

Pharmacy Institutional Readiness for Ex-vivo (Cell Based) GMO Gene Therapy Medicinal Products

Guidance for Chief Pharmacists

Pan UK Pharmacy Working
Group for ATMPs

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**The first stop
for professional
medicines advice**

Pharmacy Institutional Readiness for ex-vivo (cell based) GMO Gene Therapy Medicinal Products

Guidance for Chief Pharmacists

1. Background

Advanced Therapy Medicinal Products (ATMPs) are innovative medicines which provide challenges in delivery. As Gene Therapy Medicinal Products (GTMPs) are classed as ATMPs, Chief Pharmacists are required to ensure that governance arrangements are in place to ensure the safe and secure handling of these medicines within their organisations.

Gene therapy medicinal products (GTMPs) are defined as biological medicinal products which have both of the following characteristics:

- a) contain an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding, or deleting a genetic sequence.
- b) therapeutic, prophylactic, or diagnostic effect relating directly to the recombinant nucleic acid sequence they contain, or to the product of genetic expression of this sequence.

Gene Therapy Medicinal Products (GTMPs) are classified as **genetically modified organisms (GMO's)** or **non-GMO's**. Guidance for non- GMO GTMPs is currently being developed e.g. mRNA based and gene edited products.

GMO GTMP's are designed to introduce genetic material into cells to:

1. compensate for abnormal genes.
2. make a beneficial protein which then multiplies and exerts a positive effect.
3. introduce a normal copy of the gene to restore the function of the protein if a mutated gene causes a necessary protein to be faulty or missing.

A GTMP is classed as an **ex-vivo GMO gene therapy** when genetic modification occurs outside the body, during the manufacturing process. In contrast, **in-vivo GMO gene therapy** directs the GTMP into a specific tissue in the body and the GMO is then taken up by individual cells, or (more usually) it is administered intravenously (IV). For further information on [in-vivo GMO GTMPs](#), refer to guidance. This document is relevant to GTMPs that are in the **ex-vivo GMO GTMP category**.

The manufacture of GMO GTMPs is complex. For Governance and Operational considerations, refer to [Gene Therapy Medicinal Products Governance and Preparation Requirements](#).

GMO GTMPs utilise a carrier, which can be a viral vector e.g. adenoviral vectors/ retroviruses or lentiviruses, to deliver the gene to the cell by infecting the cell and facilitating subsequent antigen specificity delivery. The viruses are genetically modified to ensure that they are non-pathogenic and cannot cause disease when used in people. The viruses can be non-replicating or replicating.

Retroviruses, including lentiviruses, integrate their genetic material (including the new gene) into a chromosome in the human cell and are known as integrating viral vectors. Adeno-associated viruses introduce their DNA into the nucleus of the cell, but the DNA is not integrated into a chromosome – i.e. they are non-integrating viral vectors.

This guidance is for GMO GTMPs that are classified as '**ex-vivo**' where cells are taken from a donor, usually the patient, and are used as the starting material for the medicinal product. A viral vector is used to introduce the gene to the donor cells. The donor cells undergo genetic modification and expansion in cell culture to form the medicinal product. The genetically modified cells, now classed as a medicine, are administered to the patient. Where the starting material originates from the patient's own cells, this is called an "autologous" therapy. It should also be noted that the starting material may originate from

another donor and this is termed “allogeneic” therapy. This guidance should be used in association with the SmPC and/or the Clinical Trial Protocol/Pharmacy Manual.

An example of an autologous ex-vivo (cell based) GMO GTMP treatment is marketed CAR-T (Chimeric Antigen Receptor T cells) products. CAR-T cell therapies have led the way in demonstrating that a consistent approach to implementation encompassing governance and operational issues is required in addition to clinical readiness. To this end [Pharmacy Institutional Readiness for Marketed CAR-T Therapy](#) was prepared and used to good effect in sites commissioned to provide CAR-T cell therapy.

Other useful documents produced by the Pan UK Pharmacy Working Groups for ATMPs, to manage the pipeline of ATMPs are:

- [PIR guidance for delivery of in-vivo \(cell based\) GMO Gene Therapies](#)
- [PIR guidance for Somatic Cell Therapies](#)
- [PIR Tissue Engineered Products \(TEPs\)](#)
- [Governance and Preparation of GTMPs](#)
- [Outsourcing ATIMPs](#)
- [Outsourcing Marketed Products](#)
- [Risk Assessment Tools for ATMPs](#)
- PIR guidance for non-GMO gene therapies e.g mRNA immunotherapies or gene edited products using CRISPR Cas9 technology is currently under development.

