Embargoed until 02 June 2020, 17:00 CEST

Press Release

European Academies of Science and Medicine on Regenerative Medicine:

Great Medical Promises Threatened by Booming Miracle Cures and Undue Pressure to Gain Fast-Track Approvals

In a first-time report, the European Academies of Science (EASAC) and Medicine (FEAM) call upon European lawmakers to protect biomedical science from false claims. "Stem cell and gene-based therapies hold great medical promises. But we are alarmed over a trend to lower requirements of evidence. Also, we see an increasing problem of commercial clinics offering unregulated products and services," says Prof. Volker ter Meulen, Co-chair of the EASAC-FEAM Working Group and Past President of EASAC.

Science and medical experts from all over Europe caution that enthusiasm on the broad potential of regenerative medicine applications has led to a gap between expectations and the realities of translating regenerative medicine technologies into clinical practice. In an era of stark competition on the global medicine and healthcare market, some regulators have become increasingly permissive.

Fast-track approvals put patients at risk

"Analysts expect the market for regenerative medicine to grow fast over the next years. It is only natural that this raises high hopes both from desperate patients and the biotech industry", says Prof. Giulio Cossu of the University of Manchester. "As a result, regulators are pressured to accelerate authorisation procedures for stem cell and gene-based therapies. This trend puts patients at risk."

"We are now at the threshold of being able to correct major genetic and other diseases. But for many diseases, more evidence is needed, especially for the more complex polygenic and acquired degenerative disorders. The consequences of not addressing the critical scientific issues for evidence-based implementation would be to waste investment, research efforts and aspirations to cure."

Unethical offers of miracle cures

The Academies also point out that the idea of regenerative medicine is to tackle diseases which up to now are incurable. According to the report, cosmetic applications, for example, are inappropriate for the time being.

"So far, regenerative medicine has proven itself only in few specific clinical indications, for example for skin disorders. Yet, we see an increasing number of unregulated clinics promising a wide range of benefits on the basis of poorly characterised medicinal products with little evidence of effectiveness. They usually advertise their services via the internet with the primary intention of financial profit," explains EASAC Biosciences Programme Director Dr. Robin Fears.

The scientists therefore urge the EU to resist the pressure and put patients first. "When countries lower regulatory standards in their eagerness to support national economic interests, it is even more important for the EU as a major global player to defend the principles of international cooperation in health regulation", says Prof. George Griffin, Co-chair of the Working Group and President of FEAM.

"We all want cures to be available in the shortest time frame possible. But our analysis and recommendations aim at ensuring that regulatory procedures are robust, transparent and evidence-based," concludes Cossu. "Scientific research and proof are more important than ever. The EU and national regulators should be wary of not undermining public trust in science."

Annex:

What is regenerative medicine:

Regenerative medicine can be defined (Cossu et al. 2018) as an emerging medical endeavour aimed at restoration of tissue function via small molecule drugs, biological therapies, medical or tissue-engineered devices, or cells and genes.

The present EASAC-FEAM report does not cover cell and gene therapy in cancer research. While these approaches are of great importance, their main goal is to eliminate cancer rather than to regenerate diseased tissues.

At present, patients in the EU can access regenerative medicine in four ways:

- When the therapy has been tested and received regulatory authority approval;
- In the context of a clinical trial;
- Through permitted access to a treatment that does not have centralised marketing approval e.g. hospital exemption within EU compassionate use (1394/2007/EC);
- Through direct purchase e.g. via the internet by commercial entities whose activity is not scrutinised or approved by any regulatory body.

Key recommendations to protect patients and promote research:

- Promote good biomedical science – from fundamental research and its translation to clinical trials. This has implications for EU commitment to well-planned first-in-human trials with reliable, shared and objective end points determined with input from supporting expert networks (that also consider engagement with the public and media);
- Base proportionate and consistent regulatory authorisation for marketing on robust and replicable science. The EU must deter unregulated provision of regenerative medicine and rigorously address the ethical and regulatory issues discussed in the report;
- Make sure researchers must follow professional guidelines on responsible research and its translation, and standard-setting, in pursuit of good practice;
- Include teaching on regenerative medicine in the medical curriculum;
- Put patient interests first and ensure a robust scientific basis for the clinical intervention and for the endpoints selected for measurement. A crucial criterion for patients in deciding whether to consent to novel therapies is that they should not be expected to pay clinical research costs;
- Engage with the public and patients and debunk misinformation. Providing reliable sources of information, such as the International Society for Stem Cell Research (ISSCR) document "A closer look at stem cells", is integral to this process.

EASAC-FEAM Report: INSERT LINK

Contacts:

Professor Giulio Cossu
University of Manchester
Email: giulio.cossu@manchester.ac.uk

Dr Robin Fears
EASAC Biosciences Programme Director
Email: robin.fears@easac.eu

Professor George Griffin
FEAM President
Email: george.griffin@feam.eu

Professor Volker ter Meulen
EASAC Biosciences Steering Panel Chair
Email: volker.termeulen@mail.uni-wuerzburg.de

For general enquiries
Ms Sabine Froning
EASAC Communications Officer/Communication Works
Email: sabine.froning@easac.eu
Phone: +49 15208727000

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