# ALBANIA[i]

**a) Laws governing clinical trials**

- Law No. 9323 on Drugs and Pharmaceutical Service, Nov 25, 2004
- Law n. 105/2014 on Drugs and Pharmaceutical Services, ratified on 31st July 2014

**b) Ad hoc provisions for paediatric trials**

- Article 4 Directive 2001/20/EC implemented

**c) Ethics Committees / National Competent Authority**

- National Ethics Committee
- 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)**

Not applicable.

**f) Requested documents to be submitted**

*A DOCUMENT CONTAINING THE PARTICULARS SPECIFIED AS FOLLOWS*:

(**a**) The name and address of:
(1) the sponsor
(2) any person that has been authorized by the sponsor to make the request on his behalf
(3) the persons taking responsibility for the initiation, management and financing (or arranging the financing) of the clinical trial
(4) the person responsible for carrying out the functions of the sponsor
(5) any other person to whom the sponsor has delegated any of his responsibilities in relation to the proposed trial.
(**b**) The address of each trial site and the names and address of the investigator responsible for the conduct of the trial at each site.
(**c**) Where the trial is to be conducted at trial sites in another State, a list of the competent authorities to which a request for authorization has been made.
(**d**) A description of any investigational medicinal product to be used in the trial.
(**e**) The name and address of the person responsible for the manufacture or importation of any finished investigational medicinal product to be used in the trial.
(**f**) The address of any premises at which the investigational medicinal product to be used in the clinical trial is to be stored.

(**g**) A description of the proposed clinical trial.

*THE FOLLOWING DOCUMENTS OR AN EXPLANATION OF WHY THAT DOCUMENT IS NOT BEING PROVIDED*

(**a**) the protocol
(**b**) the investigator's brochure for the proposed trial (if the investigational medicinal product has a marketing authorization and the product is to be used in accordance with the terms of that authorization, the summary of product characteristics relating to that product)
(**c**) any document providing evidence of any insurance to cover the liability of the sponsor and investigator
(**d**) copies of the advertisement material (including video or audio cassettes) for recruitment of research participants
(**e**) a copy of any letter inviting a subject to participate in the trial
(**f**) a copy of any questionnaire, diary or sample card to be completed by the subject in writing
(**g**) a copy of all written information to be given to a potential subject or their legal representative prior to seeking informed consent
(**h**) a copy of the form to be used to record the consent of a subject or their legal representative
(**i**) a summary curriculum vitae for the chief investigator and each investigator.

*SOURCES:* http://www.moh.gov.al/moh/index.php

[i] *This document has been prepared by TEDDY Network as part of its research activity. Information have been derived by questionnaires filled in by researchers and from official national databases where available. It does not replace the official data that can be accessed directly or are provided at the experimental site .*
*The material cannot be distributed nor re-utilised without acquiring a specific preliminary consent from the Network.*