STATUTORY INSTRUMENTS

2008 No. 941

The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008

Amendment of regulation 15 of the Clinical Trials Regulations

3. In regulation 15 of the Clinical Trials Regulations (ethics committee opinion)—

(a) for paragraph (1), substitute the following paragraph—

"(1) Except as provided for in paragraph (4A) (which removes the requirement on the Gene Therapy Advisory Committee to give an opinion) and subject to paragraphs (3) and (4) (which suspend and disapply time limits respectively), an ethics committee shall give an opinion in relation to the clinical trial to which a valid application relates within the specified period beginning with the date of receipt of the valid application.";

(b) after paragraph (3) insert the following paragraphs—

"(3A) An ethics committee may give a favourable opinion subject to conditions specified in writing in relation to a clinical trial.

(3B) If an ethics committee gives a favourable opinion subject to conditions, the ethics committee is to be treated as having given a favourable opinion in relation to the clinical trial only if the specified conditions are satisfied."; and

(c) after paragraph (4), insert the following paragraphs—

"(4A) Where a notification under paragraph (4B) is received by the Authority—

(a) the Gene Therapy Advisory Committee shall not give an opinion in relation to the clinical trial to which the application subject to that notification relates;

(b) the Authority shall direct that the application be considered by another ethics committee specified in the direction;

(c) the Gene Therapy Advisory Committee shall send the application to the ethics committee specified in the direction immediately following the direction being given; and

(d) the ethics committee specified in the direction shall, subject to the application being valid, give an opinion in relation to the clinical trial to which that application relates within the specified period beginning with the date of the Gene Therapy Advisory Committee's receipt of the application.

(4B) The Chairman, vice-chairman or alternate vice-chairman of the Gene Therapy Advisory Committee may notify the Authority (instead of giving an opinion) within the specified period beginning with the date of the Committee's receipt of an application that the clinical trial to which that application relates does not merit an opinion from the Gene Therapy Advisory Committee.".