2. Purpose

The purpose of this document is to outline the key areas where chief pharmacists should focus pharmaceutical expertise prior to an organisation implementing any ex-vivo (cell based) GMO Gene Therapy Medicinal Products (GTMPs). The principles outlined in this document are relevant for marketed, investigational and unlicensed medicines.

This document presents a flow diagram outlining a stepwise approach to implementing processes to prepare and administer ex-vivo (cell based) GMO GTMPs. It is followed by checklists which relate to the various steps presented in the diagram. These are presented as appendices.

In preparation for the implementation of NHS patient treatment, representatives from The Pan UK Pharmacy Working Group for ATMPs and Advanced Therapy Treatment Centres (ATTC) have prepared exemplar documents and templates for some of the key steps in the delivery of ex-vivo (cell based) GMO GTMPs, where outputs from this work are demonstrated throughout this document (see appendices). The checklists may be used as appendices to local procedures as a way of documenting key steps or as an aid to check that local procedures are comprehensive.

As ex-vivo (cell based) GMO GTMPs are routinely individualised for each patient, it is imperative that systems are established to ensure that the therapy is administered to the intended patient and that associated risks, particularly with tracking and traceability, are minimised.

Ex-vivo (cell based) GMO gene therapies may be stored under vapour phase nitrogen and require thawing before administration and in some cases additional aseptic manipulation. Manipulation of cellular medicines requires skilled operators who are trained and understand the risks associated with handling a living product, as well as associated health and safety risks. It is recognised that most Pharmacy Services do not usually have the expertise to manipulate these products and consequently, Pharmacy Services may not come directly into contact with the product if these tasks are performed by other specialists e.g. the Cell Laboratory or a third party provider such as a blood and transfusion service. For guidance on [Outsourcing Marketed ATMP Products](#) and Technical Agreements for [Outsourcing ATIMP Handling](#), please refer to the guidance provided. However, it is important where Pharmacy Services are not directly performing some of the outlined steps, that the roles and responsibilities of those undertaking the aforementioned steps are clearly documented and undertaken with pharmacy oversight. Ideally, an overarching Technical Agreement between the Chief Pharmacist and the Head of the relevant service, with reference made to relevant organisational SOPs should be in place.

The following process flow chart outlines the stages which require Pharmacy consideration when an organisation wishes to use a ex-vivo (cell based) GMO GTMP.

Process Flow Encompassing Points for Consideration by Chief Pharmacists

Governance

- Chief pharmacists should ensure that governance for Ex-Vivo GMO GTMPs is documented as follows:
 1. For a marketed product, centres will need to meet the requirements of the commissioning process and become a designated centre for administration of the ex-vivo (cell based) GMO GTMP which may be documented in a National Service Specification.
 2. For an investigational ATMP, centres will need to be designated by a Sponsor in a clinical trial.
 3. For an unlicensed medicine, local organisational unlicensed medicines policy will apply.
 4. Clinical approval re patient selection (MA)/Trial eligibility (ATIMP):
 - An approved centre will need to understand the national processes for patient selection if applicable.
 5. Local Governance:
 - As referenced in [Gene Therapy Medicinal Products Governance and Preparation Requirements](#) organisational governance prior to providing any ATMP is advised. This may involve an ATMP Committee and/or Medicines Management Committee, and as it is a GMO GTMP it will involve a Genetic Modification Safety Committee (GMSC) (mandated for IMP and ULM). Local requirements should be defined prior to implementation of a GMO GTMP service in an organisational policy.
 - Optimal location for cell storage and handling requires trained and competent operators, typically in stem cell labs or blood and transfusion service teams. If a pharmacy department needs to outsource this service or gain advice to define responsibilities with internal departments, further guidance on outsourced activity can be found for [Outsourcing of Storage/ Preparation of ATIMPs Across Legal Boundaries](#), [Outsourcing Activity for Cryopreserved ATIMPs](#), [Outsourcing Template Technical Agreements](#) and guidance on [How to Undertake an Audit of a Cell Therapy Laboratory](#) can be found on the SPS website.
 - Implementation sites may be asked to complete Commercial Agreements with the relevant Pharmaceutical companies/Sponsors. These will require review by Pharmacy.
 - Due to the cost of the GTMP, local financial governance requirements may need to be documented in an SOP as there may be a variation to routine standard financial instructions. Financial approval processes should be defined as part of organisational governance.
 - A centre wishing to provide ex-vivo (cell based) GMO GTMPs will define additional local governance requirements e.g. for private patients.
 6. Local Medicines Management: a SOP will be required to ensure Pharmacy's involvement with the following process:
 - Process cancellation
 - Credit claims
 - Deviations

An exemplar Medicines Management Checklist is available in Appendix 1



Class and containment level

For clinical trials, the following bullet points are mandated for GMO GTMPs, however risk assessment is recommended for all GTMPs.

See [Gene Therapy Medicinal Products Governance and Preparation Requirements](#) for more information.

- Class and containment level of gene therapy medicine (usually class 1 or 2) to be assessed.
- Check hospital site is registered with HSE to handle gene therapy medicines for appropriate class (coordinated by GMSC) if clinical trial.
- Hospital site will have a GMO certificate number issued after notification to HSE of site involvement of containment level 1 and/or 2 viral vectors in clinical trial.
- Risk assessment of risks to human health and environment to be reviewed by Genetic Modification safety committee (GMSC) or biological safety officer (BSO).
- Contained use control measures to be put in place in line with risk assessment.

GMSC risk assessment is covered in [Gene Therapy Medicinal Products Governance and Preparation Requirements](#) and involves assessment of the product, the patient and the waste.

An exemplar Pharmacy Class and Containment checklist is available in Appendix

2



Approval of the Order

- Where the patient has been referred from another hospital the clinical pharmacist at the treatment site, should verify the patient's status and ensure all criteria are fulfilled prior to approving the order. Where applicable, the clinical pharmacist at the referral site should provide information to the clinical pharmacist at the treatment site.
- A pharmacist's approval and/or the provision of a pharmacy purchase order is necessary. This will require an SOP to be defined which will need to reference any commercial operating system which an individual ex-vivo (cell based) GMO GTMP company may require to be used. Companies may suggest that the approval required is little more than a data accuracy check, however, recognising that time pressures will exist, the pharmacy SOP should ensure that the process covers all governance aspects detailed above, and any appropriate clinical verification.
- Additionally, links with pharmacy purchasing systems, and prescribing systems will require definition and may form part of this SOP or be documented separately.

An exemplar Pharmacy Patient Referral checklist is available in Appendix 3

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An exemplar Pharmacy Patient Approval checklist is available in Appendix 4

Apheresis and Manufacture

- For both an “autologous” and an “allogeneic” product the starting material must be collected in the UK under an HTA licence.
- The pathway for the manufacture of the ex-vivo (cell based) GTMP should be clearly described, and roles and responsibilities understood.
- If required, regulatory arrangements e.g. HTA licence for export/import, should be identified and implemented.

Product Receipt

- Certain ex-vivo (cell based) GMO GTMP may be supplied in a ready to administer form e.g. CAR-T therapies, following thawing. Other ex-vivo (cell based) GMO GTMP may require further aseptic manipulation.
- Ex-vivo (cell based) GMO GTMP are generally not handled in pharmacy (usually in stem cell laboratories) but receipt, storage, preparation, and issue are pharmacy responsibilities and should be co-ordinated under pharmacy oversight.
- An SOP for receipt of GMO GTMP covering those holding marketing authorisation as well as IMPs is required. Checks on receipt should include integrity of the product, labelling and temperature compliance during transit. Certificate of Analysis/QP certificates detailing the dose, if applicable. This should be reviewed by an appropriately trained clinical pharmacist or Clinical Trials pharmacist.

An exemplar Product Receipt checklist is available in Appendix 5

Storage

- Optimal storage location for ex-vivo GMO GTMP will depend on storage temperature conditions and duration. If ambient, refrigerator or -80°C freezer or short-term vapour phase nitrogen dewar then pharmacy storage may be an option for ready to administer products. For storage and handling guidance for products requiring below -20°C storage, refer to [Dry Ice and Vapour Phase Nitrogen Shipper](#) guidance. Cell based products should be segregated where possible and always stored in a secure manner which minimises the risk of cross-contamination.
- Ex-vivo (cell based) GMO GTMPs will require to be stored under specified temperature storage conditions. This may be at ambient, refrigerated or freezer temperatures. In some cases, this may be as low as -150°C. It is important that appropriate equipment is sourced, as necessary, to accommodate specific requirements. Stem cell Labs with pharmacy oversight or outsourcing may be an option and the various options should be risk assessed. (See Governance)
- Continuous temperature monitoring is required from receipt through to administration.

