FOI 23/325 - NaOH and HCl Excipients in Pfizer's SmPC for Comirnaty

REQUEST
21 February 2022

Recently, both sodium hydroxide and hydrochloric acid have been added to the list of excipients in Section 6.1 of the SmPC for Pifzer's experimental drug for the purpose of pH-adjustment [1]. Neither excipient is listed in Table 2 of Pfizer's Summary Basis for Regulatory Action (SBRA) [2].

You are required to comment on this discrepancy and this recent change to the SmPC. In particular, you should now publicly clarify whether this change in the excipient list applies retrospectively or only from the date these two excipients were added to the SmPC.

Disclose all documentation in possession of the MHRA concerning the recent addition of both sodium hydroxide and hydrochloric acid as excipients.

MHRA RESPONSE
16 MAY 2023

Dear

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

Your request was for information about the COVID-19 Pfizer Vaccine and two of the excipients: sodium hydroxide and hydrochloric acid. You requested:

Disclose all documentation in possession of the MHRA concerning the recent addition of both sodium hydroxide and hydrochloric acid as excipients.

In expectation of being able to provide reassurances in relation to sodium hydroxide and hydrochloric acid, we have re-approached the Marketing Authorisation Holder (MAH) in relation to representations on the tables of quantitative formulae. The MAH have re-considered their position in relation to these documents which we now release in full, one version pre-dates the NaOH variation the other was approved in relation to the NaOH variation (please find both attached).

On the topic of the NaOH variation, please be aware that small quantities of pharmaceutical grade hydrochloric acid and sodium hydroxide are commonly used to adjust the pH of medicines during manufacture to ensure that the final pH is suitable for injection (close to the pH which is found naturally in the body). Hydrochloric acid and sodium chloride have been added to the list of ingredients because they are

used in this way in the formulation. The excipients in a given pharmaceutical formulation include ingredients called buffers which keep the pH at a safe level.

In relation to the formulation tables, we also wish to mention the following to avoid any confusion. The number of doses available per vial changed from 5 to 6 between these two document versions, with no change to overall content, based on further data & regulatory review (as per MHRA website details). Please also note, q.s. = quantum satis (as much as may suffice), this term is commonly used to describe the quantity of excipients such as water for injection or buffers like sodium hydroxide to make up the total agreed volume of a medicine or vaccine.
https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19

“**26 January 2021**
We have updated the Product Information to state that the vaccine is manufactured with enough volume for six doses, if our latest guidance for Healthcare Professionals is followed.

24 December 2020
Updated guidance for Healthcare Professionals on obtaining a sixth dose from a vial”
Please note, some of the information included in the scope of your request is exempt under Section 21 of the Freedom of Information (FOI) Act i.e. that included in the procedural steps document and accompanying public assessment report on the EMA website for this vaccine.

We are exempting other information covered by the request because it is commercially sensitive information and so is exempt under S.41 (information provided in confidence) and S.43 (commercial interests).

*Section 41 – is an absolute exemption and no consideration of the public interest is required, except to state that we would consider the release of this information to be an actionable breach of confidence.

*Section 43 – Release of all, or part of, the information would be likely to, cause harm to the third party's commercial interests.
We have considered the balance of the public interest when applying this exemption. The exemption is to safeguard the commercially sensitive information / industrial secrets of a third party / commercial enterprise (which can include a Government Department). This exemption is conditional on the public interest in releasing it not outweighing the company's/commercial enterprise's right to confidentiality and the probable damage that the company/commercial enterprise could suffer as a result of the information being released. In this case we have not identified any issues which would benefit the public as a whole by being brought to their attention (examples of issues would be a major public health risk or a major procedural failure or irregularity). We have evaluated the probability of commercial (prejudice) harm to meet the upper threshold i.e. disclosure of the information ‘would’ cause commercial

harm. This is because the change relates to the manufacturing process and therefore, product development insights could be obtained by competitors.

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
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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