



Regulation on Advanced Therapy Medicinal Products

(COM(2005)0567 – C6-0401/2005 – 2005/0227(COD))

As patients and families of patients affected by severe, heavily debilitating and often life threatening diseases, we, the undersigned, call on the Members of the European Parliament to thoroughly consider the potential benefits of Advanced Therapy Medicinal Products (ATMPs) and to vote accordingly. To protect our patients, we urge you to ensure that ALL patients from the 27 European Member states have timely access to Advanced Therapy Medicinal Products which have undergone a robust evaluation process **at the European level**.

The centralised procedure will ensure the highest level of safety for our patients. A uniform level of quality, safety and efficacy can only be ensured by a European regulatory framework drawing on the collective scientific expertise across the EU.

1. We therefore call on MEPs to ensure that **ALL** these complex products are evaluated by the EMEA **centralised procedure for technical assessment**. The centralised procedure guarantees a uniformly high level of expertise and will avoid variations between Member States. The centralised procedure is consistent with EU Pharmaceutical Legislation, controlling the licensing of biotechnology medicines (Regulation (EC) No 726/2004 of 31 March 2004 - Article 7).

We urge you to [vote against amendment 66](#) (M. Liese).

2. For the same reasons of safety, quality and efficacy of medicinal products, we urge MEPs to include **ALL** ATMPs aimed at curing European children and adults in the scope of the proposed Regulation. The proposal from the EP Legal Service (as reflected in amendment 62) does ensure that **subsidiarity** will apply regarding **access to national markets** of non-consensual products. We urge MEPs to keep this subsidiarity provision in mind and ensure that **solidarity** towards severely sick citizens also applies when shaping European policies.

We therefore call on you to [vote in favour of amendment 62](#) (Ms Roth-Behrendt)

3. On the specific issue of embryonic stem cell research - and the products that may be derived from this research – we remind MEPs that the Regulation aims to establish a harmonised scientific evaluation for Advanced Therapy Medicinal Products to guarantee an **even level of safety and efficacy** throughout the EU. This Regulation does not seek to address different national ethical approaches for which there is no EU competence. For this reason, we urge MEPs **to leave considerations other than safety and efficacy up to Member States, patients and their families**.

We therefore urge you to [vote against amendments 3 and 17](#) (Ms Breyer).



This statement is signed by the following European or global patient networks and associations:



European Organisation for rare Diseases
<http://www.eurordis.org>



European Aids Treatment Group
<http://www.eatg.org/home.php>



European Cancer Patient Coalition
www.ecpc-online.org



International Diabetes Federation
<http://www.idf-europe.org>



European Genetic Alliances' Network
<http://www.egaweb.org>



French National Union of Parents Associations of children with cancer or leukaemia
<http://unapecle.medicalistes.org>



International Confederation of Childhood Cancer Parent Organisations
<http://www.icccpo.org>



Global Alliance of Mental Illness Advocacy Networks
<http://www.gamian.org>



European Federation of Neurological Associations
www.efna.net



European Federation of Allergy and Airways Diseases Patients Associations
<http://www.efanet.org>



Retina International
<http://www.retina-international.org>



European Patients' Forum
<http://www.eu-patient.eu>



Stand together to End Paralysis Now
<http://www.stepnow.org>