STATUTORY INSTRUMENTS

2008 No. 941

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

Amendment of regulation 2 of the Clinical Trials Regulations

2. In regulation 2 of the Clinical Trials Regulations (interpretation), in paragraph (1)—

(a) for the definition of "the Directive" substitute the following definition—

> ""the Directive" means 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(**1**);";

(b) for the definition of "Directive 2001/83/EC" substitute the following definition—

> ""Directive 2001/83/EC" means Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use(**2**);"; and

(c) in the definition of "the Gene Therapy Advisory Committee" omit the words from "to" to the end.

(**1**) OJ No. L121, 1.5.2001, p.34; this Directive has been amended by Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ No. L378, 27.12.06, p.1).

(**2**) OJ No. L311, 28.11.01, p.67; the Directive has been amended by Directive 2002/98/EC of the European Parliament and of the Council (OJ No. L33, 8.2.2003, p.30), Commission Directive 2003/63/EC (OJ No. L159, 27.6.2003, p.46), Directive 2004/24/EC of the European Parliament and of the Council (OJ No. L136, 30.4.2004, p.85), Directive 2004/27/EC of the European Parliament and of the Council (OJ No. L136, 30.4.2004, p.34) and Regulation (EC) No 1901/2006 of the European Parliament and of the Council (OJ No. L378, 27.12.06, p.1).