DECISIONS

COUNCIL DECISION

of 9 July 2013

on the position to be adopted, on behalf of the European Union, in the Joint Committee established by the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco

(2013/455/EU)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207 in conjunction with Article 218(9) thereof,

Having regard to Council Decision 2003/885/EC of 17 November 2003 concerning the conclusion of the Agreement on the application of certain Community acts on the territory of the Principality of Monaco [1], and in particular Article 3(2) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco [2] (hereinafter referred to as 'the Agreement') entered into force on 1 May 2004.

(2) Article 1(1) of the Agreement provides that the Annex to the Agreement shall be amended by the Joint Committee established by the Agreement to ensure that Union acts falling within the scope of the Agreement apply on the territory of Monaco.

(3) Since the entry into force of the Agreement, the Union has adopted a number of acts that fall within its scope and some acts appearing in the Annex have been repealed. It is therefore necessary to update the Annex to include the new acts and to delete the acts that have been repealed. In addition, it is necessary to include acts falling within the scope of the Agreement but not currently referenced in the Annex, including Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components [3] and 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, resting, processing, preservation, storage and distribution of human tissues and cells [4] because certain of their provisions apply to the manufacturing of medicinal products.

(4) The position of the Union in the Joint Committee should be based on the attached draft Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken by the European Union within the Joint Committee established by the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco shall be based on the draft Decision of the Joint Committee attached to this Decision.

Technical modifications to the draft Decision may be agreed to by the representatives of the Union in the Joint Committee without further decision of the Council.

Article 2

The Decision of the Joint Committee shall be published in the *Official Journal of the European Union*.

Article 3

This Decision shall enter into force on the day of its adoption.

Done at Brussels, 9 July 2013.

For the Council
The President
R. ŠADŽIUS

[1] OJ L 332, 19.12.2003, p. 41.
[2] OJ L 332, 19.12.2003, p. 42.
[3] OJ L 33, 8.2.2003, p 30.
[4] OJ L 102, 7.4.2004, p. 48.

DRAFT

DECISION No .../... OF THE EU-MONACO JOINT COMMITTEE

established by the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco

of ...

amending the Annex to that Agreement

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco ([1]), signed in Brussels on 4 December 2003 (hereinafter referred to as 'the Agreement'), and in particular Article 1(1) thereof,

Whereas:

(1) Since the entry into force of the Agreement on 1 May 2004, the Union has adopted a number of acts that fall within its scope and some acts appearing in the Annex have been repealed. A Decision of the Joint Committee is therefore necessary to update the Annex to include the new acts and to delete the acts that have been repealed.

(2) It is recalled that acts of the European Commission adopted in application of the acts listed in the Annex to the Agreement are applicable on the territory of Monaco without the need for a Joint Committee Decision, as provided for by Article 1(2) of the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The text set out in the Annex to the Agreement between the European Community and the Principality of Monaco on the application of certain Community acts on the territory of the Principality of Monaco is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision shall enter into force on the day of its adoption.

By the Joint Committee
The Chairman

([1]) OJ L 332, 19.12.2003, p. 42.

ANNEX

'I. **MEDICINAL PRODUCTS**

ACTS REFERRED TO

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended by:

— Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 as regards pharmacovigilance (OJ L 299, 27.10.2012, p. 1);

— Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ L 174, 1.7.2011, p. 74);

— Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use. (OJ L 348, 31.12.2010, p. 74);

— Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products (OJ L 242 15.9.2009, p. 3);

— Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products. (OJ L 168, 30.6.2009, p. 33);

— Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission (OJ L 81, 20.3.2008, p. 51);

— Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121);

— Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1);

— Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 34);

— Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, p. 85);

— Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 159, 27.6.2003, p. 46) and

— Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p 30).

2. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended by:

— Regulation (EU) no 1027/2012 of the European Parliament and of the Council of 25 October 2012 as regards pharmacovigilance. (OJ L 316, 14.11.2012, p. 38);

— Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products (OJ L 348, 31.12.2010, p. 1);

— Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11);

— Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 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 Two (OJ L 87, 31.3.2009, p. 109);

— Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004. (OJ L 324 10.12.2007, p. 121) and

— Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. (OJ L 378, 27.12.2006, p. 1).

3. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended 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 (OJ L 188, 18.7.2009, p. 14);

— Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products (OJ L 168, 30.6.2009, p. 33);

— Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11) and

— Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use (OJ L 44, 14.2.2009, p. 10).

— Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (OJ L 136, 30.4.2004, p. 58).

4. Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products, as amended by:

— Council Regulation (EC) No 2743/98 of 14 December 1998 (OJ L 345, 19.12.1998, p. 3);

— Commission Regulation (EC) No 494/2003 of 18 March 2003 (OJ L 73, 19.3.2003, p. 6);

— Council Regulation (EC) No 1905/2005 of 14 November 2005 (OJ L 304, 23.11.2005, p. 1);

— Commission Regulation (EC) No 312/2008 of 3 April 2008 (OJ L 93, 4.4.2008, p. 8);

— Commission Regulation (EC) No 249/2009 of 23 March 2009 (OJ L 79, 25.3.2009, p. 34);

— Commission Regulation (EU) No 261/2010 of 25 March 2010 (OJ L 80, 26.3.2010, p. 36);

— Commission Regulation (EU) No 301/2011 of 28 March 2011 (OJ L 81, 29.3.2011, p. 5);

— Commission Regulation (EU) No 273/2012 of 27 March 2012 (OJ L 90, 28.3.2012, p. 11) and

— Commission Regulation (EU) No 220/2013 of 13 March 2013 (OJ L 70, 14.3.2013, p. 1).

5. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

6. Commission Regulation (EC) No 668/2009 of 24 July 2009 implementing Regulation (EC) No 1394/2007 of the European Parliament and of the Council with regard to the evaluation and certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises (OJ L 194, 25.7.2009, p. 7).

7. Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin, as amended by:

— Commission Regulation (EU) No 758/2010 of 24 August 2010 (OJ L 223, 25.8.2010, p. 37);

— Commission Regulation (EU) No 759/2010 of 24 August 2010 (OJ L 223, 25.8.2010, p. 39);

— Commission Regulation (EU) No 761/2010 of 25 August 2010 (OJ L 224, 26.8.2010, p. 1);

— Commission Regulation (EU) No 890/2010 of 8 October 2010 (OJ L 266, 9.10.2010, p. 1);

— Commission Regulation (EU) No 914/2010 of 12 October 2010 (OJ L 269, 13.10.2010, p. 5);

— Commission Regulation (EU) No 362/2011 of 13 April 2011 (OJ L 100, 14.4.2011, p. 26);

— Commission Regulation (EU) No 363/2011 of 13 April 2011 (OJ L 100, 14.4.2011, p. 28);

— Commission Implementing Regulation (EU) No 84/2012 of 1 February 2012 (OJ L 30, 2.2.2012, p. 1);

— Commission Implementing Regulation (EU) No 85/2012 of 1 February 2012 (OJ L 30, 2.2.2012, p. 4);

— Commission Implementing Regulation (EU) No 86/2012 of 1 February 2012 (OJ L 30, 2.2.2012, p. 6);

— Commission Implementing Regulation (EU) No 107/2012 of 8 February 2012 (OJ L 36, 9.2.2012, p. 25);

— Commission Implementing Regulation (EU) No 122/2012 of 13 February 2012 (OJ L 40, 14.2.2012, p. 2);

— Commission Implementing Regulation (EU) No 123/2012 of 13 February 2012 (OJ L 40, 14.2.2012, p. 4);

— Commission Implementing Regulation (EU) No 201/2012 of 8 March 2012 (OJ L 71, 9.3.2012, p. 37);

— Commission Implementing Regulation (EU) No 202/2012 of 8 March 2012 (OJ L 71, 9.3.2012, p. 40);

— Commission Implementing Regulation (EU) No 221/2012 of 14 March 2012 (OJ L 75, 15.3.2012, p. 7);

— Commission Implementing Regulation (EU) No 222/2012 of 14 March 2012 (OJ L 75, 15.3.2012, p. 10);

— Commission Implementing Regulation (EU) No 436/2012 of 23 May 2012 (OJ L 134, 24.5.2012, p. 10);

