

Dear Mr. Paweł Woliński,

We received your letter concerning the appeal for an ethical vaccine against Measles, Mumps, and Rubella in Europe. Please allow us to state our position in this matter:

Certain vaccines against viral diseases from GlaxoSmithKline (GSK) and other manufacturers are produced on living cell lines from human diploid origin. The MRC-5 cell line was established in the United Kingdom by the Medical Research Council (MRC) in 1966 as a stem cell line that continuously clones itself, allowing for the continual generation of multiple identical cells. The cells were originally derived from the lung tissue of a 14 week-old fetus which was removed from a 27 year-old female for medical reasons, unrelated to any research purposes.¹ The cell line was grown independently since its inception. No additional sources of fetal cells are needed to make these vaccines.

GSK received the MRC-5 cell line on September 1994 from the National Institute for Biological Standards and Control (NIBSC, UK) and it was expanded at GSK to establish a GSK Master Cell Bank.² GSK Working Cell Banks derived from the same GSK Master Cell Bank have been used since that time for the production of different vaccine antigens (i.e. rubella, varicella, hepatitis A, oral poliovirus) and are tested in accordance with the applicable relevant guidelines of World Health Organization (WHO), the International Conference on the Harmonization of technical requirements for human use (ICH) and competent Regulatory Authorities.

Any current or future use of fetal cells by GSK or by its outside collaborators follows established ethical requirements and rigorous scrutiny, which includes confirmation that the provider of the material has obtained informed consent from the donor.³

Rubella is the leading vaccine-preventable cause of birth defects. Rubella infection in pregnant women may cause fetal death or congenital defects known as congenital rubella syndrome. There is no specific treatment for rubella but the disease is preventable by vaccination. Mass immunization campaigns in the Region of the Americas involving more than 250 million adolescents and adults did not identify any serious adverse reactions associated with the vaccine. As of December 2016, 152 out of 194 countries had introduced rubella vaccines. Reported rubella cases declined 97%, from 670,894 cases in 102 countries in 2000 to 22,361 cases in 165 countries in 2016.⁴

Given the origin of the MRC-5 cell line, the way it is used, and the high importance of rubella prevention for mothers and their unborn children, GSK does not consider rubella vaccine as an "unethical" vaccine.

References

1. Jacobs JP, Jones CM, Baille JP. Characteristics of a human diploid cell designated MRC-5. *Nature*.1970;227(5254):168-170.
2. Data on file. 2015N232030_00 . 2017.
3. GSK Public policy positions: Cloning and Stem Cell Technologies. Available at: <https://www.gsk.com/media/2929/cloning-technologies-and-stem-cell-research-policy.pdf>. Last accessed: January 31, 2019.
4. World Health Organization. Rubella Fact Sheet. Available at: <https://www.who.int/news-room/fact-sheets/detail/rubella>. Last accessed: January 31, 2019.

Kind regards,

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