Inspection report on compliance with HTA licensing standards
Inspection date: **28 September 2022**

Medherant Ltd

HTA licensing number 12652

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation
Medherant Ltd	Licensed	Not licensed

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Medherant Ltd (the 'establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and quality systems. The shortfalls were related to a lack of documented procedures and risk assessments around the receipt, storage, and monitoring of frozen skin.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative

actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	The establishment has developed procedures for receiving, storing and monitoring frozen skin but these have not been formally documented. ***The establishment submitted sufficient evidence to address this shortfall before the report was finalised.***	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	As a result of supply and transport issues the establishment has begun to import and store a collection of frozen skin rather than importing fresh skin as needed. Risks associated with this change in process have not been sufficiently assessed or documented. ***The establishment submitted sufficient evidence to address this shortfall before the report was finalised.***	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete

actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

The HTA advises the DI to consider the following to further improve practices:

Number	Standard	Advice
1.	C1(c)	The establishment retains a documented assurance from its commercial tissue supplier that appropriate consent is in place for all donated material. The DI is advised to review how often assurances should be reviewed and/or renewed as the current assurance was issued by the supplier in 2014.
2.	GQ1(a)	On one previous occasion, the establishment was notified by their supplier that a tissue sample that they had received was from a donor with a confirmed blood-borne infection. The sample was disposed of appropriately. The DI is advised to document the procedure for disposing of high risk samples in case this is relevant again in the future.
3.	GQ3(a)	The establishment undertakes competency-based, staff training assessments, which are recorded in a colour-coded spreadsheet. To facilitate the review of staff training records, the DI is advised to separately document successful completion of the individual activities in the training spreadsheet. This will help to provide assurances that staff are appropriately trained for their roles.
4.	GQ3(b)	The DI is advised to supplement the current staff training with additional information on the requirements of the Human Tissue Act 2004. While this may be developed internally, the DI may wish to consider one of the Human Tissue training resources available online.

Background

Medherant is a clinical-stage company involved in the development of treatments using a transdermal drug delivery technology. Its research uses imported skin samples, sourced with ethical approval and appropriate consent in France. Initially the establishment followed a procedure where fresh skin was imported as required, stored and generally used within 48 hours. Recently - in response to supply and shipping issues, and a change in the use of the tissue - the establishment has begun to import frozen tissue and store it for an extended period of time.

Medherant Ltd has been licensed by the HTA since 2016. This was the first inspection of the establishment since it was licensed.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

There are 47 standards in the Research sector, of which 36 were assessed. Standards C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b), C2(c), T1(f), T1(g) and PFE2(b) could not be assessed as the establishment does not directly seek consent, provide material to others, or store material from the deceased (standards published 3 April 2017).

Review of governance documentation

The assessment included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents relating to licensed activities, supplier agreements, equipment records, risk assessments, arrangements for temperature monitoring for the storage unit, staff training records, a review of the physical Human Tissue Sample Log and corresponding electronic spreadsheet used to record and track relevant material, and audits.

Visual inspection

No site visit was undertaken as part of this inspection. However, the establishment provided photographs of the storage unit for review during the assessment.

Audit of records
A recent internal audit was reviewed as part of this assessment. In addition, details of tissue recorded in the physical Human Tissue Sample Log were reviewed against the electronic spreadsheet.

Meetings with establishment staff
The assessment included discussions with the DI and the Corporate Licence Holder contact.

Report sent to DI for factual accuracy: 24 October 2022

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 24 November 2022

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or

- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.