Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

15th March 2023

Dear [redacted]

RE: FOI 23/141

Thank you for your email on 15th February where you requested:

"My enquiry is regarding SJS/TEN reported cases from all the Covid-19 vaccines from the 14th July 2021 up to the present day, 15th February 2023."

I understand that previously you may have been advised that adverse drug reaction data relating to Covid-19 vaccinations was not available via Freedom of Information requests due to section 22 (information intended for future publication). Section 22 is a qualified exemption which means we have considered whether there is a greater public interest in releasing the information requested or withholding it. Please be advised that section 22 no longer applies to adverse drug reaction data relating to Covid-19 vaccinations as in December 2022 the MHRA began publishing COVID-19 Vaccine reports which contain interactive charts and tables displaying data for all COVID-19 vaccines including reports of Stevens-Johnson syndrome and Toxic Epidermal Necrolysis. This data is available for each Covid-19 vaccine in the Reaction Profile section under the Skin and subcutaneous tissue disorders, Epidermal and dermal conditions, Bullous conditions, Stevens-Johnson syndrome/Toxic Epidermal Necrolysis respectively.

As our database is dynamic and subject to change over time we would not recommend calculating overall numbers of suspected adverse reactions from information provided at different times, this is highly likely produce an inaccurate reflection of the data we hold. Should you require information different to that published in the Covid-19 Vaccine reports we are happy to look into whether this can be provided to you.

We have recently made changes to the way in which we provide data on spontaneous ADR reports. We implemented changes in policy which further strengthens our duty to protect patients and reporters to the Yellow Card scheme. Therefore, we are unable to provide data where the number of reports is less than 5. Where there are less than 5 reports, numbers have been replaced with a ^ in order to prevent patient/reporter identification in line with our duty of confidentiality to patients and reporters.

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

- A reported reaction does not necessarily mean it has been caused by the medicine, only that the reporter had a suspicion it may have. The fact that symptoms or events occur after use of a vaccine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the vaccines. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that Yellow Card data cannot be used to determine the incidence of a reaction or to compare the side effect profiles of different medicines or vaccines. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug or vaccine and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines or vaccines during the first one to two years on the market and then falls over time.

As this data does not necessarily refer to proven side effects, you should refer to the product information (Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL)) for details on the possible side effects of each COVID-19 vaccine, which can be found on the Yellow Card coronavirus website here.

For a vaccine to be considered safe, the expected benefits will be greater than the risk of having harmful reactions. It is important to note that most people receive vaccinations without having any serious side effects.

As you may know the Coronavirus vaccine – summary of Yellow Card reporting, is available here which includes summaries of our assessment so far on particular safety topics surrounding the COVID-19 vaccinations. The MHRA has revised the format of the Summary of Yellow Card reporting to focus on the COVID-19 vaccines administered from the beginning of the Autumn 2022 booster campaign. Any new assessments or safety issues regarding vaccines used in the primary and initial booster campaigns will also be included in this record, however previous and known information on these vaccines will remain available as a record only and can be viewed on the government website (Coronavirus (COVID-19) vaccines adverse reactions - GOV.UK (www.gov.uk)).

We note that you have also been in touch regarding accessing your Yellow Card report via your online account. We are happy to help you with this issue and our team will contact you shortly.

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 this response's date and can be addressed to this email address.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division

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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