*** LR Konstitucijos 25 straipsnis:**

Žmogus turi teisę turėti savo įsitikinimus ir juos laisvai reikšti. Žmogui neturi būti kliudoma ieškoti, gauti ir skleisti informaciją bei idėjas.

..... cia tik truputi info is EMA puslapio apie pfizer genu inzinierijos produkto registracija ale

“v..a----------

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Kodel skubama vakcinuoti? ....

EMA registravo “vakcina” isimties tvarka.....kad pratesti isimties tvarka, tam tikri duomenys turi buti pateikti iki rugpjucio 31d., kitu atveju, pavelavus pateikti duomenys, isimties tvarka nebus pratesta ir produktui prades galioti standartine registracijos procedura...vadinasi “bus reikalu”.

Taip pat aiskiai parasyta: nezinoma ar sis produktas apsaugo nuo “besimtomes” infekcijos, nezinoma ar stabdo perdavima, kiek laiko apsaugos irgi nezinoma.....

Jei kas dar abejojate jog esate nemokami klinikines studijos dalyviai arba kitaip “bandomieji triusiai”, tai cia parasyta aiskiai... finaline studija planuojama baigti 2023 metais.

Ir tokia info apie visus siuos naujos kartos genu inzinerijos produktus..

Ant kiek Zmogus turi saves nemyleti, negerbti, nemastyti ir pasiduoti sitokiai pigiai nesamoniai.....

https://www.ema.europa.eu/.../comirnaty-epar-public...

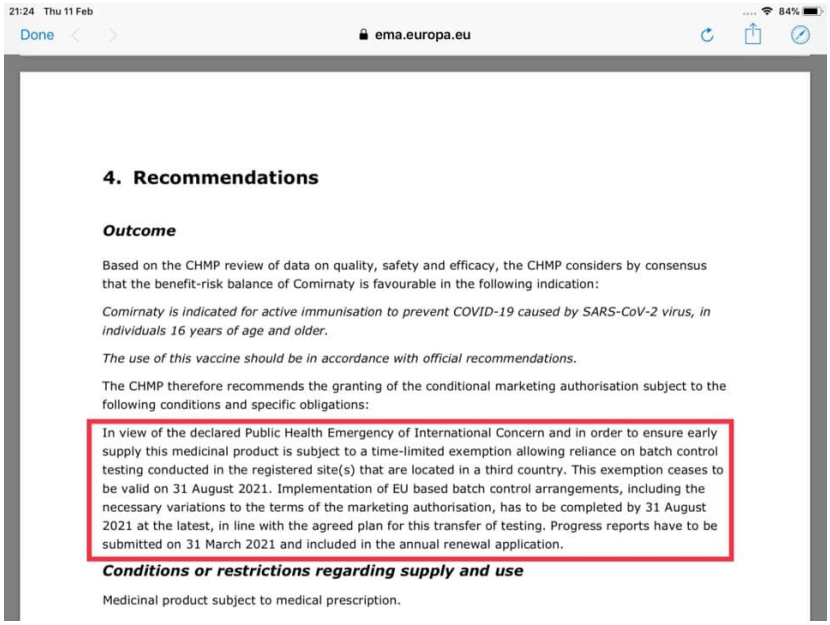
### 3.4. Teisės aktai dėl genetiškai modifikuotų organizmų

Paplitęs vakcinų kūrimo metodas grindžiamas susilpnintais virusais ir virusiniais vektoriais. Dėl jų susiformuoja paskiepyto asmens imunitetas, tačiau jie nėra patogeniniai. Taip kuriamos ir kai kurios COVID-19 vakcinos.

Šiems produktams gali būti taikoma genetiškai modifikuotų organizmų (GMO) apibrėžtis, todėl jiems gali būti taikomi ir atitinkami ES teisės aktai. Valstybių narių nacionaliniai reikalavimai ir procedūros, kuriais įgyvendinamos GMO direktyvos ir kurie taikomi vertinant vaistų, kurių sudėtyje yra GMO arba kurie susideda iš GMO, klinikinių tyrimų riziką aplinkai, labai skiriasi. Dėl to klinikiniai tyrimai, ypač jei jie daugiacentriai ir vykdomi skirtingose valstybėse narėse, gali labai vėluoti. Būtent tokių klinikinių tyrimų reikia siekiant užtikrinti populiacijų, kurioms skirtos vakcinos, reprezentatyvumą ir gauti patikimus ir įtikinamus duomenis apie COVID-19 vakcinas.

