Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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4th October 2023

Dear [redacted]

FOI 23/682

Thank you of your email dated 11th September 2023, where you requested the following:

1) How a reported yellow card adverse reaction is verified.
2) Who verifies such a reaction if caused by the vaccine.
3) What is the criteria (or how many same reactions) required before safety signals are raised on the safety of vaccines ie updated literature being issued for the said vaccines.
4) At what level of similar adverse reaction rates does it become a serious concern (as a percentage of similar adrs v amount of vaccinations?)
5) As currently there have been approx. 151 million doses with around 1.5 million plus adverse reactions reported which equates to around 1 in 100 adrs reported however is it not true that the yellow card only reports app 2 to 10 percent of adverse reactions real time are reported as shown in 2018.
6) Who determines if a vaccine has led to the death of someone.
7) How many have now to date been paid out the vaccine damage payment for (a) deaths (b) disability.
8) How many are waiting yet to be investigated.

I can confirm that we hold some of the information you have requested. Please find responses to your queries outlined below.

1) How a reported yellow card adverse reaction is verified.

A reported adverse reaction included in a Yellow Card report may not necessarily be due to a medicine or vaccine, as the MHRA encourages reporting of any *suspected* adverse drug reactions (ADR) i.e. the reporter does not have to be sure of a causal association between the drug and the reactions – a mere suspicion will suffice. 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 verify reports or assign causality (i.e., whether the patient's reaction was caused by the medicinal product) at the level of individual reports.

2) Who verifies such a reaction if caused by the vaccine.

Patient safety is our highest priority and the MHRA is continuously conducting signal detection activities. Signal detection is the continual review of ADR reports alongside other sources of evidence to identify previously unrecognised concerns about medicines, vaccines or blood products, which may warrant further action. Signals that meet defined criteria are evaluated further by a team of safety experts to assess the likelihood of a causal relationship between the drugs and reported reactions. Should a new link between a medicine or vaccine and a safety concern be confirmed, the MHRA will take regulatory action, which can range from restricting use of a particular product to updating product information to include a warning for patients and healthcare professionals to enable swift recognition and clinical care where reactions occur.

As per the response to question 1 individual Yellow Cards are not assigned causality by the MHRA. 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.

3) What is the criteria (or how many same reactions) required before safety signals are raised on the safety of vaccines ie updated literature being issued for the said vaccines.

The MHRA does not have a specific threshold for the number of suspected ADR reports required to raise a signal for a medicine or vaccine. 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, taking into account other sources of information and independent expert opinion where appropriate.

4) At what level of similar adverse reaction rates does it become a serious concern (as a percentage of similar adrs v amount of vaccinations?)

Please see response to question 3.

5) As currently there have been approx. 151 million doses with around 1.5 million plus adverse reactions reported which equates to around 1 in 100 adrs reported however is it not true that the yellow card only reports app 2 to 10 percent of adverse reactions real time are reported as shown in 2018.

The reporting rate for spontaneous adverse drug reactions (ADR) is variable and can depend on a multitude of factors. Although some historical studies have estimated only 10% of ADRs are reported, the actual rate is unknown and variable because it is influenced by public awareness and seriousness of the event. For the COVID-19 vaccines, there is a higher-than-normal public awareness of Yellow Card reporting and therefore the reporting rate for these products is expected to be higher.

Please note that for the article that you quoted (Yellow Card: please help to reverse the decline in reporting of suspected adverse drug reactions - GOV.UK (www.gov.uk)) we have added a clarification note on this article explaining that this 10% figure is inaccurate.

MHRA has in place a Yellow Card Strategy to promote the scheme and raise awareness amongst healthcare professionals and patients alike. All spontaneous ADR reporting systems worldwide, like the Yellow Card scheme, are known to be subject to under-reporting. Underreporting of ADRs is

thought to occur less frequently with serious and unlabelled reactions (those reactions which are not yet on the product information). The disproportionality statistical analyses which we use to routinely review the whole Yellow Card database are purposefully designed to minimise the impact of under-reporting by comparing between drugs or vaccines rather than with unexposed patients. Further, the MHRA can also apply additional sensitivity analyses into its statistical evaluation of a potential safety concern which takes account of a range of levels of possible reporting.

Specifically, for COVID-19 vaccines, information about reporting suspected side-effects using the Coronavirus Yellow Card website and app is contained in the materials given to vaccine recipients which are also available on-line. We also optimised website search functionality and worked with media outlets to encourage them to carry messages about reporting of side effects. During the height of the pandemic we also ran a targeted social media campaign and encouraged anyone, who has not already done so, to report through the Coronavirus Yellow Card site.

During the vaccine campaign we worked in close collaboration across the healthcare system to ensure healthcare professionals and patients were and still are aware of the Yellow Card scheme and how they can report to us. Information on Yellow Card reporting has been included in NHS training materials, as well as the materials available to individuals both before and after vaccination. Both vaccine recipients and healthcare professionals are strongly encouraged to report any suspicion of a side effect to the MHRA.

6) Who determines if a vaccine has led to the death of someone.

Please see response to question 2.

7) How many have now to date been paid out the vaccine damage payment for (a) deaths (b) disability.

The Vaccine Damage Payments Scheme (VDPS) is operated by the NHS Business Services Authority (NHSBSA) and the Yellow Card scheme has no relationship to the VDPS. As such the MHRA does not hold any information related to the VDPS. Information on VDPS can be found here, Vaccine Damage Payment: Overview - GOV.UK (www.gov.uk).

8) How many are waiting yet to be investigated.

Please see response to question 7.

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

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