Addressing donor testing issues for the development of human embryonic stem cell-derived advanced therapy medicinal products: Amending Annex II

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Recent scientific advances in human embryonic stem cell (hESC)-derived advanced therapy medicinal product (ATMP) development have brought to light issues for this sector with meeting the donor testing requirements outlined in the European Tissues and Cells Directive (EUTCD) 2004/23/EC and EUTCD 2006/17/EC. Overcoming the issues with EU donor testing requirements is a key challenge for the clinical translation of UK/EU hESC-derivatives. The draft proposal presented to the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) today outlines the challenge and recommends a course of action to address it, including amending the donor testing requirements in Annex II of EUTCD 2006/17/EC. The impact of the proposed amendments on the future of UK-based regenerative medicine is also discussed in the proposal.

The HTA proposes to lead this work as donor selection for tissues and cells for patient treatment (including ATMPs and ATMP starting material) falls within our remit. During the first phase of engagement with other regulatory bodies, support in principle for the draft proposal was received from the Human Fertilisation and Embryology Authority (HFEA), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health (DH). We are also seeking comments on the draft proposal from select parties within the regenerative medicine sector, since policy changes in this area could impact on their work.

Productive engagement with the sector, groups such as SaBTO and the other regulators will enable the HTA to take forward an appropriate course of action to achieve the shared long-term goal of ensuring the safe, ethical and lawful production of therapeutic products from UK-derived hESCs. The proposal will be presented at the November 2012 meeting of the European Association of Tissue Banks in Vienna and to the European Commission in December.