



Medicines & Healthcare products  
Regulatory Agency

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[REDACTED]

5 March 2024

**FOI 24/119 & FOI 24/121**

Dear [REDACTED]

Thank you for your Freedom of Information requests, both dated 6 February 2024 where you requested:

*Information on how many yellow card reports were received and deaths per year for each vaccine offered on the Isle of Man, excluding vaccines for covid (unless they are combined with another vaccine and please state so). Please also provide number of those classified as serious, and separately criteria used to classify that. Provide this information In excel format showing 6 columns:*

- year
- Brand of vaccine
- Type (flu vaccine, flumist, HPV, MMR, tetanus, shingles, etc) number of reports number serious number deaths

And

1. Provide updated figures for adverse events for Isle of Man postcodes for ALL brand Covid-19 vaccines to date.
2. provide the updated DAP attachments for each vaccine to the current date in the PT level rather than HLT level as in FOI 23/381.
3. Please state number of reports classed as serious, and state criteria used for this classification.
4. How many deaths have been reported?
5. How many people have had follow ups to their reports?
6. List the number of requests for yellowcard information from Isle of Man gov departments, ex manxcare, DHSC, pharmaceutical or otherwise and state the month and year of when the request was answered.



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7. *Provide any information on the timeframe of reported symptoms after the injections. Happy for this to be in a % format of hrs, days, weeks. Please also state the most often reported injection - 1st dose, 2nd, booster etc that was reported to cause symptoms.*
8. *Provide the top 3 most reported batch numbers for the Isle of Man.*

There are provisions under the FOIA that allow for the aggregation of requests of the same or similar information from a requestor within a 60-day time period. This means that the time needed to retrieve information for the requests can be added together. As such your two requests have been aggregated and a single combined response has been provided below. In general, we would recommend allowing one request to conclude prior to submitting a further request. When requests are aggregated, if the total time needed exceeds the appropriate limit in section 12 of the FOIA, then we may refuse the request.

While I can confirm that the MHRA hold the vast majority of the information you have requested, upon review of your requests we have determined that the information you have requested is exempt under section 12 of the FOIA. Section 12 of the Act allows public authorities to refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information. We have undertaken numerous sampling exercises in order to obtain estimations for the time spent to fulfil your requests.

**For your first request logged under FOI 24/119, you asked for “*information on how many yellow card reports were received and deaths per year for each vaccine offered on the Isle of Man, excluding vaccines for covid*” and for those reports the “*number of those classified as serious*”.**

In order to fulfil this request a separate report is built and run for each vaccine which is expected to take on average 22 minutes. The output of this report is then validated against the system to ensure no appropriate data is excluded; this time estimate varies with few taking 15 minutes, but others taking 30 minutes or longer where there are large volumes of reports, or the data does not validate, therefore an average of 20 minutes was concluded. The report is then restricted to Isle of Man postcodes only and to include all appropriate outputs such as the seriousness of the reports, as defined in your request; this step took 19 minutes. These steps total to 61 minutes, to perform this for each of the 18 vaccines currently listed on the [Isle of Man vaccination programme](#) amounts to 18 hours and 18 minutes.

Lastly after each run is complete the data needs to be put into the excel form as you requested which is expected to take 49 minutes for all vaccines together. Overall, this first part of your request is expected to take approximately 19 hours 7 minutes.



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**In regard to points 1, 2, 3 and 4 in your second email you asked for the MHRA to “Provide updated figures for adverse events for Isle of Man postcodes for ALL brand Covid-19 vaccines to date”, “updated DAP attachments for each vaccine to the current date in the PT level”, “number of reports classed as serious” and “how many deaths have been reported?”.**

In order to fulfil these requests a separate report is built and run for each vaccine, which based on performing this step for two of the COVID-19 vaccines took on average 35 minutes due to the large data set. The output of this report is then validated against the system to ensure no appropriate data is excluded; this step took a further 15 minutes. Once the data set is validated the report is then restricted to Isle of Man postcodes only and re-run which again took 15 minutes. Finally, the reports identified as being from the Isle of Man are then added to a data query which is run to compile the information into a DAP attachment taking 13 minutes. These steps total a time of 78 minutes, and for the 7 COVID-19 vaccines which have been used in the Isle of Man up to this point, the time taken to fulfil this part of your request is 9 hours and 6 minutes.

