

FREEDOM OF INFORMATION ACT REQUEST

VIA EMAIL

April 28, 2022

Medicines and Healthcare Products Registry Agency
10 South Colonnade
Canary Wharf
London
E14 4PU
info@mhra.gov.uk

Re: Documents for MHRA's Approval of Janssen's COVID-19 Vaccine (*IR#0751C*)

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, please provide the following records to foia@sirillp.com in native format and/or searchable electronic form:

All documents the MHRA relied upon to approve the use of Janssen's COVID-19 vaccine and/or COVID-19 vaccine Ad26.COV2-S [recombinant].

We ask that you waive any and all fees or charges pertaining to the processing of this request because ICAN is a United States registered not-for-profit 501(c)(3) organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. In pursuit of its mission, ICAN relies primarily on its own investigative reporting.

ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website¹ hosts the organization's largest education program, The HighWire with Del Bigtree.² Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 140,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers.

¹ <https://www.icandecide.org/>

² <https://thehighwire.com/>

Critical to ICAN's mission is its proven ability to find and review important scientific and governmental records and meaningfully report about their social impacts. ICAN seeks the information in this FOIA request to allow it to contribute to the public understanding of governments' COVID-19 vaccine programs, including governments' regulatory processes, and criteria for vaccine safety and vaccine efficacy. The information we are requesting will not contribute to any commercial activities.

Furthermore, we ask you provide expedited processing for this request. The information requested concerns matters of urgent public concern. The only time MHRA has ever approved or authorized an mRNA vaccine for public use was for the COVID-19 vaccines.³ Moreover, there has never been a faster development, testing, and regulatory approval of any vaccine on the market. The speed in which the COVID-19 vaccines have been developed, tested, and regulatorily approved for widespread public use has sparked a public debate regarding the vaccines' safety and effectiveness. The ongoing public debate regarding the safety and effectiveness of a group of novel vaccines requires complete transparency over the MHRA's approval process.

Beyond the transparency needed to enable a productive and fact-based public debate over the safety and effectiveness of these vaccines, transparency is even more critical now that some private and public institutions have created policies that grant or restrict certain privileges based upon a person's COVID-19 vaccination status.⁴ Without disclosure, consumers that are confronted with COVID-19 vaccine mandates are forced to choose between taking a vaccine without all the science-based information available to make an informed decision, or losing certain societal privileges based upon their vaccination status. Therefore, no matter a person's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the science-based information used to obtain regulatory approval of the COVID-19 vaccines would compromise the public's significant recognized interest of informed consent.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately file an administrative appeal.

³ <https://ec.europa.eu/research-and-innovation/en/horizon-magazine/five-things-you-need-know-about-mrna-vaccine-safety>.

⁴ <https://www.theguardian.com/law/2021/aug/08/bosses-battle-over-rights-and-wrongs-of-no-covid-jab-no-job>.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact us at (212) 532-1091 during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.