Risk regulation of tissue engineering in the EU
A political economy of medicine

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Summary

Tissue engineering is an emerging biomedical innovation surrounded by potentiality and risk. Based on documentary analysis and expert interviews, this study discusses different constructions of risk according to main constituencies (scientists, clinicians and manufacturers), the way they prioritise and balance these risks, and how issues are framed as problematic or not. Complexity and uncertainty are the main drivers in this exercise, interpreted in terms of boundary drawing around contested risk domains. This is followed by a discussion of the translation of risk into regulatory policy, by focusing on two recent legislative initiatives by the European Commission: one to control the quality and safety aspects of human tissues and cells (the SANCO Directive) and the other to facilitate the marketing of tissue engineered products in the EU (DG Enterprise Regulation).

These two legislative initiatives aim to overcome the current regulatory lag in Europe, where tissue engineered applications are either unregulated or subject to a broad variety in national controls. This situation is problematic for manufacturers wanting to market their products in Europe, for regulators in evaluating the risks of these technologies and defining an appropriate approval route, and for patients in terms of unequal access to potentially beneficial therapies across the continent.

Firmly rooted in ambitions to make the EU a techno-scientific and bio-economic powerhouse, regulation of this domain is troubled by competing agendas of promoting trade versus protecting public health. Social and ethical considerations about the impact of tissue engineering technology allow a reconsideration of the bio-society as alternative model, taking into account the technological as well as social character of innovation.