



Alliance for Regenerative Medicine, European Federation of Pharmaceutical Industries and Associations, and European Association for Bioindustries Call for Advanced Therapies to be Exempt from EU GMO Legislation

COVID-19 highlights how the EU can adapt legislation to meet urgent health needs

A permanent exemption would help to accelerate access to life-changing medicines for European patients

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The European Commission should exempt advanced therapies from Genetically Modified Organism (GMO) legislation, which hurts Europe’s ability to attract clinical trials and delays patient access to transformative medicines, said the Alliance for Regenerative Medicine (ARM), the European Federation of Pharmaceutical Industries and Associations (EFPIA), and the European Association of Bioindustries (EuropaBio) in a [paper](#) published online yesterday in the journal *Human Gene Therapy*.

The European Commission recognized that GMO requirements hinder the conduct of clinical trials in its April 29 study on new genomic techniques and in the 2020 Pharmaceutical Strategy for Europe, when it called for GMO legislation to be “fit for purpose” for addressing medicines. The original GMO legislation was primarily enacted to protect food consumers and the environment, but Advanced Therapy Medicinal Products (ATMPs) such as gene therapies are affected as an unintended consequence. The uneven application of GMO requirements across EU Member States causes significant clinical trial delays despite findings that gene therapies pose a negligible risk to the environment.

Galvanized by the pandemic, the European Commission granted a temporary derogation from GMO requirements to investigational COVID-19 medicinal products to accelerate the development of vaccines and treatments. An industry survey suggested that the temporary derogation decreased the amount of time required to complete clinical trials in Europe. A similar, but permanent, exemption is justified for gene therapies -- which often treat life-threatening diseases that have few, or no, treatment options – while still preserving high quality and safety standards.

“The European Commission recognised that time was of the essence when lifting GMO requirements for COVID-19 vaccines and treatments,” said Paige Bischoff, ARM’s Senior Vice President of Global Public Affairs. “Time is also very much of the essence for people with cancer, inherited disorders and other life-threatening conditions. We call on the European Commission to take the same measures for advanced therapies and remove the unnecessary and unintended burden of GMO legislation so patients have timely access to transformative, potentially curative medicines.”

The organisations call on the European Commission to put forward a proposal by 2022, the timeframe proposed by the Pharmaceutical Strategy for Europe. Without an exemption for gene therapies, the GMO requirements threaten the region’s competitiveness with other parts of the world where GMO legislation is less complex and cumbersome. A 2019 ARM [report](#), for example, found that the number of ATMP clinical trials in Europe stayed roughly flat over a four-year period (2014-2018) while increasing substantially in North America (+36%) and in Asia (+28%). Europe is at risk of falling further behind: At the end of 2020 the ATMP sector was conducting 1,220 clinical trials worldwide, up from 1,066 in 2019.

"In 2020, we welcomed the derogation from GMO legislation for COVID-19 treatments or vaccines in clinical trials," said Pär Tellner, Director of Regulatory Affairs at EFPIA. "Member companies are increasingly reporting how the derogation has removed the significant and time-consuming hurdles associated with GMO submissions, in addition to the clinical trial application. Swift action to a permanent exemption from GMO legislation allows the EU to prosper and most importantly for patients to continue to receive transformative, potentially life-saving therapies."

“Freeing the conduct of clinical trials with investigational gene therapies from the heavy EU GMO administrative burden is critical for cutting-edge biotechnology companies,” added Violeta Georgieva, EuropaBio’s Legal Affairs Manager. “The use of CRISPR/Cas9, the latest promising tool in genome editing, can be overshadowed in the EU if developers and regulators are to follow the 2018 ruling of the EU Court of Justice, which puts the controversial GMO label on the Nobel Prize-winning CRISPR technology. Our hopes are set on the European Commission to improve patient access to revolutionary treatments by exempting them from the disproportionate and outdated GMO framework.”

ARM, EFPIA, and EuropaBio look forward to engaging with the European Commission and other stakeholders to find the best possible solutions to ensure that Europe is a competitive destination for the development of advanced therapies and that European patients have access to the most innovative, life-changing treatments.

Press enquiries

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About the Alliance for Regenerative Medicine (ARM)

The Alliance for Regenerative Medicine (ARM) is the leading international advocacy organisation dedicated to realizing the promise of advanced therapy medicinal products (ATMPs). ARM promotes legislative, regulatory, reimbursement and manufacturing initiatives in Europe and internationally to

advance this innovative and transformative sector, which includes cell therapies, gene therapies and tissue-based therapies. Early products to market have demonstrated profound, durable and potentially curative benefits that are already helping thousands of patients worldwide, many of whom have no other viable treatment options. Hundreds of additional product candidates contribute to a robust pipeline of potentially life-changing ATMPs. In its 11-year history, ARM has become the global voice of the sector, representing the interests of 380+ members worldwide and 85+ members across 15 European countries, including small and large companies, academic research institutions, major medical centres and patient groups. To learn more about ARM or to become a member, visit <http://www.alliancerm.org>.

About the European Federation of Pharmaceutical Industries and Associations (EFPIA)

The [European Federation of Pharmaceutical Industries and Associations \(EFPIA\)](#) represents the biopharmaceutical industry operating in Europe. Through its direct membership of 36 national associations, 39 leading pharmaceutical companies and a growing number of small and medium-sized enterprises (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy

About the European Association for Bioindustries (EuropaBio)

The [European Association for Bioindustries \(EuropaBio\)](#) promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 1800 biotech SMEs. Read more about our work at www.europabio.org.