Medicines & Healthcare products
Regulatory Agency

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[redacted]

24 January 2024

Dear [redacted]

FOI 23/1002

Thank you for your email dated 21 December 2023, in which you made a request for further information related to our response to your previous request, reference FOI 22/1232.

Specifically you asked:

Please could you send me:
a) a copy of any other reports and presentations originated by MHRA since 1 September 2020 relating to the issue of 'masking' of potential safety signals in Disproportionality Analysis
b) a copy of any 3rd party reports and presentations received by MHRA since 1 September 2020 relating to the issue of 'masking' of potential safety signals in Disproportionality Analysis
c) a copy of all Emails to/from MHRA/CEO ([redacted]) from 1 September 2020 to date which include the word "signal" together with any of "suppress", "suppressed", "suppressing", "suppression", "mask", "masked", "masking", "competition bias"
d) copies of minutes of meetings of the CHM Vaccine Safety Expert Working Group subsequent to its 4th meeting on 27 October 2020.

On 7 January 2024 you emailed to amend this request to remove part d) in light of the internal review we conducted on an earlier request from yourself (FOI 23/695). This response will therefore address parts a-c of this request.

We confirm that we may hold data fulfilling your request. However, we consider that the information is exempt under Section 14 (1) of the Freedom of Information Act. When applying Section 14 to this request, we have particularly considered the burden in terms of both cost and effort which fulfilling your request will place on the MHRA and the balance of this against the public interest in the disclosure of the information.

The primary reasons for us arriving at this decision relate to part c) of the request. The wording here is very specific, giving no flexibility in how it is approached. However it is noted that several of the words you have requested the search to be on are common English language words, can be part of longer words (e.g. a search would return emails including signalled or signalling when searching for signal), and/or have multiple meanings or contexts which mean that they will feature often on emails during the period asked given the wider remit of the MHRA (e.g. masks as in personal protective equipment). A search has been run against the requested key words which has resulted in 858 emails. Many of these emails have multiple attachments. In a review conducted on around 30 of these, it was identified that the use of the word signal was in an entirely different context to the other key word. Given the reasons listed above there is no way to easily isolate potentially exempt information because it will be scattered extensively through the emails and attachments. On the basis of our sample of search results, while we appreciate that you have intended your request to identify specific information, the combination of terms you provided and the variability in usage of those terms when applied to a keyword search, means that a large number of results of potential relevance need to be reviewed in order to identify any results that meet the terms of the request. This is unsurprising, particularly given that the role of the CEO and the broad organisational remit. It is also noted that given what has already been provided to you, and the advice that we are able to offer below with regards to the other aspects of your request, it is highly unlikely that any new information of value would come into the public domain as a result of this request.

In considering parts a) and b) it is noted that an extensive document search would be required to ensure the capture of all potentially relevant reports and presentations. The key word terms that would be required are not clear from the request and potential terms listed in the request are, as already noted, common English or very widely used in the context of vigilance, which would impose a burden by obliging the MHRA to sift through a substantial volume of information. However, while the burden of part c) of your request applies to the whole request under Section 14 (1), we are able to provide some useful information to you in which is included below.

Firstly, we have considered how your request could be refined to reduce the burden required. The principal issue identified is on the generality of the terms that any search would be based upon, therefore restricting to a smaller time period would be unlikely to substantially impact. However, we have sought to identify information that would be relevant to your request.

It is noted that in our response to your previous request (22/1232) we provided copies of both the report entitled “Impact of COVID-19 vaccine reports on disproportionality analyses for other vaccines” and an accompanying background slide set entitles “Overview of Signal Detection and Disproportionality”. Following discussion with relevant colleagues, I can confirm that to the best of our knowledge no other reports or presentations have originated from the MHRA since 1 September 2020 relating to the issue of 'masking' of potential safety signals in disproportionality analysis.

Finally, MHRA are aware of work on this issue that has been undertaken by the Uppsala Monitoring Centre (UMC) using the World Health Organization’s (WHO) global database of reported side effects of medicinal products, VigiBase. This work has been published and is accessible via the WHO website at the following link:

https://www.who.int/publications/m/item/unmasking-safety-signals-during-pandemic. MHRA have received a presentation that referenced this work as part of a substantially broader discussion. The relevant slides have been provided to you along with this response. Again, following discussion with relevant colleagues, I can confirm that to the best of our knowledge no other 3rd party reports or presentations have been received by the MHRA since 1 September 2020 relating to the issue of 'masking' of potential safety signals in disproportionality analysis.

Yours sincerely,

FOI Team,
Safety and Surveillance Group

If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF