From: Silke Dorner <silke.dorner@ages.at>
Sent: 11 September 2018 12:46
To: SANTE PHARMACEUTICALS B5
Cc: Verena Plattner
Subject: TSC 01/2018 on GCP for ATMPs

To whom it may concern,

Please find below the comment of the austrian competent authority to the Consultation Document "Good Clinical Practice for Advanced Therapy Medicinal Products".

Category: Austrian competent authority (national): Austrian Agency for Health and Food Safety, Federal Office for Safety in Health Care, Department Blood, Tissue & Vigilance

Line 140 - 143:
In some cases, e.g. CAR-T cell production, the procured cells/tissues can be cryo-preserved (processed) and stored at the blood or tissue establishment, before they are passed on to the ATMP manufacturer. If these steps of processing and storage are done in the responsibility of the blood or tissue establishment, they should also be performed in accordance with the Directive 2004/23/EC or Directive 2002/98/EC. Otherwise there might be a gap between the procurement of the cells/tissues and the start of the manufacturing process at the ATMP manufacturer. At this point only the donation, procurement and testing would be recommended to be done in accordance with the directives.

In case there are any questions, please do not hesitate to contact me.

Sincerely,
Silke Dorner

Priv.-Doz. Dr. Silke Dorner

Institut Überwachung
BASG - Bundesamt für Sicherheit im Gesundheitswesen / Federal Office for Safety in Health Care
AGES - Österreichische Agentur für Gesundheit und Ernährungssicherheit / Austrian Agency for Health and Food Safety
Adresse: Traisengasse 5, 1200 Wien
Tel. national: 050555-36451
Tel. international: +43-50555-36451
E-Mail:silke.dorner@ages.at
web: www.basg.gv.at| www.ages.at