— Commission Implementing Regulation (EU) No 466/2012 of 1 June 2012 (OJ L 143, 2.6.2012, p. 2);

— Commission Implementing Regulation (EU) No 1161/2012 of 7 December 2012 (OJ L 336, 8.12.2012, p. 14);

— Commission Implementing Regulation (EU) No 1186/2012 of 11 December 2012 (OJ L 338, 12.12.2012, p. 20);

— Commission Implementing Regulation (EU) No 1191/2012 of 12 December 2012 (OJ L 340, 13.12.2012, p. 35);

— Commission Implementing Regulation (EU) No 59/2013 of 23 January 2013 (OJ L 21, 24.1.2013, p. 21);

— Commission Implementing Regulation (EU) No 115/2013 of 8 February 2013 (OJ L 38, 9.2.2013, p. 11.);

— Commission Implementing Regulation (EU) No 116/2013 of 8 February 2013, (OJ L 38, 9.2.2013, p. 14);

— Commission Implementing Regulation (EU) No 394/2013 of 29 April 2013, (OJ L 118, 30.4.2013, p. 17) and

— Commission Implementing Regulation (EU) No 406/2013 of 2 May 2013, (OJ L 121, 3.5.2013, p. 42).

8. Commission Regulation (EU) No 488/2012 of 8 June 2012 amending Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 150, 9.6.2012, p. 68).

9. Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products, as amended by Commission Regulation (EU) No 712/2012 of 3 August 2012 amending Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 209, 4.8.2012, p. 4).

10. Commission Implementing Regulation (EU) No 198/2013 of 7 March 2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring (OJ L 65, 8.3.2013, p. 17).

11. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 1).

12. Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (OJ L 109, 30.4.2009, p. 10).

13. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121), as amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 (OJ L 348, 31.12.2010, p. 1).

14. Commission Regulation (EC) No 658/2007 of 14 June 2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 155, 15.6.2007, p. 10).

15. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1), as amended by:

   — Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 (OJ L 152, 16.6.2009, p. 1) and

   — Regulation (EC) No 1902/2006 of the European Parliament and of the Council of 20 December 2006 (OJ L 378, 27.12.2006, p. 20).

16. Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 92, 30.3.2006, p. 6).

17. Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises (OJ L 329, 16.12.2005, p. 4).

18. Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products (OJ L 91, 9.4.2005, p. 13).

19. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44), as amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (OJ L 87, 31.3.2009, p. 109).

20. Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (GLP) (OJ L 50, 20.2.2004, p. 28) as amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council of 11 March 2009 (OJ L 87, 31.3.2009, p. 109).

21. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).

22. Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines (OJ L 135, 3.6.2003, p. 5), as amended by:

— Commission Regulation (EC) No 1876/2004 of 28 October 2004 (OJ L 326, 29.10.2004, p. 22) and

— Commission Regulation (EC) No 1662/2005 of 11 October 2005 (OJ L 267, 12.10.2005, p. 19).

23. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1), as amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ L 188, 18.7.2009, p. 14).

24. Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70).

25. Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems. (OJ L 40, 11.2.1989, p. 8).

26. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34), as amended by:

— Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 (OJ L 378, 27.12.2006, p. 1) and

— Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ L 188, 18.7.2009, p. 14).

27. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30) (only as regards the collection and testing of blood and blood components used as starting materials for manufacturing medicinal products).

28. 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 (OJ L 102, 7.4.2004, p. 48) (only as regards the procurement, donation, coding and testing of tissue and cells, as well as the coding of donations and packaging thereof, used as starting materials for advanced therapy medicinal products as referred to in Regulation (EC) No 1394/2007 of the European Parliament and of the Council).

