HTA Policy

Policy for handling allegations about individuals or establishments on matters within HTA's remit

Purpose

1. This policy outlines the approach the HTA takes when it receives allegations and aims to mitigate the risk of inconsistent and inappropriate handling of allegations. When considering allegations, the role of the HTA is to establish whether there has been a statutory or regulatory breach and to take action where necessary. In the first instance, allegations will be assessed to determine whether the matter is within the HTA's remit and what actions should follow.

Background

2. The HTA's aim is to make sure that the statutory requirements of The Human Tissue Act 2004 (HT Act 2004), The Human Tissue [Quality and Safety for Human Application] Regulations 2007 (as amended) (Q & S [tissue and cells] Regulations) and The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) (Q & S [organs] Regulations] are met. The HTA does this by setting standards that are clear and reasonable and in which professionals and the public can have confidence. The HTA has also published HTA Directions and codes of practice.

3. The HTA licenses organisations that remove, store and use human tissue for specific purposes such as research, human application, organ donation and transplantation, post mortem examination, teaching and public exhibitions. The HTA also gives approval for organ and bone marrow donations from living people through an independent assessment process.

4. The HTA is a risk based regulator and assesses allegations according to risk. In this context, the risk the HTA refers to is normally regulatory risk, i.e. the risk of non-compliance with the requirements of the legislation the HTA was set up to implement.

5. The HTA may investigate allegations that suggest:

    a) a licensed establishment is not meeting HTA statutory or regulatory requirements; or
    b) licensable activities are taking place on unlicensed premises.

6. It is possible for an allegation to be made by a third party to the HTA under the Public Interest Disclosure Act 1998 (PIDA). However, the circumstances where this is the case are narrow, and are included at paragraphs 9 to 13. Such an allegation is commonly referred to as whistleblowing.

Terminology used in this policy

- **Allegation:** a statement made by one of the HTA's stakeholders (including a member of the public, another regulator or a Government department) about a licensed or unlicensed establishment, or a person working at such an establishment, that alleges an activity has occurred or is being carried out in breach of the statutory requirements of the HT Act, the Q & S [tissues and cells] Regulations, Q & S [organs] Regulations, including the licensing requirements or other regulatory requirements of the HTA.

- **Licensed establishment**: an establishment that is licensed by the HTA. The allegation may relate to one person's practices or overall practices within the licensed establishment.

- **Unlicensed establishment:** an establishment that is not licensed by the HTA but whose activities may fall within the regulatory remit of the HTA.

- **Investigation:** one of the formal actions taken by the HTA in response to allegations received, that involves the gathering of and examination of evidence to support or disprove those allegations.

- **Whistleblowing**: an allegation made by a third party under PIDA 1998.

General principles for dealing with allegations

7. These are the principles that the HTA will consider when dealing with allegations about licensed and unlicensed establishments:

    a) ways of reporting such allegations to the HTA are made clear and transparent;

b) where an allegation is made by an individual, that individual will be asked to consent to the HTA disclosing their identity to the relevant establishment; if they do not consent, the HTA will explain that (i) this may prevent them from taking forward the investigation and (ii) if an investigation does take place, the HTA may be required to disclose their name even if consent has been withheld in certain circumstances. Personal data processed by the implementation of this document will be done so in accordance with the HTA's Privacy Notice;

c) where the allegation is made by an employee of an establishment who is raising concerns about practices taking place, they will be given appropriate support and advice and their interests are protected as far as possible by the HTA;

d) except where it would be inappropriate to do so (for example where notifying an establishment or person about an investigation may prejudice the investigation itself), the establishment about which the allegations are made will be informed of the investigation;

e) persons making allegations, and establishments subject to these allegations, will be advised of any constraints of the investigation, for example limitations relating to the HTA's statutory remit;

f) where appropriate, the HTA will consider providing the person(s) making allegations with further information; for example, a summary at the conclusion of an investigation. It will not provide information if it is deemed that it may impede an investigation by another authority (for instance a criminal investigation);

g) any investigation will be open and transparent, and details will be shared with the establishment concerned wherever possible;

h) the focus of the HTA investigation into any allegation made should be to assess the evidence that exists, or is needed to support the allegation, and to address what possible impact this may have on any existing licence, or the need for a licence;

i) allegations provide an opportunity for the HTA and the establishment concerned, whether licensed or unlicensed, to work together to ensure compliance with regulatory and legal requirements.

