

2007 No. 400

CONSUMER PROTECTION

The Medical Devices (Amendment) Regulations 2007

<i>Made</i>	- - - -	<i>15th February 2007</i>
<i>Laid before Parliament</i>		<i>16th February 2007</i>
<i>Coming into force</i>		
	<i>for the purposes of regulations 3 and 6</i>	<i>10th March 2007</i>
	<i>for all other purposes</i>	<i>1st September 2007</i>

The Secretary of State makes the following Regulations, in exercise of the powers conferred on her by section 2(2) of the European Communities Act 1972(a) and section 11 of the Consumer Protection Act 1987(b).

She is designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to medical devices(c).

In accordance with section 11(5) of the Consumer Protection Act 1987, she has consulted such organisations as appeared to her to be representative of interests substantially affected by these Regulations, such other persons as she considered appropriate and the Health and Safety Commission.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medical Devices (Amendment) Regulations 2007 and shall come into force—

- (a) for the purposes of regulations 3 and 6, on 10th March 2007; and
- (b) for all other purposes, on 1st September 2007.

(2) In these Regulations, “the principal Regulations” means the Medical Devices Regulations 2002(d).

Amendment of regulation 2 of the principal Regulations

2. In regulation 2 of the principal Regulations (interpretation), in paragraph (1)—

- (a) after the definition of “Directive 2003/32” insert—

(a) 1972 c.68.

(b) 1987 c.43; section 11 was amended by S.I. 2005/1083; there are other amendments but none are relevant.

(c) The Secretary of State was designated in relation to measures relating to active implantable medical devices by S.I. 1991/2289 and in relation to measures relating to medical devices other than active implantable medical devices in S.I. 1993/2661.

(d) S.I. 2002/618; as amended by S.I. 2003/1697; there are other amending instruments but none are relevant.

““Directive 2005/50” means Commission Directive 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices(a);”; and

(b) after the definition of “harmonised standard” insert—

““hip, knee or shoulder replacement” means an implantable component part of a total joint replacement system which is intended to provide a function similar to that of either a natural hip joint, a natural knee joint or a natural shoulder joint, other than ancillary components (screws, wedges, plates and instruments);”.

Amendment of regulation 3 of the principal Regulations

3. In regulation 3 of the principal Regulations (scope of the Regulations)—

(a) in paragraph (c), for “stable derivatives devices” substitute—

“—

- (i) stable derivatives devices,
- (ii) active implantable medical devices and accessories to such devices, and
- (iii) *in vitro* diagnostic medical devices and accessories to such devices;”;

(b) in paragraph (d), at the end insert “, except for active implantable medical devices, *in vitro* diagnostic medical devices and accessories to such devices”; and

(c) for paragraph (e), substitute—

“(e) transplants or tissues or cells of animal origin, unless—

- (i) a device is manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue, or
- (ii) a product is an active implantable medical device or an *in vitro* diagnostic medical device, or an accessory to such a device;”.

Amendment of regulation 4 of the principal Regulations

4. After regulation 4 of the principal Regulations (transitional provisions), insert the following regulation—

“Transitional provisions for hip, knee and shoulder replacements

4A.—(1) This regulation applies to hip, knee or shoulder replacements.

(2) Regulation 13(4) shall not apply in respect of a replacement—

(a) whose manufacturer or his authorised representative has before 1st September 2007—

- (i) fulfilled the applicable obligations imposed by Annex II, excluding Section 4 of that Annex,
- (ii) declared, in accordance with a declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it, and
- (iii) ensured that the device meets the provisions of Directive 93/42 which apply to it; and

(b) in respect of which an examination under Section 4 of Annex II has been carried out and an EC design-examination certificate under that Section has been issued before 1st September 2009.

(a) OJ No. L210, 12.8.2005, p.41.

(3) Regulation 13(4) shall not apply before 1st September 2009 in respect of a replacement—

- (a) whose manufacturer or his authorised representative has—
 - (i) fulfilled the applicable obligations imposed by Annex II, excluding Section 4 of that Annex,
 - (ii) declared, in accordance with a declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 93/42 which apply to it, and
 - (iii) ensured that the device meets the provisions of Directive 93/42 which apply to it; and
- (b) which is covered by the decision of a notified body issued in accordance with Section 3.3 or 3.4 of Annex II before 1st September 2007.

(4) Regulation 13(4) shall not apply before 1st September 2010 in respect of replacement—

- (a) whose manufacturer or his authorised representative has—
 - (i) fulfilled the applicable obligations imposed by Annex III together with Annex VI,
 - (ii) declared, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 93/42 which apply to it, and
 - (iii) ensured that the device meets the provisions of Directive 93/42 which apply to it; and
 - (b) which is covered by the decision of a notified body issued in accordance with Section 3.3 or 3.4 of Annex VI before 1st September 2007.
- (5) Regulation 13(4) shall not apply in respect of a replacement which—
- (a) satisfies the conditions set out in paragraph (4)(a) and (b);
 - (b) has been placed on the market before 1st September 2010; and
 - (b) is put into service on or after that date.”.

