New licensed/unlicensed ATMP Governance Checklist

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NEW LICENSED/UNLICENSED ATMP PRODUCT PHARMACY GOVERNANCE CHECKLIST

Product Name			
Supplier			
Manufacturer (if different to above)			
Regulatory status	Licensed/Unlicensed* *For Unlicensed products **in addition** please complete Appendix 1		
Checking step	**Yes\No**	**Checker Initials**	**Date**
Treatment centre selected by NHSE to deliver ATMP therapy			
Type of Therapy			
Treatment centre accredited by JACIE to deliver CAR-T cell therapy			
Treatment centre qualified by manufacturer to deliver product			
Governance approvals in place for use of product as applicable: - Medicines Management/Formulary - ATMP Oversight Group/ (or similar)			
ATMP safety risk assessment completed / Virologist involved in the decision for gene therapy			
SMPC available			
Prescription added to electronic SACT prescribing system			
Product added to Pharmacy Ordering system			
Intravenous risk assessment completed			
Trust funding process approved			
Ordering process in place			

Ensure product being tracked by Medicines Finance team and Contracts for Trust reimbursement			
Pharmacy product specific folder in place			
Pharmacy SOP in place for cancellation of order			
Pharmacy SOP in place for credit claims			
Pharmacy SOP in place for deviations			
Pharmacist Final Check (Print name, sign, date)			
Comments			

Appendix 1. Additional Checklist for Unlicensed Products

Is the product licensed in another country outside UK, if so, please add the name of country	
Is the product being delivered as part of a trial? If so, indicate name of the trial, sponsor and in which countries the trial is delivered	
Will the protocol be followed, please attach it. Indicate any modifications to the clinical protocol	
Will the Investigational Brochure be followed as a safety reference document and to report any adverse event? Indicate any exceptions	

Checking step	Yes\No	Checker Initials	Date
Approval of Local Ethics Committee			
Patient Information Leaflet and written consent designed and approved by the local Ethics committee			
External Peer review by an expert for suitability of treatment and patient (including HTA when applicable)			
Hospital Medical Director Approval			
MFT quality and Safety Approval			
Vendor assessment and Technical/quality agreement in place for the manufacturing and supply of the product. - This will include verification that the correct manufacturing, importing/exporting licenses are in place			