EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Ulrich Keil
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EMA/644204/2022
Stakeholders and Communication

Dear Mr Keil,

Subject: **COMIRNATY (COVID-19 mRNA vaccine (nucleoside-modified)) - ASK-113461 batch 2 - Letter to the requester; documents not held by the Agency**

Thank you for your request for access to documents received on 25 May 2022 and the clarification on 15 June 2022, for which the procedure was initiated on 16 June 2022, in which you apply for copies of the following documents concerning COMIRNATY (COVID-19 mRNA vaccine (nucleoside-modified)), in particular:

- *anonymized individual participant data (IPD) of all participants of study C4591015 from the time of screening (i.e. before randomization), through group allocation (vaccine versus placebo) and follow-up, explicitly including those women who withdrew (or were withdrawn) after receiving only one dose and to all screened and/or enrolled participants of centers eliminated from the trial site list including all respective case report forms (CRFs)*
- *PRAC Rapporteur's preliminary AR EMEA/H/C/005735/II/0087*

Your request has been handled in accordance with Article 7 of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (the Regulation)[1] and Section 3 of the Annex to the "*European Medicines Agency policy on access to documents - POLICY/0043*"[2].

As it concerns a number of documents, and the Agency has to assess each document individually to ensure that no private or public interests are being compromised, we are not in a position to fulfil your request immediately. Therefore, the Agency endeavours to provide you with sets of documents at certain intervals. This decision is in line with the principle set out in our policy which states the Agency will apply the principle of proportionality in order to avoid the core business tasks of the Agency and its performance being jeopardised by the administrative workload related to activities conducted by the Agency in accordance with the Regulation.

Batch 2 is related to the first part of your request, and we would like to inform you that no individual patient data (IPD) from participants of study C4591015 have been submitted by the company to the Agency yet. Please note that the submission of the final clinical study report where IPD are expected to be present is currently planned for 30 April 2023.

1 OJ L 145, 31.5.2001, P. 43-48
2 EMA/729522/2016 "*European Medicines Agency policy on access to documents - POLICY/0043*" of 4 October 2018, available at https://www.ema.europa.eu/documents/other/policy/0043-european-medicines-agency-policy-access-documents_en.pdf.

Consequently, the Agency regrets to inform you that the documents you requested are not held by the Agency. We are therefore not in a position to provide you with access to these documents.

As provided for in Article 2(3) of the Regulation, the right of access, as defined in that Regulation, applies only to existing documents that are held by the Agency.

In light of the above, the Agency is not in a position to satisfy the first part of your request.

Should you wish to avail yourself of the remedies available under Union law against this decision, please be informed that you can bring a complaint before the European Ombudsman, pursuant to Article 228 of the Treaty on the Functioning of the European Union (TFEU). Alternatively, you can institute legal proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU.

If you have any queries on the enclosed, please do not hesitate to contact the Access to Documents Coordinator for this request, Isabella Ronci, email: Isabella.Ronci@ema.europa.eu, using the ASK Procedure Number mentioned in the subject line.

Yours sincerely,

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