Dear Ing. Plicka,

Thank you for contacting the European Medicines Agency (EMA).

Your letter, dated 13 March 2021, requests access to documents and information regarding the registration of vaccines against COVID-19 and the supervision of the proper conduct of this procedure. Your letter was forwarded to Access to Documents Service on 07 April 2021.

In your letter you indicate the importance of transparency for the benefit of EU citizens and EU Member States with regard to the legitimacy, quality and availability of decision-making processes. EMA's values and core work in protecting public health is indeed by ensuring that any authorised medicinal product and vaccine must have the highest possible degree of efficacy and safety. In response to the Covid-19 pandemic, EMA and regulatory Agencies in Europe have focused their resources on speeding up processes for evaluation and authorisation of treatments and vaccines without altering standards of quality, safety and efficacy. As for other vaccines in the EU, the highest regulatory standards continue to apply, and the integrity and independence of the scientific assessment is not compromised.

With regards to your specific questions:

1. Authorisation of COVID-19 products (your points a, f, I and k)

EMA is responsible for the scientific evaluation of applications for centralised marketing authorisations in the European Union. This authorisation procedure allows pharmaceutical companies to submit a single marketing authorisation application to EMA, market the medicine and make it available to patients and healthcare professionals throughout the European Economic Area on the basis of a single marketing authorisation. An authorisation procedure is therefore initiated by the application of a company that wishes to obtain a marketing authorisation. Typically, developers submit applications for marketing authorisation after they have all the relevant data, and the submission is followed by an evaluation that can last up to 210 days.

One tool EMA is using to speed up the evaluation of COVID-19 vaccines is the 'rolling review.' With the rolling review, developers can submit data from studies as and when they become available, allowing EMA to start evaluating data at an earlier stage and before the developer submits a formal application. The result is a swifter review of data with no change to the robustness of the evaluation.

When an evaluation is complete, EMA has the option of recommending a conditional marketing Authorisation (CMA). Applicants may be granted a CMA for such medicines on less comprehensive clinical data than normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still

required. A CMA is also intended for a public health emergency (e.g. a pandemic). For these medicines, less comprehensive pharmaceutical and non-clinical data may also be accepted. The legal basis is Article 14(7) of Regulation (EC) No 726/2004. The provisions for granting a conditional marketing authorisation are further elaborated in Regulation (EC) No 507/2006.

EMA considers that the CMA is an appropriate regulatory mechanism for use in the current pandemic emergency to grant all EU citizens' access to a vaccine and to underpin mass vaccination campaigns. CMA provides a controlled and robust framework for accelerated approval still with all the usual safeguards and controls firmly in place, including the ability to ensure that adequate studies continue after approval. It is a type of approval for medicines addressing unmet medical needs, and in particular those to be used in emergency situations in response to public health threats such as COVID-19. The timelines are such that it allows for a thorough assessment of the available data to reach a scientific opinion on whether the vaccine is safe, effective and of good quality and is therefore suitable to vaccinate people.

More information about the development, evaluation, approval and monitoring of COVID-19 vaccines can be found here: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-development-evaluation-approval-monitoring

Also addressing your points f and k (on the approval process and responsibilities within this process), it should be noted that vaccines are authorised by the European Commission on the basis of a scientific opinion and recommendation of EMA's Committee for Medicinal Products for Human Use (CHMP), following a procedure that involves the Member States.

2. Information on the content of the reports (side effects – EPAR, clinical reports, RMP, mechanism of action, efficacy – EPAR, clinical reports (your points b, c, d, e, g, h, i and h)

As explained above, EMA is responsible for the scientific evaluation of applications for centralised marketing authorisations in the European Union. The CHMP evaluates marketing authorisation applications submitted through the centralised procedure, with input from the Pharmacovigilance Risk Assessment Committee (PRAC) on aspects of the risk-management plan (and the Committee for Advanced Therapies (CAT) for advanced-therapy medicines). The CHMP's recommendation forms the basis of the decision taken by the European Commission to authorise a medicinal product.

You may be aware that for many years EMA has been a pioneer in providing an unprecedented level of transparency with respect to the evaluation of medicines. In relation to COVID-19, we are increasing our transparency measures still further. We have published the product information with

details of the conditions of use of the four authorised COVID-19 vaccines before the formal marketing authorisation was granted as well as the risk management plan (RMP).

In this respect, please note that in the European Union, companies must submit an RMP to the Agency at the time of application for a marketing authorisation. RMPs include information on a medicine's safety profile such how its risks will be prevented or minimised in patients, plans for studies and other activities to gain more knowledge about the safety and efficacy of the medicine. Marketing authorisation applicants for COVID-19 vaccines are required to reflect special safety monitoring measures for COVID-19 vaccines by providing considerations and requirements for several sections of the RMP. You can find a set of regulatory documents, including the product information and RMPs, in the main page of each COVID-19 vaccine in the following link: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-authorised#authorised-covid-19-vaccines-section

In addition, EMA has made all efforts to expedite the publication of the full European Public Assessment Report (EPAR) for each vaccine within 3 days of its authorisation by the European Commission (EC).