II. **COSMETICS**

ACTS REFERRED TO

1. Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169), as amended by:

— Council Directive 79/661/EEC of 24 July 1979 (OJ L 192, 31.7.1979, p. 35);

— Commission Directive 82/147/EEC of 11 February 1982 (OJ L 63, 6.3.1982, p. 26);

— Council Directive 82/368/EEC of 17 May 1982 (OJ L 167, 15.6.1982, p. 1);

— Commission Directive 83/191/EEC of 30 March 1983 (OJ L 109, 26.4.1983, p. 25);

— Commission Directive 83/341/EEC of 29 June 1983 (OJ L 188, 13.7.1983, p. 15);

— Commission Directive 83/496/EEC of 22 September 1983 (OJ L 275, 8.10.1983, p. 20);

— Council Directive 83/574/EEC of 26 October 1983 (OJ L 332, 28.11.1983, p. 38);

— Commission Directive 84/415/EEC of 18 July 1984 (OJ L 228, 25.8.1984, p. 31);

— Commission Directive 85/391/EEC of 16 July 1985 (OJ L 224, 22.8.1985, p. 40);

— Commission Directive 86/179/EEC of 28 February 1986 (OJ L 138, 24.5.1986, p. 40);

— Commission Directive 86/199/EEC of 26 March 1986 (OJ L 149, 3.6.1986, p. 38);

— Commission Directive 87/137/EEC of 2 February 1987 (OJ L 56, 26.2.1987, p. 20);

— Commission Directive 88/233/EEC of 2 March 1988 (OJ L 105, 26.4.1988, p. 11);

— Council Directive 88/667/EEC of 21 December 1988 (OJ L 382, 31.12.1988, p. 46);

— Commission Directive 89/174/EEC of 21 February 1989 (OJ L 64, 8.3.1989, p. 10);

— Council Directive 89/679/EEC of 21 December 1989 (OJ L 398, 30.12.1989, p. 25);

— Commission Directive 90/121/EEC of 20 February 1990 (OJ L 71, 17.3.1990, p. 40);

— Commission Directive 91/184/EEC of 12 March 1991 (OJ L 91, 12.4.1991, p. 59);

— Commission Directive 92/8/EEC of 18 February 1992 (OJ L 70, 17.3.1992, p. 23);

— Commission Directive 92/86/EEC of 21 October 1992 (OJ L 325, 11.11.1992, p. 18);

— Council Directive 93/35/EEC of 14 June 1993 (OJ L 151, 23.6.1993, p. 32);

— Commission Directive 93/47/EEC of 22 June 1993 (OJ L 203, 13.8.1993, p. 24);

— Commission Directive 94/32/EC of 29 June 1994 (OJ L 181, 15.7.1994, p. 31);

— Commission Directive 95/34/EC of 10 July 1995 (OJ L 167, 18.7.1995, p. 19);

— Commission Directive 96/41/EC of 25 June 1996 (OJ L 198, 8.8.1996, p. 36);

— Commission Directive 97/1/EC of 10 January 1997 (OJ L 16, 18.1.1997, p. 85);

— Commission Directive 97/18/EC of 17 April 1997 (OJ L 114, 1.5.1997, p. 43);

— Commission Directive 97/45/EC of 14 July 1997 (OJ L 196, 24.7.1997, p. 77);

— Commission Directive 98/16/EC of 5 March 1998 (OJ L 77, 14.3.1998, p. 44);

— Commission Directive 98/62/EC of 3 September 1998 (OJ L 253, 15.9.1998, p. 20);

— Commission Directive 2000/6/EC of 29 February 2000 (OJ L 56, 1.3.2000, p. 42);

— Commission Directive 2000/11/EC of 10 March 2000 (OJ L 65, 14.3.2000, p. 22);

— Commission Directive 2000/41/EC of 19 June 2000 (OJ L 145, 20.6.2000, p. 25);

— Commission Directive 2002/34/EC of 15 April 2002 (OJ L 102, 18.4.2002, p. 19);

— Commission Directive 2003/1/EC of 6 January 2003 (OJ L 5, 10.1.2003, p. 14);

— Commission Directive 2003/16/EC of 19 February 2003 (OJ L 46, 20.2.2003, p. 24);

— Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 (OJ L 66, 11.3.2003, p. 26);

— Commission Directive 2003/80/EC of 5 September 2003 (OJ L 224, 6.9.2003, p. 27);

— Commission Directive 2003/83/EC of 24 September 2003 (OJ L 238, 25.9.2003, p. 23);

— Commission Directive 2004/87/EC of 7 September 2004 (OJ L 287, 8.9.2004, p. 4);

— Commission Directive 2004/88/EC of 7 September 2004 (OJ L 287, 8.9.2004, p. 5);

