This Statutory Instrument has been made in consequence of a defect in S.I. 1994/102 and is being issued free of charge to all known recipients of that Statutory Instrument.

STATUTORY INSTRUMENTS

1995 No. 309

MEDICINES

The Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995

Made - - - -	*10th February 1995*
Coming into force - -	*20th February 1995*

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and agriculture in Wales and in Scotland respectively, 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, in exercise of the powers conferred by sections 4 and 129(4) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by the said provisions and now vested in them(**2**) and of all other powers enabling them in that behalf, having regard pursuant to section 4(1) of that Act to the recommendations made by the Medicines Commission under section 3(2) of that Act and after consulting such organisations as they consider appropriate pursuant to section 4(1) of that Act and those appearing to them to be representative of interests likely to be substantially affected by the following Order(**3**), hereby make the following Order—

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995 and shall come into force on 20th February 1995.

(2) In this Order—

"certificate of registration" means a certificate for the purposes of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**4**);

(**1**) 1986 c. 67. The expression "the Ministers", used in section 4(1), is defined in section 1(1)(a) of that Act as amended by S.I. 1969/388, Schedule 1.

(**2**) 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).

(**3**) See section 129(6) of the Medicines Act 1968.

(**4**) S.I. 1994/105, amended by S.I. 1994/899.

"homoeopathic medicinal product" means a medicinal product (which may contain a number of principles) prepared from products, substances or compositions called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State.

Advisory Board on the Registration of Homoeopathic Products

2.—(1) The Advisory Board on the Registration of Homoeopathic Products, provision for the establishment of which was made by article 2 of the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1994(**5**), is a committee established for the purpose of giving advice with respect to the safety and quality of—

(a) any homoeopathic medicinal product in respect of which the conditions set out in paragraph (2) below are met; and

(b) any homoeopathic medicinal product which satisfies the conditions set out in Article 7 of Council Directive 92/74/EEC(**6**),

and to which any provision of the Medicines Act 1968 is applicable.

(2) The conditions referred to in paragraph (1)(a) above are that:

(a) the product is one to which Article 2(1) of Council Directive 92/73/EEC(**7**) applies;

(b) the product is for oral or external administration;

(c) no specific therapeutic indication appears on the labelling of the product or in any information relating thereto;

(d) the product is one in respect of which—

(i) an application for a certificate of registration has been made in accordance with regulation 4(1) of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, or

(ii) an application for the renewal of such a certificate has been made in accordance with regulation 8(3) of those Regulations, or

(iii) the licensing authority proposes to suspend or revoke the certificate of registration.

Revocation

3. The Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1994 is hereby revoked.

Signed by authority of the Secretary of State for Health

Tom Sackville
Parliamentary Under Secretary of State
Department of Health

6th February 1995

(**5**) S.I. 1994/102.
(**6**) OJ No. L297, 13.10.92, p.12. This Directive widens the scope of Council Directive 81/851/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homoeopathic veterinary medicinal products.
(**7**) OJ No. L297, 13.10.92, p.8.

John Redwood
7th February 1995 Secretary of State for Wales

Fraser of Carmyllie
8th February 1995 Minister of State The Scottish Office

Angela Browning
Parliamentary Secretary, Ministry of Agriculture,
8th February 1995 Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 7th February 1995.

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 10th February 1995.

L.S.

J. Murray
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Order)

This Order revokes the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1994, which contained technical defects. It makes fresh provision for the establishment of the Advisory Board on the Registration of Homoeopathic Products, clarifying the purposes for which the Board is established.