FOI 23/641

Dear

Thank you for your request of 25 August 2023 under the Freedom of Information Act.

You requested:

Please can you complete Tables 1 & 2 below which relate to MHRA's follow-up of Yellow Card reports of death and serious adverse events potentially associated with the Covid vaccines.

I am aware that some of the requested information requires manual extraction from MHRA's records and about the FOI cost limit (Section 12 Exemption). I have therefore limited my request to September and October 2021. That should be perfectly acceptable for Table 1 (deaths). However, for Table 2, the number of Serious Adverse Events will, I assume, be greater than for Deaths (Table 1). If the number of YCs Sep - Oct 21 for Table 2 would breach the FOI cost limit (Section 12 Exemption), please restrict the analysis to the first 250 YC reports from 1 September 2021 (ie 12.5hrs @ 3mins per report).

TABLE 1

Follow-up of YC reports of Death	*Number of YC reports of Covid vaccine related deaths received*	*Number of YC reports which included this information when submitted*	*Number where MHRA has subsequently obtained this information*
Vaccine batch information	*N*		
Time between vaccination and death			
Individual's medical records			

TABLE 2

Follow-up of YC reports of Serious Adverse Events	*Number of YC reports of Covid vaccine related Serious Adverse Events received*	*Number of YC reports which included this information when submitted*	*Number where MHRA has subsequently obtained this information*
Vaccine batch information · *All ages (x)* · *0-17yrs (y)* · *Pregnancy (z)*	*x* *y*		

	z	*a* *b* *c*	*d* *e* *f*
Time between vaccination and Serious Adverse Event · *All ages* · *0-17yrs* · *Pregnancy*		*g* *h* *i*	*j* *k* *l*
Individual's medical records · *All ages* · *0-17yrs* · *Pregnancy*		*m* *n* *o*	*p* *q* *r*

We confirm that we hold the data you have requested. However, we consider that the information is exempt under Section 14 (1) of the Freedom of Information Act. When considering and applying Section 14 to this request, we have considered the burden which fulfilling your request will place on the MHRA.

In order to comply with your request, we have calculated based on a sampling exercise that it would take us over 200 hours to review the reports received in the September to October 2021 date range that you have specified, as this period covers over 17,500 reports in scope of your request. In order to provide the information requested in Table 1 and Table 2 the data would need to be split by whether a fatal outcome was reported or whether the report was deemed serious, alongside the categories stated in Table 2. Furthermore, each of these ADR reports would then need to be manually reviewed. Firstly, to determine if they contain the specified data field (e.g., vaccine batch information) on initial receipt of the Yellow Card report, whether a request for further information was sent and whether this specified data field was requested, and lastly whether this information was then received from the reporter. We note the wording of your request made an estimate of 3 minutes per report. However, this is not based on retrieval of the information you have requested and is not an accurate assessment of the time required to fulfil your request. We have conducted a random sampling exercise, based on both the retrieval and recording of the information that you have requested which indicated

that provision of these data would be closer to 6 minutes per case and in some instances longer.

We have considered whether Section 12 would be the appropriate exemption in this case. Given the amount of Yellow Card reports in scope for this request, and even with your suggestion of 3 min per report, this would exceed the 24 hour time limit, meaning that Section 12 would indeed apply to your request. However, the final line of your request states:

If the number of YCs Sep - Oct 21 for Table 2 would breach the FOI cost limit (Section 12 Exemption), please restrict the analysis to the first 250 YC reports from 1 September 2021 (ie 12.5hrs @ 3mins per report).

This appears to suggest that restriction of the request is dictated by the maximum time allowable under the Act rather than to request a data set that would provide some meaningful value; the issues with this approach are outlined further below in the explanation as to why the exemption has been applied. The request could be refined using any of the many variables (reports in pregnancy, reports with a fatal outcome, particular age bands) to focus on a particular area of interest. However, because of the current breadth we do not have any further suggestions as to how you could refine this request at this point, as we do not know which information is of most interest to you. We can advise that we have recently provided higher level statistics on follow-ups for numbers of Yellow Card reports with a fatal outcome for the Pfizer vaccine that have been followed up with healthcare professionals and members of the public, if this would be of interest to you for instance.

