

2006 No. 1952

MEDICINES

**The Medicines for Human Use (National Rules for
Homoeopathic Products) Regulations 2006**

<i>Made</i> - - - -	<i>19th July 2006</i>
<i>Laid before Parliament</i>	<i>21st July 2006</i>
<i>Coming into force</i> - -	<i>1st September 2006</i>

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(a). She has been designated for the purposes of that section in relation to medicinal products(b).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines for Human Use (National Rules for Homoeopathic Products) Regulations 2006.

(2) These Regulations shall come into force on 1st September 2006.

(3) In these Regulations, “the Marketing Authorisation Regulations” means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(c).

Amendment of regulation 1 of the Marketing Authorisation Regulations

2. In regulation 1 of the Marketing Authorisation Regulations (citation, commencement and interpretation)—

(a) in paragraph (2), after the definition of “first level nurse”, insert the following definition—

““national homoeopathic product” has the meaning given in regulation 4(1B);” and

(b) after paragraph (7), insert the following paragraph—

“(8) In these Regulations, in relation to a national homoeopathic product, any reference to the relevant Community provisions is to be read as a reference to those provisions as if—

(a) in Articles 19(1), 26 and 116 of the 2001 Directive, any reference to Article 8 is a reference to—

(i) Article 8, except the second and third indents of paragraph 3(i) of that Article, and

(ii) Parts 2 and 3 of Schedule 1A to these Regulations;

(a) 1972 c.68.

(b) S.I. 1972/1811.

(c) S.I. 1994/3144, relevant amending instruments are S.I. 2001/795, 2002/236, 2003/2321, 2004/3224, 2005/50, 2005/768 and 2005/2759.

- (b) in Article 21(4) of the 2001 Directive, the reference to the results of the pre-clinical tests and the clinical trials of the medicinal product concerned is a reference to the particulars and documents submitted pursuant to Parts 2 and 3 of Schedule 1A to these Regulations in relation to the medicinal product concerned; and
- (c) in Article 23 of the 2001 Directive, the reference to Articles 8(3), 10, 10a, 10b and 11, or 32(5), or Annex I is a reference to—
 - (i) Article 8(3), except the second and third indents of Article 8.3(i),
 - (ii) Articles 10, 10a, 10b and 11,
 - (iii) Annex I, other than the provisions set out in paragraph 2(1) of Schedule 1A to these Regulations, or
 - (iv) Parts 2 and 3 of Schedule 1A to these Regulations.”.

Amendment of regulation 4 of the Marketing Authorisation Regulations

3.—(1) Regulation 4 of the Marketing Authorisation Regulations (applications for the grant, renewal or variation of a United Kingdom marketing authorization) is amended as follows.

(2) In paragraph (1), after “parallel imports” insert “and paragraph (1A)”.

(3) After paragraph (1), insert the following paragraphs—

“(1A) Schedule 1A shall have effect in relation to applications for the grant of a United Kingdom marketing authorization for a national homoeopathic product.

(1B) A national homoeopathic product is a homoeopathic medicinal product which—

- (a) does not satisfy the conditions set out in article 14(1) of the 2001 Directive; and
- (b) is indicated for the relief or treatment of minor symptoms or minor conditions in humans.

(1C) For the purposes of paragraph (1B), symptoms or conditions are minor if they can ordinarily and with reasonable safety be relieved or treated without the supervision or intervention of a doctor.”.

Provisions relating to applications for national homoeopathic products

4. After Schedule 1 to the Marketing Authorisation Regulations, insert the following Schedule—

“**SCHEDULE 1A** Regulation 4(1A)

**APPLICATION FOR GRANT OF MARKETING
AUTHORIZATION FOR NATIONAL HOMOEOPATHIC
PRODUCT**

**PART 1
GENERAL**

1.—(1) An application for the grant of a United Kingdom marketing authorization for a national homoeopathic product is not required to be made in accordance with, and the applicant for such an authorization is not required to comply with—

- (a) the second and third indents of Article 8.3(i) of the 2001 Directive (the requirement to submit the results of pre-clinical tests and clinical trials); and
- (b) the provisions of Part I of Annex I to that Directive set out in paragraph 2(1).

