STATUTORY INSTRUMENTS

2007 No. 1522

The Human Fertilisation and Embryology (Quality and Safety) Regulations 2007

PART 2

AMENDMENTS TO THE 1990 ACT

Other terms used in the 1990 Act

6.—(1) Section 2 (other terms) is amended as follows.

(2) In subsection (1), in the appropriate places, insert the following definitions—

""basic partner treatment services" means treatment services that are provided for a woman and a man together without using—

(a) the gametes of any other person, or

(b) embryos created outside the woman's body,",

""competent authority", in relation to an EEA state other than the United Kingdom or in relation to Gibraltar, means an authority designated in accordance with the law of that state or territory as responsible for implementing the requirements of the first, second and third Directives,",

""distribution", in relation to gametes or embryos intended for human application, means transportation or delivery, and related terms are to be interpreted accordingly,",

""human application" means use in a human recipient,",

""non-medical fertility services" means any services that are provided, in the course of a business, for the purpose of assisting women to carry children, but are not medical, surgical or obstetric services,",

""processing", in relation to gametes or embryos intended for human application, means any operation involved in their preparation, manipulation or packaging, and related terms are to be interpreted accordingly,",

""procurement", in relation to gametes or embryos intended for human application, means any process by which they are made available, and related terms are to be interpreted accordingly,",

""serious adverse event" means—

(a) any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a donor of gametes or a person who receives treatment services or non-medical fertility services—

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

(ii) might result in, or prolong, hospitalisation or illness, or

(b) any type of gametes or embryo misidentification or mix-up," ,

““serious adverse reaction” means an unintended response, including a communicable disease, in a donor of gametes intended for human application or a person who receives treatment services or non-medical fertility services, which may be associated with the procurement or human application of gametes or embryos and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or illness,”,

““store”, in relation to gametes or embryos, means preserve, whether by cryopreservation or in any other way, and “storage” and “stored” are to be interpreted accordingly,”, and

““traceability” means the ability—

(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,

(b) to identify the donor and recipient of particular gametes or embryos,

(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and

(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety,”.

(3) In subsection (2), for the words from “, whether preserved” onwards substitute “in storage”.

(4) After subsection (2), insert—

“(2A) For the purposes of this Act, a person who, from any premises, controls the provision of services for transporting gametes or embryos is to be taken to distribute gametes or embryos on those premises.

(2B) In this Act, any reference to a requirement of a provision of the first, second or third Directive is a reference to a requirement which that provision requires to be imposed.”.