AskEMA - Response to ASK-266407 - Questions about decisions related to approval and safety monitoring of COVID19 vaccines

Vanjski

Pristigla pošta
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AskEMA No-Reply <AskEMA.noreply@ema.europa.eu> sri, 2. tra 21:18 (prije 2 dana)

prima ja

Prijevod na hrvatski

Dear Dr Pavelić,

Thank you for your email. Please see below a point-by-point answer to your request:

1. How was the safety of COVID-19 vaccines assessed for the specific effect of spike distribution throughout the organism upon the vaccination with the COVID-19 vaccines (i.e. as it passes the blood-brain and placental barrier);

Information on how the safety of COVID-19 vaccines was assessed can be found in the assessment report of the respective COVID-19 vaccine. These can be found on EMA's website: https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines

EMA and the EU Member States continuously monitor and assess the reports of suspected side effects and any other data on the safety of COVID-19 vaccines. Evidence from billions of vaccine doses given worldwide shows that COVID-19 vaccines have a very good safety profile in all age groups.

Whenever evidence emerges indicating that a vaccine may cause a new side effect, EMA's safety committee investigates and recommends appropriate action.

More information about the safety of COVID-19 vaccines is available in the links below: https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/safety-covid-19-vaccines#:~:text=Page%20contents&text=COVID%2D19%20vaccines%20authorised%20for,safety%20of%20COVID%2D19%20vaccines

1. How to explain the recommendation for COVID-19 vaccination even for those people who have recovered from Covid-19? Specific antibodies are known to

remain in the body for at least 11 months after recovery. Elaborate accordingly, why to vaccinate those who have recovered from the disease? The Cleveland Clinic for example (https://doi.org/10.1093/cid/ciac022), states in one of its studies: those who have recovered should not be vaccinated

EMA's remit is the evaluation of vaccines for authorisation purposes whereas recommendations for vaccination are the remit of national level by public health bodies.

COVID vaccines are authorised for preventing coronavirus disease 2019 (COVID-19) regardless of prior COVID-19 vaccination status. SARS-CoV-2 keeps changing and the duration of protection afforded by the vaccine is unknown. Therefore revaccination may be needed to maintain protection against new variants and continue saving lives worldwide.

4. How you evaluated the possibility of the so-called frame-shift after COVID-19 vaccination: production of mutations after "vaccination" has been now reported in the journal Nature https://doi.org/10.1038/s41586-023-06800-3

See answer to question 1.

5. Why the so-called vaccines (products based on gene therapy technology) were put on the market without proper testing while repurposing of some existing drugs on the market with potential effects against COVID-19 remained without action

See answer to 5.

6. Why EMA did not recommend additional, independent state-led COVID-19 vaccines product control, safety monitoring/assessment having in mind that these were all experimental products

The COVID-19 vaccines are not experimental vaccines, but fully approved vaccines that have gone through the same rigorous evaluation procedure as all medicinal products approved by EMA.

The vaccines Comirnaty, Spikevax and Nuvaxovid were originally granted a Conditional Marketing Authorisation (CMA). A CMA is one of the EU's regulatory mechanisms to facilitate early access to medicines that fulfil an unmet medical need, including in emergency situations such as the current pandemic.

As part of the CMA the marketing authorisation holder was required to fulfil specific obligations (for example the provision of more data on longer term safety) within defined timelines. These were met for the respective COVID-19 vaccines and their marketing authorisation has been converted to a full authorisation.

EMA continuously monitors the medicines safety. In case of a safety issue, EMA always considers whether there is a causal relationship between specific batches and the respective adverse events. As for other vaccines the Official Medicines Control Laboratories (OMCLs) in EU Member States also check data on the quality of all batches of COVID-19 vaccines before they are released for use in the EU. Only batches that comply with EMA's approved quality specifications can be used in

1. Why the EMA insisted to work with the term "vaccine" for products meant for COVID-19 vaccination when the products granted to be used for the purpose of COVID-19 vaccinations fall into the group of gene therapy, which was also recently communicated by an American court as well (https://www.themainewire.com/2024/06/u-s-appeals-court-rules-that-mrna-covid-shots-do-not-qualify-as-vaccines/);

COVID-19 vaccines are vaccines against an infectious disease and are not considered gene therapy, as they do not aim to restore, correct or modify human genes.

