Response to the DG Enterprise consultation paper " Proposal for a harmonised regulatory framework on human tissue engineered products (HTEPs)"

We are concerned that the definitions of what constitutes a HTEP are vague and imprecise, and that as a result some (if not all) tissue allografts (as regulated under the Tissues and Cells Directive) could be classified as HTEPs. We propose that these definitions be refined so that there is a clear demarcation between products that will be classified as tissue allografts, and regulated under the Tissues and Cells Directive, and products that will be classified as HTEPs.

1. We feel that the definition of "engineering" should be clarified, so as to exclude specific processes that are applied to treat tissue allografts, for example to disinfect, sterilise, preserve and simplify by removing unwanted components. Examples of such processed include:

I) Disinfection using chemical disinfectants, for example antibiotic treament applied to skin or vascular grafts.

II) Sterilisation processes, such as gamma irradiation or ethylene oxide gas, applied to hard tissue grafts.

III) Preservation processes, such as cryopreservation used for skin and vascular allografts, or lyophilisation used for hard tissue grafts.

IV) Processes to simplify grafts by removal of unwanted components; for example washing processes to remove marrow components from mineralised bone, demineralisation processes to remove the mineral and lipid phases of bone and prepare demineralised bone matrix, or decellularisation treatments to create acellular soft tissue matrices.

The purpose of such treatments is to retain as much as possible of the normal biomechanical and biological functions of the tissue, whilst rendering the graft safer, amenable to long term preservation, and more clinically effective. They do not seek to to add to, improve or alter any of these functions.

2. We propose that decellularised, sterilised allogeneic tissue matrices, as described above, be regulated solely under the Tissues and Cells Directive. When used in combination with autologous cells the resulting HTEP would be categorised as an autograft, under the proposed regulation for HTEPs. However, if used with allogeneic cells it would be an allograft. This would seem to be in keeping with the statement in the definitions section of the proposal which states that: ""HTEPs are derived from living cells or tissues, with the final product containing viable or non viable cells."

This response is from the Tissue Services section of the UK National Blood Service