

From: [REDACTED]
Sent: 29 March 2013 16:26
To: SANCO ADVANCEDTHERAPY REPORT
Cc: Fehily Deirdre; elio.eliana@infinito.it; elio.eliana@alice.it; Lombardini Letizia; Bariani Fiorenza; Mariani MariaPia
Subject: Public consultation on Regulation(EC) 1394/2007

Follow Up Flag: Follow up
Flag Status: Completed

Please find the views of the Italian National Transplant Center concerning the public consultation paper on Regulation(EC) 1394/2007 hereafter:

Topic 2.3 (Hospital exemption)

In order not to discourage marketing authorization and also not to induce too much variability in the implementation of art. 28 into national laws it could have been useful to better distinguish the term "prepared on a non-routine basis" compared to industrial production.

Furthermore the term "specific quality standards ... equivalent to those provided for at Community level ..." leaves space to interpretation about how much the quality standards may differ from the GMP standards required by art. 5 of the Regulation.

Finally there is no indication about the need to monitor the clinical safety and efficacy of these single patient treatments, although it is a very important aspect that MS should require from the medical practitioner.

We believe that in case of a possible future revision of art. 28 the above mentioned clarifications could be taken into consideration in order to reduce the variability of the national implementation of art. 28 among Member States.

Topic 2.5 (Scope and adaptation to technical progress)

Instead of the "scope" we believe that the technical progress should be rather considered in relation to the term "...cells and tissues are not intended to be used for the same essential function or functions in the recipient as in the donor", as indicated in art. 2 paragraph 1 c .

In some cases the biological activities of cells and tissues are not yet sufficiently understood and the so called "homologous" or "non-homologous function" is not easy to be proven , it can only be " claimed". Technical progress might bring to a better understanding of these aspects.

With best regards,
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L'Istituto Superiore di Sanità (ISS) è tra i beneficiari dei proventi del 5 per mille dell'IRPEF.

Nella scheda allegata alla dichiarazione dei redditi è sufficiente apporre la propria firma nel riquadro "Finanziamento della Ricerca Sanitaria" e indicare il Codice Fiscale dell'ISS, che è 80211730587, per destinare tali fondi a sostegno dell'impegno scientifico dell'ISS a difesa della salute di tutti.

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