



Authority Paper

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Agenda item	8	Author	Sandy Mather

Regulatory enforcement policy

Purpose of paper

1. To seek approval of the HTA's Regulatory enforcement policy.

Background

2. The HTA will be inspected by the Better Regulation Executive (BRE) in December 2008 to assess compliance with the standards set out in the Statutory Code of Practice for Regulators. One of the requirements of this Code is that regulators should have an open and accessible enforcement policy. Although the Executive works to an enforcement policy based on the agreed proportionate and risk based regulatory approach, there is no formally documented and ratified enforcement policy. Consequently as part of the preparation for the BRE inspection, the Regulation Directorate has drafted an enforcement policy with input from Authority Members involved in the Regulation Members' Group.
3. The attached enforcement policy is based on the HTA's current practice and contains only high level principles. It is supported by a range of standard operating procedures and working instructions which provide operational detail for executive staff to use. The enforcement policy is based on a three-tiered approach that applies to establishments that hold, or should hold a licence:
 - firstly, investigate and gather evidence to ensure that we are as certain as we can be of the facts.
 - secondly, in the case of licensed establishments, the HTA takes a compliance based approach wherever possible and offers advice and guidance to help the establishment comply. Where establishments should

be licensed, but are not, the HTA again provides advice and guidance but also normally requires the establishment to suspend activities, immediately apply for a licence and to transfer material to alternative licensed premises.

- Thirdly, where enforcement through regulatory action is also necessary, the HTA aims to make evidence-based, justifiable and proportionate decisions.
4. The policy is one of several relating to regulatory issues, including the Criminal Prosecution Policy, which applies where a potential offence under the HT Act or associated Regulations is identified.

Conclusion

5. Members are asked to approve this enforcement policy which has already been reviewed and amended by both the Regulation Members' Group and the HTA Senior Management Team.

Regulatory enforcement policy

Background

1. The HTA's functions include superintending compliance with the requirements of the Human Tissue Act 2004 (HT Act) and the HTA's codes of practice. In addition, the HTA also has duties under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to ensure that the requirements of the European Union Tissue and Cells Directive and its technical Directives are met. As part of its statutory remit, the HTA licenses establishments, carries out inspections, conducts investigations and seeks to help establishments improve standards by providing advice and guidance. Where regulatory breaches are identified, appropriate regulatory action is taken in line with this enforcement policy.
2. It is a statutory duty of the HTA to have regard to the principles of best regulatory practice, including the need to act in a proportionate and consistent way and to target regulatory action where it is most needed. To this end, the HTA regulates according to risk by focusing on establishments whose non-compliance with the HTA's standards poses the greatest risk to regulatory compliance or where there is a higher likelihood of non-compliance. The HTA also has regard to the Better Regulation Executive's (BRE) Statutory Code of Practice for Regulators in carrying out its functions: in keeping with the BRE's Code, this enforcement policy aims to deter future non-compliance by being proportionate to the nature of the offence and the potential harm caused.

The HTA's approach

Licensed establishments

3. If the HTA becomes aware of a possible regulatory breach or potential offence under the HT Act or associated Regulations by an establishment licensed by the HTA, the Regulation Directorate will carry out an investigation and provide advice and guidance to the establishment concerned to assist it in complying with our standards and any licence conditions attached to its licences. Where appropriate, we may also give guidance to all Designated Individuals and Licence Holders in the sector by way of a Regulatory Alert, and may also develop or revise our policies and provide further information via the HTA website, e-newsletter or in other suitable ways.
4. The HTA works as a compliance-based regulator, which means we place a strong emphasis on the value of providing advice and guidance to professionals working within the sector so that they understand the regulatory requirements and are better equipped to meet our standards. The provision of advice and guidance can be reactive or proactive, and it can be offered verbally – for example during on-site inspection or at

training events for Designated Individuals – or in written format, for example via the website and e-newsletter.

5. Where enforcement through regulatory action is also necessary, we aim to make evidence-based, justifiable and proportionate decisions. Where a potential offence is identified, the Criminal Prosecution Policy will be triggered.

Unlicensed establishments

6. If the HTA receives information that licensable activities are being carried out without a licence, we undertake an investigation and if necessary issue both advice and warning. The HTA normally requires the establishment to suspend activities, apply for a licence and to transfer material to alternative licensed premises pending the grant of a licence. In some cases, where a breach of the licensing requirements is also a criminal offence, the HTA will consider referring the case to the police, in line with its Criminal Prosecutions Policy.

Regulatory Action

7. Where the HTA finds that a standard is not being met (or a licence condition is not being complied with), formal regulatory action may be taken where the non-compliance triggers the HTA's power to revoke and therefore vary a licence. There are several different types of regulatory action that may be considered by the HTA: variation of licences through, for example, the imposition of additional conditions; issue of special directions; suspension of a licence or revocation of a licence. In the majority of cases, the HTA will take regulatory action by varying a licence to impose additional conditions. Additional conditions are time-bound and Designated Individuals (DIs) are required to inform the HTA when they have taken appropriate action to comply with them. The HTA then assesses this information to decide whether the establishment has met the condition or whether further regulatory action should be taken.
8. Complex regulatory issues are normally brought before a Regulatory Action Panel (RAP) to ensure that all relevant considerations are taken into account and that a fair, proportionate and justifiable licensing decision is made. Regulatory action resulting from these panels can take the form of heightened risk inspections (see below), licence suspensions, revocations, variations, Special Directions or verbal and written advice and warning. All licensing decisions made following a RAP are reasoned and consistent where possible although any exceptional circumstances, which may warrant a departure from previous similar decisions, will be considered.
9. Where the HTA considers that there has been an increase in the establishment's risk, we may choose to carry out a previously unscheduled inspection, possibly unannounced (a heightened risk inspection). Following a heightened risk inspection the findings are normally considered by a RAP and further regulatory action may be taken.

10. For each establishment the HTA maintains a licensing record. This ensures that any regulatory action taken is fully informed and based on a good understanding of the establishment's particular circumstances and regulatory history.

Representations and appeals

11. Establishments have a statutory period of 28 days (from the date the establishment is notified of the proposed decision) to indicate that they wish to make representations against certain proposed licensing decisions such as refusal to grant a licence, licence variations and revocations. Representations are a means by which the Licence Holder, or, where different, the Designated Individual has an opportunity to state their case as to why a proposed licensing decision should not be made. Certain licensing decisions of the HTA may be subject to a request for a reconsideration (essentially an appeal) and in that instance, the reconsideration will be undertaken by an Appeals Committee. Establishments have a statutory period of 28 days (from the date the establishment is notified of the licensing decision) to indicate that they wish the HTA to reconsider that decision.