(2) But the applicant must submit with his application particulars and documents relating to—

- (a) the safety of the medicinal product to which the application relates, in accordance with Part 2 of this Schedule; and
- (b) the efficacy of that product, in accordance with Part 3 of this Schedule.

(3) The last sub-paragraph of Article 8.3 of the 2001 Directive applies to an application referred to in sub-paragraph (1) as if the reference to the results of pre-clinical tests and clinical trials referred to in point (i) of Article 8.3 were a reference to the safety and efficacy data provided pursuant to Parts 2 and 3.

2.—(1) The provisions of Part I of Annex I to the 2001 Directive referred to in paragraph 1(1) are—

- (a) sections 2.4 to 2.7 (non-clinical and clinical overview and non-clinical and clinical summaries);
- (b) section 4 (Module 4: non-clinical reports); and
- (c) section 5 (Module 5: clinical study reports).

(2) The applicant must submit—

- (a) the particulars and documents required by Part 2 of this Schedule in place of Module 4 of the particulars and documents accompanying his application, and
- (b) the particulars and documents required by Part 3 of this Schedule in place of Module 5 of the particulars and documents accompanying his application.

(3) References in Annex I to the 2001 Directive, in provisions other than those referred to in sub-paragraph (1), to—

- (a) non-clinical reports, non-clinical documentation and non-clinical data, and
- (b) clinical study reports, clinical documentation and clinical data,

shall apply in relation to such an application as if they were references to the particulars and documents referred to in sub-paragraphs (2)(a) and (b), respectively.

(4) An application for the grant of a United Kingdom marketing authorization for a national homoeopathic product is not required to be made in accordance with, and the applicant for such an authorization is not required to comply with, the guidance referred to in paragraph (1) of Annex I (in the section headed “Introduction and general principles”), insofar as that guidance relates to the requirement to submit the results of pre-clinical tests and clinical trials.

PART 2

SAFETY DATA

3.—(1) Subject to paragraph 4, the applicant must submit data as to the safety of the medicinal product.

(2) The data submitted by the applicant—

- (a) must include data which provides information about the following aspects of the safety of the product—
 - (i) pharmacology,
 - (ii) pharmacokinetics, and
 - (iii) toxicology, including—
 - (aa) toxicity,
 - (bb) genotoxicity,
 - (cc) reproductive and developmental toxicity, and

- (dd) local tolerance,
of the medicinal product; and
 - (b) subject to sub-paragraph (4), must be scientific data.
- (3) For the purposes of sub-paragraph (2)(b), “scientific data” means—
- (a) study reports in relation to the product which is the subject of the application,
 - (b) published scientific literature,
- or a combination of both.
- (4) In relation to any aspect of safety of the product, the applicant may submit data other than scientific data if the conditions in sub-paragraph (5) are satisfied.
- (5) The conditions are that—
- (a) the applicant has made reasonable attempts to obtain scientific data in relation to that aspect; and
 - (b) having made those attempts—
 - (i) he is satisfied that no scientific data is available as to that aspect of safety, or
 - (ii) he considers that such scientific data as is available may be inadequate to demonstrate an acceptable level of safety in relation to that aspect.
- (6) The applicant must include with his data—
- (a) a table of contents;
 - (b) an evaluation of the scientific data, including an explanation as to how the data demonstrates an acceptable level of safety; and
 - (c) where the applicant is submitting data other than scientific data—
 - (i) a statement that he has met the conditions of sub-paragraph (5); and
 - (ii) an explanation as to why an acceptable level of safety can be demonstrated, notwithstanding the lack of scientific data.
- 4.—(1) The applicant is not required to submit data as to the safety of the product if—
- (a) sub-paragraph (2), (3) or (4) applies; and
 - (b) the application is accompanied by a written statement that the product satisfies the conditions set out in that sub-paragraph.
- (2) This sub-paragraph applies if the product—
- (a) is derived from a homoeopathic stock which is commonly present in food; and
 - (b) is intended to be administered orally,
- and for these purposes “food” has the meaning given to it by Regulation EC No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the Food Safety Authority and laying down procedures in matters of food safety^(a).
- (3) This sub-paragraph applies if—
- (a) the national homoeopathic product is derived from a homoeopathic stock from which a medicinal product which has a marketing authorization, certificate of registration, traditional herbal registration or product licence is derived;
 - (b) that medicinal product is within a description, or falls within a class, specified in an order under section 51 of the Act; and
 - (c) the national homoeopathic product has the same route of administration and the same degree of dilution as that medicinal product.

