

2005 No. 2787

MEDICINES

The Medicines (Advertising Amendments) Regulations 2005

Made - - - - *10th October 2005*

Laid before Parliament *10th October 2005*

Coming into force - - *30th October 2005*

The Secretary of State, in exercise of the powers conferred on her by section 2(2) of the European Communities Act 1972(a), being designated for the purposes of section 2(2) of the Act in relation to medicinal products(b), and the Secretary of State concerned with health in England and the Department of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred on them by sections 95(1), (2) and (3) and 129(5) of the Medicines Act 1968(c) or, as the case may be, the powers conferred by those provisions and now vested in them(d), make the following Regulations.

In accordance section 129(6) of the Medicines Act 1968, they have consulted such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Advertising Amendments) Regulations 2005 and shall come into force on 30th October 2005.

(2) In these Regulations, “the principal Regulations” means the Medicines (Advertising) Regulations 1994(e).

Amendment of regulation 2 of the principal Regulations

2. In regulation 2 of the principal Regulations (interpretation)—

(a) in the appropriate alphabetical place, insert the following definitions—

““certificate of registration” means a certificate of registration granted by the licensing authority under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(f);

(a) 1972 c.68.

(b) 1972 c.68.

(c) 1968 c. 67; the expression “the appropriate Ministers” and the expression the “Health Ministers”, which are relevant to the powers being exercised in the making of these regulations, are 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.

(d) In the case of the Secretary of State concerned with health in England, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142; and in the case of the Department for Health, Social Services and Public Safety, by virtue of the powers vested in the Minister 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) which 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 renamed by virtue of Article 3(6) of S.I. 1999/283 (N.I.1).

(e) S.I. 1994/1932; the relevant amending instruments are S.I. 1994/3144, 1996/1552, 1999/267, 2002/236 and 2004/1480.

(f) S.I. 1994/105; as amended by S.I. 1994/899, 1995/541, 1996/482, 1998/574, 1999/566, 2001/795, 2002/236 and 542, 2003/625 and 2321, and 2004/666.

“homoeopathic medicinal product” means a medicinal product (which may contain a number of principles) prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, any pharmacopoeia used officially in a Member State; and

“traditional herbal registration” means a registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005(a);”;

(b) in the definition of “the 2001 Directive”, after “as amended” insert—

“by—

(a) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(b),

(b) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(c),

(c) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use(d), and

(d) Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(e)”;

(c) for the definition of “marketing authorization” substitute—

““marketing authorization” means—

(a) a marketing authorization granted by the licensing authority under the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(f),

(b) a marketing authorization granted by the European Commission under Council Regulation (EEC) 2309/93(g) or under Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(h),

(c) an authorization granted by the licensing authority in accordance with Article 126a of the 2001 Directive, or

(d) a product licence granted by the licensing authority under Part II of the Act;”;

(d) in the definition of “relevant medicinal product”—

(i) for paragraph (a) substitute—

“(a) a medicinal product for human use to which the 2001 Directive applies and accordingly includes products to which Title II of Regulation (EC) No. 726/2004 applies, or”,

(ii) in paragraph (b), in sub-paragraph (ii), omit “or”, and

(iii) omit paragraph (c); and

(e) in the definition of “summary of product characteristics”, for “product licence” substitute “marketing authorization or traditional herbal registration”.

(a) S.I. 2005/2750.

(b) OJ No. L33, 8.2.2003, p.30.

(c) OJ No. L159, 27.6.2003, p.46.

(d) OJ No. L136, 30.4.2004, p.85.

(e) OJ No. L136, 30.4.2004, p.34.

(f) S.I. 1994/3144; relevant amending instruments S.I. 1998/3105, 2000/292, 2001/795, 2002/236, 2002/542, 2003/2321, 2004/3224 and 2005/2759.

(g) OJ No. L214, 24.8.1993, p.1.

(h) OJ No. L136, 30.4.2004, p.1.

Amendment of regulation 3 of the principal Regulations

3. In regulation 3 of the principal Regulations (prohibition of advertisements for unlicensed products), in paragraph (1) after “marketing authorization”, insert “or traditional herbal registration”.

