Inspection of establishment storing tissues for end use “dépôt” (repository)

Feedback of the French experiences

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Reminder

EU directive (o) : “tissue establishment” means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, **storage** or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells;

French définition : The « dépôt » (repository) located in health establishment, receive validated tissues, (packaged and labeled) coming from one or several tissue banks. These tissues are stored and delivered to practitioners (surgeons) within the same hospital with regard to a nominated medical prescription and for an immediate use.

The « dépôt » must in return provide the tissue bank supplier with the information relating with the become (future) of the tissues. The tissues can not be distributed to another health establishment (dépôt) or another tissue bank but they must be only returned to the tissue bank supplier.

Inspection regarding

- GP for manufactured Tissues (dec. 29th 1998)

  Article IV : Specific provisions for the “repository” and health care units that apply tissues and cells in the hospital

Others provisions

- Personal (medical doctor or pharmacist)
- Facilities and equipment
- Storage area
- Labeling (no relabeling)
- Distribution
- Documentation (all steps to ensure the traceability, including agreement with the suppliers)
- Vigilance and surveillance after graft (management of recall)

Authorization

French Regulation :

Before June 2008 (decree of 30 august 1999) :

- no legal framework for the authorization of these activities that was inspected only through the review of the documentation of the tissue bank supplier

After June 2008 (decree of 16 september 2008)

- an authorization is required for the activities of storage and distribution. The application (format of dossier) is lighter than the one requested to a TE carrying out all the activities

French situation

- Around 500 « dépôts » inventoried
- Type of tissues stored :
  - Freeze-dried or dried bones (99%)
  - Veins stored at +4°C (< 1%)

- From 2005 to may 2008 : only 70 have been inspected :

  Context ?
  - 2004 and 2005 : after a recall of products imported
  - 2007 : Afssaps inspection schedulled program

  How ? : risk approach based on :
  - Volume of tissues stored and grafted
  - Number of adverse event notified
  - Deficiencies highlighted during the inspection of tissue bank (suppliers)

INSPECTIONS RESULTS

- **Main deficiencies**
  - Failure to ensure a complete traceability (no formal register)
  - Failure to update the agreement signed between the tissue bank supplier
  - Failure to return to the supplier the implantation form
  - Lake of information among the staff relating with the product used (origin)
  - Lake of QA system (SOP's)
  - Lake of documentation relating with the transportation and the storage requirement
  - Nurseries are usually responsible for the management of the products (no training)
  - Lack of knowledge of the legislation

ISSUES FOR FRANCE

- **500 establishments which store tissue for end use**
- **37 tissue banks and 44 cell banks**
- **Renewal of the authorization every 5 years**
- **Inspection every two years**
- **4 inspectors**

Risk analysis

- **Tissues are manufactured under :**
  - **an authorized process**
  - **an authorized tissue establishment (tissue bank)**

Question ?

- Is there a need to inspect and authorize health establishment which store tissues for end use ?
- Could we can make a comparison with medicinal products (drugs) and medical devices (bovine bone) that are stored and traced on the same way in surgery area ?

Need to inspect and authorize ?

Pros

- Official authorization delivered
- Control of the whole chain of the traceability
- Awareness of the actors of this activity (final users)
- Risk of penalty for whom doesn’t ensure a complete traceability (info to be returned to the TE)

Cons

- Inspection every 2 years (need of a plenty of inspectors)
- Large extra work of inspections
- Cost of each inspection for the CA
- Products already known by the CA which has authorized the marketing of the products and the process
- What about the dentists using these products ? Should they be controlled as well ?

Tank you for your attention

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