

April 25, 2007

EU lawmakers back rules for stem cell, other cures

STRASBOURG (Reuters) - European lawmakers backed new rules for stem cell and other advanced medical therapies on Wednesday, despite opposition from a key member of the European Parliament.

The European Union legislature rejected so-called ethical amendments to the regulation that will create a centralized process for approving new tissue and cell engineering therapies.

"It is a big day for European biotech," said Johan Vanhemelrijck, secretary general of EuropaBio, representing the region's biotechnology companies.

"The Advanced Therapies Regulation will put an end to the bewildering patchwork of guidelines, regulations and procedures that exist today, where some countries have no specific framework at all," he added.

Negotiations between the European Commission, European Parliament and EU member states had collapsed two weeks ago.

Supporters of the new treatments -- for diseases or injuries including skin burns, Alzheimer's, cancer or muscular dystrophy -- blamed the breakdown on the religious beliefs of a lawmaker responsible for getting the rules through the legislature.

Miroslav Mikolasik, a member of the parliament from Slovakia, insisted on two amendments that would have excluded certain advanced therapies, such as treatments using embryonic stem cells, from the new centralized approval process.

The European Commission, which penned the regulation, welcomed the vote and said it expected EU governments to provide their support as well.

"Harmonised EU rules are urgently needed to ensure uniform patients' access to treatments and support the development of this emerging biotechnology industry," it said in a statement.

The regulations were also supported by Europe's biotech industry which has warned the region could face a block on potentially vital new medicines without the new rules.

Stem cell therapy is still a long way from the market but the potential therapeutic use of embryonic stem cells is a politically charged issue in many countries.

Proponents say it offers major hope of cures for such ailments as Parkinson's disease, diabetes and spinal cord injuries. But research requires destruction of days-old embryos that is condemned by many anti-abortion advocates.

(Additional reporting by Ben Hirschler in London)