

Authority Paper

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Quarterly regulatory action report April – August 2008

Introduction

1. This is a summary of significant regulatory action taken by the Regulation Directorate between 1 April and 31 August 2008.

Regulatory action panels

2. Regulatory action panels (RAP) are convened whenever significant regulatory action is considered. The aim of the RAP is to provide a robust framework to escalate licensing decisions to ensure a fair, proportionate, justifiable evidence-based decision. In order to achieve this, RAPs can be suspended and the HTA may provide advice and guidance to the establishment(s) concerned offering them the opportunity to respond with further information. The RAP is then re-convened and a final regulatory decision made.

The panel is normally chaired by the Director of Regulation and consists of the Head of Regulation for the geographic patch in which the establishment falls, the Regulation Manager responsible for making the licensing decision under discussion and a legal advisor.

Regulatory action resulting from these panels can take the form of licence suspensions, special directions,* revocations, variations, heightened risk inspections or verbal and written advice and warning.

Nine RAPs were convened between 1 April and 31 August 2008.

i. Human application – 5

In the human application sector five RAPs were held regarding five licensed establishments. Four of these were suspended in order that the HTA could request more information from the establishments before a final regulatory decision was made. Topics included unsuitable practices, a lack of risk assessment and inadequate quality management systems. Also inadequate air quality monitoring and inadequate staffing levels and qualifications.

ii. Post mortem – 4

In the post mortem sector four RAPs were held regarding four licensed establishments. Three of these were suspended in order that the HTA could request more information from the establishment or to allow the establishment to work towards meeting additional licence conditions before a final regulatory decision was made. Topics included the lack of risk assessments, quality management systems and documented policies/ procedures. Also inadequate record management and air quality control, unsuitable premises and suspected unsuitable practices.

Revocations

3. Following a phase two inspection the HTA revoked three licences held by one establishment in the post mortem sector during this period. The reason for revocation of the licences was that the premises were unsuitable.

Special directions

4. Two sets of special directions were issued during this period; both were subsequent to RAPs.
- i. Human application – 1
- The special directions related to inadequate air quality monitoring systems, document cleaning processes and risk assessments of tissue/ cell processing.

* Licence suspensions and special directions have immediate effect whereas licence variations and revocations require a 28 day period for establishments to indicate their intention to make a representation against the licensing decision

ii. Post mortem – 1

The special directions related to termination of activities at a licensed establishment and the transfer of all relevant material and associated records to another licensed site whilst maintaining traceability and dignity of the deceased.

Representations

5. Representations are a means by which the Licence Applicant, Licence Holder or where different, the Designated Individual can request the Authority to give them an opportunity to state their case as to why a proposed licensing decision of the Authority should not be made. A request for representations must be made within 28 days of the establishment being notified of the proposed licensing decision. Representations are heard by a representation panel consisting of a minimum of three people, including the Regulation Manager who made the proposed licensing decision. It is chaired by the Director of Regulation or another member of the Authority's Senior Management Team.

The HTA received two notifications of intention to make representations during this period. The representations will be heard within the next two months.

Heightened risk inspections

6. Entry and inspection of licensed premises may be undertaken at any reasonable time by a duly authorised person under Schedule 5 s2 (1) of the HT Act. The HTA conducts inspections based on establishment risk. If the risk of an establishment increases the HTA may choose to bring forward the date of inspection. This inspection may be announced or unannounced.

Two heightened risk inspections were carried out between 1 April and 31 August 2008. Both were of post mortem establishments and both were informed of their inspection in advance.

i. Post mortem – 2

Two heightened risk inspections were carried out between 1 April and 31 August 2008. One heightened risk inspection followed the report of an adverse event at the licensed establishment. The other followed inspection by the CPA who reported low compliance levels with CPA standards at the licensed establishment. The subsequent HTA inspection found no significant deficiencies in relation to HTA standards.

Conclusion

7. Members are asked to note the regulatory action taken by the Regulation Directorate between 1 April and 31 August 2008.