Medicines & Healthcare products Regulatory Agency

Ms Gillian Dymond
By Email: gillian.dymond@gmx.co.uk

Reference: CEO 19104/19077

25 April 2022

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000

**gov.uk/mhra**

Dear Ms Dymond,

**Open letter: MHRA's failure to analyse Yellow Card data**

Thank you for your response to my previous correspondence dated 3 April 2022. Within your email you asked for a response to the following questions:

1. **What are the exact procedures performed and criteria required by the MHRA to validate a serious adverse reaction to the injections? On what basis would you reject a claim?**

As you know, part of our monitoring role includes reviewing reports of suspected side effects and this has been continuously carried out since the beginning of the vaccination campaign using the Yellow Card scheme. The scheme relies on voluntary reporting of incidents to a healthcare product by the public (including patients, parents and carer givers) as well as from healthcare professionals.

In order for a report to be accepted as valid, it must contain a medicinal product, a suspected side effect and an identifiable patient and reporter. All reports which meet these criteria are included on our database for subsequent analysis. The nature of Yellow Card reporting means that reported events are not always proven side effects, individuals are encouraged to report symptoms even if they only have a suspicion that they were caused by a medicinal product. Therefore, inclusion of a Yellow Card report on our system does not necessarily mean that a medicine or vaccine has caused the event, just that there is a suspicion that it could have been responsible. Many factors have to be taken into account in assessing causal relationships including temporal association and any underlying or undiagnosed illness. Some events may have happened anyway, regardless of vaccination.

A team of MHRA scientists continually review individual reports and contact reporters to obtain more information, where required. Scientific and clinical assessment is used to determine if an individual or series of reports indicate a new safety ‘signal’. Using specialised software, Yellow Card data are subjected to statistical analysis of all drug reaction combinations on the database. An established statistical approach known as empirical Bayes geometric mean (EBGM) is used to facilitate this. This identifies ‘signals’—drug-reaction combinations that occur more frequently than would be expected when compared to the background frequency of other drug-reaction combinations in the database. Signals that meet defined criteria are evaluated further by a team of safety experts to assess the likelihood of causal relationship.

Whilst Yellow Cards in isolation are sufficient to allow signal detection, any potential signal needs to be compared to the background frequency of the medical condition in question to determine if the frequency of the condition has increased in those who have been administered the medical product. For COVID 19 vaccines the MHRA have enhanced this system by analysing reports in the context of near real-time information on the number of doses of administered at the relevant time point, stratified by age and gender, and the background rate of the medical condition experienced in the absence of vaccination. This allows continuous evaluation of the 'observed' number of reports of a suspected serious side effect compared to 'expected' numbers – i.e. based on the naturally-occurring rate that would normally happen in a given time period in the same sized group and in the absence of vaccination.

The MHRA is separate from the NHS Business Services Authority who manage the Vaccine Damage Scheme, which is important given our role in authorisation and safety monitoring. Therefore, the MHRA do not have a role in accepting/rejecting claims against possible vaccine damage. It is important to note that the MHRA cannot comment on individual cases or provide medical advice.

2. **Will you set up a complete, easily navigable risk/benefit analysis of the injections on your website or, if not, pass on the necessary data to others capable of providing this service?**

We regularly publish our weekly summary of Yellow Card reporting to ensure the public are aware of what has been reported to the MHRA in association with the COVID-19 vaccines. Within this document you will find our analysis of Yellow Card data which includes our benefit/risk analysis.

The MHRA will be developing a route to publication of further data in 2022 and subsequently begin implementing new systems for provision of data across all medical products including vaccines, enabling us to produce an improved and more suitable format for publishing data in general. This will enable the COVID-19 data collected to be published in such a way as to minimise the risk of misuse and through providing context to the data and clear guidance around what is being presented. This will allow us to mitigate risks we have identified such as undermining the wider Government public health campaign for widespread COVID-19 vaccination and the subsequent risk to public health and safety. Data will be available in the new format by the end of 2022.

We continue to adhere to the highest standards of quality, safety and efficacy with the available COVID-19 vaccines. Should you have any additional questions, please contact: pharmacovigilanceservice@mhra.gov.uk.

Yours sincerely,

Dr Alison Cave
Chief Safety Officer
Medicines and Healthcare products Regulatory Agency

T 020 3080 6188
E alison.cave@mhra.gov.uk