Dear Sir, I convey to you my comments to the meeting held in Bruxelles the 16 April

PROPOSAL FOR A HARMONISED REGULATORY FRAMEWORK ON HUMAN TISSUE ENGINEERED PRODUCTS: DG ENTERPRISE CONSULTATION PAPER*

On page 4
Suggested approach

1) Fisrt paragraph
"……be specific" : the word *specific* should be rather "for a precise established use"

2) third Paragraph
It looks unclear why an authorization for allogeneic products should be done by EMEA . Why alloegeneic product should be centrally authorised and autologous product should not?

3) In this present form the document does not clarify why one needs a centralised procedure. For instance the phrase…*scientific assessment by EMEA*…
If a scientific judgement has to be given why exclude the same for autologous products.

4) One solution would be as follows: if the donor and the recipient are identified a central regulation may not be needed and the regulation may fall under the 2001/83/EU
On the contrary, a centralised regulation may apply for *universal* use of a given cell product.

On Page 5
Scope
"Human tissue engineered…."
It should be clarified what is the divide between research and development for cell therapy at present.
The majority of studies involving cell therapy (tissue engineering) are still phase I or II.

"The donation…."
The last sentence is unclear

On page 7
Definitions

-“has properties for……..” “ …functionally analogous….” It is inappropriate since a lot of studies are based on trans-differentiation process.

“Engineering means……..” “…. So that their normal physiological functions are affected.” may be substituted with “ may be or may not be changed”