FOI 23/927

Dear

Thank you for your communication dated 22 November 2023, where you asked for information regarding vaccines given to those serving in the Gulf War of 1990-91.

We have considered your request under the Freedom of Information Act. Please find our response to each of your requests for recorded information below.

Question 1. Please could you confirm the manufacturer of the vaccines (which included protection against bubonic plague and anthrax) and confirm that the license was never awarded?

Our response:

The MHRA do not hold records regarding administration of vaccines to service personnel during the Gulf War of 1990-91 and we are therefore unable to confirm the manufacturer or authorisation status of any such vaccines.

We can confirm that a number of anthrax and plague vaccines have been granted Marketing Authorisations (licences) by the MHRA and some of these vaccines may have been authorised at the time that you are interested in. Please find the list of licences attached, which includes the date that the Marketing Authorisation was granted, the Marketing Authorisation Holder and the current authorisation status. As stated above, we do not hold records as to whether any of the vaccines listed were administered to service personnel.

We would advise you to contact the Ministry of Defence directly for information regarding any vaccines that may have been administered. They can be contacted at the following email address: cio-foi@mod.uk

Question 2. Please could you also advise whether you have received complaints from other individuals subjected to the vaccines and tablets?

Our response:
The MHRA collect reports of adverse reactions to medicines and vaccines through the Yellow Card scheme. It is a voluntary scheme for patients and healthcare professionals whilst pharmaceutical companies have a legal obligation to report to us.

The MHRA have not received any UK spontaneous Adverse Drug Reaction (ADR) reports associated with either Plague vaccines listed in the table provided in answer to your first question.

It is not mandatory to report the specific product when reporting to the Yellow Card scheme, reports can be made based on substance only. The substance contained in Anthrax vaccines is ANTHRAX BACILLUS. The MHRA have received 139 UK spontaneous suspected ADR reports associated with this substance, five of which

were reported with the ANTHRAX VACCINE with the authorisation holder of SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE specifically. No ADR reports have been received for either the PORTON BIOPHARMA LIMITED or EMERGENT SALES AND MARKETING GERMANY GMBH products.

It's important to note that a reported reaction to the MHRA does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of routine vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines or different brands of vaccine. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time.

We hope that you find the above information useful. We now consider this request closed. 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 email: info@mhra.gov.uk

After that, if you remain dissatisfied, you may write to the Information Commissioner at; The Information Commissioner's Office Wycliffe House Water Lane Wilmslow Cheshire SK9 5AF

They will make a decision on whether or not we have interpreted the FOIA correctly in handling your request.

Yours sincerely,
HQA FOI Team