From: [redacted]
Sent: 15 March 2013 15:58
To: SANCO ADVANCEDTHERAPY REPORT
Cc: [redacted]
Subject: ATMP consultation

Follow Up Flag: Follow up
Flag Status: Completed

To whom it may concern:

The development of ATMPs is a major challenge for all participants but in particular for biotech companies which are committed to the implementation, development and manufacturing of ATMPs according to GMP and GCP guidelines for clinical trials and potential market authorization. Besides the enormous development costs, there are other major obstacles:

- Uncertainties of the (national) authorities on the implementation of the existing regulations
- Significant underfunding of the GMP manufacturing and clinical implementation of ATMPs in EU funding programs
- Dramatic underestimation of the time to implement an ATMP (from an R&D program to a GMP-grade product)
- Improper comparison of ATMPs tested under hospital exemption and those being developed according to pharmaceutical (industrial) standards – this relates in particular to the GMP-manufacturing and the approval of the clinical trial design

Therefore it would be desirable

- to harmonize the EU-wide regulation for ATMPs implementation
- to consider a reasonable funding of ATMP development programs in EC calls
- to adjust the conditions for hospital exemptions

Sincerely,
Ralf Huss

Prof. Dr. Ralf Huss
Managing director & CSO

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