1. How the EMA or experts working for the EMA evaluated the origin of the construct called SARS-CoV-2 in the contexts of COVID-19 vaccines approval (viroid synthesis from the group of SARS-CoV viruses in the laboratory was not that new at the time of COVID-19 outbreak);

This question is not clear and we would like to point to the vaccines' assessment report for details about EMA's evaluation.

1. How does EMA explain the dates of procurement of supplies for COVID-19 (i.e. tests) accessible on the public web site of the WITS before the declaration of the pandemic in the context of emergency usage approval for COVID-19 vaccines that was supposed to be given in a new circumstance of new imminent public health danger (https://archive.org/details/2017-covid-19-testkits);

EMA has no remit in the evaluation or authorisation of COVID-19 testing kits and cannot comment on your question. However you may wish to refer to the following statement by the world
bank: https://www.worldbank.org/en/news/statement/2020/09/08/statement-on-trade-data-related-to-covid-19-related-medical-supplies

1. How to explain the approval of numerous vaccine patents relevant for COVID-19 before the declaration of a pandemic in the contexts of emergency use approval (i.e. Patent US10702600 for the vaccine candidate mRNA-1273 was in fact registered in its new composition on March 28, 2019.; https://www.ncbi.nlm.nih.gov/books/NBK349040/; https://patents.google.com/patent/US7491489B2/en);

EMA cannot comment on patents as this is outside our remit. However, the technology behind the mRNA vaccines was not new and had been in development for around 20 years.

1. British regulators have decided that pregnant women do not need vaccines against COVID-19. The Vaccine Advisory Committee of the United Kingdom (UK) accordingly does not recommend that pregnant women take the vaccine against COVID-19 in the period 2025 to 2026, according to an article published in the BMJ (British Medical Journal https://www.bmj.com/content/380/bmj.p241/rr). They cite the low risk of serious illness from Covid-19 in pregnant women and infants and the cost of the vaccine. Why the safety of the products were not evaluated again by EMA after new findings;

We cannot comment on the advice by British regulators.

EMA continues to analyse emerging real world data which has shown that vaccines are as safe in special populations, such as people with underlying medical conditions, immunocompromised patients and pregnant women, as they are in the general population.

Regarding pregnancy, the advice is as follows and is reflected the vaccines' product information:

Data on the use of COVID-19 vaccines in pregnancy come from pregnant women vaccinated with COVID-19 vaccines during the second or third trimester of their pregnancy. The data did not show an increase in pregnancy complications and this is.

Recommendations for vaccination in the EU are the remit of national level by public health bodies.

1. How to explain the 'high probability' link between COVID-19 vaccines and death? The largest autopsy study of Covid-19 vaccine deaths to date has been republished in a peer-reviewed journal - after being censored twice (https://pubmed.ncbi.nlm.nih.gov/39120477/). This means that the criteria for a product recall have been met, warranting an immediate withdrawal from the market but the EMA does not take any action. Explain why;

The study claims that Covid-19 vaccines cause sudden cardiac failure and death: A Systematic Review Of Autopsy Findings In Deaths After COVID-19 Vaccination - Science, Public Health Policy and the Law

Sudden Cardiac Failure and Death (SCD) is one of the leading causes of natural death and based on a very large amount of post-marketing data, no safety signal has been found suggesting a causal link between SCD and COVID-19 vaccines (with billions of

doses administered worldwide). SCD is therefore not currently listed as a known side effect in the product information for COVID-19 vaccines.

As for all medicines, EMA will continue to monitor all emerging evidence on the safety of COVID-19 vaccines; this includes suspected side effects with a fatal outcome. In case of new safety concerns, EMA will take any necessary regulatory action as needed, including communication to healthcare professionals and patients.

1. How exactly and with what measures the EMA addressed the Parliamentary Assembly of the Council of Europe Resolution 2361, from 27th January 2021, that member states must ensure all COVID-19 vaccines are supported by high quality trials that are sound and conducted in an ethical manner?

All clinical trials included in applications for marketing authorisation for human medicines in the European Economic Area (EEA) are required to meet internationally agreed ethical and data quality standards. They must meet good clinical practice standards and can be subject to inspection to ensure compliance.

