



- Press Release -

## **EU Regulation Urgently Needed! European Patients are Waiting for the Next Generation of Medical Treatments**

*Patients' Organisations, Scientists and Life Sciences Industry urge European Parliamentarians and Member States to adopt a well-worded EU "Advanced Therapies" Regulation soon*

**BRUSSELS, 27th February 2007** –Representatives from European patients' organisations, academia, science and industry urged Europe's decision-makers to approve the common framework for "Advanced Therapies" – treatments made from cells, genes or tissue engineering – last evening at a dinner debate organised by EPPOSI, hosted by Mrs. Avril Doyle, Member of the European Parliament.

More than 9 MEPs and/or their Political Assistants gathered to listen to points of view from across the stakeholder spectrum – including patients' representatives, scientists developing treatments for rare genetic diseases and representatives of the Life Sciences sector – to understand why the Regulation was important to them. And the overwhelming message was: ***this Regulation is needed and it is needed now.***

The draft Regulation is currently under discussion at the European Parliament, which is expected to vote on 13th March 2007. But parliamentarians also need to reach agreement with Member States – whose government representatives are set to meet tomorrow, 28th February 2007, with the Parliament to discuss the chances of agreement.

*“Advanced Therapies have the potential to revolutionise the way that patients are treated and, in many cases, offer treatments where none existed previously,”* explained Mrs. Doyle. *“This Regulation is the key to getting those products out of the laboratories and making sure that they are safely available to the patients,”* she confirmed.

Currently, each individual Member State of the EU regulates these products differently. In some countries, they are not regulated at all, meaning that patients cannot be sure of the safety of products that they might be receiving. Therefore, patients urged that all products should be subject to the evaluation. *“It is unacceptable that some products are left in the unregulated grey zone,”* explained Alastair Kent, president of EGAN, the European Genetic Alliances Network. *“Delaying the approval of the Regulation, or excluding some products from this Regulation will prevent some patients having access to them. But worse, those that do get them will have no guarantee of their safety.”*

And for the Life Sciences sector, the bewildering patchwork of rules and regulations means that each product must be registered country by country. Evidence must be gathered and formatted according to each individual system, meaning that patients in one country will receive the treatment long before others as the registration must be done step by step.

The new EU Regulation would solve all of this by putting in place a single EU evaluation – similar to that currently required for normal medicines – which would allow patients all over the EU assurances of safe, efficacious and high-quality products all at the same time.

The draft, endorsed by the European Parliament’s own Environment Committee which has primary responsibility for the draft legislation, calls for all products to be evaluated to the same standards, nevertheless leaves it up to individual Member States to accept the product in its market or not. *“This is the same approach as that taken with contraceptive products, where views differ from one country to another,”* continued Alastair Kent.

*“This Regulation is particularly important for those who suffer from incurable, often genetic diseases,”* explained Flaminia Macchia, speaking on behalf of EURORDIS, the European Organisation for Rare Diseases. *“Millions of patients are waiting for the fruits of new research and this Regulation will open up that possibility,”* she confirmed.

EPPOSI aims to positively work on policies in human healthcare in Europe by facilitating discussion and identifying consensus between its stakeholders. Any joint views developed by its stakeholders as consensus recommendations are shared with European decision-makers at all levels.

**– ENDS –**

**For further Information or interview opportunities, please contact:**

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