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

12 December 2023

Dear [redacted]

RE: FOI 23/903

Thank you for your email on 21st November. We have interpreted your request as relating to your enquiry made to NHS England where you requested:

1. *"Please tell me why it was necessary to place a Section 22 on the information that from 14th July 2021 it was not in the public interest to know about cases of Stevens-Johnson Syndrome/TEN?"*

2. *"What are the precise reasons for the Section 22 please and who made this decision? Also is the Section 22 still in place or has it been removed, in which case who decided it could be removed and on what date please."*

Within our response FOI 23/141 we outlined how a Section 22 exemption was previously applied to all requests for information relating to suspected adverse reactions to Covid-19 vaccinations. 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. This was because the information was intended for future publication by the MHRA in full and with appropriate context provided to enable interpretation by healthcare professionals and members of the public alike. In December 2022 the MHRA began publishing Covid-19 vaccine reports online at https://coronavirus-yellowcard.mhra.gov.uk/datasummary which contain interaction 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 soon as the MHRA published this data in December 2022 the Section 22 exemption applied to FOI requests previously was no longer applicable.

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,

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

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