

Update on Cell Based Advanced Therapies Work

At the meeting on 11th September, SaBTO discussed a paper by Professor Marc Turner highlighting some of the potential risks and issues associated with cellular therapies, and the request for advice received from the UK National Clinical Human Embryonic Stem Cell Forum (NChESF). It was agreed that SaBTO members and the secretariat should explore whether the risks noted by Professor Turner fell within the remit of regulatory bodies; and consider the assessment of microbiological risk associated with stem cell therapy.

A meeting was held on 18th October, chaired by the Department of Health policy lead on genetics and advanced therapies, with SaBTO members; the Chair of the NChESF, and representatives of the regulatory bodies - the Human Tissue Authority (HTA), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Human Fertilisation and Embryology Authority (HFEA).

It was agreed that a way forward was needed that would support new developments while ensuring safety and quality. While the NChESF had been particularly concerned with the perception of TSE risk, it would be important to consider and assess a wider range of risks. The development and application of a high quality risk assessment process for its cell based advanced therapies will place the UK well in an internationally competitive field.

It was recognised that a number of bodies would have an interest in this work, including other government departments such as the Department for Business, Innovation and Skills, and other advisory bodies such as the Advisory Committee on Dangerous Pathogens (ACDP) and the Emerging Science and Bioethics Advisory Committee (ESBAC). It was agreed, however, that SaBTO was best placed to lead the work, drawing on others' expertise as necessary.

Following the 18th October meeting, Professor Turner was appointed to Chair the SaBTO Working Group, and draft Terms of Reference¹ have been drawn up.

¹ Note: being draft, these are still confidential to SaBTO.