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Oifig an Príohoifigeach Cliniciúil Eatromhach
Feidhmeannacht na Seirbhíse Sláinte
Seomra 101 | Ospidéal Dr. Steevens | Baile Átha Cliath 8 | D08 W2A8

Deputy Mattie McGrath
Dail Eireann
Leinster House
Kildare Street
Dublin

Date: 12th June 2019

PQ 18896/19

To ask the Minister for Health if the use of CRISPR gene editing technology is available or licensed here; and if he will make a statement on the matter.

Dear Deputy McGrath,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question, which you submitted to the Minister for Health for response. I have sought input from the National Cancer Control Programme and have the following response.

Response

Genome or gene editing technologies are ones which provide the ability to change the DNA of an organism. This means that genetic material can be removed, added or changed at particular places in an organism's genome, including a human's. Research currently undertaken internationally in genome editing is done to understand diseases using cells and animal models. These gene changes are limited to somatic cells, i.e. not egg or sperm cells, and as such the changes made are not passed on to future generations. When the edits are undertaken in germline cells, these edits can be passed on to future generations. These edits are currently illegal in many countries.

The CRISPR gene editing technology which recently made international news was when He Jiankui, a Chinese scientist, announced that he had created the world's first gene-edited babies. The medical / scientific intention in this case was to prevent the transmission of HIV from their father through gene modification, an intention felt unnecessary given that

successful methods for significantly reducing the risk of HIV transmission already exist clinically.

Ireland does not currently have legislation pertaining to these specific issues, but does have guidelines which prohibit the production of embryos for research and by default therefore, gene modification for reproduction. There are also international standards for ethical clinical research on humans.

The HSE abides by these guidelines and would welcome explicit legislation in this area, particularly legislation aligned with many other countries in prohibiting germline gene editing.

The HSE would not be the licensing body for such technologies. Therapeutic uses of gene-editing technologies can apply to the European Medicines Agency for consideration as an 'advanced therapy medicinal product', in order to be considered for licensing. As far as we are aware, there is no such clinical application of CRISPR gene editing technology that would be eligible to take this path at this time.

https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/2017_11_22_guidelines_gmp_for_atmps.pdf
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/advanced-therapies/advanced-therapy-classification

I trust this information is of assistance to you but should you have any further queries please do not hesitate to contact me.

Yours sincerely,

Sharon Dwyer

Sharon Dwyer
General Manager
Office of the Chief Clinical Officer