

REGULATION OF EMERGING HEALTHCARE TECHNOLOGIES:
THE NEED FOR A RENEWED REGULATORY APPROACH TO GAIN PUBLIC CONFIDENCE

A number of recent reports have highlighted that achieving zero risk regulation is neither a realistic nor a desirable target.¹ This is especially true for the healthcare sector, where attempts to introduce zero risk regulation would inevitably make it very difficult to put new medicines and innovative therapeutic treatments into the market, depriving patients of the benefits of promising cures.

Current approaches based on the introduction of the precautionary principle have not yielded the expected results. Often incorporated in an unsatisfactory way into regulatory procedures, it has not allowed decision making to progress,² and for healthcare regulators, adopting a precautionary approach could still lead to a severe “drug lag”.³

The move away from “zero risk regulation” has therefore rendered it necessary to find other ways to work under uncertainty. For healthcare regulatory agencies, this change of strategy has triggered a shift in their role. Traditionally tasked with safeguarding public health by setting up safety standards and requirements and monitoring researchers’, manufacturers’ and clinicians’ compliance, healthcare regulators have been required to redefine their approach to risk management and to engage in a more proactive strategy.

With regard to emerging healthcare technologies, a trend away from “zero risk regulation” can already be observed. Three recent examples highlight this shift: the public consultation on hybrids and chimeras launched by the UK Human Fertilisation and Embryology Authority; the discussion forum launched by the European Commission on stem cell therapies and the Japanese regulatory approach to encourage public support of biotechnology.

These examples point toward a revision of the relationship between regulators and the public in the sense of greater engagement on behalf of regulators to encourage public acceptance. In fact, convincing people to accept the risks of new treatments can only be achieved when there is sufficient public confidence in their potential benefits. In the specific context of biotechnological innovations, such as cell therapy or tissue-engineered products, the creation of a “public sphere” of understanding has consequently become critically important.⁴

This paper considers what such a creation implies for healthcare regulators, especially in the case of innovative treatments, and analyses the work methods developed by regulatory bodies to gain public confidence.

This paper is based on research carried out as part of the REMEDI project, one of the Engineering and Physical Sciences Research Council (EPSRC) Grand Challenges. Further details on the REMEDI project can be found at www.remediqc.org.

¹ Better Regulation Commission (2006). Risk, responsibility and regulation – whose risk is it anyway? Cabinet Office, UK.

² Tait J. (2001). Risk assessment and regulation: interactions among industry, public and policymakers. University of Edinburgh, UK.

³ Sunstein C. R. (2003). The Paralyzing Principle. *Regulation*, pp. 32-37.

⁴ Department of Trade and Industry (2003). Report: Biosciences 2015, UK.