SCHEDULE 1

Regulation 4(1)

ACCOMPANYING MATERIAL AND INFORMATION FOR APPLICATIONS FOR CERTIFICATES OF REGISTRATION

1. The name or corporate name of and the permanent address of—

(a) the person responsible for placing the product on the market in the United Kingdom,

(b) the manufacturers and the sites involved in the different stages of the manufacture of the product (including the manufacturer of the finished product and the manufacturers of the homoeopathic stock or stocks), and

(c) where relevant, the importer of the product.

2. Details of the scientific name or other name given in a pharmacopoeia of the homoeopathic stock or stocks.

3. A statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered.

4. A dossier describing how the homoeopathic stock or stocks is or are obtained and controlled and justifying its or their homoeopathic nature.

5. A manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentization.

6. A copy of the manufacturer's licence or corresponding authorisation granted by a member State other than the United Kingdom in respect of the product.

7. Copies of any registrations or authorisations obtained for the same product in member States other than the United Kingdom.

8. One or more specimens of mock-ups of the sales presentation of the product to be registered.

9. Data concerning the stability of the product.