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STATUTORY INSTRUMENTS

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**1991 No. 1474**

**MEDICINES**

The Medicines (Products for Human  
Use — Fees) Regulations 1991

<i>Made</i>	- - - -	<i>27th June 1991</i>
<i>Laid before Parliament</i>		<i>27th June 1991</i>
<i>Coming into force</i>		<i>18th July 1991</i>

THE MEDICINES (PRODUCTS FOR  
HUMAN USE — FEES) REGULATIONS 1991

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

PART I — INTERPRETATION

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

PART II — CAPITAL FEES FOR APPLICATIONS FOR LICENCES AND  
CERTIFICATES

1. Product licences
2. Notwithstanding the provisions of paragraph 1, in the case of...
3. Where a major application is made by a person who...
4. (1) In this paragraph— “joint development” means the development by...
5. (1) Subject to sub-paragraphs (2) and (3), where an application...

6. Manufacturers' licences
7. Wholesale dealers' licences
8. Clinical trial certificates

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

1. Product licences
2. Where a product licence has been granted in accordance with...
3. The fee payable under regulation 7(a) in connection with an...
4. The fee payable under regulation 7(a) in connection with an...
5. Manufacturers' licences
6. The fee payable under regulation 7(a) in connection with an...
7. Wholesale dealers' licences
8. The fee payable under regulation 7(a) in connection with an...
9. Clinical trial certificates
10. Where an application is made for a variation to a...
11. Identical variations
12. Where more than one complex application is made at the...

SCHEDULE 2 — FEES FOR INSPECTIONS

1. Interpretation
2. Fees
3. (1) Subject to sub-paragraph (2), unless the applicant or, as...
4. In the case of an inspection in connection with the...
5. 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) below, “turnover” means, for the...
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 LICENCES

1. Product licences
2. Notwithstanding the provisions of paragraph 1, in the case of...
3. Subject to paragraph 4 below, where a licence is held...
4. (1) The appropriate fee specified in the Table in paragraph...
5. Where a product licence relates to any two or more...
6. Where a reduced rate fee or a maintenance fee may...
7. Manufacturers' licences
8. Wholesale dealers' licences
9. Where in respect of any relevant licence fee period, the...

PART IV — TYPES OF PRODUCT LICENCE FOR WHICH ONLY ONE PERIODIC FEE IS PAYABLE

1. Product licences (parallel import) held by the same person each...
2. Licences held in respect of homeopathic or anthroposophic products which...

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 product licence...

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3. In connection with an application to which paragraph 5 of...
4. In connection with an application for a manufacturer's licence or...
5. In connection with an application for a product licence, manufacturer's...

**SCHEDULE 5 — WAIVER, REDUCTION OR REFUND OF CAPITAL FEES**

1. Where the manufacture, assembly, sale or supply of medicinal products...
2. (1) Subject to sub-paragraph (2), where an application for the...
3. Where an application for the grant of, or a variation...
4. Where the same site is inspected at the same time...
5. In relation to a product licence (parallel import), the fee...

**SCHEDULE 6 — ADJUSTMENT, REDUCTION OR REFUND OF PERIODIC FEES**

1. (1) Subject to sub-paragraphs (2) and (3) below, where a...
2. Where, after payment of any periodic fee payable in accordance...
3. Any sums payable to the applicant by way of refund...

Explanatory Note