Response from Professor Paul V. Hatton to the public consultation document: **"Proposal for a harmonised regulatory framework on human tissue engineered products – DG Enterprise consultation paper"**

The EU is to be congratulated on the preparation of a sensible and carefully considered approach to the regulation of tissue engineered products. The document suggests that a good level of protection will be provided to the citizen (including public, patients and clinicians). I am also satisfied that the regulations for allogeneic products need to be stringent and carefully implemented.

I am however concerned that the barriers to clinical use may yet be set too high for tissue engineered implants produced using fully autologous cells and serum. The challenge presented by the ageing popuation is great, and autologous tissue engineering is one promising and relatively low risk route to address this problem. I propose that the EU do NOT leave this for national regulation, but provide an EEA-wide regulatory framework that reduces risks and maximises potential for develoment of new therapies and exploitation. This must:

1. Enable hospitals and related laboratories (e.g. in industry and universities) to self-certify that their facillities and procedures meet written standards (and such facillities be open to inspection to check compliance).

2. Demand compliance with standards that apply to cell harvest, culture (inc. media, chemicals and other additives e.g. growth factors), biomaterials, storage and re-implantation.

3. Each product to be approved by a competent authority against a risk assessment procedure covering each stage above.

A transparent European directive, giving authority to a national competent authority to manage the marketing of autologous tissue engineered implants, will give impetus to transnational research in this field and provide the EU with a competitive advantage that at the same time minimises risks. To leave this for national regulation will create confusion and uncertainty in the industry, and inhibit the development of viable autologous solutions.

Paul V. Hatton
Professor of Biomaterials and Tissue Engineering
Centre for Biomaterials and Tissue Engineering
School of Clinical Dentistry
University of Sheffield
Claremont Crescent
SHEFFIELD S10 2TA, UK
tel. (direct) 0044 114 271 7938
tel. (secretary) 0044 114 271 7939
fax 0044 114 266 5326