

Enabling stem cell research in the UK? A short history of the regulatory maze

Beyond Pattison:SCI Final Conference

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The UK model of regulation

Without doubt the enabling and consistent regulatory environment is currently one of the strongest assets to UK stem cell research. Indeed, overseas researchers have been attracted to the UK precisely because of its coherent regulatory framework covering all forms of stem cell research in the public and private sector (Pattison, p43)

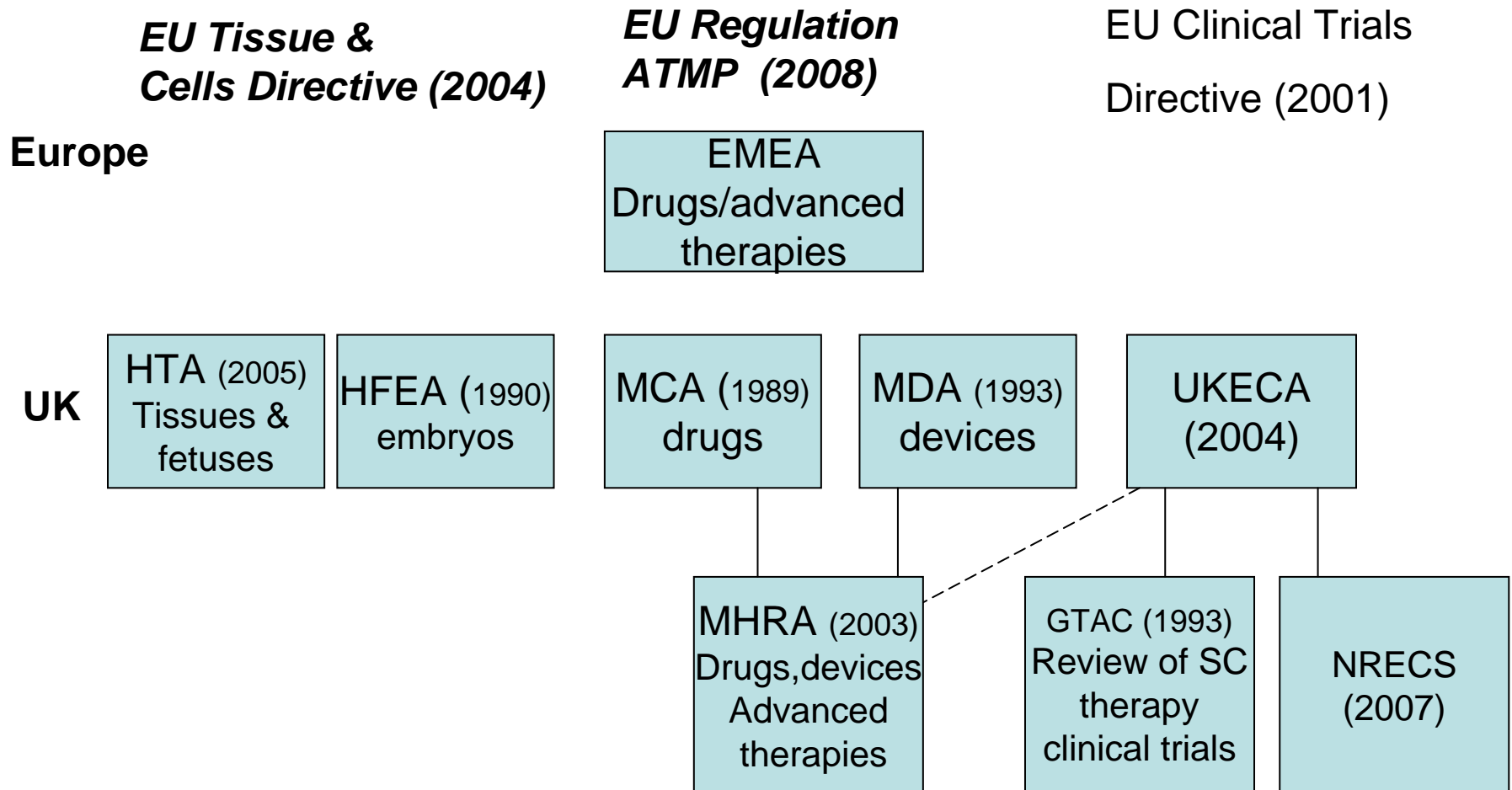
Constructing 'regulatory objects'

- Regulatory discourse constructs different kinds of 'regulatory objects';
- 'Embryos' and 'Fetal tissue' are regulated separately.
- In relation to fetal tissue use in SC science there has been confusion, lack of transparency and oversight. (Pfeffer& Kent 2007).

Towards a new 'regulatory order'

How do we understand the political histories of the institutions governing Stem Cell Science in the UK?

Regulatory regimes



Progressive science and UK science policy

“the examination of the rights and wrongs of embryo research in Britain during the 1980’s was highly unusual in the degree to which it subjected a particular branch of scientific inquiry to sustained, collective appraisal” (Mike Mulkey 1997:2).

