DRAFT STATUTORY INSTRUMENTS

# 2007 No.

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

## PART 4

## OBLIGATIONS OF THE AUTHORITY

**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.