Allegations made under the Public Interest Disclosure Act 1998

8. PIDA applies to people at work who raise concerns in good faith about crimes, civil offences, miscarriages of justice, dangers to health and safety or the environment, and the cover up of any of the above matters. In addition to employees, it covers workers, contractors, trainees, agency staff, homeworkers, police officers and every professional in the NHS.

9. PIDA states that a person who wishes to raise a whistleblowing allegation should do so **directly** to the organisation about which it is being made (so a person working at a hospital should raise it directly within that hospital). It also makes special provision for disclosures to 'prescribed persons', who are regulators included in the list of prescribed persons and bodies published by the Department for Business and Trade.

10. The HTA is not a prescribed person and therefore a whistleblowing concern raised to the HTA by a person who does not work for the HTA is a 'wider disclosure'. A wider disclosure is protected if, in addition to the tests for regulatory disclosures outlined in PIDA, it is reasonable in the circumstances and not made for personal gain. A wider disclosure must also fall within one of the following four categories to be a whistleblowing allegation made to the HTA:

    a) the whistleblower reasonably believed he would be victimised if he had raised the matter internally or with a prescribed regulator; or
    b) there was no prescribed regulator and he reasonably believed the evidence was likely to be concealed or destroyed; or
    c) the concern had already been raised with the employer or a prescribed regulator; or
    d) the concern was of an exceptionally serious nature.

11. If a person intends to make an allegation to the HTA under PIDA, it is suggested that they seek advice as to whether the disclosure would be protected. Protect, a professional body or union, or a legal advisor will all be able to provide such advice. If advice has not been sought prior to the person approaching the HTA, the HTA should consider whether it should take advice on the person's standing under PIDA.

12. All allegations made under PIDA will be bought to the attention of the Director of Regulation at the first possible opportunity. The Director of Regulation will oversee the investigation (as per paragraph 26).

Principles for dealing with persons making allegations confidentially or anonymously

13. This section sets out how the HTA deals with information provided by a third party, which may come from various sources, including from a person within an

organisation, a member of the public, another regulator or a Government department.

Persons making allegations who request that their identity is kept confidential

14. If someone makes an allegation anonymously or refuses consent to disclose their identity to the establishment, the HTA must take a view as to how to proceed. The HTA will explain that confidentiality cannot be guaranteed as the HTA may be required to disclose their name to the establishment or to another investigating authority in certain circumstances.

15. In order to maintain the anonymity of a person making an allegation, the HTA may be able to follow up the allegation in a non-specific way. This may be done by treating the information provided as a confidential “tip off” and determining whether there is any evidence to substantiate the allegation during the course of a scheduled inspection, without making the establishment aware that the information has been received. Consequently, any action taken by the HTA will be based on the findings (evidence) of the inspection rather than the concern raised by the person making the allegation. In this case, the person making the allegation should be informed that, without the ability to identify them, the investigation may be limited in scope.

16. In circumstances where the allegation warrants a full investigation, for instance where the allegation is so serious that public safety may be at risk, the HTA will explain to the individual that they will try to protect their identity but that the HTA may be required to disclose their identity to the establishment or to another investigating authority and so cannot give a guarantee that their personal details will not be disclosed. Where the individual has concerns about their own safety, the HTA will work closely with them to ensure that they have support available.

