STATUTORY INSTRUMENTS

2006 No. 2386

MEDICINES

The Medicines (Advisory Board on the Registration of Homoeopathic Products) Amendment Order 2006

Made - - - -	*29th August 2006*
Coming into force - -	*1st September 2006*

The Secretary of State for Health and the Department of Health, Social Services and Public Safety, acting jointly, make the following Order in exercise of the powers conferred on them by sections 4 and 129(4) of the Medicines Act 1968(**1**) or, as the case may be, the powers conferred by that section and now vested in them(**2**).

In accordance with section 129(6) of the Medicines Act, they have consulted such organisations as appear to them to be representative of interests likely to be substantially affected by the Order.

Citation and commencement

1. This Order may be cited as the Medicines (Advisory Board on the Registration of Homoeopathic Products) Amendment Order 2006 and shall came into force on 1st September 2006.

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

2.—(1) The Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995(**3**) is amended as follows.

(2) In article 1 (citation, commencement and interpretation), in paragraph (2), after the definition of "homoeopathic medicinal product" insert the following definitions—

(**1**) 1968 c. 67; the expression "the Health Ministers" is defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388 and by articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142. Section 4 of the Act was amended by S.I. 2004/1031, S.I. 2005/1094 and S.I. 2005/2754.

(**2**) In the case of the Secretary of State, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388 and articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142, and in the case of the Department of Health, Social Services and Public Safety, the powers vested in the Ministers in charge of that Department by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47) may now be exercised by the Department by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c.1). The Department was re-named by virtue of Article 3(6) of S.I. 1999/283 (N.I.1).

(**3**) S.I. 1995/309, amended by S.I. 2002/236 and 2005/2753.

""marketing authorization" means a marketing authorization for a national homoeopathic product granted by the licensing authority under the Marketing Authorisation Regulations(**4**);

"national homoeopathic product" has the same meaning as in regulation 4(1B) of the Marketing Authorisation Regulations;".

(3) In article 2 (Advisory Board on the Registration of Homoeopathic Products)—

(a) in paragraph (1), for the words from "the safety and quality of" to the end, substitute—

"—

(a) the safety and quality of any homoeopathic medicinal product—

(i) in respect of which a certificate of registration has been granted, or

(ii) which is the subject of an application for such a certificate; and

(b) the safety, quality and efficacy of any homoeopathic medicinal product—

(i) in respect of which a marketing authorization has been granted,

(ii) which is the subject of an application for such an authorization, or

(iii) in respect of which a licence of right has been granted."; and

(b) omit paragraph (2).

Signed by authority of the Secretary of State for Health

Andrew Burnham
Minister of State
Department of Health

18th August 2006

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

Andrew McCormick
Permanent Secretary
Department of Health, Social Services and Public Safety

29th August 2006

(**4**) S.I. 1994/3144 as amended by S.I. 2006/1952 ; *see* the definition of "the Marketing Authorisation Regulations" in section 132(1) of the Medicines Act 1968, as inserted by S.I. 2005/1094.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, to extend the functions of the Advisory Board on the Registration of Homoeopathic Products to include the provision of advice on the safety, quality and efficacy of homoeopathic medicinal products which have a product licence of right, or national homoeopathic products which have a marketing authorisation or in respect of which an application for such an authorisation is made. A national homoeopathic product is a homoeopathic medicinal product which is not eligible for the procedure for registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**5**) and which is for the relief or treatment of minor symptoms or conditions.

A full regulatory impact assessment has not been produced for this instrument as it has no impact on the costs of business.

(**5**) S.I. 1994/105, amended by S.I.2005/2753; there are other amending instruments but none is relevant.