IRISH MEDICINES BOARD

# Notice Information: Human Medicines - Warning 24 October 2008

## Part 1. Product Information

a) Title: European Commission issue Rapid Alert to Competent Authorities for Human Tissues and Cells

b) Product Name/Type: Allomatrix Bone Putty and Allomatrix Injectable Putty – Manufactured by Wright Medical Technologies in the USA.

## Part 2. Target Audience

a) Target Audience: Tissue Establishments / Orthopaedic Surgeons

## Part 3. Problem/Issue

a) Problem/Issue: The Belgian Competent Authority for Human Tissues and Cells has notified the European Commission of a recall of two products, Allomatrix Bone Putty and Allomatrix Injectable Putty, which are manufactured by Wright Medical Technologies in the USA and which have been distributed to Tissue Banks in Europe. The European Commission circulated the text of this notification to the Irish Medicines Board and all other Competent Authorities for Human Tissues and Cells and requested that this notification be circulated to all Tissue Banks.

## Part 4. Background Information

a) Background Information: For more information on this notice please click here

## Part 5. Action to be taken

a) Action to be taken: The Irish Medicines Board should be notified immediately if either of these products are in use at any Hospital or Clinic in Ireland. Stakeholders are also requested to be aware that the import of such products directly from third countries (i.e. outside the EEA) must be performed by a Tissue Establishment as defined in Commission Directive 2004/23/EC. If there are any queries in relation to this Rapid Alert, please do not hesitate to contact the Irish Medicines Board.