Summary

This is a report on the additional task that has been entrusted to the Committee on Genetic Integrity concerning embryonic stem cell research. According to the terms of the directive, the committee is to consider and submit proposals for those changes in legislation that are considered necessary to permit research on stem cells from surplus fertilised eggs from in vitro fertilisation. The committee has also been given the task not only of investigating whether the requirements for the transfer of somatic cell nuclei can be formulated in such a way as to be ethically acceptable, but also of proposing a clear prohibition of so-called reproductive cloning. The committee is also to decide what conditions should apply if women are to donate eggs for research purposes. In this context the committee is also to decide on matters concerning the European Convention on human rights and biomedicine and the prohibition stipulated in the Transplant Act against dealing commercially in biological material.

The background to this particular task is the discussion concerning the ethics of research that have taken place in connection with the guidelines from the Swedish Research Council concerning the ethical evaluation of research on human stem cells (verdict of 3 December 2001) and the pronouncement of the Swedish National Council on Medical Ethics concerning the same issues (pronouncement of 13 January 2002).

The issue of research has been the principal task of the committee in this interim report. The principal issues on which the opinion of the committee has been sought are research on fertilised eggs, research concerning the transfer of somatic cell nuclei and the donation of human eggs for research purposes. At this point in time, no decision will be taken concerning what is to be permitted by way of treatment in the context of the health service and medical treatment, even if the issue naturally has significance as far

as the considerations that should be taken with respect to research are concerned. In the course of its deliberations the committee has presumed that new legal and ethical issues will need to be put to the test if and when the research in question reaches the point of clinical application.

At the same time that the committee has been working on this matter, proposals for a new system for reviewing the ethics of research have been put forward. The proposal has been examined by the Council on Legislation and is expected to be submitted to the Swedish parliament at the same time that this report is presented. The proposed legislation means that the organisation responsible for the review of the ethics of any research carried out would be regulated by law, and a uniform organisation is to be created to govern how the review is to be carried out. No research involving humans and biological material from humans is to be carried out unless it has first been approved following a review of the ethics of the research in question. Apart from giving the ethical review a more solid structure, the new legislation will contain fundamental requirements for a research project to be approved.

The proposal entails considerably more stringency than is the case under the current regulations. As far as the issues that the committee must decide on are concerned, this means that generally speaking, additional legislation in these particular respects does not appear to be quite so necessary. It might also entail dual regulation of pertinent issues. In the course of its work, the committee has presumed that these new norms will be implemented and has given this a great deal of emphasis in the course of its deliberations.

In the light of this, the committee's deliberations have resulted in the following proposals:

It is not proposed to implement a general prohibition against *producing fertilised eggs for research purposes*. It is the opinion of the committee that such production must take place in order for research to be carried out into infertility and the development of the fertilised egg etc. It is not possible to set a legal limit with sufficient clarity that would delineate what, on the contrary, would be forbidden. This delineation should rather be done on a case-by-case basis within the framework of the ethical review of research. Those restrictions that apply to research on fertilised eggs should also apply to the production of such eggs. When adopting the European Convention on human rights and biomedicine, Sweden should register a reservation with respect to article 18.2, the

purport of which is to forbid the production of embryos for research purposes. A notification of this should be submitted to the Council of Europe and the signatory states immediately.

Research on fertilised eggs will still be permitted, subject to the conditions stipulated in the legislation of 1991 concerning measures taken with fertilised eggs from humans for the purpose of research or treatment. However, the measure will be revised in the light of the committee's proposals.

The transfer of somatic cell nuclei should not be prohibited, but in line with the proposals of the committee, the matter should be subject to limitations corresponding to those that apply to research on fertilised eggs. *Reproductive cloning* should be unequivocally forbidden. No detailed regulation concerning research based on the transfer of somatic cell nuclei should be introduced. The system of norms concerning the ethics of research that is currently being introduced is more suitable for the more thorough control that is required.

It is the opinion of the committee that the *donation of eggs for research purposes* should not be forbidden. It will be subject to scrutiny concerning the ethics of the research in question. For the time being, any treatment that requires the removal of eggs can involve such discomfort that the assessment must be extremely restrictive. Needless to say, requirements that there be informed and documented consent must apply. The donor must not be in a position of dependence with respect to the researcher or researchers for whose benefit the donation takes place. Financial compensation to the donor must only consist of expenses and loss of income. Any consent that is given with respect to the ethics of any research that involves the donation of eggs for research purposes is to be notified to the Swedish National Board of Health and Welfare.