(a) OJ No. L 31, 1.2.2002, p.1, to which there are amendments not relevant to these Regulations.

(4) This sub-paragraph applies if the product is derived from a homoeopathic stock which—

- (a) is diluted to at least 1 in 10²⁴ of the stock, and
- (b) is not a material of biological origin.

PART 3

EFFICACY DATA

- 5. The applicant must submit data as to the efficacy of the medicinal product.
- 6. The data must consist of at least one of the following types of data—
 - (a) study reports in relation to the product which is the subject of the application,
 - (b) published scientific literature, or
 - (c) the results of investigations, commonly known as homoeopathic provings, which consist of the administration of a substance to a human subject in order to ascertain the symptoms produced by that substance.
- 7. The applicant must include with his data—
 - (a) a table of contents, and
 - (b) an evaluation of the data, including an explanation as to how the data establishes that the product has a recognised level of efficacy in the therapeutic indication for which authorization is sought.”.

Amendment of Schedule 3 to the Marketing Authorisation Regulations

- 5. In Schedule 3 to the Marketing Authorisation Regulations (offences, penalties etc)—
 - (a) in paragraph 6(a), for “or Article 6 of Council Regulation (EEC) No. 2309/93” substitute “, Article 6 of Regulation (EC) No. 726/2004 or, in the case of a holder of an authorization for a national homoeopathic product, Article 8.3 of the 2001 Directive as applied by paragraph 1(3) of Part 1 of Schedule 1A”; and
 - (b) in paragraph 6(cc), for the words after “licensing authority” substitute—
 - “as required by—
 - (i) the third paragraph of Article 23 of the 2001 Directive or, in the case of the holder of an authorization for a national homoeopathic product, that paragraph read in accordance with the modifications in regulation 1(8)(c),
 - (ii) the fourth paragraph of Article 23 of the 2001 Directive, or
 - (iii) the first paragraph of Article 23a of the 2001 Directive.”.

Signed by authority of the Secretary of State for Health

19th July 2006

Andrew Burnham
Minister of State
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (“the 1994 Regulations”), which implement the provisions of Directive 2001/83/EC on the Community code relating to medicinal products for human use (“the 2001 Directive”)(a) relating to marketing authorisations, to introduce a new scheme for applications for such authorizations for certain homoeopathic medicinal products. Article 16(2) of the 2001 Directive permits Member States to introduce in their territory specific rules for pre-clinical tests and clinical trials of such products.

Regulation 2 amends the 1994 Regulations to introduce a definition of national homoeopathic product, and to modify the expression “the relevant Community provisions” as it applies to such products. Regulations 3 and 4 and Schedule 1A set out the specific rules for applications for marketing authorisations for national homoeopathic products, as permitted by article 16(2); in particular they provide that an applicant need not comply with certain requirements in the 2001 Directive relating to the submission of the results of pre-clinical tests and clinical trials for those products and instead must comply with the requirements relating to safety and efficacy data set out in Schedule 1A. Regulation 5 amends Schedule 3 (offences, penalties etc.) so as to make it an offence for the holder of a marketing authorization for a national homoeopathic product to fail to update the data required by Schedule 1A, or to fail to supply information which might entail the amendment of that data.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. A copy of that assessment has been placed in the libraries of both Houses of Parliament.

(a) OJ L311, 28.11.2001, p.67.

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