Specialist Pharmacy Service
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Advanced Therapy Treatment Centres

CATAPULT Cell and Gene Therapy

Pan UK Pharmacy Working Group Advice Document

Regulatory Requirements for Export of ATMP Starting Materials September 2019

Scope

This guidance aims to clarify the regulatory requirements for the export of human tissues and cells for use as starting materials for marketed advanced therapy medicinal products (ATMPs) and investigational ATMPs for administration at UK sites.

Background

Although some ATMPs currently in use in the UK are manufactured entirely within the UK or in other EU Member States, some are manufactured outside of the EU. Where this is the case, the tissues or cells used as the starting material require export from the EU.

Clarification has been sought from both the Medicines and Healthcare products Regulatory Agency (MHRA) and the Human Tissue Authority (HTA) on the regulatory requirements for the export of tissues and cells in such circumstances.

Background to the MHRA and HTA

In the UK, the HTA is the Competent Authority (CA) responsible for regulating human tissues and cells intended for human application. They do this in line with Directive 2004/23/EC and associated EU Directives which have been transposed in the UK as the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (the Q&S Regulations).

In the UK, the MHRA is the CA responsible for regulating human medicines, devices and blood and blood components for transfusion. Medicinal products, including those classified as ATMPs are regulated under Directive 2001/83/EC (amended by the ATMP Regulation No 1394/2007) on the Community code relating to medicinal products for human use which have been transposed in the UK as the Human Medicines Regulations 2012 (SI 2012/1916). The conduct of clinical trials on medicinal products for human use are regulated under Directive 2001/20/EC and Directive 2005/28/EC which have been transposed in the UK as The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1013).

Regulatory Requirements for Export of ATMP Starting Materials

The MHRA and HTA have confirmed that the export of tissues and cells outside of the EU for use in the manufacture of ATMPs falls under the scope of the EU Tissues and Cells Directives and the Q&S Regulations. Consequently, **establishments wishing to undertake this activity must either hold a HTA Human Application (HA) licence which includes the activity of 'Export', or be operating under the terms of an appropriate third party agreement with another establishment holding such a licence.**

A release process must be in place for the procured tissues or cells to ensure that prior to each batch of material leaving the establishment (and thus the EU), activities have been performed in line with the requirements of the Q&S Regulations. A technical agreement must be in place between the HTA licence holder and the manufacturer clearly defining the responsibilities of each party, including in relation to the transportation of the starting material and incident reporting.

Implications for EU Exit

In the event of a no-deal EU exit, it is possible that the requirements detailed above will also apply to the export of tissues and cells to EU Member States.

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