EMA/639632/2020
Stakeholders and Communication

Dear [redacted]

Subject: **Confirmatory application according to EU regulations 1049/2001 and 1367/2006 ASK-74583 - Rejection letter to the requester - confirmatory application (appeal)**

We refer to your confirmatory application (hereafter referred to as "appeal") of 27th October 2020 and we also note your Ombudsman complaint of 20th November 2020 concerning your request to access the following documents:

- 1.zwingende Nachweise unter Einhaltung höchster wissenschaftlicher Standards für die Erfüllung der folgenden Anforderungen (Henle-Koch-Postulate) durch SARS-CoV-2:

  (1) Der mutmaßliche Krankheitserreger muss immer mit der Krankheit assoziiert sein und darf in gesunden Menschen nicht nachgewiesen werden.

  (2) Der mutmaßliche Erreger muss in Reinkultur gezüchtet werden.

  (3) Eine Reinkultur des mutmaßlichen Erregers muss bei einem gesunden Menschen die Krankheit auslösen.

  (4) Der Organismus muss reisoliert werden und identisch mit dem ursprünglichen Erreger sein.

- 2. zwingende Nachweise unter Einhaltung höchster wissenschaftlicher Standards für die vollständige Isolierung, Abbildung und komplette Sequenzierung von SARS-CoV-2.

- 3. zwingende Nachweise unter Einhaltung höchster wissenschaftlicher Standards dafür, dass SARS-CoV-2 das Syndrom COVID-19 beim Menschen verursacht.

Falls Sie als Antwort auf Frage 1 auf die Veröffentlichung in der Fachzeitschrift "Nature" vom 07.05.2020 unter dem Titel "The pathogenicity of SARS-CoV-2 in hACE2 transgenic mice" verweisen, so möchte ich dem Folgendes entgegenhalten und bitte Sie gleichzeitig um Stellungnahme zu diesen Einwänden:

a) Der verwendete Viren-Stamm SARS-CoV-2 HB-01 wurde von W. Tan bereitgestellt. Laut der referenzierten Studie wurde dieser jedoch nicht unter Einhaltung der Henle-Koch-Postulate gewonnen. Die Verwendung dieses Viren-Stammes kann daher keinen Beweis für die Erfüllung der Henle-Koch-Postulate durch SARS-CoV-2 erbringen.

Zitat aus der referenzierten Veröffentlichung "Novel Coronavirus from Patients with Pneumonia in China, 2019": "Although our study does not fulfill Koch's postulates"

b) Der Virus wurde nicht direkt aus den Versuchstieren gewonnen und in deren Wirtszellen kultiviert, sondern in fremden Zellkulturen. Zudem konnte aus den "wild-type mice" gar kein Virus isoliert werden.

"We isolated infectious virus using Vero E6 cell culture from the lung, and observed SARS-CoV-2 particles using electron microscopy (Fig. 1d). However, the virus was not isolated from the lungs of HB-01-infected wild-type mice or mock-treated hACE2 mice along the detecting timeline (Fig. 1c),"

c) Die Kulturzellen wurden "ausgehungert" und mit Antibiotika versetzt, was für sich genommen schon zu den beobachteten Effekten mit der Bildung von Exosomen führen kann, welche man dem behaupteten Virus zuschreibt.

d) Es wurden keine Negativkontrollen durchgeführt. Diese sind jedoch erforderlich um eine Fehldeutung der beobachteten Effekte auszuschließen..

At the outset, we would like to express our sincere regret that your initial application did not reach directly our access-to-document team, which can be reached at https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency. We are sorry that you had to wait for our reply. You may wish to avail yourselves of this communication channel in the future.

Your confirmatory application has been handled in accordance with Article 8(1) of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (the Regulation)[1], and Section 4 of the Annex to the "*European Medicines Agency policy on access to documents - POLICY/0043*" (the Agency policy)[2]. Moreover, it has been assessed pursuant to Article 4 of the Regulation, Section 4.1.1 of the Agency policy and Section 1 of the Annex to the same policy.

The Agency has conducted an individual assessment of your appeal and hereby confirms that the Agency does not hold any documents that would fall under the scope of your request.

As you may know the Agency is a decentralised body of the European Union and its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

The Agency is responsible for the scientific evaluation of applications for European marketing authorisations for both human and veterinary medicines (centralised procedure). Under the centralised procedure, companies submit a single marketing authorisation application to the Agency. Once granted by the European Commission, a centralised (or 'Community') marketing authorisation is valid in all European Union (EU) and EEA-EFTA states (Iceland, Liechtenstein and Norway).

Further information about what the Agency does and does not do can be found on the Agency's website on the following page: https://www.ema.europa.eu/en/about-us/what-we-do

Your request concerns documents which would prove beyond any doubt that SARSCOV2 is responsible for COVID19 infection. The Agency does not hold any documents of this kind, as EMA doesn't carry out basic research in any therapeutic fields and we do not formally 'approve' the scientific evidence (including literature and published documents) concerning the physiopathology of diseases. We are only responsible for the scientific assessment of regulatory applications (e.g. marketing authorisation

[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.

applications and variations thereof) that applicants may submit to the Agency in accordance with the provisions of Regulation (EC) no. 726/2004.

Consequently, we regret to inform you that the subject of your query falls outside of the Agency's scope of activities. We are, therefore, not in a position to advise you on this matter and we hold no documents relevant to your query to which we could give you access.

This decision terminates the procedure before the Agency. 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). In the alternative, you can institute legal proceedings before the General Court of the European Union in accordance with Article 263 of the TFEU.

Should you, in the future, wish to send a request for information or to make a formal request to access unpublished documents please contact us via our webform (https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency) as this will ensure that your correspondence reaches directly the access to documents team and is managed in the most efficient way.

Yours sincerely,

Carr Melanie
Digitally signed by Carr Melanie
Date: 2020.11.27 15:48:49 +01'00'

Melanie Carr
Head of Stakeholders and Communication Division

Marino Stefano
Digitally signed by Marino Stefano
Date: 2020.11.27 10:13:22 +01'00'

Stefano Marino
Head of Legal Department