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Dear Colleague

General Directions 001/2010 and 002/2010, given under the Human Tissue Act 2004

I am writing to you about two sets of General Directions we are issuing today. You were put on notice about the issue of these Directions via a regulatory alert issued on 8 December 2009.

The General Directions require two courses of action:

1. Submission of a report on compliance with HTA standards by 30 June 2010
2. Submission of an audit report of retained material by 30 September 2010

This letter also gives information about the introduction of a formal system for reporting serious untoward incidents in the post mortem sector to the Human Tissue Authority (HTA).

Background

The HTA is the regulatory body responsible for implementing the requirements of the Human Tissue Act 2004 (HT Act) in England, Wales and Northern Ireland. The HTA is engaged in a programme of work to address non-compliance with the HTA's consent, traceability and disposal standards by PM sector establishments. This programme is supported by the Department of Health and the Home Office and is being undertaken in consultation with RCPATH. Because the vast majority of post-mortem examinations are conducted under the authority of a Coroner, we have also consulted with the Ministry of Justice which has responsibility for coroner law and policy.

The HTA has a statutory remit to ensure compliance with the requirements of the HT Act and seeks to mitigate the risk of regulatory breaches through enforcement of its standards, codes of practice and legal directions, and the provision of advice and guidance to stakeholders.

The HTA will assure itself through these General Directions that licensed establishments in the post mortem sector have robust and reliable governance systems, and that there is knowledge about the nature and quantity of relevant material stored on licensed premises.

Where non-compliances are identified, advice and guidance will be offered and the HTA will work with establishments to help ensure that improvements are made where necessary.

Failure to comply with the requirements of the General Directions may lead to more serious regulatory action.

General Directions: annual compliance update against core HTA standards

These Directions apply to all establishments that are licensed by the HTA for the storage of post-mortem tissue and/or the making of a post-mortem examination.

The HTA moved to system of continuous licensing in April 2009. As part of this change in our process, we require establishments to provide an annual update of their compliance with HTA standards so that we can assure ourselves of the continued suitability of the establishment to be licensed. The compliance information will also inform the scheduling of site-visit inspections in the sector. These General Directions initiate the annual compliance reporting process.

Instructions about how to submit the compliance information will be available on the HTA website from 1 June 2010.

General Directions: audit of relevant material from the deceased stored on HTA-licensed premises

These Directions apply to all establishments that are licensed by the Human Tissue Authority for 'the making of a post-mortem examination'. They do not apply to establishments licensed for storage only.

The HTA has consulted with the Royal College of Pathologists to define the specification of the audit, to help ensure that it is proportionate whilst giving the HTA the necessary assurances of compliance with the consent requirements of the HT Act.

Organs and wet tissue are far less likely to be retained for future use than blocks and slides and therefore we anticipate that there will be fewer of these items and they will be easy to locate. The completion of an inventory and audit of whole organs and wet tissue currently retained is required by all post mortem sector establishments.

Each year post mortem establishments generate thousands of blocks and slides. It would not be reasonable or proportionate to require every block and slide to be counted. Therefore, post mortem sector establishments are required to undertake an audit of a representative sample of cases in which tissue blocks were made from relevant material removed from deceased persons.

Instructions about how to submit the audit information will be available on the HTA website from 1 June 2010.

Reporting of serious untoward incidents to the HTA

From 1 May 2010, the HTA is introducing a formal system for notification of serious untoward incidents (SUIs) in the post mortem sector. The HTA will review establishments' SUI investigations and action plans and provide advice and guidance where appropriate. The HTA intends to provide information back to the PM sector on the nature and frequency of serious untoward incidents, and will share the learning that has been gained from investigation of these incidents. This is a mandatory requirement that all Designated Individuals are expected to meet.

Outcomes

The information gathered from post mortem sector establishments following the issue of the General Directions will be used as follows:

- a. To provide tailored advice and guidance to individual establishments on tissue retention;
- b. To identify establishments that require support in reviewing their systems governing consent, traceability and disposal, in order to achieve full compliance with HTA standards;
- c. To inform the advice and guidance provided to the PM sector as a whole on common areas of difficulty;
- d. To provide information to the HTA on the issues facing post-mortem sector establishments to inform the continued development of HTA policy affecting the sector.

Information on how to complete the annual compliance update and the audit is provided separately with this letter, along with supporting forms and guidance. More detailed information about how to report SUIs is also provided.

We would like to stress that it is not the intention of the HTA to use the results of the exercises required by these General Directions or the reports of SUIs to target establishments for regulatory action. The HTA will provide advice and guidance to individual establishments and the sector as a whole, and will take regulatory action only where it is appropriate and necessary to do so in cases of serious non-compliance. However, non-compliance with the General Directions would constitute a regulatory breach.

Yours sincerely



Adrian McNeil
Chief Executive