STATUTORY INSTRUMENTS

2007 No. 1523

The Human Tissue (Quality and Safety for Human Application) Regulations 2007

PART 1

CITATION, COMMENCEMENT, EXTENT AND INTERPRETATION

Interpretation of other terms

5.—(1) In these Regulations—

"the 2004 Act" means the Human Tissue Act 2004(**1**);

"autologous graft" means tissue or cells removed from and applied in the same person within the same surgical procedure;

"blood" means whole human blood collected from a donor and processed either for transfusion or for further manufacturing;

"blood component" means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods, but does not include lymphocytes intended for use for the purpose of haematopoietic stem cell transplantation;

"the commencement date" means 5 July 2007;

"cells" means individual human cells or a collection of human cells when not bound by any form of connective tissue, including cell lines grown outside the human body but not including—

(a) gametes,

(b) embryos outside the human body, or

(c) blood and blood components;

"designated individual", in relation to a licence under Schedule 1, means the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on;

"export" means export from the United Kingdom to a place outside the United Kingdom;

"human application", in relation to tissue or cells, means use on or in a human recipient, including use in extracorporeal applications but not including use for autologous graft;

"import" means import into the United Kingdom from a place outside the United Kingdom;

"licence holder" means a person who holds a licence under Schedule 1;

"licensed activity", in relation to a licence, means an activity which the licence authorises under Schedule 1;

"relevant third party premises" has the meaning given by regulation 6(2);

(**1**) 2004 c.30.

"serious adverse event" means any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissue or cells intended for human application and which, in relation to a donor of tissue or cells intended for human application or a recipient of tissue or cells—

(a) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or

(b) might result in, or prolong, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in a donor of tissue or cells intended for human application or a recipient of tissue or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;

"storage" means maintaining tissue or cells, whether by preservation or in any other way, for more than 48 hours, and "store" is to be interpreted accordingly;

"tissue" means all constituent parts of the human body formed by cells, but does not include—

(a) gametes,

(b) embryos outside the human body, or

(c) organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body;

"third party" has the meaning given by regulation 6(2); and

"third party agreement" has the meaning given by regulation 6(1).

(2) Subject to paragraph (1) and except as otherwise provided in these Regulations, words and expressions used in these Regulations have the same meaning as in Article 3 of the first Directive, Article 1 of the second Directive and Article 2 of the third Directive (definitions).

(3) Subject to paragraphs (1) and (2) and except as otherwise provided in these Regulations, words and expressions used in these Regulations have the same meaning as in the 2004 Act as amended by these Regulations.

(4) For the purposes of these Regulations—

(a) a person who, from any premises, controls the provision of services for transporting tissue or cells is to be taken to distribute tissue or cells on those premises; and

(b) any reference to a requirement of any provision of the first, second or third Directive is a reference to a requirement which the provision requires be imposed in relation to the procurement, testing, processing, storage, distribution, import or export of tissue or cells intended for human application.