Guidance for establishments on the use of alternative reagents and materials for the processing of tissues and cells in the event of supply disruption resulting from the UK exiting the EU

The following guidance has been issued to set out the HTA's expectations regarding the use of alternative reagents and materials during the processing of tissues and cells in the event there is a supply disruption to critical reagents and materials as a result of the UK exiting the EU.

Processes used to prepare tissues and cells for human application must be validated to ensure that they do not render the samples clinically ineffective or unsafe. Establishments wishing to introduce a new preparation processes are required to submit a Preparation Process Dossier (PPD) to the HTA prior to implementation of the procedure. Details of reagents and materials that come into contact with tissues and cells must be included in the PPD and validated for use as part of the preparation process.

Establishments are also required to submit a PPD if significant changes are made to an authorised preparation process. Changes to critical reagents or materials may necessitate the submission of a PPD depending on the potential for those changes to affect the preparation process.

Replacement with an equivalent reagent or material from a different supplier

As set out in guidance issued by the HTA, establishments are not required to submit a PPD if the reagents or materials used in a preparation process are replaced by equivalent products. The HTA defines an equivalent reagent or material as one with similar constituents or composition, and the use of which is unlikely to impact significantly on the quality and safety of the tissues and cells.

In such situations, we would expect the move to the use of alternative reagents or materials to be managed under a formal change control procedure which takes into account factors such as the need to amend standard operating procedures, the need for staff training and any impact the change may have on the processing environment. Appropriate checks should be made following implementation of any changes to ensure that the quality and safety of the tissues or cells has not been adversely affected.

Where possible, CE-marked reagents and consumables should be used. Where a change to a different reagent or material requires a move to non-CE marked version, this should be supported by an appropriate risk assessment.

Replacement with a non-equivalent reagent or material

If the supply disruption requires significant changes to be made to an authorised preparation process, establishments should contact the HTA as soon as the need for this change is identified so that we can advise on what validation should be submitted to support the change. The HTA considers significant changes to be those that have the potential to affect

the quality and safety of the tissues and cells and include the introduction of non-equivalent reagents or materials into an authorised preparation process.

The HTA can be contacted at 0207 269 1900 or at enquiries@hta.gov.uk.