Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

CHAPTER VI

CONSULTATION OF COMMITTEES

Article 28

Technical requirements and their adaptation to scientific and technical progress

[[F1]The following technical requirements and their adaptation to scientific and technical progress shall be decided by the Commission:**]**

(a) requirements for the accreditation, designation, authorisation or licensing of tissue establishments;

(b) requirements for the procurement of human tissues and cells;

(c) quality system, including training;

(d) selection criteria for the donor of tissues and/or cells;

(e) laboratory tests required for donors;

(f) cell and/or tissue procurement procedures and reception at the tissue establishment;

(g) requirements for the tissue and cell preparation process;

(h) tissue and cell processing, storage and distribution;

(i) requirements for the direct distribution to the recipient of specific tissues and cells.

[[F2]Technical requirements referred to in points (a) to (i), being measures designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 29(3).

On imperative grounds of urgency, the Commission may have recourse to the urgency procedure referred to in Article 29(4) as regards technical requirements referred to in points (d) and (e) of this Article.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

F2 Inserted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 29

Committee

1 The Commission shall be assisted by a Committee.

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

[[F1]3 Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.**]**

[[F2]4 Where reference is made to this paragraph, Article 5a(1), (2), (4) and (6) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.**]**

Textual Amendments

F1 Substituted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

F2 Inserted by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny Adaptation to the regulatory procedure with scrutiny — Part Four.

Article 30

Consultation of one or more scientific committees

The Commission may consult the relevant scientific committee(s) when defining or adapting the technical requirements referred to in Article 28 to scientific and technical progress.