Licence application assessment visit report on compliance with HTA licensing standards
Site visit date: **04 February 2020**

MedPharm Ltd

Proposed HTA licensing number 12690

Application for a licence under the Human Tissue Act 2004

Activities to be licensed

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
MedPharm Ltd	To be licensed	Not to be licensed

Summary of visit findings

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

Although the HTA found that MedPharm Ltd (the 'establishment') had met the majority of the HTA's standards one minor shortfall was found against the standards for Governance and Quality systems.

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 shortfall identified during the visit.

Compliance with HTA standards

Minor shortfall

Standard	Visit findings	Level of shortfall
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.	The establishment's risk assessments are focused on health and safety matters and do not cover all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice. ***Prior to the report being issued the proposed DI submitted evidence of the actions taken in relation to this shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be now met.***	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(c)	For each specific tissue type, establishment staff order material from suppliers that have been authorised after a review of their consent and collection procedures. The proposed DI is advised to implement a process where he assesses any purchase of a new tissue type from authorised suppliers to ensure the new tissue type has been collected and supplied in line with the consent that was provided by the donor, and that appropriate consent is in place for its use.
2.	GQ3(a)	The proposed DI is advised to consider including HTA specific training as part of the establishment induction programme, for all staff working with or having access to, relevant material. This will provide an assurance that all staff are aware of the need to store and use human material appropriately.
3.	PFE2(c)	The establishment is currently in the process of acquiring a continuous monitoring system for freezer units where relevant material will be stored. Once the system has been purchased, the proposed DI is advised to consider implementing a process to trend the routine temperatures of the units. Deviations in these temperatures may provide an early warning of a potential unit failure.

Background

MedPharm Ltd (the ‘establishment’) is a privately held biotechnology company that has applied for a HTA licence to store relevant material which has come from a human body for use for scheduled purposes. The company provides a number of experimental models to assess the formulation and efficacy/penetration of drugs across a biological surface. The establishment will only receive relevant material that has been purchased from commercial suppliers.

Description of activities undertaken during visit

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during the visit:

Standards assessed against during visit

There are 47 standards in the Research sector, of which 38 were assessed. Standards C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b), C2(c) and T1(g) could not be assessed as the establishment does not directly seek consent or distribute material (standards published 3 April 2017).

Review of governance documentation

The visit included a review of documentation relevant to the establishment's proposed licensable activities. This included policies and procedural documents, equipment records, risk assessments, temperature monitoring for the storage units, staff training records, and a review of the database that will be used to record and track relevant material.

Visual inspection

The visit included a visual inspection of the areas where the establishment proposes to undertake the licensable activity. This included the areas where relevant material will be received into the establishment and stored.

Meetings with establishment staff

The visit included discussions with the proposed DI, proposed Corporate Licence Holder contact, and establishment staff involved with ordering and receiving relevant material, as well as those involved with governance and quality systems.

Report sent to proposed DI for factual accuracy: 11 February 2020

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

Final report issued: 04 March 2020

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 site visit 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 site visit.

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

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