Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

21st June 2023

Dear [redacted]

FOI 23/403 – FW: MHRA Yellow Card Contact Us Form Submission

Thank you for your Freedom of Information request dated 4th May 2023, where you asked for:

1. All data and reports the yellow card scheme have on the vaccine 'Bexsero'.

Firstly, please accept my apologies for the delay with this response, I can confirm that up to and including 8th June 2023 we have received 2963 UK spontaneous reports in association with the brand name Bexsero.

Please find attached a Drug Analysis Print (DAP) for Bexsero which lists information on all the UK spontaneous) reports received through the Yellow Card scheme up to and including the 8th June 2023. Please note, as it is possible for one report to contain multiple ADRs, the number of ADRs is greater than the number of individual cases. Please find attached a DAP guidance sheet which provides you with further information on how to interpret the print.

When considering the attached spontaneous data, it is important to be aware of the following points:

- A reported reaction 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. 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.

As these data do not necessarily refer to proven side effects, you should refer to the product information which can be found here: https://www.medicines.org.uk/emc/ for details on the possible side effects of each vaccine.
I hope the information provided is helpful; however, 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.

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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
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF