Inspection report on compliance with HTA licensing standards
Inspection date: **15 September 2022**

# Pharmaron UK Ltd

HTA licensing number 12633

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 |
|---|---|---|
| **Pharmaron UK 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 Pharmaron UK Ltd (the 'establishment') had met the majority of the HTA's standards, two minor shortfalls were found against standards for Governance and quality systems, and Premises, facilities and equipment. The shortfalls identified were related to establishment audits and monitoring of the vapour phase Liquid Nitrogen tank.

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 |
|---|---|---|
| **GQ2 There is a documented system of audit** | | |
| b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these. | Audit findings are cascaded to staff but there was no evidence of a formalised audit follow-up process. | **Minor** |

| | | |
|---|---|---|
| **PFE2 There are appropriate facilities for the storage of bodies and human tissue** | | |
| c) Storage conditions are monitored, recorded and acted on when required. | There was no documented procedure for monitoring the conditions in the vapour phase Liquid Nitrogen storage tank. | **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 documented assurances from its commercial suppliers that appropriate consent is in place for all donated material. One of the assurances reviewed had been issued in 2014. To ensure that agreements remain valid, the DI is advised to review how often assurances should be reviewed and/or renewed. |
| 2. | GQ2(a) | Audits are undertaken by a member of staff working directly under the HTA licence, separately to the establishment's overarching audit framework. To provide improved and consistent oversight, support and follow-up, the DI is advised to consider whether it would be beneficial to incorporate HTA-related audits into the establishment's wider governance framework. |
| 3. | GQ2(a) | To assist in demonstrating compliance with our standards and whether the establishment is meeting the requirements of their own systems, the DI is also advised to consider extending the scope of audits. Possible examples include those related to process observations and a full audit against the HTA's licensing standards. |
| 4. | GQ5(a) | The establishment document, 'Carrying Out a Risk Assessment For Human Tissues' also provides examples of potential adverse events and the procedure to follow should one occur. To improve clarity and awareness of adverse event reporting, the DI is advised to consider developing a separate procedure for responding to an adverse event. |
| 5. | T1(b) | In addition to storing relevant material under the HTA licence, the establishment also stores material under approvals from recognised Research Ethics Committees (RECs). To improve awareness and |

| | | |
|---|---|---|
| | | oversight of storage requirements for all material, the DI is advised to record and track the expiry dates of REC approvals. |

**Background**

Pharmaron UK Ltd provides contract research and development services for clients in the life sciences industry. The establishment imports skin samples and cryopreserved hepatocytes from commercial suppliers in Europe and the United States. The establishment has documented assurances of appropriate consent from the commercial suppliers. In addition, the establishment also stores faeces and urine under recognised Research Ethics Committee (REC) approval for ongoing research projects and clinical trials. Depending on the tissue type, samples are stored in fridges, freezers and in vapour phase Liquid Nitrogen (LN2) tanks.

Pharmaron UK Ltd has been licensed by the HTA since 2015. This was the second inspection of the establishment; the most recent previous inspection took place in February 2016.

Since the previous inspection, the establishment has changed its name, appointed a new DI, a new Corporate Licence Holder contact, and three new Persons Designated.

**Description of inspection activities undertaken**

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager 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, agreements with suppliers, equipment records, risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the physical Human Material Tissue 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 facility that allowed an assessment of security around the storage units and the signage on the individual units.

*Audit of records*
A recent internal audit was reviewed as part of this assessment. In addition, several current pages from the physical Human Material Tissue Log were reviewed against the electronic spreadsheet.

*Meetings with establishment staff*
The assessment included discussions with the DI, four Persons Designated working under the licence, and the Director of Quality Assurance.

**Report sent to DI for factual accuracy: 14 October 2022**

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

**Final report issued: 3 November 2022**

**Completion of corrective and preventative actions (CAPA) plan**

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Virtual Regulatory Assessment Report.

**Date: 2 February 2023**

## 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.