FOI 23/346 - Exact definitions of PF-07305885 and PF-07302048 in BNT162b2

REQUEST
21 February 2022

In Section 3.2 of Pfizer's Safety Data Sheet (SDS) for BNT162b2, substances PF-07305885 and PF-07302048 appear as separate ingredients [1]. According to Pfizer's Summary Basis for Regulatory Action (SBRA), SARS-CoV-2 spike glycoprotein mRNA (modRNA) has a per-vial quantity of 225 µg and is the active pharmaceutical ingredient (API) [2]. There is thus no obvious way therefore to map these two ingredients from the SDS to the SBRA.

You are required to clarify the distinction between PF-07305885 and PF-07302048. Disclose all documentation in possession of the MHRA concerning these two chemicals, including documentation on their respective exact definitions and the distinction between the two. Disclose all communication between the MHRA and Pfizer and between the MHRA and other medical regulators (FDA, EMA etc.) on these two ingredients.

MHRA RESPONSE
16 May 2023

Dear

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

You requested:

> "In Section 3.2 of Pfizer's Safety Data Sheet (SDS) for BNT162b2, substances PF-07305885 and PF-07302048 appear as separate ingredients [1]. According to Pfizer's Summary Basis for Regulatory Action (SBRA), SARS-CoV-2 spike glycoprotein mRNA (modRNA) has a per-vial quantity of 225 µg and is the active pharmaceutical ingredient (API) [2]. There is thus no obvious way therefore to map these two ingredients from the SDS to the SBRA.
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For the first part of your request regarding the definitions of PF-07305885 and PF-07302048, we provide the below excerpt which includes the description for these terms. Please note DP – drug product. To clarify the distinction, PF-07302048 is the drug product i.e. mRNA encapsulated in the LNP, PF-07305885 is the drug substance (mRNA alone).

BACKGROUND

PF-07302048 is a COVID-19 Vaccine Lipid Nanoparticle (LNP) Drug Product. The vaccine is the BNT162b2 construct (SARS CoV 2 full spike protein S-P2 variant). The mRNA concentration for DP will be 0.5 mg/mL. The drug substance (PF-07305885) RNA concentration is 2.25mg/mL. The plasmid (PF-07305883) DNA concentration is 2.0mg/mL.

We confirm that we hold information in scope of your request regarding PF-07305885 and PF-07302048. However, we are 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. Please note, the term 'all' applied in your request casts a wide scope and means that multiple avenues would need to be searched and this contributes to the need to apply Section 12. Whilst at this stage we cannot suggest a way that you can refine this request, we nevertheless, expect that the definitions we have provided may alleviate the need for your request. It may also be helpful to mention that with the passage of time these terms (e.g. PF-07305885 etc.) appear to have been used less frequently in instead favouring use of the commonly understood names e.g. lipid nanoparticle (LNP), drug product, drug substance etc.

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
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