The exemplar Product Receipt checklist is available in Appendix 5 which covers aspects of storage

Preparation Location Decision

- Some ex-vivo (cell based) GMO GTMPs will require a thaw/preparation/reconstitution step. Optimal location for ex-vivo (cell based) GMO gene therapy preparation will be as per SmPC or clinical trial protocol. Where the location is not specified guidance can be found in [Gene Therapy Medicinal Products Governance and Preparation Requirements](#). Preparation location should have been defined in the GMSC risk assessment.
- On receipt, it is recommended that the product can either be: -
 - Transported to the clinical area and then thawed prior to administration – stability <4 hours
 - Thawed in pharmacy and transported to the clinical area – stability >4 hours
 - Thawed and aseptically manipulated e.g. in stem cell laboratories then transported to the clinical area for administration to the patient. Pharmacy oversight is required.
 - Manipulation could be outsourced - Technical agreement is required. For further information, refer to

Aseptic Preparation e.g. stem cell laboratory

Where aseptic preparation/manipulation is to be carried out, Pharmacy oversight needed for the following:

- Governance:
 - Roles and responsibility clear
 - GMSC risk assessment compliance
- Operator protection
- Preparation process
- Cleaning agent suitability
- Waste management
- Transportation
- Worksheet approved in line with SmPC or Protocol
- Confirmation when the patient is ready for ex-vivo (cell based) GTMP treatment.

For further information on each point, see [Gene Therapy Medicinal Products Governance and Preparation Requirements](#).

Storage and manipulation could be outsourced, in which case a technical agreement will be required. For more information, refer to [Outsourcing ATMP Guidance](#).

Preparation checklist is available in Appendix 6a

Pharmacy Storage, Issue & Transportation to the clinical area

- Ex-vivo (cell based) GMO GTMPs, where prolonged storage is not required, may be routinely received via Pharmacy. They may be thawed by trained and competent staff and transported to the clinical area – without any further aseptic manipulation.
- Confirmation when the patient is ready for ex-vivo (cell based) GMO GTMP treatment should be obtained.
- Procedure for retrieval from storage, if applicable, or reference to SOP if no different to routine should be available. Guidance for below -20°C storage can be found [here](#).
- Procedure for pharmacy thaw (if applicable) should be available and competency training in place.
- Transportation method to clinical area approved by GMSC.
- Transportation performed by trained and competent staff.

An exemplar Pharmacy Dispensing checklist is available in Appendix 7

Issue & Transportation to the clinical area

The product should then be released by a pharmacist and will be in its ready-to-administer presentation. This should be issued and transported according to a local SOP:

- Procedure for retrieval from storage, if applicable, or reference to SOP if no different to routine should be available.
- Transportation method to clinical area approved by GMSC.
- Transportation performed by trained and competent staff.
- Spill kit available.

An exemplar Pharmacy Dispensing checklist is available in Appendix 7

Clinical Area Preparation

If thaw or any manipulation is required, in the clinical area, (due to insufficient stability for aseptic suite manipulation) then the Chief Pharmacist should ensure that the following are included in the approved Pharmacy SOP.

- Roles and responsibilities should be clearly documented.
- A Pharmacy approved clinical area worksheet in line with the SmPC/Protocol should be issued.
- PPE appropriate to the containment level should be available.
- Any preparation should be undertaken by trained and competent staff and be in line with an SOP detailing whether additional labelling is required.

An exemplar Clinical Area Preparation checklist is available in Appendix 6b

Administration & Monitoring

- The pharmacist with clinical responsibility for the patient needs to be an expert on any required pre-medication, concomitant medication, and post GMO GTMP administration medication. They also need to be aware of toxicity management and contra-indicated medicines.
- Resources available include SmPC and company literature as well as protocol, investigators brochure and Pharmacy Manual for Advanced Therapy Investigational Medicines Products.
- The clinical subgroup of the Pan UK Pharmacy Working Group for ATMPs will endeavour to produce specific clinical guidelines where risk assessment deems it appropriate. Guidance on [PIR for Marketed CAR-T Therapy](#), [Supportive Medicines for Adults Receiving Marketed CAR-T Therapy](#), [Medication Restrictions for Patients Having CAR-T Cell Therapy](#) and [Diagnosis and Medical Management of Acute CAR-T Cell Toxicities in Adults](#) are available.

