

(English version)

**Question for written answer E-001550/19
to the Commission
María Teresa Giménez Barbat (ALDE)
(29 March 2019)**

Subject: Use of genome editing technologies in healthcare

As evidenced by the recent debate in Parliament on 12 February 2019, there is a growing interest in and awareness of genome editing technologies. Technologies such as CRISPR-Cas9 could have the potential to significantly improve healthcare, by providing treatments for previously untreatable patients.

Last year, Commissioner Moedas, conscious of both the bigger picture of genome editing — including possible therapeutic applications — and specific aspects of concern, asked the European Group on Ethics in Science and New Technologies to put together an opinion on genome editing.

Does the Commission support treatments that might involve genome editing?

What action is the Commission taking to support the development of and access to advanced therapy medicinal products (ATMPs), especially genome editing technologies, for patients in the EU?

Would the Commission consider carrying out a Special Eurobarometer public opinion survey on ATMPs, especially genome editing technologies, as a follow-up to the survey 'Biotechnology and Genetic Engineering: what Europeans think about it in 1993'?

**Answer given by Mr Moedas on behalf of the European Commission
(3 June 2019)**

Genome-editing technologies can cure or treat patients affected by life-threatening diseases. In order to support these technologies, the EU has already invested more than EUR 450 million in research projects, including more than EUR 166 million since the start of Horizon 2020 ⁽¹⁾.

Examples include the projects Cell-PID ⁽²⁾ and UPGRADE ⁽³⁾, always complying with our framework's ethical principles and relevant national and international legislation. Remaining calls in Horizon 2020 further support genome editing approaches and support will continue in Horizon Europe through the 'Health' Cluster of Pillar II, paving the way for their swift uptake into health systems.

Regulation No 1394/2007 ⁽⁴⁾ governs the use of genome editing techniques in medicinal products for human use. The regulation provides for strict controls of quality, safety and efficacy and a centralised assessment by the Committee for Advanced Therapies.

Recognising the potential of gene therapy medicinal products — including genome-editing approaches, the Commission is working with the Committee and Member States to support developers while ensuring a high level of public health protection.

Examples are the recent Guidelines on Good Manufacturing Practices (GMP) for Advanced Therapy Medicinal Products and the ongoing development of scientific guidelines for gene therapy medicinal products, including genome editing approaches.

The Commission is exploring different activities to stimulate and inform the scientific and social debate on the applications of genome editing technologies for healthcare. A public survey such as Eurobarometer could be considered.

⁽¹⁾ The EU Framework Programme for Research and Innovation (2014-2020)

⁽²⁾ on advanced cell-based therapies for the treatment of primary immunodeficiency <https://cordis.europa.eu/project/rcn/96787/reporting/en>

⁽³⁾ which aims to improve precision gene therapy — <https://cordis.europa.eu/project/rcn/219838/factsheet/en>

⁽⁴⁾ OJ L324, 10/12/2007.