Proposal for a harmonised regulatory framework on human tissue engineered products :

DG Enterprise Consultation paper*

Introduction.

We wellcome the legal outline of a Regulation because this facilitates and simplifies a "harmonised regulatory framework on human tissue engineered products".

1 . Manufacturing authorisation (p11)

- Good Manufacturing Practices should be the same as for medicinal products and are at this moment only possible for common forms.
  In the case of manipulations, the best is to work in open systems and to invest in procedures (very expensive !…) that allow slowly but surely a step forward aiming Good Manufacturing Practices.
  We emphasize that the standards of GMP must be met.

- Safety of the products should be guaranteed.
  Security measures need to be put also in place for autologous cells coming from hospitals.
  Small regional hospitals don't have an infrastructure like in large academic hospitals and medical supervision is necessary to be tightened especially when they work autonomous.
  Cooperation with local bloodbanks means a push in the right direction.

2. Marketing authorisation : clinical testing specifications (content of the dossier) (p17)

We emphasize the importance of comparative clinical trials.

3.Validity of marketing authorisation (p13)

As with Medicinal Products, efficacy and safety should be closely evaluated for tissue engineering products.
Therefore a periodic safety report shall be submitted immediately upon request and at least - every six months during the first two years following autorisation and once a year for the following two years . Thereafter, the reports shall be submitted at three - yearly intervals, or immediately upon request.