Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (Text with EEA relevance)

COMMISSION REGULATION (EU) No 722/2012

of 8 August 2012

concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 90/385/EEC of 20 June 1990 on the approximation of laws of the Member States relating to active implantable medical devices[(1)], and in particular Article 10c thereof,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(2)], and in particular Article 14b thereof,

Whereas:

(1) Specific rules for medical devices manufactured utilising tissues of animal origin were initially adopted by Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin[(3)]. This Directive was applicable only to medical devices falling within the scope of Directive 93/42/EEC.

(2) In order to maintain a high level of safety and health protection against the risk of transmitting animal spongiform encephalopathies to patients or other persons via medical devices manufactured utilising non-viable animal tissues or derivatives rendered non-viable, including custom-made devices and devices intended for clinical investigation, it is necessary to update the rules laid down in Directive 2003/32/EC on the basis of the experience with the application of this Directive and to apply them also to active implantable medical devices manufactured utilising tissues of animal origin that fall within the scope of Directive 90/385/EEC.

(3) Taking into account that this measure lays down clear and detailed rules that do not give room for diverging transposition by Member States, a Regulation is the appropriate legal instrument which shall replace Directive 2003/32/EC.

(4) Prior to being placed on the market or put into service, active implantable medical devices and medical devices of class III in accordance with the classification rules

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set out in Annex IX to Directive 93/42/EEC, whether they originate in the European Union or are imported from third countries, are subject to the conformity assessment procedures laid down in Article 9(1) of Directive 90/385/EEC and in Article 11(1) of Directive 93/42/EEC, respectively. Annex 1 to Directive 90/385/EEC and Annex I to Directive 93/42/EEC, respectively, set out the essential requirements that active implantable medical devices and other medical devices must meet in this regard.

(5) With regard to active implantable medical devices and other medical devices manufactured utilising tissues of animal origin it is necessary to adopt more detailed specifications in relation to the requirements set out in point 6 of Annex 1 to Directive 90/385/EEC and points 8.1 and 8.2 of Annex I to Directive 93/42/EEC. Moreover, it is appropriate to specify certain aspects relating to the risk analysis and risk management in the framework of the conformity assessment procedures referred to in Article 9 of Directive 90/385/EEC and Article 11 of Directive 93/42/EEC, respectively.

(6) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules concerning animal by-products not intended for human consumption[(4)] sets out provisions on the sourcing of materials used in medical devices. It is appropriate to lay down additional provisions on the use of such materials as starting tissue for the manufacture of medical devices.

(7) European and international scientific bodies, such as the European Medicines Agency[(5)], the European Food Safety Agency[(6)], the former Scientific Steering Committee[(7)] and the former Scientific Committee on Medicinal Products and Medical Devices[(8)], adopted several opinions on specified risk materials and on minimising the risk of transmitting animal spongiform encephalopathy agents which are of relevance to the safety of medical devices.

(8) The Member States should verify that the notified bodies designated to assess the conformity of medical devices manufactured utilising animal tissues have the necessary expertise and up-to-date knowledge to perform this task.

(9) The period for scrutiny granted to the competent authorities of the Member States in relation to the notified bodies' summary evaluation report should be shorter for medical devices manufactured using starting material which is certified by the European Directorate for the Quality of Medicines than in cases where uncertified material is used. In both cases, there should be a possibility to shorten the standstill period.

(10) To facilitate the smooth transition to the new requirements it is appropriate to provide for an adequate transitional period allowing for active implantable medical devices already covered by an EC design-examination certificate or by an EC type examination certificate to continue to be placed on the market and put into service.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Medical Devices set up by Article 6(2) of Directive 90/385/EEC,

HAS ADOPTED THIS REGULATION:

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Article 1

1 This Regulation lays down particular requirements in relation to the placing on the market and/or putting into service of medical devices, including active implantable medical devices, manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

2 This Regulation shall apply to animal tissues, as well as their derivatives, originating from bovine, ovine and caprine species, deer, elk, mink and cats.

3 Collagen, gelatine and tallow used for the manufacturing of medical devices shall meet at least the requirements as fit for human consumption laid down in Regulation (EC) No 1069/2009.

4 This Regulation shall not apply to any of the following:

a Tallow derivatives, processed under conditions at least as vigorous as those laid down in Section 3 of Annex I;

b medical devices referred to in paragraph 1, which are not intended to come into contact with the human body or which are intended to come into contact with intact skin only.

Article 2

For the purposes of this Regulation, the following definitions apply in addition to the definitions set out in Directive 90/385/EEC and Directive 93/42/EEC:

(a) ‘cell’ means the smallest organised unit of any living form which is capable of independent existence and of replacement of its own substance in a suitable environment;

(b) ‘tissue’ means an organisation of cells, extra-cellular constituents or both;

(c) ‘derivative’ means a material obtained from animal tissue through one or more treatments, transformations or steps of processing;

(d) ‘non-viable’ means having no potential for metabolism or multiplication;

(e) ‘TSEs’ means all transmissible spongiform encephalopathies as defined in Article 3(1)(a) of Regulation (EC) No 999/2001 of the European Parliament and of the Council[9];

(f) ‘TSE infectious agents’ means unclassified pathogenic agents which are capable of transmitting TSEs;

(g) ‘reduction, elimination or removal’ means a process by which the number of TSE infectious agents is reduced, eliminated or removed in order to prevent infection or pathogenic reaction;

(h) ‘inactivation’ means a process by which the ability to cause infection or pathogenic reaction by TSE infectious agents is reduced;

(i) ‘source country’ means the country or countries in which the animal was born, has been reared and/or has been slaughtered;

(j) ‘starting materials’ means raw materials or any other product of animal origin out of which, or with the help of which, the devices referred to in Article 1(1) are produced.

