University of Sussex
Global Studies

European Commission
DG SANCO

13 May 2013

Dear Sir/Madam,

ATMP Regulation consultation

I write as an academic social science researcher in biomedical innovation and governance. I have no conflicts of interest in relation to ATMPs, and have a detached point of view as regards different industry sectors, issues of sourcing of materials, commercial vs. non-profit aspects, etc. I have studied the evolution of the ATMP Regulation extensively since the mid-2000s, and my research has had the backing of and been financially supported during this time by the UK's Economic and Social Research Council (I have published several articles on it in academic journals, see P.S.). I have attended various meetings of stakeholders, including the European Parliament ENVI Committee during the negotiation of the Regulation, and subsequently meetings of CAT-EMA-ESGCT and the CAT Focus group meeting in 2012, and a UK stakeholders discussion in late 2012 including MHRA.

In these comments I address mainly the issues to do with Incentives and the Hospital Exemption, though comment on others.

Consultation Topics:

2.1 and 2.2. Judging by the very small number of applications to CAT, and the lack of combined product applications, there appear to be disincentives to use this route to marketing authorisation. For combined products, the representation on the CAT of only two medical device experts may be a disincentive

2.3. It follows, and it appears from discussions that I have observed, that both commercial and non-commercial producers are entertaining strategies that seek to take advantage of the HE more or less in preference to the central CAT MA route, often with products or preparations that have orphan drug designation (thus attracting much lower application fees etc). There is a lack of centrally collected information on the workings of this exemption in individual member states although there are some attempts to remedy this. It's clear though that different MSs are implementing it in different ways, with different (numerical) definitions of 'standardised 'industrial' etc product thresholds, and some MSs have not yet implemented it nationally, leaving part of the regenerative medicine effort

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in a similar state of variegated national regulation, as was the case pre-ATMP Regulation for tissue engineered products. I am concerned from a **public health** point of view that the biased response to this legal framework is leading to skewed market signals favouring development of products/therapies for 'rare diseases' (for which there is vocal lobbying) and unusual medical conditions, at the expense of therapies which might target more common conditions.

2.4 Incentives: as per my comments on 2.3, the very low uptake of the certification incentive by SMEs suggests that this incentive, while embodying a useful principle, appears not to be sufficient to enable many SMEs to engage with it as part of their business model and strategy. Further public explanation to SMEs and investors by EMA-CAT of this may be beneficial to the sector therefore. Equally, although there appears to be a sort of unintended incentive to clinical investigators and practitioners to use the hospital exemption route to national authorisation, there is no explicit equivalent of the SME certification for the hospital/academic/charitable sector to produce commercialisable products that could be of wide benefit to patients. I believe that such a measure would be beneficial for the sector as a whole (a fairer, more level playing field) as well as ultimately to encourage the development of more, safe, and regulated products for the European patient.

Lastly, an overall effect of the current situation may be to encourage more producers to consider *medical device* development and regulation for regenerative medicine products in the EU context.

Thank you for the opportunity to comment on this Regulation.

Yours sincerely

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P. S. References to articles on the ATMP Regulation

Article in *Law, Innovation & Technology:*
http://www.ingentaconnect.com/content/hart/lit/2012/00000004/00000002/art00004

Article in *INNOVATION: European Journal of Social Science Research*:
http://www.tandfonline.com/doi/full/10.1080/13511610.2012.723333