From: [redacted]
Sent: 29 March 2013 11:21
To: SANCO ADVANCEDTHERAPY REPORT
Subject: Comments on Public consultation Paper on the Regualtion of ATMPs

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Dear Sir or Madam

Please find below comments from the SME Innovacell Biotechnologie AG, Innsbruck, Austria, on the Public Consultation Paper on the Regulation of ATMPs.

Innovacell Biotechnologie AG is developing an ATMP (SMDC, an autologous cells based medicinal product) for the treatment of stress urinary incontinence (SUI) in female patients.

Innovacell would like to comment on the following topics:

2.1 MAA requirements for ATMPs

The ATMP regulation is not very specific with respect to particular requirements for ATMPs, nor is the CHMP guideline on human cell-based medicinal products. A higher level of detail is warranted taking into account the EMA's current experience with scientific advice given for ATMPs and/or MAAs for ATMPs. It should be considered that certain requirements which are derived from conventional small molecule developments are not or only partly applicable to ATMPs, e.g. non-clinical pharmacokinetic studies (ADME) or human dose finding studies.

2.3 Hospital exemption

A clear definition of "preparation on a non-routine basis" is required that regulates that any serial manufacturing of a product i.e. at standardized conditions, procedures or routines is out of scope of the hospital exemption. Detailed description of attributes of "non-routine" should be provided. It should be made clear that the hospital exemption is only applicable to individual cases under the responsibility of the attending physician and that any serial manufacturing of a product is prohibited. Clinical trials for generation of data should not be bypassed through hospital exemption. MAA requirements for treatment of patients should not be bypassed through hospital exemption.

2.4 Incentives for the development of ATMPs

Scientific advice:

There is no particular advantage for development of an ATMP since fee reduction is granted for all SMEs. When applying for scientific advice, Innovacell had the expectation that CAT members would be involved in the advice procedure which was actually not the case for a discussion meeting held at the EMA in September 2010 for SMDC, i.e. Innovacell's product for treatment of SUI in females.

Certification of quality and non-clinical data:

Innovacell used the certification procedure for both quality data and non-clinical data at a relatively late stage of development. The potential benefit is not yet clear, but it is expected that there will be no major issues in the up-coming MA procedure.

With kind regards,

Anita Friedrich

On behalf of Innovacell Biotechnologie AG

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