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Article 3

1 Before lodging an application for a conformity assessment pursuant to Article 9(1) of Directive 90/385/EEC or Article 11(1) of Directive 93/42/EEC, the manufacturer of medical devices referred to in Article 1(1) of this Regulation or his authorised representative shall carry out the risk analysis and risk management scheme set out in Annex I to this Regulation.

2 For custom-made devices and devices intended for clinical investigation which fall under Article 1(1), the statement of the manufacturer or his authorised representative and the documentation in accordance with Annex 6 to Directive 90/385/EEC or Annex VIII to Directive 93/42/EEC, respectively, shall also address compliance with the particular requirements set out in section 1 of Annex I to this Regulation.

Article 4

1 Member States shall verify that bodies notified under Article 11 of Directive 90/385/EEC or Article 16 of Directive 93/42/EEC have up-to-date knowledge of the medical devices referred to in Article 1(1), in order to assess the conformity of those devices with the provisions of Directive 90/385/EEC or Directive 93/42/EEC, respectively, and with the particular requirements laid down in Annex I to this Regulation. Member States shall regularly verify that those bodies maintain the required up-to-date knowledge and expertise.

Where, on the basis of that verification, it is necessary for a Member State to amend the tasks of a notified body, that Member State shall notify the Commission and the other Member States accordingly.

2 The Member States shall inform the Commission and the other Member States regarding the outcome of the verification referred to in the first sentence of paragraph 1 by 28 February 2013.

Article 5

1 Conformity assessment procedures for medical devices referred to in Article 1(1) shall include the evaluation of compliance of the devices with the essential requirements of Directive 90/385/EEC or Directive 93/42/EEC, respectively, and the particular requirements laid down in Annex I to this Regulation.

2 Notified bodies shall assess the documentation submitted by the manufacturer to verify that the benefits of the device outweigh the residual risks. Particular account shall be taken of:

a the manufacturer's risk analysis and risk management process;

b the justification for the use of animal tissues or derivatives, taking into consideration lower risk tissues or synthetic alternatives;

c the results of elimination and inactivation studies or results of the analysis of relevant literature;

d the manufacturer's control of the sources of raw materials, finished products, production process, testing, and subcontractors;

e the need to audit matters related to the sourcing and processing of animal tissues and derivatives, processes to eliminate or inactivate pathogens, including those activities carried out by suppliers.

3 Notified bodies shall, during the evaluation of the risk analysis and risk management in the framework of the conformity assessment procedure, take account of the TSE certificate of suitability issued by the European Directorate for the Quality of Medicines, hereinafter 'TSE certificate of suitability', for starting materials, where available.

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Where additional information is necessary to assess the suitability of the starting material for a given medical device, notified bodies may require submission of additional information to allow the evaluation as set out in paragraphs 1 and 2.

4 Before issuing an EC design-examination certificate or an EC type-examination certificate, the notified bodies shall, through their competent authority, hereinafter 'coordinating competent authority', inform the competent authorities of the other Member States and the Commission of their assessment carried out pursuant to paragraph 2 by means of a summary evaluation report in accordance with Annex II to this Regulation.

5 The competent authorities of the Member States may submit comments on the summary evaluation report referred to in paragraph 4 within the following deadlines:

a in relation to medical devices using starting materials for which a TSE certificate of suitability as referred to in paragraph 3 has been submitted, within four weeks from the date on which the notified body informed the coordinating competent authority pursuant to paragraph 4;

b in relation to medical devices using starting materials for which a TSE certificate of suitability has not been submitted, within 12 weeks from the date on which the notified body informed the coordinating competent authority pursuant to paragraph 4.

The competent authorities of the Member States and the Commission may agree on shortening the time periods set out in points (a) and (b).

6 The notified bodies shall give due consideration to any comments received in accordance with paragraph 5. They shall convey an explanation as regards this consideration, including any due justification not to take account of one or more of the comments received, and their final decisions to the coordinating competent authority, which shall then make these available to the Commission and the competent authorities from which comments were received.

7 The manufacturer shall collect, evaluate and submit to the notified body information regarding changes with regard to the animal tissue or derivatives used for the device or with regard to the TSE risk in relation to the device. Where such information leads to an increase of the overall TSE risk, the provisions of paragraphs 1-6 are applicable.

Article 6

Without prejudice to Article 7(2), Member States shall take all necessary steps to ensure that medical devices referred to in Article 1(1) are placed on the market and/or put into service only if they comply with the provisions of Directive 90/385/EEC or Directive 93/42/EEC, respectively, and the particular requirements laid down in this Regulation.

Article 7

1 Holders of EC design-examination certificates or EC type-examination certificates issued before 29 August 2013 for active implantable medical devices referred to in Article 1(1) shall apply to their notified body for a complementary EC design-examination certificate or EC type-examination certificate attesting compliance with the particular requirements laid down in Annex I to this Regulation.

2 Until 29 August 2014, Member States shall accept the placing on the market and the putting into service of active implantable medical devices referred to in Article 1(1) which are covered by an EC design-examination certificate or an EC type-examination certificate issued before 29 August 2013.