Primary responsibility for ensuring that a clinical trial is conducted in accordance with existing standards including ethical standards lies with the sponsor of that trial and with the clinical investigators they select to carry out the trial.

For clinical trials conducted in the EU/EEA, it is the national regulatory authority and the ethics committees responsible for the investigator sites in the country where the trial is taking place who have responsibility for the authorisation and supervision of clinical trials in their country.

1. Under the Parliamentary Assembly of the Council of Europe Resolution 2361, member states are required to inform citizens that vaccination is not mandatory and ensure that no one is politically, socially, or otherwise pressured to become vaccinated. States are further required to ensure that no one is discriminated against for not receiving the vaccine. How exactly and with what measures the EMA addressed this requirement?

National vaccination campaigns in the EU and decisions on how the vaccines will be given are outside the EMA’s legal mandate and are decided by the health authorities in each EU country.

1. Is EMA in possession with all clinical trials data from COVID-19 vaccines producers, and if yes, why does it not publish publicly the results and not only those prepared for public release?

EMA publishes clinical data submitted by pharmaceutical companies to support their regulatory applications for human medicines under the centralised procedure.

Throughout the COVID-19 pandemic, the European Medicines Agency (EMA) has implemented exceptional measures to maximise the transparency of its regulatory activities on treatments and vaccines for COVID-19 that are approved or are under evaluation. In addition, EMA published trial data on its clinical data website after marketing authorisation; additional trial data also published after major changes to authorisation.

As for all medicines, EMA publishes the European Public assessment report (EPAR) for each vaccine, which contains the detailed assessment report including all the data evaluated supporting the marketing authorisation.

Please find below the link to the Agency's website where you can find the background information to the clinical data publication policy, relevant documents as well as the Clinical data publication website, where you will be able to search for the Clinical Study Reports published by the Agency:
https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/clinical-data-publication/background-clinical-data-publication-policy

1. How exactly EMA collaborates with national agencies that are obliged by law to monitor safety and effects of the medical products and drugs confined to the specific countries' populations? What measures and directives were given to national agencies for this particular activity given the fact that experimental products were allowed for a wide usage and marketing? If yes, what are the results of such activities and where can the accompanying documentation be found?

As for all medicines, EMA together with national agencies continuously monitors vaccines' safety. All suspected side effects reported are collected in EudraVigilance and are assessed and analysed together with other similar cases (as well as with results of clinical studies and scientific literature) to determine whether they reveal unusual or unexpected patterns in the reporting which could indicate a possible new side effect — or a new aspect of a known side effect — and therefore require further investigation. This emerging information is known as a 'safety signal'. When a safety signal requires further investigation, EMA's safety committee, Pharmacovigilance Risk Assessment Committee (PRAC), gets involved to carry out a full assessment; new data may be brought to bear and other bodies may be consulted.

At the peak of the pandemic, EMA published monthly safety updates for all authorised COVID-19 vaccines, based on safety reporting by the marketing authorisation holders. Since August 2023, periodic safety update reports (PSURs) and their EMA assessments are made available for each vaccine. You can find these safety updates on vaccine's webpage. For example:

- https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty#safety-updates

- https://www.ema.europa.eu/en/medicines/human/EPAR/spikevax#safety-updates.

For more about the safety of the COVID-19 vaccines please see: https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/safety-covid-19-vaccines.

We hope you find this information useful.

With kind regards,

On behalf of Juan García Burgos

Head of Public and Stakeholders Engagement Department

We would be grateful if you could take part in a short survey on our service. Please access the survey through the following link: https://ec.europa.eu/eusurvey/runner/AskEMASurvey5137ad0a-8a76-4425-26ed-93ab3c955448

European Medicines Agency

Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands
Send us a question.

