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BANCA DEL TESSUTO MUSCOLO - SCHELETRICO
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Bologna, 02/07/04
OGGETTO: Contribution to proposal for tissue engineered products

The document is necessary for clarifying a sector where different existing legislations can't be applied.
The choice of a Regulation can be accepted because we need a quick and uniform regulatory framework.
As Director of a public National Musculoskeletal Tissue Bank, I'd like to present some observations on your proposal hoping to help in a decision, which has to interface with the needs of Tissue Banks and not only of private biotechnological industries.
It's necessary to give a clear definition of

a) no manipulated product,
b) minimally manipulated product,
c) substantially manipulated (engineered) product.

a) "No manipulated product" means human tissue and/or cells procured from autologous/homologous source, tested, stored and distributed.
b) "Minimally manipulated product" means human tissue and/or cells procured from autologous/homologous source, tested, processed without substantial modification of physiologic functions, stored and distributed. It includes freeze dried, irradiated, demineralized human tissues and human cells isolated and cultured for quantitative expansion, even on biomolecules or biomaterials.
c) "Substantially manipulated (engineered) product" means human tissue and/or cells procured from autologous/homologous source, tested, processed with substantial modification of physiologic functions, stored and distributed.

The products in groups a) and b) fall under the Directive 2004/23/EC.
The products in groups c) fall under the Directive 2004/23/EC only for donation, procurement and testing of tissues/cells.

Sincerely yours

Dr. Pier Maria Fornasari
Responsabile Sanitario della BTM