Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

P Newton
request-705260-47e55303@whatdotheyknow.com

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

10th December 2020

Dear P Newton,

FOI 20/442

Thank you for your information request, dated 12th November, where you asked for information on the AI software to be used for managing suspected adverse event reports associated with COVID-19 vaccines and the active ingredients contained in the Pfizer vaccine, specifically

1. The contract awarded to Genpact (UK) Ltd for procurement of an Artificial Intelligence (AI) software tool to process the expected high volume of Covid-19 vaccine Adverse Drug Reaction (ADRs) to ensure that no details from the ADRs' reaction text are missed.

2. The information determining the anticipation of a [high volume] of COVID-19 vaccine Adverse Drug Reactions (ADRs) and details of the anticipated ADRs.

3. A list of active and inactive ingredients so far known to be contained within the overtly bleated Pfizer and other manufacturer COVID-19 vaccine.

I am pleased to provide you with some of the information requested. Unfortunately, some of the information is exempt from release under section 41 (information provided in confidence) and Section 43 (commercial interests) of the Freedom of Information (FOI) Act.

As background, the MHRA is responsible for monitoring the safety of all medicines and vaccines as well as medical devices and other healthcare products in the UK. The Yellow Card scheme is the UK system for collecting and monitoring information on suspected safety concerns or incidents involving medicines and medical devices. The scheme is run by the MHRA and currently relies on voluntary reporting of suspected adverse drug reactions (ADRs) by health professionals and patients. The purpose of the scheme is to provide an early warning that the safety of a product may require further investigation. Reports can be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market.

The safety of the public will always come first. With any major new vaccination campaign, we always develop a proactive vigilance strategy, and COVID-19 vaccines are no exception. Like all medicines, vaccines can cause side effects. Most are mild and short-term, and not everyone gets them. Some

side effects can come to light when used by a larger number of people than took part in clinical trials.

With respect to the anticipated volume of suspected ADR reports for any forthcoming COVID-19 vaccination programme, this has been estimated from a number of previous vaccination campaigns. Actual numbers of reports will be dependent on various factors including the number of doses administered and use of concurrent treatments (for instance to manage fevers). Our past experience with other new immunisation campaigns is that we tend to receive around 1 Yellow Card report per 1,000 doses administered and we are preparing our surveillance systems on that basis. It is important to note that a report of a suspected side effect is not proof that the vaccine caused it but a suspicion by the reporter that the vaccine may have caused the side effect. We take every report of a suspected side effect seriously and we will combine the review of these individual reports with statistical analysis of anonymised clinical records.

We have a range of resources and technology to support the proactive vigilance of any COVID-19 vaccination programme. The use of artificial intelligence (AI) will be one element of that. This specific AI tool is for the surveillance of COVID-19 vaccines due to the potential size and scale of the vaccination campaign. The contract awarded to introduce AI is attached as requested. The Agency has redacted elements considered to be commercially sensitive, privileged and that contain personal data.

The list of ingredients is published here https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF