Relaxing of regulations for regenerative medicines has cascading effect internationally

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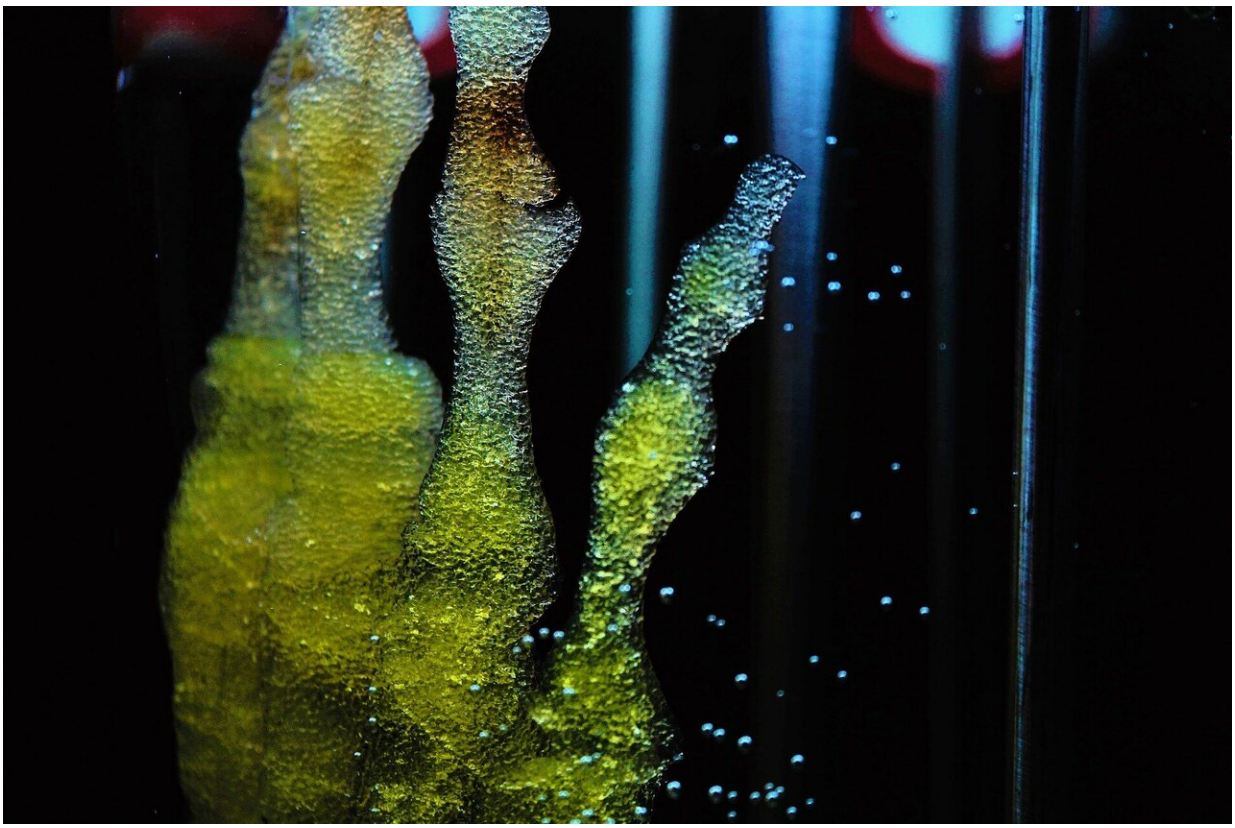

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Countries that relax regulations for regenerative medicines could be causing a downward spiral in international standards, according to new

research published today.

Researchers warn that if just one country decides to relax regulations in the field, a heightened sense of competition can spur others to do the same.

It's unclear whether this deregulation best serves competition, science or the patients.

Regenerative medicine focuses on developing therapies to regenerate or replace injured, diseased or defective cells, tissues or organs, like stem cell 'treatments'.

Due to the use of living cells, it can be hard to set regulations in the same way as for other drugs so differences in the rules can occur.

But, according to Professor Margaret Sleeboom-Faulkner from the University of Sussex and Douglas Sipp, from the RIKEN Centre for Developmental Biology (CDB), Kobe, Japan, one thing that should always be maintained is efficacy—the ability to reliably produce a certain therapeutic result.

Professor of Social & Medical Anthropology, Margaret Sleeboom-Faulkner said: "Regenerative medicine contains a lot of economic promise, and there's already been enormous investments into it.

"While this is good in terms of focusing on new and innovative treatments to improve healthcare, it also leaves the field particularly vulnerable to regulatory brokerage. When one country relaxes their regulations, others are tempted to do the same in order to 'keep up'.

"Competition is the last way we want medicine to be progressing."

The paper, published today in the journal *Science*, uses the example of South Korea as the first country to give preferential regulatory treatment to stem cell medicine. Their decision to issue a flurry of three stem cell-based medical products between 2011-12, and a fourth in 2014, attracted international scepticism for sacrificing clinical data standards in exchange for speed to market.

Yet Japan, who had launched a multi-billion dollar initiative to lead the world in regenerative medicine, instead began to see South Korea as a competitor. This resulted in a change of the law in 2013, to allow regenerative medicine products a faster entry to the market.

Professor Sleeboom-Faulkner explained: "The International Society for Stem Cell Research has published general guidelines around regenerative medicines but countries regulate it in different.

"At the moment, Britain has the safety net of the EU stamp on its regulations. While we're not expecting to lose that, with Brexit looming, we could see new interpretations of the existing guidelines and find ourselves starting to compete with other countries too.

"The UK has a reputation for high standards in medicines regulation and should continue to uphold this and to be vigilant in the face of political pressures for eye-catching innovation."

Professor Sleeboom-Faulkner also notes that strict regulations can have a negative impact too, making things hard for developing countries who have to import equipment and resources. As a result, strict regulations can cause some lower income countries to relax the implementation of their regulations and take measures to be able to catch up. Of late, however, it is the wealthy countries that have become more permissive.

Professor Sleeboom-Faulkner said: "What's needed is a greater

awareness that the regulations of one country can have cascading effects internationally.

"Regenerative medicines are often trialled on patients with a terminal illness, so it's hard to know the precise effect of all of this. With less stringent clinical trials and the fast-tracking of 'treatment', we'd assume standards are slipping and risks increase, but it's hard to prove that.

"Ideally, regulations should be internationally coordinated and there should be a collaborative global approach in order to maintain basic standards."

Professor Sleeboom-Faulkner is cautioning countries to be vigilant when it comes to developing treatments particularly in the face of deviant ventures such as the recent case of gene-edited foetuses in China, and the current trend of increasing flexibilities in regulations internationally.

More information: D. Sipp at RIKEN Center for Biosystems Dynamics in Kobe, Japan el al., "Deregulation trends in regenerative medicine," *Science* (2019). science.sciencemag.org/cgi/doi … 1126/science.aax6184

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