# Freedom of Information Act 2000 (FOIA)

## Decision notice

**Date:** 19 August 2022

**Public Authority:** Medicines and Healthcare Products Regulatory Agency (MHRA)

**Address:** 10 South Colonade
London
E14 4PU

### Decision (including any steps ordered)

1. The complainant made a request for information relating to how many LNP (lipid nanoparticles) were contained (on average) within a single shot of BNT162b2 and their respective sizes in order to meet with Health and Safety of patients receiving the shots. MHRA has confirmed that it does not hold the information requested under section 1(1)(a) FOIA.

2. The Commissioner considers that MHRA were correct to confirm that it does not hold the requested information.

3. The Commissioner requires no steps to be taken.

### Request and response

4. The complainant made the following information request to MHRA on 1 September 2021:

"Please may I formally request an FOI response to the following questions. These all relate to the document you provided to the UK Government (https://assets.publishing.service.gov.uk...

1. Within the document, you show, on page 14, links to a variety of research studies that were included within the application for the intervention. Please supply PDF copies of all 8 of those studies referenced in the Pharmacology, Pharmacokinetics and Toxicology

sections?
a: Study 20-0211 - In vitro expression of BNT162b2 drug substance and drug product
b: Study R-20-0085: COVID-19: Immunogenicity of BNT162b2 in mice
c: Study R-20-0112: Characterizing the immunophenotype in spleen and lymph node of mice
treated with SARS-CoV-2 vaccine candidates
d: Study VR-VTR-10671: BNT162b2 immunogenicity and evaluation of protection against
SARS-CoV-2 challenge in rhesus macaques
e: Study PF-07302048: Single dose pharmacokinetics study of ALC-0315 and ALC-0159
following intravenous bolus injection of a nanoparticle formulation in rats
f: Study R-20-0072: Biodistribution of BNT162b2 using the luciferase protein as a surrogate
marker protein after intramuscular injection in mice.
g: Study 38166: Repeat-dose toxicity study of three LNP-formulated RNA platforms encoding
for viral proteins by repeated intramuscular administration to Wistar Han rats
h: Study 20GR142: 17-day Intramuscular Toxicity Study of BNT162b2 and BNT162b3 in
Wistar Han Rats

2. In granting approval, it must have been discussed with the manufacturer how many LNP (lipid nanoparticles) were contained (on average) within a single shot of BNT162b2 and their respective sizes in order to meet with Health and Safety of patients receiving the shots. Documentation elsewhere shows that it is 30 micrograms of mRNA LNP and an email I have from Pfizer confirms this. Please can you provide any minutes, emails or paperwork copies that show what that quantity is per injection (with plain language for example; 11 trillion LNP) and whether or not they are restricted in size or the shot contains a variety of different sizes of LNP molecules?"

5. As MHRA refused to comply with this request under section 12 FOIA due to costs, on 7 September 2021 the complainant refined his request:

"I will leave the first question as read as this is just the supply of the study papers which are already in existence, and my second question to be reduced considerably to just the stated information you have on the approximate number of lipid nanoparticles per single shot."

6. MHRA responded to the refined request on 28 September 2022, it explained that:

"The parameters and their acceptance criteria described in the drug product specification provide sufficient assurance of the consistency of every dispensed dose in terms of LNP size, numbers of LNP particles and mRNA content so that these parameters will have no impact on established safety and efficacy of the vaccine in use.

Please note, the acceptance criteria are confidential information."

7. Following an internal review, on 16 December 2021, the MHRA revised its position:

"Unfortunately, the initial response to your FOI request included an error; the number of lipid nano-particles (LNP) is not an acceptance criterion included in the specifications. We would like to clarify that the MHRA does not hold data on the number of LNP per dose because this information is not deemed crucial to the safety of the Moderna vaccine. The safety of the vaccine is demonstrated by the non-clinical and clinical studies that have been described in the Public Assessment Reports and the batch testing results. Furthermore, the vaccines are also subject to specific monitoring as explained on the webpage included below. Independent experts, in particular those members of the Vaccine Benefit-Risk expert working group and Commission on Human Medicines regularly review pharmacovigilance data on the COVID-19 vaccines, including data related to the COVID-19 vaccine Moderna."

## Reasons for decision

8. Section 1(1) FOIA provides that:

"Any person making a request for information to a public authority is entitled –

(a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and
(b) if that is the case, to have that information communicated to him."

9. The Commissioner has sought to determine whether, on the balance of probabilities, MHRA holds the requested information.

10. As data on the number of LNP per dose is not deemed crucial to the safety of the Moderna vaccine, MHRA has confirmed that this information is not held.

11. On the balance of probabilities the Commissioner is satisfied that the requested information is not held by MHRA because data on the LNP per

dose is not deemed necessary for safety of the vaccine. Therefore there is no requirement for this information to be held.

12. MHRA has complied with its obligations under section 1(1)(a) FOIA in this case.

## Right of appeal

13. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from: First-tier Tribunal (Information Rights)

    GRC & GRP Tribunals,
    PO Box 9300,
    LEICESTER,
    LE1 8DJ

    Tel: 0300 1234504
    Fax: 0870 739 5836
    Email: grc@Justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

14. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.

15. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

**Signed.....**

**Gemma Garvey**
**Senior Case Officer**
**Information Commissioner's Office**
**Wycliffe House**
**Water Lane**
**Wilmslow**
**Cheshire**
**SK9 5AF**