EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Wolfdietrich Burde
Germany

burdew@burde-wolfdietrich.de

EMA/478244/2023
Stakeholders and Communication

Dear Mr Burde,

Subject: Comirnaty COVID-19 mRNA vaccine (nucleoside-modified), ASK-148075 (batch 1) - Release letter to the requester

Thank you for your request for access to documents received on 27 July 2023, for which the procedure was initiated on 5 October 2023, in which you apply for copies of documents containing data provided by BioNTech/Pfizer concerning "DNA contamination" and changes in the same in relation to the above-mentioned product:

> *"Im Assessment Report der EMA für Comirnaty vom 19. 2. 2021 heißt es auf Seite 17:*
>
> *"The robustness of the DNase digestion step is not considered comprehensively demonstrated although there is routine control of residual DNA impurities at the active substance level. It has been confirmed that studies to enhance the robustness of this step are ongoing and these should be reported (REC7)."*
>
> *In den EMA-News vom 16. 9. 2022 "EMA recommends standard marketing authorisations for Comirnaty and Spikevax COVID-19 vaccines" heißt es:*
>
> *"These trials and additional studies, including observational studies, have provided*
>
> *reassuring data on key aspects such as how well the vaccines prevent severe COVID-19. In addition, the companies have provided all requested additional data on the pharmaceutical quality of the vaccines."*
>
> *Biontech/Pfizer müssten danach Daten vorgelegt haben, die über die DNA-Verunreinigungen bzw. deren Veränderung berichten.*
>
> *Meine Bitte: Bitte diese Dokumente zeigen bzw. deren Inhalte berichten"*

On the basis of your request, the Agency has identified several assessments reports that fall within the scope of your request.

As background to the documents being released, please also refer to the European Public Assessment Reports (EPARs) for more information:

- Comirnaty, INN-tozinameran, tozinameran/riltozinameran, tozinameran/famtozinameran (europa.eu) for the initial marketing authorisation, page 16,
- Comirnaty, INN-tozinameran, tozinameran/riltozinameran, tozinameran/famtozinameran, raxtozinameran (europa.eu) for procedure No. EMEA/H/C/005735/II/0183, page 8.

In these EPARs you will find more information regarding the manufacturing process of Comirnaty where plasmid DNA from transformed bacterial (Escherichia coli) cells is used to make a linear DNA template, which is then transcribed to make the mRNA in the vaccines, and later broken down and removed by DNase digestion. Following this DNase digestion, very small amounts of residual bacterial DNA fragments may still be present, and the Agency has set appropriate limits for the level of residual DNA in the vaccine. The manufacturer is required to test residual DNA levels in every batch of the active substance produced. An official medicines control laboratory (OMCL) of a national authority must then check these results before any vaccines batches made using this active substance can be released.

In regard to your request for access to documents, the same 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] (the Agency Policy). Moreover, it has been assessed pursuant to Article 4 of the Regulation and Section 4.1.1 of the Agency policy and Section 1 of the Annex to the same policy.

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.

In this regard, **Batch 1** of documents to be assessed includes the following documents:

- CHMP Assessment Report for the Post-Authorisation Measure REC 027, Comirnaty (EMA/CHMP/284816/2021); and
- CHMP Type IB variation report, Comirnaty (EMA/CHMP/50784/2022).

Based on the above assessment, the Agency considers that access to the requested documents in this batch should be granted.

However, both of the documents have been redacted as follows:

In accordance with Article 4(1) (b) of the Regulation and the European Union legislation regarding the protection of personal data, all protected personal data was redacted in order to avoid that the disclosure of the document(s) would undermine the privacy and integrity of any individual.

In accordance with Article 4(2) 1st indent of the Regulation, commercially confidential information, such as quality and manufacturing process, was redacted in order to avoid that the disclosure of the document(s) would undermine the protection of commercial interests of a natural or legal person, including intellectual property.

You may submit a confirmatory application (hereafter referred to as "appeal") in writing against this decision to the European Medicines Agency, within 15 working days of the release of the document(s). Should you wish to do so, you are kindly invited to provide reasons against this decision to redact parts of the document(s) at this stage, or detail any other considerations in terms of public interest, which you believe should be taken into account by the Agency in adopting a final decision.

[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.

Once your appeal has been received, you will be informed of the outcome within 15 working days (extendable in exceptional circumstances), either granting you access to redacted parts of the document(s) or confirming refusal of access. In the latter case, you will also be informed of any further appeal routes open to you to consider.

The appeal should be submitted using the online request form, available on the European Medicines Agency website, under the following location: https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency.

Please use the ASK Procedure Number mentioned in the subject line in any correspondence related to this request.

All the documents concerned will be sent to you via Eudralink no sooner than 10 working days after the legal consultation stage with the third party has been finalised. Please note that these documents are made available to you in order to provide you with access in accordance with the Regulation and the Agency policy.

In that regard, please visit the Agency's public website to know more about the applicable copyright and limited reproduction notices.

Please note that, according to Article 16 of the Regulation, the release of the requested documents in accordance with this Regulation is without prejudice to any existing rules on copyright which may limit a third party's right to reproduce, or exploit released documents. The Agency shall assume no liability for any unlawful or unauthorised use, disclosure or reproduction of these documents.

If you have any queries on the enclosed, please do not hesitate to contact the Access to Documents Coordinator for this request, Julia Chepkemoi Rotich, e-mail: juliachepkemoi.rotich@ext.ema.europa.eu, using the ASK Procedure Number mentioned in the subject line.

Yours sincerely,

Henry-Eude Anne-Sophie

Digitally signed by Henry-Eude Anne-Sophie
Date: 2023.10.25 19:03:18 +02'00'

Head of Access to Documents Service
Documents Access and Publication Department