Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

2002/0128(COD) - 16/10/2006 - Follow-up document

This Report has been prepared in accordance with Article 12 of Directive 2004/23/EC on *setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*. It analyses measures taken by the Member States to ensure voluntary and unpaid donations. It covers the donation of tissues and cells from a general point of view and has been complemented, where appropriate, with the results of the report on reproductive cells.

The Report finds that although the principle of voluntary unpaid donation is recognised by the Member States, the concrete interpretation of this principle differs from one Member State to another. Most, namely 62.5% of all the EU Member States, allow some form of compensation to be offered to donors of tissues and cells. In cases where compensation is permitted compensation comes in the form of expenses only. Although the Directive permits compensation for "inconvenience" only one Member State does so. Largely because "inconvenience" can easily be misinterpreted as an incentive. It is more difficult to objectively quantify compensation for inconvenience than it is for expenses incurred.

As far as the actual amounts reimbursed are concerned the Commission confirms that it has received scant information from the Member States. The amount of compensation paid depends on individual circumstances, the number of times a donor has visited the hospital, the type of treatment needed, the effect of voluntary donation on an individual's ability to work etc.

Different initiatives exist to promote the principle of voluntary unpaid donations. Techniques are diverse and include advertising, student information programmes and donor days. The promotional measures do not always cover the unpaid character of the donation focusing instead on the need to increase donation. Not all Member States have provisions in place that restrict or prohibit the advertising of tissues and cells for financial gain. Those restrictions that do exist vary.

Based on the above, the Commission proposes the following lines of action:

- The collection of more detailed information on the day-to-day practice of compensation at different hospitals or procurement organisation.

- Investigating the possibility of issuing guidelines on the principle of unpaid donation based on the information received. The guidelines would promote, for example, greater transparency regarding compensation for donation – specific mention of the amount paid or expenses reimbursed.

- Investigating the possibility of issuing guidelines on Article 12 (2) of the Directive and the need for appropriate restrictions/prohibitions on advertising for the financial gain of donating tissues or cells.