**In regard to point 5 where you asked, “How many people have had follow ups to their reports?”.**

Although we hold information on whether a Yellow Card report has been followed up, this information is not easily extractable. The MHRA has received 1,062 Yellow Card reports associated with a COVID-19 vaccines in the Isle of Man. An individual would need to manually open each Yellow Card report to check whether a request for further information was sent. Checking a single Yellow Card report for evidence of follow up would take a minimum of 45 seconds and in some instances longer. This would equate to an individual spending 796.5 minutes or 13 hours and 16.5 minutes for this aspect of your request.

For your initial request (FOI 24/119) and then points 1-5 in your second request (FOI 24/121), the estimated time for completion is 41 hours and 29.5 minutes. Whilst we have addressed the further points of your request below its important to note we have not performed timed sampling exercises given the points of your request thus far already far exceeds to 24-hour limit under the FOIA. We will however provide appropriate advice and assistance to refine your request at the end of this response.

**In regard to point 6 where you asked the MHRA to “list the number of requests for yellowcard information from Isle of Man gov departments, ex manxcare, DHSC, pharmaceutical or otherwise and state the month and year of when the request was answered.”**

Unfortunately, we have been unable to determine the exact information you wish to receive. If you wish to include this in a future request, please confirm as part of that request if you wish to receive the number of requests for Yellow Card information



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from Isle of Man government departments excluding requests from Manxcare and the DHSC and we can provide this to you.

**In regard to point 7 where you asked for “any information on the timeframe of reported symptoms after the injections. Happy for this to be in a % format of hrs, days, weeks. Please also state the most often reported injection - 1st dose, 2nd, booster etc that was reported to cause symptoms.”**

I can confirm that the MHRA hold information on the onset time of reported reactions however this is not a mandatory field when completing a Yellow Card and as such is often not provided. If you would like we can provide the percentage of reactions which occur after 1 day, 1 week, 1 month and 1 year for example. However, its important to note that this information will be more meaningful if particular reactions of interest are also used given the suspected adverse reactions within Yellow Card reports can vary considerably and subsequently the time to onset of symptoms.

In regard to the dose which is most often reported in Yellow Card reports, we do hold some information however this is not often provided to us or is provided incorrectly where patients are unsure which vaccine they may have received. In addition, many reports will contain multiple doses and manual review of these reports would be needed to determine which adverse reactions were related to which dose. If dates of administration of the vaccine and start dates of suspected adverse reactions are not provided in these reports, it will not be possible to determine this. You may wish to know that in the [Coronavirus vaccine- summary of Yellow Card reporting](#), the reporting rate for vaccines used within the programme initially (archived version of the report) or with booster doses is included.

**In regard to point 8 where you asked for the MHRA to “Provide the top 3 most reported batch numbers for the Isle of Man.”**

We do hold information on batch number for COVID-19 vaccines and could provide this information to you within a refined request. Please note, batch number is a free text field on a Yellow Card form and as such includes vast amounts of variation where reporters have mistyped, added spaces/hyphens, or included expiry dates, for example. Therefore, to provide this data some level of manual review is required however based on this (part 8) request we would be able to provide this in a new request within appropriate time frames.

When section 12 is applied, we are required to provide advice and assistance to the requester, to help them make a new request which could be dealt with within the 24-hour appropriate limit. As described in the response above we would be able to provide aspects of the information under a refined request, some examples of how to refine your request are listed below:

- limiting your request to your first email only, i.e. Yellow Card information for all vaccines excluding COVID-19 vaccines used in the Isle of Man, or



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- Requesting particular vaccines of interest from your initial request plus points 1-4 from your second request regarding COVID-19 vaccines, or
- Data for Yellow Card reports from the Isle of Man relating to COVID-19 vaccines that have been followed up for further information, or
- Data for Yellow Card reports from the Isle of Man relating to COVID-19 vaccines for the 10 most frequently reported batch numbers.

To reiterate, the time needed to fulfil your request would need to be less than 24 hours so we may not be able to provide information if multiple requests are made even when refined. If you interested in receiving data under a refined request as suggested, please email [MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk).

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

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If you have a query about the information provided, please reply to this email

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 you receive this response and addressed to: [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire



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