— Commission Directive 2004/94/EC of 15 September 2004 (OJ L 294, 17.9.2004, p. 28);

— Commission Directive 2004/93/EC of 21 September 2004 (OJ L 300, 25.9.2004, p. 13);

— Commission Directive 2005/9/EC of 28 January 2005 (OJ L 27, 29.1.2005, p. 46);

— Commission Directive 2005/42/EC of 20 June 2005 (OJ L 158, 21.6.2005, p. 17);

— Commission Directive 2005/52/EC of 9 September 2005 (OJ L 234, 10.9.2005, p. 9);

— Commission Directive 2005/80/EC of 21 November 2005 (OJ L 303, 22.11.2005, p. 32);

— Commission Directive 2006/65/EC of 19 July 2006 (OJ L 198, 20.7.2006, p. 11);

— Commission Directive 2006/78/EC of 29 September 2006 (OJ L 271, 30.9.2006, p. 56);

— Commission Directive 2007/1/EC of 29 January 2007 (OJ L 25, 1.2.2007, p. 9);

— Commission Directive 2007/17/EC of 22 March 2007 (OJ L 82, 23.3.2007, p. 27);

— Commission Directive 2007/22/EC of 17 April 2007 (OJ L 101, 18.4.2007, p. 11);

— Commission Directive 2007/53/EC of 29 August 2007 (OJ L 226, 30.8.2007, p. 19);

— Commission Directive 2007/54/EC of 29 August 2007 (OJ L 226, 30.8.2007, p. 21);

— Commission Directive 2007/67/EC of 22 November 2007 (OJ L 305, 23.11.2007, p. 22);

— Commission Directive 2008/14/EC of 15 February 2008 (OJ L 42, 16.2.2008, p. 43);

— Commission Directive 2008/42/EC of 3 April 2008 (OJ L 93, 4.4.2008, p. 13);

— Commission Directive 2008/88/EC of 23 September 2008 (OJ L 256, 24.9.2008, p. 12);

— Commission Directive 2008/123/EC of 18 December 2008 (OJ L 340, 19.12.2008, p. 71);

— Directive 2008/112/EC of the European Parliament and of the Council of 16 December 2008 (OJ L 345, 23.12.2008, p. 68);

— Commission Directive 2009/6/EC of 4 February 2009 (OJ L 36, 5.2.2009, p. 15);

— Commission Directive 2009/36/EC of 16 April 2009 (OJ L 98, 17.4.2009, p. 31);

— Commission Directive 2009/129/EC of 9 October 2009 (OJ L 267, 10.10.2009, p. 18);

— Commission Directive 2009/130/EC of 12 October 2009 (OJ L 268, 13.10.2009, p. 5);

— Commission Directive 2009/134/EC of 28 October 2009 (OJ L 282, 29.10.2009, p. 15);

— Commission Directive 2009/159/EU of 16 December 2009 (OJ L 336, 18.12.2009, p. 29);

— Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 (OJ L 342, 22.12.2009, p. 59);

— Commission Directive 2009/164/EU of 22 December 2009 (OJ L 344, 23.12.2009, p. 41);

— Commission Directive 2010/3/EU of 1 February 2010 (OJ L 29, 2.2.2010, p. 5);

— Commission Directive 2010/4/EU of 8 February 2010 (OJ L 36, 9.2.2010, p. 21);

— Commission Directive 2011/59/EU of 13 May 2011 (OJ L 125, 14.5.2011, p. 17);

— Council Directive 2011/84/EU of 20 September 2011 (OJ L 283, 29.10.2011, p. 36) and

— Commission Implementing Directive 2012/21/EU of 2 August 2012 (OJ L 208, 3.8.2012, p. 8).

Directive 76/768/EEC will be repealed with effect from 11 July 2013 and will be replaced by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

2. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. (OJ L 342, 22.12.2009, p. 59), as amended by:

— Commission Regulation (EU) No 344/2013 of 4 April 2013 amending Annexes II, III, V and VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 114, 25.4.2013, p. 1) and

— Commission Regulation (EU) No 483/2013 of 24 May 2013 amending Annex III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 139, 25.5.2013, p. 8).

