COMMERCIAL EXPLOITATION OF CARDIOVASCULAR TISSUE ENGINEERING PRODUCTS

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The medical need

Currently, there is a high medical need for novel therapeutic options for heart valve replacements, cardiac muscle to restore infarct regions, substitutes for coronary arteries and other blood vessels such as venous valves, and reconstruction of congenital heart defect. Tissue engineering (TE) is a promising technology addressing these needs. However, and for the time being, TE products are very expensive and therefore suitable only for a few conditions.

Regulatory Pathways

TE products are highly regulated. A sophisticated and sometimes confusing network of European Directives and Regulations [1-4], as well as national laws and guidelines, impose high demands on the authorities and companies. Simplifications are expected by an increasing number of common legal concepts and rules, such as e.g. labeling. However, as of today, national and regional rules impede the free exchange of TE products in Europe.

The conflict between altruistic donation and commercial exploitation

The first step in the manufacture of any allogeneic TE product is the donation of a tissue. Such donation is always an altruistic one, given to a non-for-profit procurement organization [1]. This requirement must be met to avoid a human tissue trade, which is banned in the European Union. However, a significant investment has to be dedicated to cover the costs for the development, approval, manufacture, quality control and the distribution of TE products. This investment is carried by private companies, who expect a fair return for their capital. An open and fair partnership between procurement organizations, TE companies and healthcare organizations can help to avoid potential ethical conflicts.

Cost structure and cost coverage

TE products are made in small quantities and mainly upon request. Due to the high demands on safety and quality, clean rooms and qualified personnel must be dedicated. This leads to a fixed cost structure, which in turn results in high production costs.

Future Trends

In the foreseeable future, TE products will be available for only a few surgical interventions, for which the national health care systems will provide cost coverage. In this context, health care assessment tools will play a major role in evaluating the risks of investing in novel TE products. However, there is a need to revise the current procedures for allocation of and the reimbursement for TE products [5] in order to prevent a 'two-tier medicine' system.

References

[1] Directive 2004/23/EC of the European Parliament and of the Council of 31st March 2004;

[2] Commission Directive 2006/17/EC of 8th February 2006;

[3] Commission Directive 2006/86/EC of 24th October 2006;

[4] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13th November 2007;

[5] World Health Organization, 63rd World Health Assembly, Document A63/24 of 25th March 2010, Item 11.21: Human organ and tissue transplantation.