

2004 No. 1480

MEDICINES

The Medicines (Advertising) Amendment Regulations 2004

<i>Made</i>	- - - -	<i>4th June 2004</i>
<i>Laid before Parliament</i>		<i>9th June 2004</i>
<i>Coming into force</i>	- -	<i>30th June 2004</i>

The Secretary of State, in exercise of the powers conferred on him 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, as respects England, Scotland and Wales, the Secretary of State concerned with health in England, and, as respects Northern Ireland, the Department of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred on them by sections 95(1)(b) and (c) 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), and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations pursuant to section 129(6) of that Act, and after taking into account the advice of the Medicines Commission pursuant to section 129(7) of that Act, hereby make the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Medicines (Advertising) Amendment Regulations 2004 and shall come into force on the 30th June 2004.

Amendment of the Medicines (Advertising) Regulations 1994

2. The Medicines (Advertising) Regulations 1994(e) shall be amended as follows—
- (a) in regulation 6 (prohibition of advertisements referring to specified diseases)—
 - (i) in paragraph (1), omit “paragraph (2) and to”, and
 - (ii) omit paragraph (2); and
 - (b) for Schedule 1 substitute—

(a) 1972 c.68.

(b) S.I. 1972/1811.

(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 instrument is S.I. 1996/1552.

“SCHEDULE 1

DISEASES IN RESPECT OF WHICH ADVERTISEMENTS TO THE
PUBLIC ARE PROHIBITED

Chronic insomnia

Diabetes and other metabolic diseases

Malignant diseases

Serious infectious diseases including HIV-related diseases and tuberculosis

Sexually transmitted diseases.”.

Signed by authority of the Secretary of State for Health

27th May 2004

Warner
Parliamentary Under Secretary of State,
Department of Health

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

4th June 2004

D. C. Gowdy
Permanent Secretary,
Department of Health, Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Advertising) Regulations 1994 which implemented parts of Council Directive 92/28/EEC (OJ No. L113, 30.4.92, p.13) concerning the advertising of medicinal products for human use and parts of Council Directive 92/73/EEC (OJ No. L297, 13.10.1992, p.8) concerning homeopathic medicinal products for human use; both of which are now repealed and re-enacted by Directive 2001/83/EC (OJ No. L311, 28.11.2001, p.67) (see Title VIII in relation to advertising).

The Regulations amend regulation 6 and Schedule 1, which implemented article 3(2) of Council Directive 92/28/EEC (see now Article 88(2) of Directive 2001/83/EC). They remove the prohibition on advertising to the public medicinal products for the treatment, prevention or diagnosis of bone, cardiovascular, endocrine, psychiatric and joint, rheumatic and collagen diseases, genetic disorders, diseases of the liver, biliary system and pancreas, serious disorders of the eye and ear, serious gastrointestinal, neurological and muscular, renal and respiratory diseases, and serious skin disorders.

The prohibition on advertising medicinal products for chronic insomnia, diabetes and other metabolic diseases, malignant diseases, serious infectious diseases and sexually transmitted diseases remains.

A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament and copies may be obtained from the Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

STATUTORY INSTRUMENTS

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