Update on the Cell Based Advanced Therapies Working Group

The Cell Based Advanced Therapies Working Group, chaired by Professor Marc Turner, was set following a meeting between SaBTO members and representatives of the regulatory bodies in October 2012. Its remit is to review the microbiological and other risks associated with cellular therapies particularly with respect to donor selection, consenting and testing, and to make recommendations to SaBTO on how these can be optimised in order to support the development of cellular therapies in the UK whilst maximising donor and patient safety.

The first meeting was unfortunately cancelled because of transport problems caused by the snow, and the Group was not able to meet until March. They agreed the scope of the work, and discussed some of the issues to be addressed, and the approach to be taken. The Group will focus on therapies developed from pluripotent stem cell lines, derived from human embryonic stem cells or, more probably, adult (somatic) cells which have been genetically reprogrammed to be pluripotent (induced pluripotent stem cells). These are capable of differentiating into most if not all of the cell types present in an adult, and can divide indefinitely, so one donation may be developed into therapies used to treat a great many patients, for a number of different conditions, over many years. Any risk relating to the donor or the starter material could therefore be multiplied up to have a very extensive impact.

It was agreed that the work falls into three sections, and sub groups have been set up to lead on these.

Infectious risk

This sub group, led by Professor Kate Gould, will consider the range of infectious agents which might affect the donor and have consequences for therapy recipients, and will look at donor selection procedures and testing strategies. The work of the Tissues and Cells: Donor Selection Review will provide valuable data. The sub group will also work closely with the UK Stem Cell Bank Adventitious Agents Working Group, which was set up to consider agents which might affect cellular therapies, not only through the donor, or through contamination of the donated product, but also during development and manufacture of the therapy.

Genetic risk

Professor Alison Murdoch is leading this sub group, which will assess the potential risk of genetic abnormalities in the donor or the starter material, and the circumstances in which they could give rise to problems for therapy recipients.

Informed consent / traceability

The third sub group, co-chaired by Mrs Gill Hollis and Professor Bobbie Farsides, will consider the issues raised by informed consent and traceability, both for a donor and for recipients of a therapy/therapies developed from their donated material. A therapy recipient may develop a genetic or infectious disease which has implications for the donor or the donor's family, possibly years after the donation. It may even be a disease discovered since the donation was made. Or a donor may develop a disease which could have implications for therapy recipients, again possibly years afterwards.

This is an area in which a wide range of other bodies have an interest. The MHRA, HTA and HFEA, who regulate different aspects, have been invited onto the Group as Observers, as have the Cell Therapy Catapult, the Medical Research Council and the BioIndustry Association.

The Working Group aims to complete its work and report to SaBTO early in 2014.