European stem cell regulations

An EU team examined the legislative context of European stem cell use. Researchers delivered recommendations that help clarify and standardise the regulations, while also fostering therapeutic and research usage of the cells.

Stem cells are capable of developing into any type of cell, enabling tremendous therapeutic potential. Although the EU regulates medical usage of the cells, research usage is unregulated, and European countries also implement the directives in separate ways.

The EU-funded EUCELLEX (Cell-based regenerative medicine: New challenges for EU legislation and governance) project examined the current European situation. The team assessed existing legislation governing the therapeutic usage of stem cells, and linked the legislation to research infrastructure and capacity building. The coordinating action consortium clarified the rules, and facilitated use of stem cells in all areas from medical treatment to research. The output was a series of recommendations.

Researchers gathered information on legal implementation of the Tissue and Cells Directive, focusing on European regulation at national and higher levels. The team additionally integrated the new knowledge into a broader analysis covering the entire spectrum of stem cell usage, focusing on banks for stem cells and umbilical cord blood.

Using European databases, the group conducted a background analysis of the field, including legislation, jurisprudence and ethics. Finally, EUCELLEX produced tools to support the involvement of professionals and key stakeholders.

The team delivered evidence about contemporary practices regarding stem cells, including a report on the comparative legal analysis. The report recommends that the characteristics of autologous cell therapies should determine whether the therapies be regulated as a product subject to marketing authorisation. Revising the existing marketing authorisation requirements may not suffice.

Evidence of contemporary practices further included a stakes and stakeholder analysis of seven European countries plus Canada. The analysis concluded that regulation depends on procurement sources and on national ethical values, and that national arrangements could be of interest to other national regulatory practices.

Researchers summarised the market for distribution between public and private sectors.

Following assessment of the implementation of the Tissues and Cells Directive, team members also delivered
recommendations aimed at legislators and policymakers. The recommendations detail suggestions for improving communications with researchers and the public.

As a result of EUCELLEX’s work, the regulatory framework of stem cell usage in Europe has been clarified.

**Related information**

| Report Summary | Final Report Summary - EUCELLEX (Cell-based regenerative medicine: new challenges for EU legislation and governance) |

**Subjects**

Life Sciences

**Keywords**

Stem cell, research usage, EUCELLEX, EU legislation, Tissue and Cells Directive

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