Medicines & Healthcare products Regulatory Agency

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[redacted]

17th January 2024

Dear [redacted]

FOI 23/989 – Vaccine damage

Thank you for your Freedom of Information (FOI) request dated 18th December 2023 where you asked:

1. *How is a vaccine related death diagnosed?*
2. *How is a vaccine damage payment death diagnosed?*
3. *What medical markers are used to ascertain if a vaccine caused harm or death?*
4. *How many claims to date have been paid out to the covid vaccine victims (both monitory and amount of claimants)? Please include the amount in ages*
5. *How many claims have been proven to be vaccine damaged but fall below the 65 percent threshold?*
6. *How many deaths would it be before these vaccines would be classed as being unsafe?*
7. *How many adverse reactions would it take for a particular reaction to be of a serious concern?*

I will address each of these questions in turn.

1. **How is a vaccine related death diagnosed?**

The MHRA does not hold the requested information regarding how a vaccine related death is diagnosed. As per our response to questions 1, 2 and 6 of your FOI 23/682, a reported adverse reaction included in a Yellow Card report may not necessarily be due to a medicine or vaccine. While the MHRA carefully assesses Yellow Card reports to facilitate assessment of the link between a medicine or vaccine and the reported adverse event, we do not assign causality (i.e., whether the patient's reaction was caused by the medicinal product) at the level of individual reports. MHRA considers data from Yellow Card reports, along with relevant information from other sources in their overall assessment of whether there may be a causal link between a medicinal product and an adverse event. Should a new link between a medicine and a safety concern be confirmed, the MHRA will take regulatory action, such as updating product information to include a warning for patients and healthcare professionals.

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In some instances where a death has occurred healthcare professionals such as hospital doctors or coroners may recognise an adverse reaction to a drug or vaccine as a cause of death on official documents relating to the deceased.

2. **How is a vaccine damage payment death diagnosed?**

Again, as per our response to questions 7 and 8 of your FOI 23/682, the MHRA has no involvement in the Vaccine Damage Payments Scheme (VDPS) (Vaccine Damage Payment: Overview - GOV.UK (www.gov.uk) and do not hold any information related to the VDPS. The NHS Business Services Authority (NHSBSA) operates the VDPS on behalf of the Department of Health and Social Care (DHSC). Information on how to make a Freedom of Information request to the NHSBSA can be found on their website (Freedom of Information | NHSBSA).

3. **What medical markers are used to ascertain if a vaccine caused harm or death?**

Please see response to question 1.

4. **How many claims to date have been paid out to the covid vaccine victims (both monitory and amount of claimants)? Please include the amount in ages**

Please see response to question 2.

5. **How many claims have been proven to be vaccine damaged but fall below the 65 percent threshold?**

Please see response to question 2.

6. **How many deaths would it be before these vaccines would be classed as being unsafe?**

As per our response to questions 3 and 4 of your FOI 23/682, the MHRA does not have a specific threshold for the number of deaths or suspected ADR reports required to raise a signal for a medicine or vaccine to be regarded as a concern. Our signal detection processes focus on highlighting drug event combinations of concern based on a combination of statistical disproportionality and a rule based approach. These drug event combinations are assessed by a group of scientists, physicians, and pharmacists to determine if risk-minimisation measures need to be implemented, considering other sources of information and independent expert opinion where appropriate.

7. **How many adverse reactions would it take for a particular reaction to be of a serious concern?**

Please see response to question 6.

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 the date of this response; and can be addressed to this email address.

Yours sincerely,

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FOI Team,
Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

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, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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