Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Nick Hunt

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

5th July 2023

Dear Mr Hunt

FOI 23/400

Thank you for your email dated 7th June 2023, where you requested:

"In MHRA-authorised clinical trials, the research body is required to assess the intensity, causality and expectedness of all "solicited" adverse reactions to the medicine under trial. Research bodies maintain a standard operating procedure (many of which are publicly available) for doing this consistent with Good Pharmacological Practice (GVP), including the categorisations used : intensity (mild, moderate, severe); causality (not related, unlikely, possibly related, probably related, definitely related); and expectedness.

Please can you send me the corresponding standard operating procedure for MHRA's categorisation of Yellow Card (i.e. "unsolicited") reports of suspected serious adverse events associated with medicines.

Please can you also send me the following information for each of the Pfizer, AstraZeneca and Moderna Covid vaccines:

a) the number of YC reports of suspected serious adverse events to date
b) the number of YC reports of suspected serious adverse events assessed as i) not related; ii) unlikely related; iii) possibly related, iv) probably related and v) definitely related
c) the number of YC reports of suspected serious adverse events which have not been assessed for causality

Please can you also send me a copy of MHRA's standard operating procedure for categorising the 'intensity', 'causality' and 'expectedness' of individual claims under the Vaccine Damage Payment Scheme."

Spontaneous reports of suspected serious adverse reactions associated with medicines and vaccines, such as the reports received through the Yellow Card scheme, are not subject to the regulations for collection of 'solicited' adverse reactions arising during clinical trials. As such we do not hold either the SOP requested, or information requested in b) and c) above.

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In relation to point a) for information on Yellow Card reports for the Pfizer, Astrazeneca and Moderna Covid vaccines, this information is publicly available in the MHRA published COVID-19 Vaccine reports which contain interactive charts and tables displaying data for all COVID-19 vaccines including the number of reports that are considered serious.

Regarding your final request for a copy of a standard operating procedure for categorising claims under the Vaccine Damage Payment Scheme (VDPS). The MHRA has no involvement in the VDPS (Vaccine Damage Payment: Overview - GOV.UK (www.gov.uk) and holds no information on any compensation paid to claimants or whether claimants have reported their suspected adverse reactions to the Yellow Card scheme. The scheme is run by the NHS Business Services Authority, information on how make a Freedom on Information request can be found on their website (Freedom of Information | NHSBSA).

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 Group

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