Amendment of regulation 4 of the principal Regulations

4. In regulation 4 of the principal Regulations (duties of licence holders), for “marketing authorisation” substitute “marketing authorization, traditional herbal registration or certificate of registration”.

Amendment of regulation 6 of the principal Regulations

5. In regulation 6 of the principal Regulations (prohibition of advertisements referring to specified diseases), omit paragraph (1).

Amendment of regulation 9 of the principal Regulations

6. In regulation 9 of the principal Regulations (prohibition of certain material in advertisements), in paragraph (1), omit sub-paragraph (1).

Amendment of regulation 10 of the principal Regulations

7. In regulation 10 of the principal Regulations (form and content of advertisements), for paragraph (2)(a) substitute—

“(a) the advertisement consists solely of the name of the product or its international non-proprietary name, where this exists, or the trademark (or, in the case of a registered homoeopathic medicinal product, the scientific name of the stock or stocks or its invented name), and”.

Amendment of regulation 11 of the principal Regulations

8. In regulation 11 of the principal Regulations (exception for approved vaccination campaigns), omit “6(1), ”.

Amendment of regulation 12 of the principal Regulations

9. In regulation 12 of the principal Regulations (prohibition of supply of medicinal products to the public), after “marketing authorization”, insert “, traditional herbal registration or certificate of registration”.

Amendment of regulation 17 of the principal Regulations

10. In regulation 17 of the principal Regulations (exception for promotional aids), for paragraph (a) substitute—

“(a) the advertisement consists solely of the name of the product or its international non-proprietary name or trademark (or, in the case of a registered homoeopathic medicinal product, the scientific name of the stock or stocks or its invented name); and”.

Amendment of regulation 21 of the principal Regulations

11. In regulation 21 of the principal Regulations (inducements and hospitality), for paragraphs (2) and (3) substitute—

“(2) The provisions of paragraph (1) shall not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply relevant medicinal products, provided that—

(a) such hospitality is strictly limited to the main scientific objective of the event, and

(b) it is offered only to health professionals.

(3) Subject to paragraph (4), no person shall offer hospitality (including the payment of travelling or accommodation expenses) at a meeting or event held for the promotion of relevant medicinal products unless—

- (a) such hospitality is strictly limited to the main purpose of the meeting or event, and
- (b) the person to whom it is offered is a health professional.”.

Insertion of regulation 22A of the principal Regulations

12. After regulation 22 of the principal Regulations (advertisements for registered homoeopathic medicinal products), insert—

“Advertisements for registered herbal medicinal products

22A.—(1) No person shall issue an advertisement relating to a herbal medicinal product which is marketed in the United Kingdom under a traditional herbal registration which does not contain a statement in the form specified in paragraph (2).

(2) The form specified is the words “Traditional herbal medicinal product for use in”, followed by a statement of one or more therapeutic indications for the product consistent with the terms of the traditional herbal registration for that product, followed by the words “exclusively based on long standing use.”.

(3) In this regulation, “herbal medicinal product” has the meaning given by Article 1(30) of the 2001 Directive.”.

Amendment of regulation 23 of the principal Regulations

13. In regulation 23 of the principal Regulations (offences), in paragraph (1)—

- (a) for “6(1) or (3)” substitute “6(3)”; and
- (b) for “or 22(1)” substitute “22(1) or 22A(1)”.

Omission of Schedule 1 to the principal Regulations

14. Omit Schedule 1 to the principal Regulations (diseases in respect of which advertisements to the public are prohibited).

Amendment of Schedule 2 to the principal Regulations

15. In Schedule 2 to the principal Regulations (particulars to be contained in advertisements to persons qualified to prescribe or supply)—

- (a) in paragraph 1, after “authorization” insert “, traditional herbal registration or certificate of registration”;
- (b) in paragraph 2, after “marketing authorization” insert “, traditional herbal registration or certificate of registration”;
- (c) in paragraph 5, after “authorization” insert “, registration or certificate”.