Disclosing the identity of the person making the allegation

17. When the person making the allegation does not give their consent for their identity to be disclosed and the HTA considers that a full investigation is warranted, the HTA will consider whether:

    a) it is reasonable in the circumstances to disclose the identity of the individual in order to investigate the allegation. This requires consideration of the public interest in revealing the identity, accountability and transparency, fairness, damage, distress and any duty of confidentiality to the individual and whether their identity is generally known. Legal advice is likely to be needed in relation to individual cases;

b) the disclosure is required by law (for example, by statutes, rules of law, court orders, etc.). Where the HTA is required by law to disclose the identity of an individual, this will usually override any obligation of confidentiality. For example, in circumstances where allegations are subsequently proven to be false or unsubstantiated, the person tainted or accused by the allegations may wish to pursue a court action against the accuser. The court may, in such circumstances, order disclosure of the identity of the whistleblower. However, the HTA has no obligation to notify any person tainted or accused by such false or unsubstantiated allegations of their right to obtain disclosure through the courts. This will be a matter for the person so tainted or aggrieved to pursue independently, at their initiative.

18. The HTA is subject to the Freedom of Information Act 2000 and therefore any information provided to the HTA may be disclosed in response to a request for information under that Act. However, the HTA will only disclose personal information where doing so will not breach data protection law or its obligations of confidentiality.

Persons making allegations anonymously

19. Persons who make allegations anonymously make disclosures with little or no information about their identity and it is therefore impossible or highly unlikely that they will be identified. Examples include persons who provide information on an answer machine or who do not disclose their name and contact details in correspondence. In certain circumstances, this may make it impossible to carry out any investigation (for example when a patient makes allegations about treatment received). Anonymity should not, however, prevent the HTA investigating where there appears to be a public interest in doing so.

Raising the allegations with the establishment

20. The HTA does not have a legal remit to investigate all allegations. Even if the HTA undertakes an investigation, the person making the allegation will normally be encouraged to raise the issue directly with the establishment concerned, providing the organisation the opportunity to deal with the matter itself. If the matter relates to their personal treatment or some aspect of service delivery, they may also be advised to pursue independent complaints-handling channels, if the establishment does not provide a satisfactory response and resolution.

Principles for dealing with the establishment

21. When any complaint or allegation is made to the HTA that affects or has the ability to affect the licence held by any establishment, the HTA will consider

options. The HTA will be mindful at all times of its responsibility as set out in the HT Act 2004 (section 38 of Part 2) to be transparent, accountable, proportionate, consistent and to target action only at cases in which action is needed.

22. The HTA does not have statutory powers to investigate allegations or complaints. The HTA does, however, need to act on concerns raised that affect a licence holder. The HTA has power to enter and inspect premises and to take away documents or other material from a licence holder. Where possible, the HTA will always seek to alert the licence holder of the allegation raised so that a full dialogue can take place for resolution. In some cases, this may not be appropriate. The HTA has a procedure on regulatory decision making, which ensures consideration is given to a range of actions in relation to licensed premises (SOP-REG-026 Regulatory Decision Making), and this is the process that will be followed where an allegation is received.

23. Where an allegation is raised about an activity under the Human Tissue legislation that affects a business or person who does not have a licence from the HTA, the HTA will consider whether the nature of the allegation is so serious it should be referred to the police under its applicable policy, or to an external regulator.

Allegations concerning unlicensed establishments

24. Where there is an allegation about an activity that falls within the remit of the HTA (as detailed in s14 of the Act), but for which no licence is required, the HTA will decide what format of investigation is appropriate (if any) taking into account the statutory position detailed in s15 of the Act.

The HTA investigation process

25. An investigation by the HTA may not be necessary in every case; however where an investigation is conducted, the following will apply.

Roles and responsibilities

26. The Director of Regulation has overall responsibility for the investigation of allegations about licensed and unlicensed establishments; however management of these will usually be delegated to a Head of Regulation who may assign a Regulation Manager to lead the investigation. The Head of Regulation/Regulation Manager's responsibilities will include keeping relevant parties informed and communicating the outcome of the investigation. In some cases, it may involve leading an inspection as part of an investigation.