Amendment of regulation 7 of the principal Regulations

5. In regulation 7 of the principal Regulations (classification of general medical devices), after “Directive 2003/12”, in both places those words appear, insert “and Directive 2005/50”.

Amendment of regulation 61 of the principal Regulations

6. In regulation 61 of the principal Regulations (enforcement etc.), for paragraph (6) substitute—

“(6) In respect of an offence committed under section 12 of the 1987 Act relating to a contravention of these Regulations—

- (a) a magistrates’ court in England or Wales may try any information laid—
 - (i) if the offence was committed before 10th March 2007, within 12 months from the time when the offence is committed, or
 - (ii) if offence was committed on or after 10th March 2007, within three years from the time when the offence was committed or within one year from the discovery of the offence by the prosecutor, whichever is the earlier;
- (b) a magistrates’ court in Northern Ireland may hear and determine any complaint made—
 - (i) if the offence was committed before 10th March 2007, within 12 months from the time when the offence is committed, or

- (ii) if the offence was committed on or after 10th March 2007, within three years from the time when the offence was committed or within one year from the discovery of the offence by the prosecutor, whichever is the earlier; and
- (c) in Scotland, summary proceedings for the offence may be commenced—
 - (i) if the offence was committed before 10th March 2007, at any time within 12 months from the time when the offence is committed, or
 - (ii) if the offence was committed on or after 10th March 2007, within three years from the time when the offence was committed or within one year from the discovery of the offence by the prosecutor, whichever is the earlier.”.

Signed by authority of the Secretary of State for Health

15th February 2007

Hunt
Minister of State,
Department of Health

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medical Devices Regulations 2002 (“the principal Regulations”), which contain the legislative measures necessary for the implementation of the European Community scheme for regulating the placing on the market and putting into service of medical devices, including Council Directive 93/42/EEC of 14th June 1993 concerning medical devices^(a), as amended^(b) (“the principal Directive”).

Regulations 2, 4 and 5 amend the principal Regulations to implement Commission Directive 2005/50/EC of 11 August 2004 on the reclassification of hip, knee and shoulder joint replacements in the framework of the principal Directive. Regulations 2 and 5 require hip, knee and shoulder joint replacements to be reclassified as Class III devices, from Class IIb. Regulation 4 inserts a new regulation 4A to make related transitional provision. In particular, manufacturers of replacements which have been subject to the conformity assessment procedure under Annex II to the principal Directive (full quality assurance), as that process applies to Class IIb devices, have until 1st September 2009 to ensure that their device is subject to a complementary assessment procedure under Section 4 of Annex II and has an EC design-examination certificate. Manufacturers of replacements which have been subject to the conformity assessment procedure under Annex III (EC-type examination) coupled with Annex VI (product quality assurance) have until 1st September 2010 to ensure their device has been subject to the conformity assessment procedures applicable to class III devices. In addition, new regulation 4A(5) provides that products which have been subject to the conformity assessment procedure under Annex III with Annex VI and which have been placed on the market before 1st September 2010, may be put into service (i.e. made available to the final user) after that date.

Regulation 3 amends regulation 3 of the principal Regulations (scope) so as to provide that the Regulations apply to active implantable medical devices or *in vitro* diagnostic medical devices, or accessories to such devices, if they—

- (a) incorporate human blood, blood products, plasma or blood cells of human origin,
- (b) are transplants or tissue or cells of human origin, or incorporate or are derived from such tissues or cells, or
- (c) are transplants or tissue or cells of animal origin (other than non-viable animal tissue).

Regulation 6 amends regulation 61 of the principal Regulations (enforcement etc.) so as to provide that the time limit for commencing criminal proceedings in respect of a contravention of the Regulations committed on or after 10th March 2007 is increased from twelve months to three years from the date of the offence or one year from the discovery of the offence by the prosecutor, whichever is the earlier.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business, and a Transposition Note in relation to the implementation of Commission Directive 2005/50/EC, is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Copies have been placed in the libraries of both Houses of Parliament.

(a) OJ No. L169, 12.7.93, p.1.

(b) Council Directive 93/42/EEC has been amended by Directive 98/79/EC (OJ No. L331, 7.12.98, p.1), Directive 2000/70/EC (OJ No. L313, 13.12.2000, p.22), Directive 2001/104/EC (OJ No. L6, 10.1.2002, p.50) and Regulation (EC) No. 1882/2003 (OJ No. L284, 31.10.2003, p.1).

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