Table 1 – National laws governing the clinical trials application of investigational medicinal products as applicable at the time of DEEP-2 submission.

European countries
Cyprus
- **Κ.Δ.Π. 318/2006** *Regulatory Administrative Act on Medicinal Products for Human Use (Quality Control, Purchase and Prices)*, amending L. 70(I)/2001, 83(I)/2002, 35(I)/2004, 78(I)/2004, 100(I)/2004, 263(I)/2004, 13(I)/2005, 28(I)/2005, 97(I)/2005, 122(I)/2005, 20(I)/2006, 75(I)/2006 and 104(I)/2006. - **L. 1(I)/2005** *Law on the Safeguarding And Protection of Patients' Rights, 2004* - **Κ.Δ.Π. 175/2005** *Regulatory Administrative Act for the Establishment of Ethics Committees Reviewing Biomedical Research on Human Subjects*, decree and appendices supplementing L. 150(I)/2001 and enacted 31st March 2005 based on the operational guidelines of the World Health Organisation (WHO). - **Κ.Δ.Π. 452/2004** *Regulatory Administrative Act on Medicinal Products for Human Use (Quality Control, Purchase and Prices)*, amending L. 70(I)/2001, 83(I)/2002, 35(I)/2004 - **L. 150(I)/2001** *Law providing for the Establishing and Function of the National Bioethics Committee*, which was enacted in December 2001. - **L. 31(III)/2001** *Law Adopting the Oviedo Convention on Human Rights and Biomedicine.*
Greece
- **Ministerial Decree ΔΥΓ3/89292, ΦΕΚ Β1973/31-12-2003** (implementation of Directive 2001/20/EC), published in the Greek Republic Gazette No 1973 of 31 December 2003 and referred to the Minister of Health's decision DYG 3/89292. - **Ministerial Decree ΔΥΓ3α/79602, ΦΕΚ Β64/25-01-2007** (implementation of Directive 2005/28/EC) - Circular: Διαδικασία έγκρισης παρεμβατικών κλινικών δοκιμών - Standard Operating Procedures for the National Ethics Committee published in the Greek Republic Gazette No 1503 of 7 October 2004, referring to the Minister of Health's decision DYG 3(A) 69150. - Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4/4/1997) Law 2619/1998 (Gov.Gaz. /132/1998). - Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (Paris, 12/1/1998) Min. Dec. 0546/1/.732/.4898 (Gov.Gaz. 244/1998).
Italy

- Ministerial Decree 21st December 2007 - Directions for submitting the request for authorisation of a clinical trial on a medicinal product for human use to the Competent Authority, for communicating substantial amendments, for declaring the end of the trial and for the request of an opinion to the Ethics Committee
- Ministerial Decree of November 6th 2007: "Transposition of Directive 2005/28/EC relating to principles and guidelines for good clinical practice for medicines in experimental phase for human use, and requirements for the authorization to produce and to import these medicines"
- Ministerial Decree of May 12, 2006 "Minimum requirements for the institution, organization and functioning of Ethical Committee for clinical trials with medicines"
- Ministerial Decree of December 17, 2004 "Prescriptions and conditions of a general nature referring to the conduct of clinical trials of medicines with special reference to those designed to enhance clinical practice as an integral part of health and medical care"
- Legislative Decree no. 211 of June 24, 2003 "Transposition of Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for clinical use"
- Decree of the President of the Republic of September 21, 2001 "Regulations to simplify the Procedures and to Verify and Check New Systems and Experimental Therapeutic Protocols"
- Ministerial Decree of May 10, 2001 "Controlled clinical trials conducted by General Practitioners and Paediatricians"

United Kingdom

- 2010 No. 1882 MEDICINES. The Medicines for Human Use (Advanced Therapy Medicinal Products and Miscellaneous Amendments) Regulations 2010
- MEDICINES 2008 No. 941 The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008
- MEDICINES 2006 No. 2984 The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006
- MEDICINES 2005 No. 2754 The Medicines (Advisory Bodies) (No. 2) Regulations 2005
- MEDICINES 2004 No. 1031 The Medicines for Human Use (Clinical Trials) Regulations 2004

Non-European countries

Albania

n.a.

Egypt

- Resolution of the Minister of Health & Population No. 238/2003

Tunisia

- Décret n° 94-1939 du 19 septembre 1994, fixant les attributions, la composition et les modalités de fonctionnement du comité national d' éthique médicale.
- Décret n° 2001-2133 du 10 septembre 2001 modifiant et complétant le décret n° 94-1939 du 19 septembre 1994 fixant les attributions, la composition et les modalités de fonctionnement du comité national d' éthique médicale.