Ex-vivo GMO GTMP Pharmacy Medicines Management Checklist

Product Name			
Supplier			
Manufacturer (if different to above)			
Regulatory status	Licensed / Unlicensed / Clinical Trial <small>(Record EudraCT number if applicable)</small>		
Checking step	Yes / No / NA Data	Checker Initials	Date
Treatment centre selected by NHS to deliver GMO GTMP	Yes / No		
Treatment centre audited and approved by JACIE (or other as appropriate) to deliver ex-vivo (cell based) gene therapies	Yes / No / NA		
Treatment centre qualified by manufacturer to deliver product	Yes / No / NA		
Governance approvals in place for use of product as applicable: Medicines Management Formulary ATMP Oversight Group (or similar) Clinical trial approval	Yes / No / NA		
Biological safety risk assessment completed / Genetically Modified Organism Safety Committee approval gained	Yes / No		
HSE notification if required for clinical trial	Yes / No / NA		
SmPC and PIL available	Yes / No		
Prescription added to electronic SACT prescribing system	Yes / No		
Product added to Pharmacy Ordering system	Yes / No		

Appendix 1 (cont.)

Checking step	Yes / No / NA Data	Checker Initials	Date
If product requires aseptic manipulation by stem cell laboratory or is outsourced out-with the organisation, then a technical agreement is in place.	Yes / No / NA		
If prepared by nurses: worksheet, SOPs, staff training in place	Yes / No / NA		
Intravenous risk assessment completed	Yes / No / NA		
Trust funding process approved	Yes / No		
Ensure product being tracked by Medicines Finance team and Contracts for Trust reimbursement	Yes / No		

Pharmacy product specific folder in place	Yes / No		
Pharmacy SOP in place for cancellation of order	Yes / No		
Pharmacy SOP in place for credit claims	Yes / No		
Pharmacy SOP in place for deviations	Yes / No		
Pharmacist Final Check			
	Print Name	Signature	Date
Comments			

Ex-vivo GMO GTMP Pharmacy Class and Containment Checklist

Class and containment level <i>*circle as appropriate</i>	Class 1* / 2* / 3* / 4*		
Check hospital / organisation is registered with HSE to handle gene therapy medicines for appropriate class (coordinated by GMSC)	Yes	No	
Risk assessment			
GMSC			
NPSA			
Waste disposal			
Spillage			
Staff Training and competence			
Genetic Modification Committee (GMC) and/or Advanced Therapy Medicinal Products (ATMP) Committee Approval and/or New Interventional Procedures Committee approval			
Medicine Management Committee approval			
Preparation Facilities: <ul style="list-style-type: none"> • External to pharmacy • Freezer storage • Transport • Aseptic facilities risk assessment • Personal Protective Clothing 			
	<i>Print Name</i>	<i>Signature</i>	<i>Date</i>

Ex-vivo GMO GTMP Pharmacy Patient Referral Checklist

Product Name			
Supplier			
Patient name			
Patient Date of Birth (dd/Mmm/yyyy)			
Patient NHS Number			
Information needed		Date	
Height (cm), if applicable			
Weight (kg), if applicable			
Medication allergy status			
Current medication history – including chemotherapy and radiotherapy treatment history			
Any abnormal laboratory results			
Any other comments			
Referral Centre Pharmacist completing form	<i>Print Name</i>	<i>Signature</i>	<i>Date</i>
Referral Centre Pharmacist Contact details			

Treatment Centre Pharmacist			
Clinical verification for referred patient acceptable and meets eligibility criteria	Yes / No		
Clinically suitable pre-treatment/washout undertaken or planned, if applicable	Yes / No / NA		
Treatment Centre Pharmacist completing form	<i>Print Name</i>	<i>Signature</i>	<i>Date</i>

Ex-vivo GMO GTMP Pharmacy Patient Approval Checklist

Product Name			
Supplier			
Manufacturer (if different to above)			
Patient name			
Patient Date of Birth (dd/Mmm/yyyy)			
Patient Hospital Number			
Checking step	Yes / No / NA Data	Checker Initials	Date
Governance approval in place	Yes / No		
Patient selection approval number	Yes / No		
Blueteq ID	Yes / No / NA		
Trust funding approved	Yes / No		
Patient consent documented	Yes / No		
Pharmacist accuracy check completed	Yes / No		
Pharmacy order number issued	Yes / No		
Manufacturer's details	Yes / No		
Pharmacist approval documented	Yes / No		
Pharmacist Final Check	<i>Print Name</i>	<i>Signature</i>	<i>Date</i>
Comments			