3. Commission Directive 80/1335/EEC of 22 December 1980 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 383, 31.12.1980, p. 27), as amended by Commission Directive 87/143/EEC of 10 February 1987 (OJ L 57, 27.2.1987, p. 56).

4. Commission Directive 82/434/EEC of 14 May 1982 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 185, 30.6.1982, p. 1), as amended by Commission Directive 90/207/EEC of 4 April 1990 (OJ L 108, 28.4.1990, p. 92).

5. Commission Directive 83/514/EEC of 27 September 1983 on the approximation of the laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 291, 24.10.1983, p. 9).

6. Commission Directive 85/490/EEC of 11 October 1985 on the approximation of laws of the Member States relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 295, 7.11.1985, p. 30).

7. Commission Directive 93/73/EEC of 9 September 1993 on the methods of analysis necessary for checking the composition of cosmetic products (OJ L 231, 14.9.1993, p. 34).

8. Commission Directive 95/17/EC of 19 June 1995 laying down detailed rules for the application of Council Directive 76/768/EEC as regards the non-inclusion of one or more ingredients on the list used for the labelling of cosmetic products (OJ L 140, 23.6.1995, p. 26), as amended by:

— Commission Directive 2006/81/EC of 23 October 2006 (OJ L 362, 20.12.2006, p. 92) and

— Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ L 236, 23.9.2003, p. 33).

Commission Directive 95/17/EC will be repealed with effect from 11 July 2013.

9. Commission Directive 95/32/EC of 7 July 1995 relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 178, 28.7.1995, p. 20).

10. Commission Directive 96/45/EC of 2 July 1996 relating to methods of analysis necessary for checking the composition of cosmetic products (OJ L 213, 22.8.1996, p. 8).

11. Commission Decision of 8 May 1996 establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (OJ L 132, 1.6.1996, p. 1) as amended by Commission Decision 2006/257/EC, (OJ L 97, 5.4.2006, p. 1).

III. **MEDICAL DEVICES**

ACTS REFERRED TO

1. Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17), as amended by:

   — Council Directive 93/42/EEC of 14 June 1993 (OJ L 169, 12.7.1993, p. 1);

   — Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1);

   — Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and

   — Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ L 247, 21.9.2007, p. 21).

2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1), as amended by:

   — Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1);

   — Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivates of human blood or human plasma (OJ L 313, 13.12.2000, p. 22);

   — Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001 amending Council Directive 93/42/EEC concerning medical devices (OJ L 6, 10.1.2002, p. 50);

   — Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1) and

   — Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 (OJ L 247, 21.9.2007, p. 21).

3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1), as amended by:

   — Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 (OJ L 284, 31.10.2003, p. 1);

   — Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 (OJ L 188, 18.7.2009, p. 14) and

   — Commission Directive 2011/100/EU of 20 December 2011 (OJ L 341, 22.12.2011, p. 50).

4. Commission Decision 2002/364/EC of 7 May 2002 on common technical specifications for in vitro diagnostic medical devices (OJ L 131, 16.5.2002, p. 17), as amended by:

   — Commission Decision 2009/108/EC of 3 February 2009 (OJ L 39, 10.2.2009, p. 34);

   — Commission Decision 2009/886/EC of 27 November 2009 (OJ L 318, 4.12.2009, p. 25) and

   — Commission Decision 2011/869/EU of 20 December 2011 (OJ L 341, 22.12.2011, p. 63).

5. Commission Directive 2003/12/EC of 3 February 2003 on the reclassification of breast implants in the framework of Directive 93/42/EEC concerning medical devices (OJ L 28, 4.2.2003, p. 43).

6. 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 (OJ L 105, 26.4.2003, p. 18).

7. 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 (OJ L 210, 12.8.2005, p. 41).

8. Commission Decision 2010/227/EU of 19 April 2010 on the European Databank on Medical Devices (Eudamed) (OJ L 102, 23.4.2010, p. 45).

9. Commission Regulation (EU) No 207/2012 of 9 March 2012 on electronic instructions for use of medical devices (OJ L 72, 10.3.2012, p. 28).

10. 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 (OJ L 212, 9.8.2012, p. 3).'