An EPAR provides public information on a medicine, including how it was assessed by EMA. It reflects the scientific conclusions of the relevant EMA committee at the end of the assessment process, providing the grounds for the Committee opinion on whether or not to approve an application. EMA has seven scientific Committees and a number of working parties and related groups which conduct the scientific work of the Agency. The Committee's evaluations provide the basis for the authorisation of medicines in Europe. For more information about EMA's Committees, how they work and its Members please refer to this link: https://www.ema.europa.eu/en/committees/how-committees-work

To address your point g regarding the basis that the vaccines against Covid-19 work, please find below the EPARs for the COVID-19 vaccines authorised for use in Europe where you can find specific information on the quality (e.g. mechanism of action, manufacturing process), safety (e.g. side effects) and efficacy (e.g. results of clinical studies) as requested in your letter.

• Cominarty EPAR: https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf
• COVID-19 Vaccine Moderna EPAR: https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf
• Vaxzevria (previously COVID-19 Vaccine AstraZeneca) EPAR: https://www.ema.europa.eu/en/documents/assessment-report/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-public-assessment-report_en.pdf

• COVID-19 Vaccine Janssen EPAR:
https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-janssen-epar-public-assessment-report_en.pdf

EMA does not deal with sales, development or production (your points b and c) of any medicinal products, including Covid-19 vaccines. Please see the below a comprehensive overview (entitled “From laboratory to patient”) of all stages from initial research of a medicine to patient access, including how EMA supports medicine development, assesses the benefits and risks and monitors the safety of medicines:
https://www.ema.europa.eu/en/documents/other/laboratory-patient-journey-centrally-authorised-medicine_en.pdf

In addition, please note that there is no guarantee against side effects of the vaccine (your point j). Please refer to the EPAR that provides an overview of the scientific evaluation, especially the risk-benefit balance of products.

The Agency also publishes clinical data submitted by industry to support their marketing applications for human medicines under the centralised procedure. EMA is currently publishing clinical data for COVID-19 medicines. For information on the latest clinical data published please refer to the following website:
https://clinicaldata.ema.europa.eu/web/cdp.

With regards to your question about alternative procedures using traditional herbal medicines being taken into account into the designing of clinical trials (your point d), please note that the responsibility and choice of the designing of the trials lies within the marketing authorisation applicant. Please refer to the published clinical documents for more information.

Regarding your point h: Information related with duration of the immunity afforded by COVID-19 vaccines can be found here:
https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-key-facts

We hope that this information will prove useful to you. Should you wish to contact the Agency again in future, or request specific document(s) please submit your enquiry using the web form linked below:
https://www.ema.europa.eu/en/about-us/contact/send-question-european-medicines-agency

Thank you for considering the above.

Yours Sincerely,

European Medicines Agency

Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands
Send us a question. Go to www.ema.europa.eu/contact [1] Telephone: +31 (0)88 781 6000

We received your question(s) on: 07/04/2021

Subject of your enquiry: Claimant demanding access to the documents according to the Article 6 of the Regulation the European Parliament and Council (ES) No. 1049/2001

Your question(s):
Request received via mail
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Dear,

in the case of the procedure for the registration of vaccines against the disease known as SARSCoV-2 (Covid 19), hereinafter referred as Covid 19, and the supervision of the proper conduct of this procedure, in accordance with Art. 6 Regulation of European Parliament and of the Council No. 1049/2001, we are asking You for access - sending the documents and information mentioned below:

a) who, when and on what basis did in Your office initiate an authorisation procedure - approval of the placing on sale (use) of a covid 19 vaccine? Proof specific facts.

b) who, when and on what basis gave the assignment for development and production of, Your office-approved vaccine against Covid 19 and what was the wording of this assignment? Proof specific facts.

c) where the development of your officeapproved vaccine against Covid 19 took place, who was (or is) the head of the development and production team?When and where were the clinical studies and clinical trials of the vaccine in question conducted and with what result?

d) whether alternative procedures, using traditional herbal or other preparations or other alternative practices for the protection of the population to enhance the immunity of the population in a natural way, have been taken into account in the design of clinical trials, or elsewhere or otherwise with Your office-approved vaccine against Covid 19. If yes, state which. If not, state for what reason.

e) what are the side effects Your office-approved vaccines against Covid 19?

f) who specifically has in Your office responsibility for the approval process of Your office-approved vaccines against Covid 19?

g) on what basis does the vaccine (approved by Your office) against Covid 19 work? (e.g. based on weakened or dead disease agents, based on manipulation of RNA or DNA, or other)?

h) whether and for how long do the vaccines against Covid 19, approved by Your office, protect against Covid 19?

i) whether the Covid 19 vaccines approved by Your office undergo or have undergone a proper authorisation procedure at all stages at your office, as required the law? If not, for what reason? Which parts of the approval process have been omitted or "accelerated", if any and for what reason and on what basis did it happen?

j) which guarantees are provided by the manufacturer (or registrant) for Covid 19 vaccines, approved by Your office, against side effects of the vaccine?

k) give us the evidence of the specific decisions made by Your office on the authorisation (approval) of the use of the vaccine against Covid 19 including justifications.

Links:
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[1] http://www.ema.europa.eu/contact