STATUTORY INSTRUMENTS

2007 No. 1523

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

PART 4

OBLIGATIONS OF THE AUTHORITY

Requirement for the Authority to provide information

17.—(1) The Secretary of State may serve a notice upon the Authority requiring it to provide any information which the notice specifies about the carrying out of its functions under these Regulations in relation to England and Wales or Northern Ireland.

(2) The Scottish Ministers may serve a notice upon the Authority requiring it to provide any information which the notice specifies about the carrying out of its functions under these Regulations in relation to Scotland.

(3) The Authority shall upon receipt of a notice under paragraph (1) or (2) provide the information requested within the period specified in the notice.

Register of licences

18.—(1) The Authority shall maintain a register recording the grant, suspension or revocation of every licence granted under Schedule 1.

(2) The register shall contain the following information—

(a) the name of the licence holder,

(b) the activities authorised, and

(c) any variation of the information referred to in sub-paragraph (a) or (b).

(3) The Authority shall make such of the information included in the register as it considers appropriate available to the public in such manner as it considers appropriate.

Register of serious adverse events and serious adverse reactions

19.—(1) The Authority shall keep a register containing information provided to it under these Regulations about any serious adverse event or serious adverse reaction.

(2) The Authority shall make such of the information included in the register as it considers appropriate available to the public in such manner as it considers appropriate.

Duties of the Authority in relation to serious adverse events and serious adverse reactions

20.—(1) The Authority shall put in place procedures for communicating such information in relation to any serious adverse event or serious adverse reaction to—

(a) any person in the United Kingdom carrying-on procurement, testing, processing, storage, distribution, import or export of tissue or cells intended for human application,

(b) any person in the United Kingdom, of whom it is aware, using such tissue or cells for that purpose,

(c) the competent authorities in EEA states other than the United Kingdom and in Gibraltar, and

(d) the European Commission,

as is necessary for the purpose of enabling appropriate action to be taken, including where necessary the withdrawal from use of tissue and cells that are intended for human application but are known or suspected to be unsuitable for human application.

(2) The Authority shall investigate serious adverse events and serious adverse reactions and carry out appropriate control measures.

(3) The duty under paragraph (2) includes a duty to investigate any serious adverse event or serious adverse reaction which has occurred in the United Kingdom, and to carry out appropriate control measures, at the request of a competent authority in an EEA state other than the United Kingdom or in Gibraltar.