

**Notes from 1st Steering Group Meeting on the Tissues and Cells
Directive Implementation Group meeting in Hawkins House on
Thursday 8th September 2005.**

In attendance: Ruth Ryan, (NHO) Maura O' Donovan, (IMB) Patrick Costello, (IMB) Anne Hayes, (IMB) Tony Finch, (seconded to DoHC and HSE from IBTS) Joe Goulding, (Academy of Medical Science) Fiona Clarke, (Cappagh- representing Conor O'Keane, nominated by Faculty of Pathology) Mary Wingfield, (Irish Fertility Society) Aonghus Nolan, (Irish Clinical Embryologists) John Waterstone, (College of Obstetricians and Gynaecologists) Colette Bonner, Mary Jackson, Paul Cantwell, Tom O' Connor (DoHC).

Apologies: Paul Browne, (Irish Haematology Society) Conor O'Keane

Following introductions Mary Jackson gave a brief welcome and outlined reasons for the establishment of the group. Issues raised during the meeting included;

- One of the first tasks was to identify establishments/facilities affected by the Directive. The National Hospitals Office contacted Network Managers and a handout was distributed outlining responses to date. Clarification was required in some cases. This will be followed up by NHO in conjunction with Tony Finch.
- The question arose if IUI (intra uterine insemination) facilities are covered in the Directive and Patrick Costello agreed to get confirmation on this issue at the meeting (on 16 September) with delegates from other Member States and the European Commission. In all probability they will be covered and therefore the number of locations involved will rise. The UK has taken the view that IUI establishments are covered by the Directive.
- Aonghus Nolan will forward a list of fertility units to Ruth Ryan, for information.
- Stem cell collection, procurement and expansion will be covered by the Directive.
- A number of changes were suggested to the draft Terms of Reference.

- Private Clinics to be added to point 2
 - In point 4 replace “To assist” with “To advise”
- Derogation is not an option for Ireland. In the UK the situation was different in that legislation already exists and derogation was possible in their situation.
- Fertility clinics are privately operated. While it would not be possible to provide funding for staffing or equipment staff in these clinics could avail of workshops and support in developing quality manuals and in complying with the requirements of the Directive. Mary Jackson agreed to consult the Secretary General and the CMO on this matter.
- The Directive is on course to become legislation by 7th April 2006. It is hoped to have a copy of the draft legislation at the next meeting. Clarification and legal advice is required on certain aspects. The Irish Medicines Board will be the Competent Authority under Irish legislation.
- There are capital and staffing issues involved with implementation of this Directive. NHO will identify resource needs in establishments.
- There are certain similarities between this Directive and the Blood Directive and Tony Finch outlined the approach taken with implementation of the Blood Directive.
- It might be beneficial to tap into guidelines issued by the UK Association of Tissue Banks. They have issued quality standards which we could possibly use. Accreditation was a problem in UK as some buildings were not suitable and similar problems can be expected here.
- Standard Operational Procedures are specified in the Directive. The Irish Medicines Board indicated that it will be up to each individual establishment to ensure that these standards are being met. The two draft Commission Directive specify the criteria for all technical requirements under Article 28 of the main Directive.

- In certain situations different types of tissue banking are located in one hospital. It was suggested that one person should take overall responsibility and become a co-ordinator for that hospital's activities. A single licence would be issued specifying the activities authorised.
- A question was raised about whether the Directive had to apply retrospectively (for tissues and cells already in storage). The IMB will clarify this with the Commission.
- The Technical Requirements Directives and Annexes will be discussed on the 16th September at the next EU Commission meeting. One of the Directives is still in open consultation stage.
- The European Assisted Conception Consortium (EACC) requires 3 nominations (a regulator, scientist and clinician working in the field) from each country. It was agreed the groups representing these fields should nominate their representative (IMB, ICE and IFS). They can report to this Committee on any developments in that forum.
- Workshops were suggested as the best way forward as they worked quite well with the blood Directive. There are three categories involved in the tissues/cells legislation:
 - a) Stem cells
 - b) Bone, skin, eyes/corneas, heart valves, etc.
 - c) Fertility, reproduction.

Tony Finch will be funded to facilitate the workshops.

- There will be traceability requirements regarding tissue vigilance, 30 years is specified in the Directive. There is a separate Directive on tissue engineering expected in the near future and the wording is nearly finalised.
- Deputies are permitted to attend steering group meetings and an invitation to attend the next meeting. HIQA and ISAB will be informed of the activities of this Committee.
- The next meeting was set for Thursday 10th November at 11 am in the Department of Health and Children.