We do not apply Section 14 lightly, and we review the circumstances of each individual request alongside the ICO guidance which states that the purpose of Section 14…"must be to protect the resources (in the broadest sense of that word) of the public authority from being squandered on disproportionate use of FOIA…" (paragraph 10). The guidance goes onto state:

> "However, some requests might:
>
> - impose a burden by obliging you to sift through a substantial volume of information to isolate and extract the relevant details;
> - encompass information which is only of limited value because of the wide scope of the request;
> - create a burden by requiring you to spend a considerable amount of time considering any exemptions and redactions; or
> - be part of a pattern of persistent fishing expeditions by the same requester."

We consider that the first point applies to your request. The second bullet point – the limited value of the information – is also relevant in this case, since even without the restriction to comply with the Section 12 requirement, you have requested data from an extremely limited stage of the vaccination campaign, which may not be representative of the overall picture, given that different groups were offered vaccinations at different stages. Any value would be further diluted, and indeed may be grossly misrepresentative if we were to follow your suggestion and simply limit to

the first reports received in September 2021, ignoring any other factors. Furthermore we consider that point 4 also applies in this instance. Within the 60 day period prior to making this request, you also made requests for:

- information on the categorisation of Yellow Card reports,
- correspondence regarding the temporary authorisation of the Covid-19 vaccines,
- the business case for the MHRA's Transformation programme,
- safety impact assessments for the programme and the organisational structure following transformation,
- details regarding the temporary authorisation of the Pfizer vaccine,
- assessments relating to Moderna's 'NextCove' clinical trial and a list of other specified clinical trials,
- correspondence from the MHRA relating to the DHSC's R174 letters concerning the temporary authorisation of Covid-19 vaccines,
- and a request for copies of the minutes of the Covid-19 Vaccines Benefit Risk and Safety Surveillance Expert Working Groups.

This demonstrates a high frequency of requests within a period of time, all relating to aspects of the MHRA's working practices, particularly in respect to COVID-19 vaccines. The volume and nature of these requests, combined with the significant retrieval alone required for the present request, demonstrates a significant cumulative burden.

We have considered the public interest and we fully acknowledge that there is a significant public interest in the safety of COVID-19 vaccines, including the data we hold and assessment of safety issues in relation to COVID-19 vaccines, both in terms of organisational transparency and building of trust. However, this must be balanced against the burden of complying with the request. In this regard, we have dedicated significant efforts to the drafting and publishing of public assessment reports for each of the vaccines, and the level of safety related information available online is extensive, including the reports accessible from the Yellow Card website. We must give due consideration to the amount of time and resources that we would need to expend in responding to a request of only limited and partial value. We consider that populating your two tables, for the reasons set out above, would be a disproportionate burden on our resources with consideration to the potential value of the data that would be generated or the purpose of such a request.

It should also be noted that use of Yellow Card data for research purposes is carefully controlled and subject to independent review of both value and methodologies by the Pharmacovigilance Expert Advisory Group of the Commission on Human Medicine. Research on the completeness of spontaneous reports has been subject to substantial international research, including by the Uppsala Monitoring Centre in Sweden who published their own methodology known as VigiGrade. Internationally, spontaneous reports are followed up based on the value that data would add to assessment of a potential safety issue, rather than simply to populate data into every database field. It is also important to be aware that spontaneous reports are just one part of the data used for surveillance of COVID-19 vaccines; other data sources, including published academic research from electronic

healthcare record datasets are statistically more powerful than spontaneous reports, particularly in the assessment of pregnancy outcomes.

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
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
SK9 5AF

Yours sincerely

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