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Rules of procedure of medical ethics committee for clinical trials, a list of data to be submitted for obtaining approval, procedure for adoption of resolutions and format of application for obtaining approval

Passed 17.02.2005 No. 17

This Regulation is established on the basis of subsection 92 (8) of the Medicinal Products Act (RT2 I 2005, 2, 4).

§ 1. Scope of application of Regulation

This Regulation establishes the rules of procedure of medical ethics committees formed for approval of conduct of clinical trials (hereinafter committee), the list of data to be submitted by the committees for obtaining approval, the procedure for the adoption of the resolutions of the committees and the format of an application for obtaining approval.

§ 2. Rules of procedure of committee and procedure for adoption of resolutions

(1) The work of a committee shall be guided by the Medicinal Products Act and legislation established on the basis thereof, this Regulation, the statutes of the committee, good clinical practice and the Helsinki declaration of the World Medical Association.

(2) The statutes of a committee are approved at the first meeting of the committee.

(3) The work of the committee shall conducted in the form of meetings which are held as necessary.

(4) The work of the committee shall be directed by the chairman of the committee or, in the absence of the chairman, by the deputy chairman.

(5) The chairman and deputy chairman of the committee shall be elected for a specified term from among the members of the committee at the first meeting of the committee.

(6) The chairman of the committee or, in his or her absence, the deputy chairman or at least one half of the members of the committee shall convene the meetings of the committee.

(7) The date and agenda of a meeting of the committee shall be communicated to the members of the committee at least ten days before the meeting is held.

(8) The committee has a quorum if at least half of the members of the committee are present at the meeting.

(9) In passing a resolution, only the members of the committee who act independently from the persons conducting the clinical trial and the manufacturer of the investigational medicinal product and their representatives who have in prior participated in the review of the data submitted and the discussion may vote in the process of passing the resolution.

(10) Minutes are taken at the meetings of the committee, the minutes of the meetings shall be preserved for 15 years and the data submitted for obtaining approval shall be preserved for three years.

(11) Information concerning the composition of the committee and the rules of procedure of the committee shall be published on the webpage of the relevant scientific research establishment.

(12) In the case of a clinical trial conducted in several centres in Estonia, the opinion of one ethics committee shall be given.

§ 3. List of data to be submitted for obtaining approval

The applicant for approval of the conduct of a clinical trial of a medicinal product shall submit the following data to the committee:

1) application for the review of data concerning the clinical trial in the format as provided for in the annex to this Regulation;
2) trial protocol with valid amendments;
3) the case report form (CRF);
4) the summary of the investigational product characteristics;
5) subject information leaflet and informed consent form;
6) updated curriculum vitae of the persons conducting the clinical trial;
7) other documents at the written request of the committee.

§ 4. Entry into force of Regulation

This Regulation enters into force on 1 March 2005.

* Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ No. L 121, 01/05/2001, pp. 34–44)

Annex