

L.N. 304 of 2013

**HUMAN BLOOD AND TRANSPLANTS ACT
(CAP. 483)**

**Human Tissues and Cells (Coding, Processing, Preservation,
Storage and Distribution) (Amendment) Regulations, 2013**

IN exercise of the powers conferred by article 16 of the Human Blood and Transplants Act, the Minister for Health, after consultation with the Licensing Authority, has made the following regulations:-

1. The title of these regulations is the Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) (Amendment) Regulations, 2013, and these regulations shall be read and construed as one with the Human Tissues and Cells (Coding, Processing, Preservation, Storage and Distribution) Regulations, hereinafter referred to as "the principal regulations". Citation.
S.L. 483.04

2. Immediately after sub-regulation (2) of regulation 1 of the principal regulations, there shall be added the following new sub-regulation: Amends
regulation 1 of
the principal
regulations.

"(3) The scope of these regulations is also to fully transpose the European Parliament and Council Directive 2004/23/EC of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells."

3. Immediately after sub-regulation (2) of regulation 2 of the principal regulations, there shall be added the following new sub-regulation: Amends
regulation 2 of
the principal
regulations.

"(3) These regulations shall not apply to:

 - (a) tissues and cells used as an autologous graft within the same surgical procedure;

 - (b) blood and blood components as defined by Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC;

(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."

Renumbers regulations 8 to 10 of the principal regulations.

4. Regulations 8 to 10 of the principal regulations shall be renumbered as regulations 9 to 11 thereof respectively.

Adds new regulation 8 to the principal regulations.

5. Immediately after regulation 7 of the principal regulations, there shall be added the following new regulation:

"Inspections, etc., by Licensing Authority.

8. (1) The Licensing Authority shall organise inspections and carry out control measures as appropriate whenever there is any serious adverse reaction or serious adverse event. In addition, such an inspection shall be organised and control measures shall be carried out at the duly justified request of the competent authority or authorities in another Member State in any such case.

(2) The Licensing Authority shall, upon the request of another Member State or the Commission, provide information on the results of inspections and control measures carried out in relation to the requirements of these regulations."