Amendment of Schedule 3 to the principal Regulations

16. In Schedule 3 to the principal Regulations (particulars to be contained in abbreviated advertisements)—

- (a) in paragraph 1, for “product licence”, substitute “marketing authorization, traditional herbal registration or certificate of registration”; and
- (b) in paragraph 4, for “licence holder”, substitute “holder of the authorization, registration or certificate”.

Amendment of Schedule 5 to the principal Regulations

17. In Schedule 5 to the principal Regulations (particulars which may be contained in advertisements for registered homoeopathic medicinal products)—

- (a) in paragraph 1, after “stock or stocks” insert “, and, where the homeopathic medicinal product is composed of two or more stocks, an invented name”; and
- (b) in paragraph 12, omit “during the use of the product”.

Amendment of the Medicines (Monitoring of Advertising) Regulations 1994

18. In regulation 2 of the Medicines (Monitoring of Advertising) Regulations 1994(a) (interpretation and application)—

- (a) in paragraph (1), after the definition of “court”, insert the following definition—
 - ““Directive 2001/83/EC” means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, as amended by—
 - (a) Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components(b),
 - (b) Commission Directive 2003/63/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(c),
 - (c) Directive 2004/24/EC of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use(d), and
 - (d) Directive 2004/27/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use(e);”;
- (b) in paragraph (6)—
 - (i) in sub-paragraphs (a) and (b), omit “ of the European Parliament and of the Council on the Community code relating to medicinal products for human use”, and
 - (ii) omit sub-paragraph (c).

Amendment of the Medicines (Data Sheet) Regulations 1972

19. In the Medicines (Data Sheet) Regulations 1972(f), in regulation 1 (citation, commencement and interpretation), in paragraph (2A), after “Council Regulation (EEC) No 2309/93”, insert “, Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency(g)”.

Signed by authority of the Secretary of State for Health

Warner
Minister of State,
Department of Health

6th October 2005

(a) S.I. 1994/1933, amended by S.I. 2002/236; there are other amending instruments but none is relevant.
(b) OJ No. L33, 8.2.2003, p.30.
(c) OJ No. L159, 27.6.2003, p.46.
(d) OJ No. L136, 30.4.2004, p.85.
(e) OJ No. L136, 30.4.2004, p.34.
(f) S.I. 1972/2076, amended by S.I. 1996/2420; there are other amending instruments but none is relevant.
(g) OJ No. L136, 30.4.2004, p.1.

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

10th October 2005

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (the 2001 Directive) and Directive 2004/24/EC of the European Parliament and Council of 31 March 2004 as regards traditional herbal medicinal products, in so far as those Directives relate to advertising. In particular, they implement paragraphs (51), (62), (64), (65), (66), (67), (68), (71) and (84) of Article 1 of Directive 2004/27/EC and Article 1(2) of Directive 2004/24/EC.

These Regulations amend the Medicines (Advertising) Regulations 1994 (the principal Regulations) by removing the prohibition on advertising medicinal products for certain diseases (regulations 5 & 14), by removing the prohibition on mentioning the grant of a marketing authorization in an advertisement for a medicinal product (regulation 6), by changing the wording of the provision relating to hospitality at promotional events for medicinal products (regulation 11) and by allowing certain alternatives to using the name of the product in advertisements on promotional aids (regulations 7 & 10).

The principal Regulations have also been amended so as to apply to products with an authorization under Article 126a of the 2001 Directive (regulation 2; see definition of “marketing authorization”), a traditional herbal registration (regulations 2, 3, 4, 12, 15 & 16) or a certificate of registration for homoeopathic medicinal products (regulations 2, 4, 9, 15 & 16), or the respective authorization or registration holder as appropriate.

These Regulations also update the references to Community legislation, in particular inserting references to Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency which replaces Council Regulation (EEC) No. 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for Evaluation of Medicinal Products.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business and Transposition Notes for the implementation of Directives 2004/27/EC and 2004/24/EC are available from the Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Copies have been placed in the libraries of both Houses of Parliament.

STATUTORY INSTRUMENTS

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