European Medicines Agency
Pre-authorisation Evaluation of Medicines for Human Use

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EMEA announcement

To manufacturers, companies and hospitals having advanced therapy medicinal products legally on the Community market in accordance with national or Community legislation.

The Regulation on Advanced Therapies (Regulation (EC) 1394/2007[1]) defines advanced therapy medicinal products (ATMPs) as gene therapy, somatic cell therapy and tissue engineered products (Article 2).

Article 29 of the above mentioned Regulation foresees that ATMPs that are on the Community market in accordance with national or Community legislation will have to comply with the new legislation by 30 December 2011 (ATMPs other than tissue engineered products) or 30 December 2012 (tissue engineered products)[2].

The European Medicines Agency (EMEA) wants to raise awareness among manufacturers, companies and hospitals having ATMPs legally on the market that these products will have to undergo a **marketing authorisation procedure**[3], unless they are exempted in accordance with Article 28(2)[4] of Regulation (EC) 1394/2007.

For the purpose of compliance with Article 29 of Regulation (EC) 1394/2007, a marketing authorisation application in compliance with Annex I to Directive 2001/83/EC, as amended, and with the Regulation on Medicinal Products for Paediatric use (Regulation (EC) 10901/2006, as amended) will have to be submitted to the EMEA for evaluation. The review process will follow the normal procedure for the centralised procedure for ATMPs.

Manufacturers, companies and hospitals should contact the Agency as soon as possible to discuss the data package to be submitted for this procedure[5]. A scientific advice request[6] is considered the most appropriate route for seeking agreement on the data package. If you have questions whether your product can be considered as an ATMP[7] or on the need of a Paediatric Investigation Plan, please contact us.

E-mail address for queries: AdvancedTherapies@emea.europa.eu

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[1] Regulation (EC) 1394/2007: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2007_1394/reg_2007_1394_en.pdf

[2] These deadlines include the time needed for evaluation (up to a maximum of 210 days' active review time) and authorisation.

[3] In line with Regulation (EC) 1394/2007. For this marketing authorisation procedure, no fee will need to be paid to the EMEA.

[4] This exemption applies to ATMPs prepared on a non-routine basis according to specific standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medicinal practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient.

[5] For Module 5, the data to be submitted can include information obtained from use of the product (surveillance data), but this might not replace the requirement for controlled clinical trials. For further information on the investigations on cell-based medical products, consult the Guideline on Human Cell-based Medicinal products: http://www.emea.europa.eu/pdfs/human/cpwp/41086906enfin.pdf

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

[6] The scientific advice request can address data requirements for all parts of the dossier. For more information on the scientific advice procedure, see: http://www.emea.europa.eu/htms/human/sciadvice/Scientific.htm. From 1 January 2009, a reduced fee will be applicable to scientific advice for ATMPs (see Article 16 of Regulation (EC) 1394/2007). Small and medium-sized companies should contact the SME office at the EMEA in advance of the scientific advice request: additional incentives and support are available for registered SMEs, see: http://www.emea.europa.eu/SME/SMEoverview.htm

[7] See: http://www.emea.europa.eu/htms/human/mes/itf.htm. From 1 January 2009, it will be possible to ask for a scientific recommendation on ATMP classification (Article 17 of Regulation (EC) 1394/2007).