SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY

Regenerative Medicine

Call for evidence

Background

1. The House of Lords Science and Technology Committee, under the Chairmanship of Lord Krebs, is conducting an inquiry into regenerative medicine. The Committee will be looking, in particular, at whether the UK is in a position to facilitate the translation of knowledge from world-leading research to treatments and to benefit from the commercial opportunities that they present. It also seeks to explore how realistic some of the reported claims of regenerative treatments and therapies are, both in the UK and internationally.

2. The term “regenerative medicine” is used to refer to any methods to replace or regenerate human cells, tissues or organs in order to restore or establish normal function. This includes cell therapies, tissue engineering, gene therapy and biomedical engineering techniques, as well as the more traditional therapies of pharmaceuticals, biologics and devices. Examples of such treatments are the transplantation of a new trachea grown using the patient’s own stem cells and the use of a hormone (Erythropoietin) to promote red blood cell production. The inquiry will also extend to cell therapies that have applications in other areas of medicine, for example, the use of cell therapies to control immune responses to conditions such as paediatric steroid resistant GvHD\(^1\), or the use of stem cells for drug screening.

3. The UK is a world leader in many areas within the field of regenerative medicine, particularly the platform technology cell therapies. Foresight’s Technology and Innovation Futures report states that regenerative medicine could be a driver of growth for the pharmaceutical sector if regulatory, financial and translational research challenges can be overcome.\(^2\) Regenerative medicine has the potential not only to lead to significant improvements in the treatment of chronic diseases (such as diabetes and certain kinds of blindness) but also to generate economic benefits for the companies that develop

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\(^1\) Graft versus Host Disease, a common disease amongst transplant or tissue graft patients where the hosts immune system attacks the transplanted cells

therapies and related infrastructure (such as manufacturing equipment).

The Committee invites submissions on the following points, with practical examples where possible (please only answer the questions of relevance to you):

**The research base**
- How does the UK rank internationally in the scientific field of regenerative medicine?
- Where does the UK have strengths and weaknesses in the field?
- Who are the major funders of research in the field of regenerative medicine? What funding is available to support this research?

**Application of the science**
- Is the science being translated into applications? What are the current applications of the science of regenerative medicine for the treatment of disease in the UK and internationally? Which treatments are available on the NHS or through private healthcare?
- What potential does regenerative medicine hold to treat disease in the next 5-10 years? What is the reality versus the headlines about what the science will deliver?

**Barriers to translation**
- Are the actions outlined in the Government’s *Strategy for UK Life Sciences their report: Taking Stock of Regenerative Medicine in the UK*, and the Research Council and Technology Strategy Board’s *Strategy for UK Regenerative Medicine* sufficient to encourage the safe development of regenerative medicine treatments and to overcome the significant regulatory barriers and challenges to innovation in this inter-disciplinary field? If not, what more action is required? In particular:
  - What difficulties are encountered when conducting clinical trials and how could these be overcome?
  - What other difficulties are encountered conducting translational research within the NHS and how could these be overcome?
  - What barriers are encountered when seeking approval for the use of such treatments on the NHS or through private healthcare?

**Barriers to commercialisation**
- What is the current, and potential future, commercial value of the sector to the UK economy? What is its value to society?
- Where there is market failure, are Government providing sufficient incentives in the current commercial environment to attract investment in companies working in this high risk area? If not what more should Government do?
  - What role does patenting play in the commercial development of regenerative treatments?
What business models are most appropriate to support the development of regenerative treatments?

What are the barriers to securing finance to develop such treatments?

Are the pricing structures for the use of such treatments on the NHS appropriate to support their development?

What infrastructure barriers exist within the NHS, or externally, that prevent the scaling-up or commercial development of such treatments?

International comparisons

- What could the UK learn from its competitors about supporting the development and commercialisation of regenerative medicines?
- How do regulations that govern the development of regenerative medicines in other countries and at an EU level impact on the development of regenerative medicines in the UK?
- Is there sufficient harmonisation between the standards and regulations that govern the development of regenerative medicines in different countries?
- What risks do UK citizens face when travelling to other countries for regenerative treatments? How do the safeguards in place to protect their interests in the UK compare to those overseas?

Written submissions should be provided to the Committee as a Microsoft Word document and sent by e-mail to hlscience@parliament.uk. Please do not submit PDFs (if you do not have access to Microsoft Word you may submit in another editable electronic form). If you do not have access to a computer you may submit a paper copy to Chris Atkinson, Clerk to the Science and Technology Committee, Committee Office, House of Lords, London SW1A 0PW, fax 020 7219 4931. The deadline for written evidence is 20 September 2012.

Short, concise submissions, of no more than six pages, are preferred. A longer submission should include a one-page summary. Paragraphs should be numbered. Submissions should be dated, with a note of the author’s name, and of whether the author is acting on an individual or corporate basis. All submissions will be acknowledged promptly.

Personal contact details supplied to the Committee will be removed from submissions before publication but will be retained by the Committee staff for specific purposes relating to the Committee’s work, such as seeking additional information.

Submissions become the property of the Committee which will decide whether to accept them as evidence. Evidence may be published by the Committee at any stage. It will normally appear on the Committee’s website and will be deposited in the Parliamentary Archives. Once you have received acknowledgement that your submission has been accepted as evidence, you may publicise or publish it yourself, but in doing so you must indicate that it
was prepared for the Committee. If you publish your evidence separately, you should be aware that you will be legally responsible for its content.

You should be careful not to comment on individual cases currently before a court of law, or matters in respect of which court proceedings are imminent. If you anticipate such issues arising, you should discuss with the Clerk of the Committee how this might affect your submission.

Certain individuals and organisations may be invited to appear in person before the Committee to give oral evidence. Oral evidence is usually given in public at Westminster and broadcast in audio and online. Persons invited to give oral evidence will be notified separately of the procedure to be followed and the topics likely to be discussed.

Substantive communications to the Committee about the inquiry should be addressed through the Clerk or the Chairman of the Committee, whether or not they are intended to constitute formal evidence to the Committee.

This is a public call for evidence. Please bring it to the attention of other groups and individuals who may not have received a copy direct.

You may follow the progress of the inquiry at http://www.parliament.uk/hlscience.