

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance)

## CHAPTER XVIII

### MISCELLANEOUS PROVISIONS

#### *Article 91*

#### **Relation with other Union legislation**

This Regulation shall be without prejudice to Council Directive 97/43/Euratom<sup>(1)</sup>, Council Directive 96/29/Euratom<sup>(2)</sup>, Directive 2001/18/EC of the European Parliament and of the Council<sup>(3)</sup>, Directive 2004/23/EC of the European Parliament and of the Council<sup>(4)</sup>, Directive 2002/98/EC of the European Parliament and of the Council<sup>(5)</sup>, Directive 2010/53/EC of the European Parliament and of the Council<sup>(6)</sup>, and Directive 2009/41/EC of the European Parliament and of the Council.<sup>(7)</sup>

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**Changes to legislation:** There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Article 91. (See end of Document for details)

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- (1) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).
- (2) Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (OJ L 159, 29.6.1996, p. 1).
- (3) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
- (4) 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).
- (5) 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).
- (6) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).
- (7) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EU) No 536/2014 of the European Parliament and of the Council, Article 91.