The HFEA Model 1990-2008



Support for the HFEA from clinicians

- “ The Ethics Committee of the RCOG believe that the HFE Act and the HFE Authority represent a highly successful and robust model for regulating assisted reproduction, widely admired throughout the world, and successful in maintaining a balance of concern between the interests of patients, professionals, scientists and the public at large in a controversial area. **It has carried out regulation and oversight of the public and private sector effectively, and its policy role has been discharged conscientiously and well.Our view is that some modifications to the HFE Act and Authority would be welcome, but that otherwise the HFE structure need not go through significant change**” (para 3). RCOG 2008.

Support from Scientists for HFE Bill

- **Dr Mark Walport, Director of the Wellcome Trust, said:**
"It is crucial that we don't close down avenues of medical research that could lead to improvements in the lives of many thousands of people. Embryonic stem cells offer potential for treating serious diseases such as Parkinson's disease and muscular dystrophy and it is important that we are able to study them using a variety of approaches, including mixing human and animal material. This legislation will provide the regulatory framework to enable scientists to pursue such work in a responsible way." (Press release Science Media Centre 12 May 2008)
- **Prof. Robin Lovell-Badge, Head of the Developmental Genetics Division at the Medical Research Council's National Institute for Medical Research, said:**
"This is excellent news. While there is still some way to go before any of this is turned into law, the positive vote follows on from the support the Bill received in the House of Lords and is yet another endorsement for the progress of scientific enquiry, one that will greatly aid our understanding of normal embryonic development, and of many types of debilitating genetic disease. This understanding will ultimately give us the best chance of developing therapies for these diseases, for infertility and for a range of other medical conditions." (Press release Science Media Centre 19 May 2008)

An Ethicist's point of view

- **“The UK now stands as one of the most advanced, if not the most advanced, countries in the world in terms of regulation of reproduction and embryo research.** Its parliament is to be congratulated. Most countries with a strong influence of religion over ethical issues have failed to make these advances. Some even ban embryonic stem cell research. Initially, the government produced a white paper suggesting banning the creation of cybrids, but after a response led by Evan Harris and proper debate, this position changed. This demonstrates how a secular ethical approach can successfully influence law and public policy for the better. What worked in this process was a range of individuals and groups making public arguments in favour of progressive reform. **The UK now not only leads scientific progress in these important areas, but ethical reflection and policy formation.”** (Savalescu)

<http://www.practicaethicsnews.com/practicaethics/2008/05/hfea-and-regula.html> (Published 22 May 2008, accessed June 2008).

A national scandal

The Human Tissue Act 2004



Human Tissue Act 2004 logo



Human tissue research and therapies: The new HTA

*Well, quite a lot of banks, quite a lot of establishments didn't recognise they came under the Code of Practice so for instance bone marrow transplanter didn't think they were covered because everybody sort of thinks of bone marrow- of tissue banking,- as the traditional tissue banks, heart valve, bone, skin, tendons, corneas – you tend not to think about the storage of blood cells, cord banking, things like that as being part of this.[.....]**they didn't see themselves as tissue bankers. R3***



MHRA: A 'Hybrid Institution'

- Pharmaceutical and medical device regulation under one agency;
- 'Hybrid' or combination products more easily regulated;
- Centralised approval for medicinal products;
- 'Lighter touch' approval for medical devices.



From process to product

- Ethical concerns about the ‘commodification’ of the body and commercialisation of human tissue and cell based therapies.
- ‘Batch production’ – manipulated tissues;
- Drawing the line – disruption and disorder



Stem cell therapies as medicinal products

ReNeuron gains UK regulatory approval to start ground-breaking clinical trial with stem cell therapy for stroke . 19/01/09

Guildford, UK, 19 January 2009: ReNeuron Group plc (LSE: RENE.L) today announces that it has received approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) to commence a first-in-man clinical trial for the treatment of patients who have been left disabled by an ischaemic stroke, the most common form of the condition. Stroke is the third largest cause of death and the single largest cause of adult disability in the developed world.

Complexity and confusion!

A:....This is a minefield, oh my goodness! We've been thrown from every regulatory authority. I mean it's just crazy.....

AND

A: Just in terms of embryo research. So if I take a four cell embryo and grow it up to the pre-implantation stage, that is their responsibility under the Act. So I have a licence from the HFEA which allows me to do that and I am the person responsible to do that. The moment it's destroyed, that's where they end really. They're not interested what happens after that because that's their point of... the embryo's destroyed. What happens after that is not their responsibility. So then you have an embryonic stem cell line. You could argue that that line is no different to tumour cell lines produced from any other tissue.[] So I do come under the HFEA but only up to that. For the GMP, that is MHRA and possibly HTA. But the HTA aren't interested at the moment. SS7

