Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 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

Article 6

Ethics Committee

1 For the purposes of implementation of the clinical trials, Member States shall take the measures necessary for establishment and operation of Ethics Committees.

2 The Ethics Committee shall give its opinion, before a clinical trial commences, on any issue requested.

3 In preparing its opinion, the Ethics Committee shall consider, in particular:

- a the relevance of the clinical trial and the trial design;
- b whether the evaluation of the anticipated benefits and risks as required under Article 3(2)(a) is satisfactory and whether the conclusions are justified;
- c the protocol;
- d the suitability of the investigator and supporting staff;
- e the investigator's brochure;
- f the quality of the facilities;
- g the adequacy and completeness of the written information to be given and the procedure to be followed for the purpose of obtaining informed consent and the justification for the research on persons incapable of giving informed consent as regards the specific restrictions laid down in Article 3;
- h provision for indemnity or compensation in the event of injury or death attributable to a clinical trial;
- i any insurance or indemnity to cover the liability of the investigator and sponsor;
- j the amounts and, where appropriate, the arrangements for rewarding or compensating investigators and trial subjects and the relevant aspects of any agreement between the sponsor and the site;
- k the arrangements for the recruitment of subjects.

4 Notwithstanding the provisions of this Article, a Member State may decide that the competent authority it has designated for the purpose of Article 9 shall be responsible for the consideration of, and the giving of an opinion on, the matters referred to in paragraph 3(h), (i) and (j) of this Article.

When a Member State avails itself of this provision, it shall notify the Commission, the other Member States and the Agency.

5 The Ethics Committee shall have a maximum of 60 days from the date of receipt of a valid application to give its reasoned opinion to the applicant and the competent authority in the Member State concerned.

6 Within the period of examination of the application for an opinion, the Ethics Committee may send a single request for information supplementary to that already supplied

by the applicant. The period laid down in paragraph 5 shall be suspended until receipt of the supplementary information.

7 No extension to the 60-day period referred to in paragraph 5 shall be permissible except in the case of trials involving medicinal products for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms. In this case, an extension of a maximum of 30 days shall be permitted. For these products, this 90-day period may be extended by a further 90 days in the event of consultation of a group or a committee in accordance with the regulations and procedures of the Member States concerned. In the case of xenogenic cell therapy, there shall be no time limit to the authorisation period.