Law of Drugs and Pharmacies in Human Medicine

(Bulgarian Drugs Act)

State Gazette 10 February 4th, 2000

CHAPTER IV

Clinical Trials of Drugs

Article 37

(1) Clinical trials with drugs may be conducted on human subjects:

1. For proving the clinical efficacy and safety of drugs which have not been granted marketing authorization in this country in the process of their scientific development;

2. For proving the clinical efficacy and safety of drugs which have been granted marketing authorization in case of a need has been identified.

(2) Drugs, which have received marketing authorization in this country for the purposes of point 2 of paragraph 1, shall be those drugs which have been entered into the register under art. 28.

(3) Clinical studies with drugs on human subjects may be conducted in compliance with the principles of Good Clinical Practice approved by the Minister of Health.

(4) The principle investigator and sponsor or a person authorized by him shall submit a application to the Executive Drug Agency for an approval of the conduct of a clinical study accompanied with documents defined in a regulation by the Minister of Health.

Article 38

A drug may be used in a clinical study as provided for in art. 37 (1), 1 if:

1. A preliminary specification of the medicinal substance and medicinal product or relevant data for compliance with the standardization document has been submitted;

2. The batches allocated for pharmaco-toxicilogical investigation are representative for manufacturing process.

3. Pharmacological and toxicological data have been obtained in compliance with the requirements of Good Laboratory Practice.

Article 39

(Repealed)

Article 40

1. The Minister of Health shall determine the composition, conditions and scope of activities of the Central Ethics Committee. It shall consist of at least 9 members. representatives of the both genders, medical and non-medical specialists.

2. Local Ethics Committees shall be established at each hospital and medical institution where clinical studies shall be conducted. The head of the relevant institution shall determine their composition. Whenever committee members are involved in the clinical study they should not participate during the vote.

3. The meetings of the committees shall be open to the public.

4. Central Ethics Committee shall be a methodological leader of the Local Ethics Committees. It shall supervise their activities and in a case of debate shall take the final decision.

5. The Local Ethics Committees and Executive Drug Agency shall perform direct control on the clinical studies and in accordance with their competence. In a case of violation they shall notify the head of the relevant medical institution and the Central Ethics Committee.

Article 41.

1. The approvals of the conduct of clinical studies under art. 37, 1, 1 are issued by the head of the relevant specialised committee under art. 21, within 2 months period from the date of submission under a motivated decision of Local Ethics Committee.

2. The conduct of a clinical study under art. 37, 1, 2 may initiate if the applicant does not receive a rejection by the Executive Director of Executive Drug Agency in a term of one month after the submission of the notification and the documents under art. 37. 4.

3. No approvals shall be granted in case the provisions of the Constitution, of the present Law and the international agreements for protection of human rights, to which Republic of Bulgaria is a party, are not obeyed.

4. A copy of the approval referred to in paragraph (1) shall be forwarded to the medical institution where a clinical study shall be conducted.

5. The principle investigators, co-investigators and the sponsors shall share the responsibility in case of affecting the health or death during the conduct of the study.

Article 42

1. The clinical studies shall be conducted under the supervision of a physician who:

1. Has not less than two years of practice after obtaining clinical speciality in the relevant medical area.

2. Has been acquainted with the results of the pharmaco-toxicological studies and the risks of the clinical study as well as with the complete documentation of the investigational drug.

1. The head of the medical institution, where the clinical study shall be conducted, shall approve the physician referred to in paragraph (1).

Article 43

(Repealed)

Article 44

The Minister of Health shall determine the conditions and the rules for the conduct of clinical studies in a regulation.

Article 45

1. Clinical studies with drugs shall be conducted only on subjects who:

1. Have given their consent after receiving a written information by the principle investigator concerning the essence, significance, scope and the potential risks of the study.

2. Are not conscripts in the armed forces, are not detained, imprisoned or sentenced to death, with the exception of the cases referred to in art. 48, (1).

3. Have been insured by the sponsor for the cases of injury or death.

Article 46

1. An informed consent referred to in art. 45 may be given only from an able person who is fully aware of the nature, significance, scope and potential risks associated

with the trial.

2. The informed consent shall be given personally and in a written form. The consent can be withdrawn at any time.

Article 47

1. Clinical studies with drugs on children and minors shall be permitted only when:

1. The drugs are intended for diagnostics or prophylaxis of diseases specific for the particular age group of children and minors.

2. The results obtained from the clinical studies on adults cannot be considered valid for children as well as minors.

(2) For conducting clinical studies on children and minors the consent of both parents shall be obtained and given under the conditions provided for in Art. 46, as well as the authorization from the relevant regional court.

(3) In case of clinical study aiming only treatment of children and minors, who do not have parents, an authorization of a relevant regional court is required.

Article 48

1. A clinical study, the immediate objective of which is the treatment the patient may be conducted, if required, to save the patient's life, for the recovery of his/her health or to alleviate his/her ailment.

2. Clinical studies on patients who are children or have been placed under partial judicial disability may be conducted only with the written informed consent of their legal representative.

3. Clinical studies on minors who have been placed under partial judicial disability may be conducted after obtaining their written informed consent and written informed consent of their parents or trustees.

4. The informed consent of the persons referred to in preceding paragraphs shall be valid only if they have been informed in writing in advance under the provisions of art. 45 (1) of the nature, the significance, the scope and the potential risks, associated with the study.

5. The consent of the persons referred to in the preceding paragraphs shall not be needed if immediate decision is required in order to save the life of the patient and if at this moment in time this consent cannot be obtained. The decision shall be taken by at least two physicians.

Article 49

The medical institution shall provide consultation with independent experts at the expense of the sponsor of the clinical study on request of the person who will be or already is subject to a clinical study, on request of the court, or on request of the persons referred to in paragraph 2 of art. 47 or paragraphs 2 and 3 of art. 48.

Article 50

No clinical study for drugs can be conducted on pregnant women or breast-feedind mothers unless the drug is needed for their treatment or cannot be tested on another group of patients.