27. The number of persons dealing with an allegation, or informed of the investigation, will be kept to a minimum.

Timelines for the investigation

28. There is no time limit for raising an allegation; however, a thorough and robust investigation is easier to carry out if it commences as soon as possible after the alleged event has occurred.

29. It is not possible to set defined time limits for responses and updates about investigation into an allegation. In some cases it may be possible to resolve matters without delay; in others, action may be required in liaison with other regulators and authorities, and the matter may take some time to resolve. In any event, the person making the allegation and the person or establishment who are the subject of the investigation, will be informed of expected timescales on a case by case basis.

Regulatory Decision Making Process

30. The HTA has a process for escalating some regulatory decisions. The process is invoked when a HTA staff member receives or uncovers information about an HTA licensed establishment which (1) they believe should be escalated internally and (2) may result in some form of significant regulatory action or (3) requires consideration in relation to regulatory requirements. The procedure stops once the decision has been resolved.

31. All licensing decisions made following this process will follow principles of better regulation and public law principles of reasonableness and proportionality, with particular emphasis placed on the risk presented by the issue under consideration and the impact of the regulatory action being considered. The HTA aims for decisions to be consistent with decisions made where similar circumstances existed; in all cases the establishment's particular circumstances and regulatory history will be considered.

Raising the allegations with another agency

32. The substance of the allegation may fall within the remit of another regulator. It may therefore be necessary for the HTA to refer the person making the allegation to another regulatory body, for example the General Medical Council, Care Quality Commission and/or Human Fertilisation and Embryology Authority, Health and Safety Executive, or to refer the matter to the relevant body itself. If the allegation relates to a matter which may be a breach of the law, the HTA policy on referring potential criminal breaches of Human Tissue legislation should be referred to (HTA-POL-023).

Actions following an investigation

33. The HTA may take one or more of the following actions following an investigation:

    a) decide to take no further action;

    b) advise the person making the allegation to pursue the allegations with establishment, if they have not already done so;

    c) refer the person making the allegation to another regulator or itself refer the matter to another regulator;

    d) undertake an inspection, either:

        (i) unannounced, where the licensed establishment will not receive prior notice of the site visit, or

        (ii) scheduled, where the licensed establishment will receive advance notice of the site visit;

    e) take regulatory action against a licensed establishment and/or the Designated Individual, for example by:

        (i) proposing additional conditions to the HTA licence, which the licensed establishment will be required to comply with by a certain date (subject to a statutory 28-day period in which they can notify the HTA that it intends to make representations)

        (ii) issuing special directions that impose requirements on a licensed establishment, with immediate effect

        (iii) suspending or revoking a licence

        (iv) providing written and oral advice and guidance or advice and warning;

    f) refer the matter to the police under its protocol for managing potential breaches of human tissue legislation after considering HTA-POL-023 if any offences are suspected of being or have been committed under the applicable legislation.

34. This list is not exhaustive and the risk based and proportionate approach to take will be determined on a case by case basis.

35. In the case of an unlicensed establishment that is allegedly carrying out licensable activities, the HTA will consider the proportionate action to take on a case-by-case basis. This will usually involve the establishment to cease activities and apply for an HTA licence without delay.

36. If the person making an allegation or the establishment subject to the allegation is dissatisfied with the outcome of the investigation, they should write to the HTA and address the correspondence to the Chief Executive. The HTA will investigate in accordance its procedure for handling complaints about the HTA. This investigation will be carried out by a person who was not involved with the original investigation.

Information held after an investigation is complete

37. The HTA will endeavour to ensure that accurate and appropriate data are held about a licensed / unlicensed establishment, the nature of the allegations and the conduct of the investigation.

38. In the event that requests are received for information relating to an investigation, either by the person or establishment subject to investigation or by a third party, consideration will be given by the HTA to its obligations under Data Protection and Freedom of Information legislation. This may result in information being provided.

Reporting

39. There is no routine reporting of allegations related to licensed or unlicensed establishments, or the outcomes of investigations. The Director of Regulation will make reports when this is considered appropriate.

Review

40. This policy will be reviewed every two years.