a) Laws governing clinical trials

- L. 1(I)/2005 Law on the Safeguarding And Protection of Patients' Rights, 2004
- L. 150(I)/2001 Law providing for the Establishing and Function of the National Bioethics Committee, which was enacted in December 2001.

b) Ad hoc provisions for paediatric trials

- Article 4 Directive 2001/20/EC implemented
- Usually both parents must give the consent. Assent is not mandatory

c) Ethics Committees / National Competent Authority

- CNBC (Cyprus National Bioethics Committee)
- Department of Medical and Public health Services of the Ministry of Health (Competent Authority)

d) Paper or electronic application / existence of a national website

Paper submission. No national databases.

e) Procedures for compiling the EU CTA form (e.g. from EudraCT or from the national database)

The EU CTA form to be completed from EudraCT.

f) Requested documents to be submitted

Documents to be submitted are available here. Specific templates for informed consent, CTA form, amendments are available.
SOURCES:

- Pharmaceutical Services (under heading Legislation, but documents are only displayed for the Greek version of the web site): http://www.moh.gov.cy/moh/phs/phs.nsf/dmlindex_en/dmlindex_en?opendocument

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