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STATUTORY INSTRUMENTS

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**1994 No. 105**

**MEDICINES**

**The Medicines (Homoeopathic Medicinal  
Products for Human Use) Regulations 1994**

*Made* - - - - - *19th January 1994*  
*Laid before Parliament* *24th January 1994*  
*Coming into force* *14th February 1994*

**THE MEDICINES (HOMOEOPATHIC MEDICINAL  
PRODUCTS FOR HUMAN USE) REGULATIONS 1994**

PART I

GENERAL

1. Citation, commencement and interpretation
2. Application
3. Placing on the market

PART II

CERTIFICATES OF REGISTRATION

4. Application for certificate
5. Determination of application for certificate
6. Grant of a certificate
7. Requirements in respect of controls
8. Duration and renewal of certificates
9. Suspension and revocation
10. Withdrawal from the market
11. Variation of certificates

PART III

FEEES

12. Application
13. Fees for applications for certificates
14. Fees for variations of certificates

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

15. Fees payable by holders of certificates
16. Time for payment of fees
17. Refund or waiver of fees
18. Civil proceedings to recover unpaid fees

#### PART IV

#### APPLICATION OF PROVISIONS OF THE ACT

19. Application of the Act to certificates of registration  
Signature

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#### SCHEDULE 1 — ACCOMPANYING MATERIAL AND INFORMATION FOR APPLICATIONS FOR CERTIFICATES OF REGISTRATION

1. The name or corporate name of and the permanent address...
2. Details of the scientific name or other name given in...
3. A statement of the various routes of administration, pharmaceutical forms...
4. A dossier describing how the homoeopathic stock or stocks is...
5. A manufacturing and control file for each pharmaceutical form and...
6. A copy of the manufacturer's licence or corresponding authorisation granted...
7. Copies of any registrations or authorisations obtained for the same...
8. One or more specimens of mock-ups of the sales presentation...
9. Data concerning the stability of the product.

#### SCHEDULE 2 — FEES FOR APPLICATIONS FOR THE GRANT OF CERTIFICATES OF REGISTRATION

1. Subject to paragraph 2, where an application for the grant...
2. Where an application for the grant of a certificate of...

#### SCHEDULE 3 — REFUND OR WAIVER OF FEES

1. Subject to paragraph 2, where an application for the grant...
2. If an application for the grant of a certificate is...

#### SCHEDULE 4 — APPLICATION OF PROVISIONS OF THE ACT

Explanatory Note