

Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance)

CHAPTER 1

SUBJECT MATTER AND DEFINITIONS

Article 1

Subject matter

This Regulation lays down specific rules concerning the authorisation, supervision and pharmacovigilance of advanced therapy medicinal products.

Changes to legislation:

There are outstanding changes not yet made to Regulation (EC) No 1394/2007 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

Changes and effects yet to be applied to :

- [Regulation revoked in part by S.I. 2019/775 Sch. 9 para. 1\(o\)](#)