Sir,
- Agree to involve autologous and allogenic human Tissue engineering in a same directive.
- xenogenic material could be a problem to be not evaluate because some scaffold could be issue to a TEP .

Definitions are well understanding.

Authorisation:

A marketing authorisation is different between autologous (national) and allogenic(EMEA).
The risk level could be evaluate and the microbiologic risk could be high for autologous and less for allogenic for example you could have a very long process in autologous with high risk in the environment or the scaffold could have high risk compatibility, and the risk of the donor in allogenic but low risk in the process. we could probably not have restriction in separation between allogenic and autologous.
To have the choice of national and European procedure could be a good opportunity for the market of a SME:National procedure in allogenic could be adapted for a SME witch would have to be in national market. European could be adapted for an SME for autologous , if logistics problems and reimbursement could be solved by this SME (if this SME do the choice).

As IPTS had reported, the major activity in TEP is done from SME, European commission need to help this small but dynamic company to help for the market, the first step for marketing (as clinical trial) is national, it could be helpfull to leave the choice of the authorisation: national or european. Economic view to ask european authorisation need to be account: language, organisation of EMEA.

I am suprise of Centers autorised by the Members States for implantation tissue (european authorisation ou national) : How you can define this hospital or clinics, private centers could be outside of the TEG ? Qualification of the physician and qualification of centers are more adapted.

Best regards
Laurence Barnouin
TBF Banque de Tissus
France