Ex-vivo GMO GTMP Receipt Checklist

Product Name			
Supplier			
Manufacturer (if different to above)			
Courier Job Number (& other ref no)			
Date & time received			
Received by			
Checking step\data	Yes / No / NA Data	Checker Initials	Date & time
Tamper-evident ties intact? Outer Inner	Yes / No Yes / No		
Dry ice competency (as appropriate)	Yes / No / NA		
Transit data logger temperature checked on receipt as per requirement	Yes / No		
Data logger within specification (no alarms)	Yes / No		
All required documentation received: Shipping log Returns documents Certificate of Analysis /QP release	Yes / No / NA Yes / No / NA Yes / No / NA		
Dose as prescribed and within range	Yes / No		
Quantity received – no of bags			
Donation ID number correct (as required)	Yes / No		
Patient name			
Patient date of birth			
Overwrap			

Appendix 5 (cont.)

Product integrity visual check	Pass / Fail		
Lot/batch number			
Expiry Date	Yes / No		
Storage requirements			
Product placed into storage	Yes / No		
Storage location			
Receipt documented	Yes / No		
1st Check (Print name, sign, date)	<i>Print Name</i>	<i>Signature</i>	<i>Date</i>
2nd Check (Print name, sign, date)	<i>Print Name</i>	<i>Signature</i>	<i>Date</i>
Completed receipt checklist sent to Pharmacy			
Comments			

Ex-vivo GMO Stem Cell Lab / Outsourced Aseptic Preparation Checklist

Process Set Up/Governance	Yes / No / NA	Checker Initials	Date & time
Roles and responsibilities documented	Yes / No		
Dedicated Isolator or BSC (II) available or campaign use agreed	Yes / No / NA		
Preparation Location Complies with the requirements in Chart 8.2 in Gene Therapy and Preparation	Yes / No / NA		
Worksheet written in line with SmPC, or Protocol / Pharmacy Manual (for Clinical Trials)	Yes / No / NA		
Appropriate label designed and approved	Yes / No		
Worksheet approved	Yes / No		
Waste pathway clear	Yes / No		
Required PPE is available	Yes / No		
Cleaning agent appropriate	Yes / No		
Process	Yes / No	Checker Initials	Date & time
SOP requires confirmation of patient readiness prior to beginning preparation	Yes / No / NA		
Operators are trained in the process	Yes / No		
Retrieval from storage (SOP available)	Yes / No / NA		
Thaw SOP in place	Yes / No / NA		
Aseptic preparation / manipulation method developed and approved	Yes/ No		
The process is covered by a suitable validation (as required)	Yes / No		
Check and release processes in place	Yes / No		
Transportation arranged	Yes / No		
	<i>Print Name</i>	<i>Signature</i>	<i>Date</i>

Appendix 6b
Ex-vivo GMO Clinical Area Preparation Checklist

Process Set Up/Governance	Yes / No	Checker Initials	Date & time
Roles and responsibilities documented			
Is the medicine a Class I Gene Therapy*	Yes / No		
Is the shelf life <4hrs post reconstitution*	Yes / No		
Does the SmPC or Pharmacy Manual allow preparation on a clinical area	Yes / No		
Is a Pharmacy approved Worksheet available	Yes / No		
Has the GMSC approved clinical area preparation	Yes / No		
Are operators trained and competent	Yes / No		
Is a process in place for communicating patient readiness to Pharmacy (to avoid prolonged GTMP storage in the clinical area)	Yes / No		
Required PPE is available	Yes / No		
	<i>Print Name</i>	<i>Signature</i>	<i>Date</i>

*If the answer is no to either of these questions, then check that clinical area preparation is optimal.

Appendix 7
Ex-vivo GMO GTMP Pharmacy Patient Dispensing Checklist

Product Name			
Supplier			
Manufacturer (if different to above)			
Patient name			
Patient Date of Birth (dd/Mmm/yyyy)			
Patient Hospital Number			
Treatment location			
Checking step	Yes / No / NA Data	Checker Initials	Date
Screened prescription available for treatment date	Yes / No		
Certificate of analysis received with product	Yes / No / NA		
Temperature deviations during storage on site	Yes / No		
Record batch number/product identifier on prescription	Yes / No		
Receive and book out GTMP on Pharmacy Dispensing system	Yes / No		

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