Ethical regulation

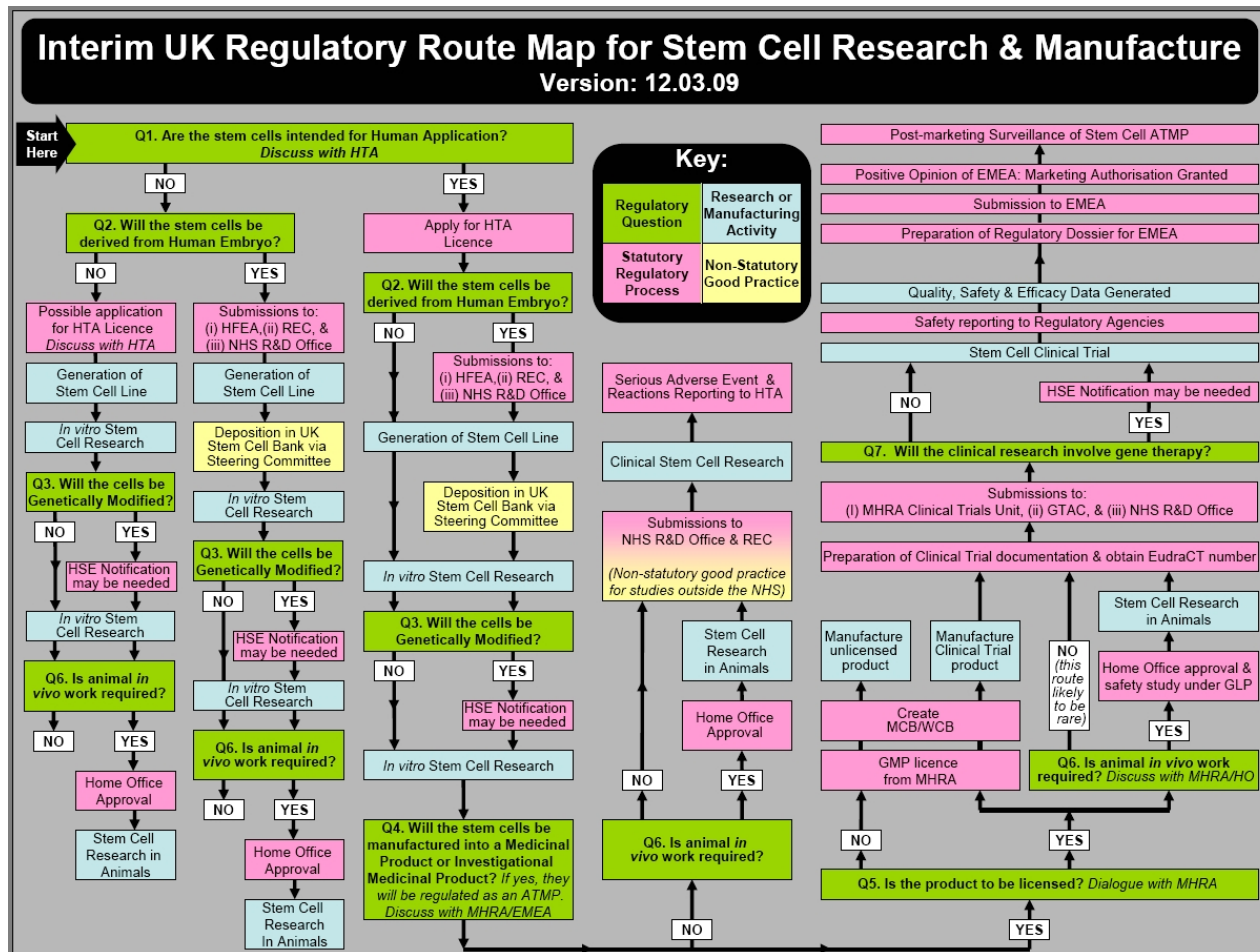
- **Gene Therapy Advisory Committee (GTAC)**
- The Gene Therapy Advisory Committee (GTAC) **has UK-wide responsibility for the ethical oversight of proposals to conduct clinical trials involving gene or stem cell therapies.** The Committee also advises Ministers on the development and use of gene and stem cell therapies and works with other Government agencies with an interest in this area, such as the Medicines and Healthcare products Regulatory Agency (MHRA), the Health and Safety Executive (HSE) and the Human Tissue Authority (HTA).



National Patient Safety Agency

National Research Ethics Service

A route map!



In summary

- HFEA supporters from pro-research community – including clinicians and scientists – a source of national pride. Securing public trust.
- HTA emerged following public concern about ‘retained organs’. Lacked support from ‘stakeholders’ as yet ‘unproven’ shift from professional self-regulation to state authority.
- MHRA – a ‘hybrid institution’ which regulates across technology sectors industry- state ‘corporatist’ alliances.
- GTAC’s remit has been extended to include ethical review of clinical trials using SC lines.

Conclusions

1. The regulatory challenge for SC researchers and industry is to negotiate a way through the 'regulatory maze';
2. Competing interests shape regulatory institutions and policy;
3. The 'regulatory ordering' of biological entities creates 'regulatory objects'.

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