (1) The appropriate fee specified in the Table in paragraph...
5. Where a marketing authorization relates to any two or more...
6. Where a reduced rate fee or a maintenance fee may...
7. Manufacturer's licences
8. Wholesale dealer's licences
9. Where in respect of any relevant fee period, the holder...

PART IV — TYPES OF MARKETING AUTHORIZATION FOR WHICH
ONLY ONE PERIODIC FEE IS PAYABLE

1. Marketing authorizations (parallel import) in respect of which separate marketing...

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2. Marketing authorizations held in respect of homoeopathic medicinal products or...

SCHEDULE 4 — TIME FOR PAYMENT OF CAPITAL FEES — APPLICATIONS MADE BY SMALL COMPANIES

1. In this Schedule a reference to an application is to...
2. In connection with a major application for a marketing authorization...
3. In connection with a complex application for a marketing authorization,...
4. In connection with an application to which paragraph 4 of...
5. In connection with an application for a manufacturer's licence or...
6. In connection with an application for a marketing authorization, manufacturer's...

SCHEDULE 5 — WAIVER, REDUCTION OR REFUND OF CAPITAL FEES

1. Where the manufacture, assembly, sale or supply of medicinal products...
2. Where, at the specific written request of the licensing authority,...
3. (1) Subject to sub-paragraphs (2) and (3), where an application...
4. Where an application for the grant of, or for a...
5. Where the same site is inspected at the same time...
6. In relation to a marketing authorization (parallel import), the fee...

SCHEDULE 6 — ADJUSTMENT, REDUCTION OR REFUND OF PERIODIC FEES

1. Where, after payment of any periodic fee payable in accordance...
2. Any sums payable to the applicant by way of refund...

Explanatory Note