Medicines & Healthcare products Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
**gov.uk/mhra**

[redacted]

16th June 2023

**FOI 23/337**

Dear [redacted]

Thank you for your email dated 11th May 2023, where you requested the following:

1. The date upon which Public Health England first informed the States of Guernsey of known adverse side effects from the Pfizer Bio-Ntech vaccination that specifically included Pericarditis

2. How this information was communicated to The States of Guernsey

The MHRA is unable to comment on communications issued by Public Health England (now known as the UK Health Security Agency, UKHSA), so the information on your two questions is not held by MHRA. However, we can provide information on when the first communications were issued by the MHRA in relation to reports of myocarditis and pericarditis following the Pfizer-BioNTech COVID-19 vaccine.

I will first provide an overview of the functions and responsibilities of the MHRA in relation to medicinal and blood products and vaccines in general, and to COVID-19 vaccines in particular. I will then provide the first risk communications undertaken by the MHRA in relation to myocarditis and pericarditis following the Pfizer-BioNTech COVID-19 vaccine.

**Role of the MHRA**

The role of the MHRA is to ensure that medicinal products authorised in the UK meet acceptable standards of safety, quality and efficacy at the time of first authorisation and thereafter. In order to do this, we have in place a comprehensive strategy to monitor the safety of medicines and healthcare products, including vaccines. All vaccines and medicines have some side effects. These side effects need to be continuously balanced against the expected benefits in preventing illness.

We have authorised the use of COVID-19 vaccines following a rigorous review of their safety, quality, and efficacy. As part of our statutory functions, we are responsible for monitoring these vaccines on an ongoing basis to ensure their benefits continue to outweigh any risks. This monitoring strategy is continuous, proactive, and based on a wide range of information sources. A dedicated team of scientists review information weekly to look for safety issues or unexpected, rare events. We use additional data sources where applicable and collaborate with other international regulators.

We have been monitoring the safety of the COVID-19 vaccines used in the UK vaccination programme since the first vaccine was administered in December 2020. Further details on the monitoring strategy can be found here.

The Yellow Card scheme is one of the sources of information used in the monitoring strategy and is the UK system for healthcare professionals and patients to report suspected side effects or adverse reactions to medicines and vaccines. From February 2021 we have published a report covering adverse reactions to approved COVID-19 vaccines, which was updated weekly then from Autumn 2022 monthly to the end of February 2023 and which summarises information received via the Yellow Card scheme, including a section on events of myocarditis and pericarditis. The Summary of Yellow Card Reporting can be found here. In December 2022 the MHRA began publishing COVID-19 vaccine safety data in the form of interactive online profiles which can be viewed here.

**Risk communications on myocarditis and pericarditis following the Pfizer-BioNTech COVID-19 vaccine**

The table below lists the first communications issued by MHRA in chronological order.

| **Date published** | **Publication medium** | **Details of communication** |
|---|---|---|
| 10 Jun 2021 | Summary of Yellow Card reporting | Coronavirus vaccine - weekly summary of Yellow Card reporting<br>Updated 10 June 2021 |
| 25 Jun 2021 | Regulatory approval of Pfizer/BioNTech vaccine for COVID-19 | All updates / 25 June 2021<br>Added a warning on myocarditis to the Information for UK recipients and the Information for Healthcare Professionals<br>Available at: Regulatory approval of Pfizer/BioNTech vaccine for COVID-19 - GOV.UK (www.gov.uk) |
| 7 Jul 2021 | Drug Safety Update | COVID-19 vaccines: updates for July 2021<br>Available at: https://www.gov.uk/drug-safety-update/covid-19-vaccines-updates-for-july-2021 |

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,
Safety and Surveillance



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
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF