Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

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10 October 2023

Dear [redacted]

FOI 23/672

Thank you for your Freedom of Information (FOI) request dated 12 September 2023 where you asked about “activities the MHRA adopts via its "ongoing safety monitoring of COVID-19 vaccines" to identify any potential batch related safety concerns for these vaccines since their authorisation (via any route) in the UK”.

Information on the proactive pharmacovigilance surveillance strategy used by the MHRA to monitor the safety of COVID-19 vaccines following the initial UK rollout is available here. There were four strands to the MHRA’s strategy, which combined to address the relative strengths and weaknesses of each form of vigilance.

With regards to Yellow Card reports specifically, all adverse drug reaction reports are added to our database and are assessed together with additional sources of evidence, by a team of safety experts. This cumulative assessment will include review of the information provided, including the batch number of the vaccine administered. Additionally, for certain adverse events of special interest, we can apply statistical techniques that can tell us if we are seeing more events than we would expect to see, based on what is known about background rates of illness in the absence of vaccination. This aims to account for factors such as coincidental illness and would also help to identify an increase in reports if there was a batch specific safety issue. We also look at the clinical characteristics to see if new patterns of illness are emerging that could indicate a new safety concern.

In monitoring for any potential batch related safety concerns, we take into account that not all batches of the vaccines are the same size, and some batches may have had more wastage than other batches or be distributed more widely outside of the UK. Therefore, we would not expect the number of Yellow Card reports for all batches to be the same as they have been administered to different numbers of patients.

Furthermore, different batches would have been used at different stages of the vaccination campaign, and in different patient groups, which could also impact reporting rates. For example, reporting rates were typically higher at the beginning of the vaccination campaign as individuals received their first dose and the likelihood of experiencing a reaction, as well as the propensity to report it, differs across patients of different ages.

Please be assured that the MHRA reviews this data regularly and we would communicate any concerns raised with the public and healthcare professionals. If you would like further information on batch usage, please contact the UK Health Security Agency (UKHSA) who hold this information.

I hope the information provided is helpful.

Yours sincerely,

FOI Team,
Patient Safety Monitoring Group

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