FOI 23/347 – information on weight of water for injection in BNT162b2 and changes to Table 2 of Pfizer's SBRA with the FDA

MHRA RESPONSE
16 May 2023

Thank you for your request under the Freedom of Information Act, we apologise for the delay in response.

You requested:

"Disclose all internal documentation, including correspondence between the MHRA and Pfizer and between the MHRA and other medical regulators (FDA, EMA etc.) on both the weight of water for injection in BNT162b2 and changes to Table 2 of Pfizer's SBRA with the FDA. In addition to this, disclose all internal documentation in possession of the MHRA on these topics, including emails, minutes of meetings and memorandums."

In relation to the first part of your request:

"Disclose all internal documentation, including correspondence between the MHRA and Pfizer and between the MHRA and other medical regulators (FDA, EMA etc.) on both the weight of water for injection in BNT162b2 and changes to Table 2 of Pfizer's SBRA with the FDA."

We have searched using reasonable avenues in relation to correspondence as per the specifics of your request, and we confirm that we do not hold any information in the form of correspondence on both the weight of water for injection in BNT162b2 and changes to Table 2 of Pfizer's SBRA with the FDA.

In relation to the second part of your request,

"In addition to this, disclose all internal documentation in possession of the MHRA on these topics, including emails, minutes of meetings and memorandums."

We confirm that we hold documentation on weight of water for injection, but the return of results was too large to mount a search to identify, locate and extract the information. This is because weight of water for injection will be mentioned in many regulatory documents, and versions of those documents. We are therefore exempting this part of your request under Section 12.

Section 12 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. At this stage we are unable to suggest how you could refine your request. However, in our reply to your request regarding sodium hydroxide (FOI 23/325), we are releasing the full composition, both the version prior to the sodium hydroxide variation and that occurring afterwards.

We trust that this information will provide the reassurance needed address your over-arching concern related to the quantity of water for injection, in the rare event that it does not do so, then it may help you to refine this request (FOI 23/347). If we have misunderstood the scope of the information you are seeking then please let us know by reply.

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
MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU