

Policy statement on the relationship between the Advanced Therapy Medicinal Products (ATMP) Regulation and the Quality and Safety Regulations

Joint statement from the Human Tissue Authority (HTA) and the Medicines and Healthcare products Regulatory Agency (MHRA).

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Overview

Regulation (EC) No 1394/2007 on Advanced Therapy Medicinal Products (ATMPs) entered into force on 30 December 2007 and will apply from 30 December 2008. The Regulation contains transitional provisions:

- ATMPs, other than tissue engineered products, which were legally on the Community market in accordance with national or Community legislation on 30 December 2008 will have until 30 December 2011 to comply with the Regulation.
- Tissue engineered products which were legally on the Community market in accordance with national or Community legislation on 30 December 2008 will have until 30 December 2012 to comply with the Regulation.

In the interim applicants should proceed as previously by contacting the MHRA for classification of a product as a Medicinal Product (MP) or Investigational Medicinal Product (IMP). If a product containing human tissues or cells is not considered an MP or IMP by the MHRA, it will be regulated entirely by the HTA under the Human Tissue (Quality & Safety for Human Application) Regulations 2007 (the 'Quality & Safety Regulations') with regard to procurement, testing, processing, storage, distribution and import / export of the product. Products classified as MPs or IMPs are regulated under the Quality & Safety Regulations only as far as procurement and testing of human tissues and cells are concerned.

Further detail

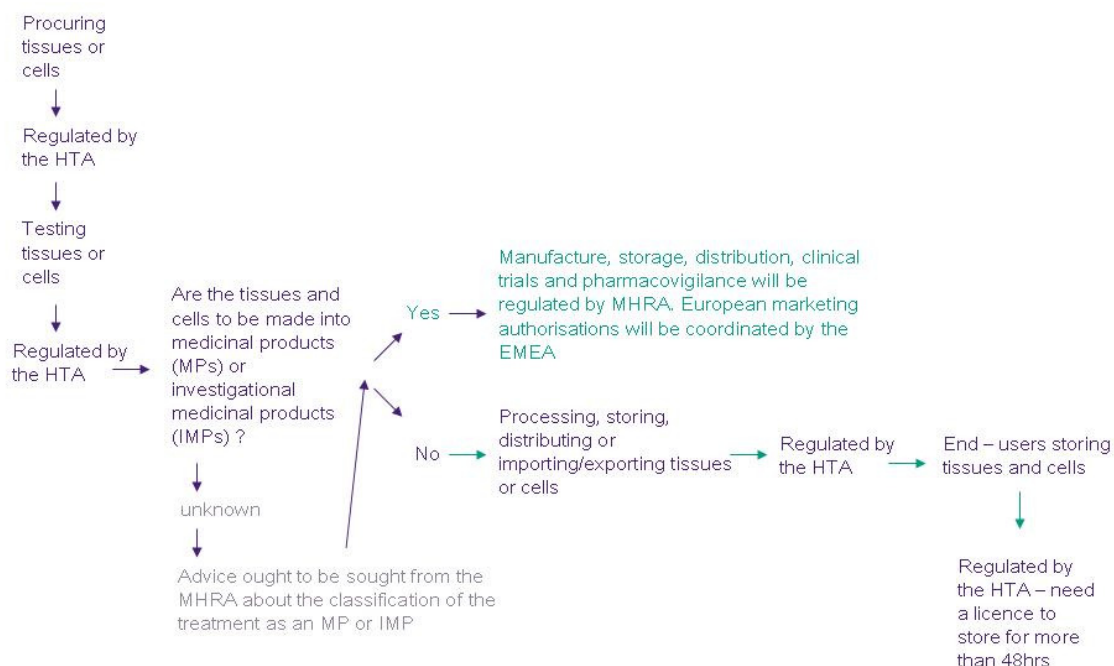
The MHRA, as the Competent Authority for medicinal products and medical devices, discharges the UK's national responsibilities for ATMPs (e.g. for manufacturing, distribution, clinical trials and pharmacovigilance). The HTA is the UK's Competent Authority under the Quality & Safety Regulations and licenses the procurement, testing, processing, storage, distribution and import/export of tissues and cells for human application.

Manufactured products that are classified as medicinal products by the MHRA or European Medicines Agency (EMA) will be regulated under the Quality & Safety Regulations only for the donation, procurement and testing of tissues and cells. The subsequent stages, including manufacture, storage and distribution, will be regulated by the MHRA. Unless exempt, ATMPs will require a marketing authorisation granted by the European Commission (the 'centralised procedure') with the EMA co-ordinating the application and assessment procedures, and post-authorisation supervision.

Treatments involving human tissues or cells that are not medicinal products will continue to be regulated by the HTA under the Quality & Safety Regulations for all licensable activities. This also applies to ethically (but not MHRA) approved clinical trials involving the use as grafts of human tissues and cells in patients.

In cases where the regulatory status of a manufactured product derived from human tissues or cells is unclear, the MHRA should be asked to determine if the product is a medicinal product. The decision of whether a given treatment falls within the scope of the European definition of medicinal product (MP) and ATMP, as opposed to a tissue or cell graft (which would then fall under HTA remit), will eventually be determined by the EMA working in conjunction with the MHRA (where the manufacture occurs in the UK). A Committee for Advanced Therapies (CAT) based at the EMA will advise whether a product falls within the definition of an ATMP.

The HTA and the MHRA have developed the following regulatory protocol for manufacturers of products derived from tissues and cells:



Glossary and notes

Procurement:

Under the Quality and Safety Regulations ‘procurement’ comprises the process by which tissues or cells are made available. Procurement therefore includes the selection and consenting of donors and the removal (donation) of material from the donor. As per definition of the ATMP Regulation ‘donation, procurement and testing’ falls under the remit of the HTA.

MP: Medicinal product

ATMP: Advanced Therapy Medicinal Product

CAT: Committee for Advanced Therapies to be formed as part of the EMEA under the ATMP Regulation

Human Tissue Authority

The HTA was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes – such as research, transplantation, and education and training – set out in the Human Tissue Act 2004 (HT Act).

The HT Act covers England, Wales and Northern Ireland. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006 – and the HTA performs certain tasks on behalf of the Scottish Executive (approval of living donation and licensing of establishments storing tissue for human application).

The HTA is the Competent Authority under the EU Tissue and Cells Directive (EUTCD) for regulating human application establishments. The EUTCD was fully implemented in the UK on 5 July 2007 with the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Under these Regulations, the procurement, testing, processing, storage, distribution and import / export of tissues for human application must be carried out under a licence by the HTA or (with the exemption of storage) must be carried out on behalf of a licensed establishment under a third party agreement.

The HTA is also responsible for approving donation of solid organs and bone marrow from living donors.

Medicines and Healthcare products Regulatory Agency

The MHRA is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. No product is risk-free. Underpinning all our work are robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices, and take any necessary action to protect the public promptly if there is a problem.