Go to www.ema.europa.eu/contact Telephone: +31 (0)88 781 6000

We received your question(s) on:15/02/2025

Subject of your enquiry:Questions about decisions related to approval and safety monitoring of COVID19 vaccines

Your question(s):1. How was the safety of COVID-19 vaccines assessed for the specific effect of spike distribution throughout the organism upon the vaccination with the COVID-19 vaccines (i.e. as it passes the blood-brain and placental barrier); 2. How to explain the recommendation for COVID-19 vaccination even for those people who have recovered from Covid-19? Specific antibodies are known to remain in the body for at least 11 months after recovery. Elaborate accordingly, why to vaccinate those who have recovered from the disease? The Cleveland Clinic for example (https://doi.org/10.1093/cid/ciac022) , states in one of its studies: those who have recovered should not be vaccinated; 3. How you evaluated the possibility of the so-called frame-shift after COVID-19 vaccination: production of mutations after

"vaccination" has been now reported in the journal Nature https://doi.org/10.1038/s41586-023-06800-3 ; 4. Why the so-called vaccines (products based on gene therapy technology) were put on the market without proper testing while repurposing of some existing drugs on the market with potential effects against COVID-19 remained without action; 5. Why EMA did not recommend additional, independent state-led COVID-19 vaccines product control, safety monitoring/assessment having in mind that these were all experimental products; 6. Why the EMA insisted to work with the term "vaccine" for products meant for COVID-19 vaccination when the products granted to be used for the purpose of COVID-19 vaccinations fall into the group of gene therapy, which was also recently communicated by an American court as well (https://www.themainewire.com/2024/06/u-s-appeals-court-rules-that-mrna-covid-shots-do-not-qualify-as-vaccines/); 7. How the EMA or experts working for the EMA evaluated the origin of the construct called SARS-CoV-2 in the contexts of COVID-19 vaccines approval (viroid synthesis from the group of SARS-CoV viruses in the laboratory was not that new at the time of COVID-19 outbreak); 8. How does EMA explain the dates of procurement of supplies for COVID-19 (i.e. tests) accessible on the public web site of the WITS before the declaration of the pandemic in the context of emergency usage approval for COVID-19 vaccines that was supposed to be given in a new circumstance of new imminent public health danger (https://archive.org/details/2017-covid-19-testkits); 9. How to explain the approval of numerous vaccine patents relevant for COVID-19 before the declaration of a pandemic in the contexts of emergency use approval (i.e. Patent US10702600 for the vaccine candidate mRNA-1273 was in fact registered in its new composition on March 28, 2019.; https://www.ncbi.nlm.nih.gov/books/NBK349040/ ; https://patents.google.com/patent/US7491489B2/en); 10. British regulators have decided that pregnant women do not need vaccines against COVID-19. The Vaccine Advisory Committee of the United Kingdom (UK) accordingly does not recommend that pregnant women take the vaccine against COVID-19 in the period 2025 to 2026, according to an article published in the BMJ (British Medical Journal https://www.bmj.com/content/380/bmj.p241/rr). They cite the low risk of serious illness from Covid-19 in pregnant women and infants and the cost of the vaccine. Why the safety of the products were not evaluated again by EMA after new findings; 11. How to explain the 'high probability' link between COVID-19 vaccines and death? The largest autopsy study of Covid-19 vaccine deaths to date has been republished in a peer-reviewed journal - after being censored twice (https://pubmed.ncbi.nlm.nih.gov/39120477/). This means that the criteria for a product recall have been met, warranting an immediate withdrawal from the market but the EMA does not take any action. Explain why; 12. How exactly and with what measures the EMA addressed the Parliamentary Assembly of the Council of Europe Resolution 2361, from 27th January 2021, that member states must ensure all COVID-19 vaccines are supported by high quality trials that are sound and conducted in an ethical manner? 13. Under the Parliamentary Assembly of the Council of Europe Resolution 2361, member states are required to inform citizens that vaccination is not mandatory and ensure that no one is politically, socially, or otherwise pressured to become vaccinated. States are further required to ensure that no one is discriminated against for not receiving the vaccine. How exactly and with what measures the EMA addressed this requirement? 14. Is EMA in possession with all clinical trials data from COVID-19 vaccines producers,

and if yes, why does it not publish publicly the results and not only those prepared for public release? 15. How exactly EMA collaborates with national agencies that are obliged by law to monitor safety and effects of the medical products and drugs confined to the specific countries' populations? What measures and directives were given to national agencies for this particular activity given the fact that experimental products were allowed for a wide usage and marketing? If yes, what are the results of such activities and where can the accompanying documentation be found?