FragDenStaat

EMA/127409/2023
Stakeholders and Communication

Dear Requester,

Subject: Lucentis (ranibizumab), ASK-92547 - Release letter to the requester

Thank you for your request for access to documents received on 30 August 2021, for which the procedure was initiated on 1 March 2023, in which you apply for copies of the following document concerning Lucentis (ranibizumab), in particular:

- 000527-PIP05-17 Summary report.

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] (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.

Having assessed your application, the Agency considers that access to the requested document should be granted.

However, the document has 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 would undermine the privacy and integrity of any individual.

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. Should you wish to do so, you are kindly invited to provide your reasons against our decision to redact parts of document at this stage, which you believe should be taken into account by the Agency in adopting a final decision.

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 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 on-line 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

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.

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

Please find attached the document concerned. Please note that this document is 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 document 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 European Medicines 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 Service, by submitting an online request form as mentioned above or by sending your request to AskEMAATD@ema.europa.eu. Please use the ASK Procedure Number mentioned in the subject line in any correspondence related to this request.

Yours sincerely,

Head of Document Access and Publication Service
Stakeholders and Communication Division
(Signature on file)

Legal Administrator
Legal Department
(Signature on file)