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From Research to Human Therapy

CCMI
Centre for Cell Manufacturing Ireland

Centre for Cell Manufacturing Ireland
(CCMI), Orbsen Building,
NUI Galway,
Ireland

Unit B5 – "Medicinal products – policy, authorisation and monitoring"
European Commission
DM24 02/133
B-1049 Brussels (Belgium)

23 Sep 2016

Dear Sir or Madam,

I am writing to provide feedback on the **Consultation Document – Good Manufacturing Practice for Advanced Therapy Medicinal Products.** This feedback is on behalf of the Centre for Cell Manufacturing Ireland (CCMI).

CCMI is located at the National University of Ireland - Galway (NUIG) and it forms part of the University. CCMI received authorisation in 2013 from The Health Products Regulatory Authority (HPRA Ireland) to manufacture Advanced Therapeutic Medicinal Products such as stem cells for use in human clinical trials.

The overall response from CCMI is positive with respect to the Consultation Document. It is welcomed that the European Commission has put forward this proposed guidelines document for review.

Working with ATMPs, it is evident that there can be some degree of variability and batch size can be limited as is noted in the document. It is obvious of course that all quality, safety and efficacy attributes of the ATMPs must meet all GMP requirements, yet it would be good to work off a set of guidelines, where the complexities of ATMPs are acknowledged and that this should ideally be a standalone set of guidelines and/or an Annex.

However, the consultation document does not appear to clarify whether or not the intention is to have such a standalone document and that this will be independent from existing guidance in EudraLex Volume 4, or will it be connected as an Appendix? The main concern is that there may be contradictions with existing requirements.

Finally two further comments on the consultation document:

- Tissue establishments: Propose that the manufacturer can decide if there is a need to audit the Tissue Establishment. This will, for example, allow the manufacturer to determine that the reconstitution procedure (where applicable) is performed satisfactorily.
- Retain samples from autologous final product is not possible in all cases.

Sincerely,

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