Todėl Komisija siūlo priimti reglamentą, kuriuo laikinai (tik tol, kol COVID-19 laikytina ekstremaliąja visuomenės sveikatos situacija) būtų leidžiama tam tikrų GMO direktyvos nuostatų netaikyti klinikiniams tyrimams, kuriuose naudojamos COVID-19 vakcinos (ir COVID-19 gydymo metodai), kurių sudėtyje yra arba kurie susideda iš GMO. Ši siūloma nukrypti leidžianti nuostata per COVID-19 pandemiją būtų taikoma veiklai, kuri yra būtina klinikinių tyrimų etape, taip pat vilties vaistų ar ekstremaliajai situacijai skirtų vaistų naudojimui. Gaminant arba importuojant klinikiniams tyrimams skirtus tiriamuosius vaistus, kurių sudėtyje yra arba kurie susideda iš GMO, ir toliau bus privaloma laikytis gerosios gamybos praktikos, o prieš suteikiant ES rinkodaros leidimą bus atliekamas produktų keliamos rizikos aplinkai vertinimas.

Komisija ragina Europos Parlamentą ir Tarybą pasiūlymą priimti nedelsiant, kad Europoje kuo greičiau būtų sudarytos sąlygos vykdyti klinikinius tyrimus.




## 4. Recommendations

***Outcome***

Based on the CHMP review of data on quality, safety and efficacy, the CHMP considers by consensus that the benefit-risk balance of Comirnaty is favourable in the following indication:

*Comirnaty is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 16 years of age and older.*

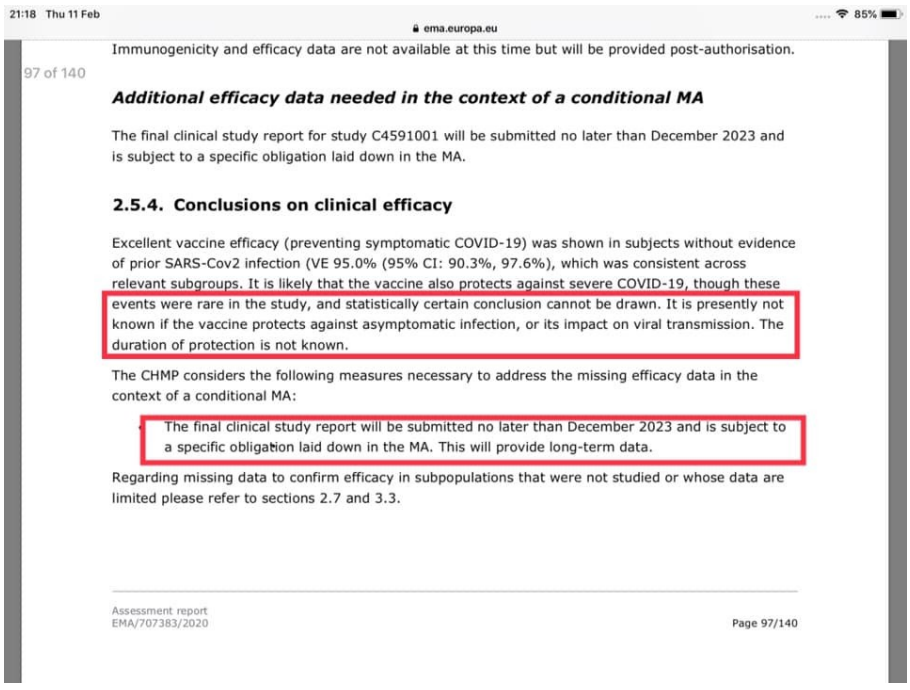
*The use of this vaccine should be in accordance with official recommendations.*

The CHMP therefore recommends the granting of the conditional marketing authorisation subject to the following conditions and specific obligations:

In view of the declared Public Health Emergency of International Concern and in order to ensure early supply this medicinal product is subject to a time-limited exemption allowing reliance on batch control testing conducted in the registered site(s) that are located in a third country. This exemption ceases to be valid on 31 August 2021. Implementation of EU based batch control arrangements, including the necessary variations to the terms of the marketing authorisation, has to be completed by 31 August 2021 at the latest, in line with the agreed plan for this transfer of testing. Progress reports have to be submitted on 31 March 2021 and included in the annual renewal application.

***Conditions or restrictions regarding supply and use***

Medicinal product subject to medical prescription.




Immunogenicity and efficacy data are not available at this time but will be provided post-authorisation.

***Additional efficacy data needed in the context of a conditional MA***

The final clinical study report for study C4591001 will be submitted no later than December 2023 and is subject to a specific obligation laid down in the MA.

### 2.5.4. Conclusions on clinical efficacy

Excellent vaccine efficacy (preventing symptomatic COVID-19) was shown in subjects without evidence of prior SARS-Cov2 infection (VE 95.0% (95% CI: 90.3%, 97.6%), which was consistent across relevant subgroups. It is likely that the vaccine also protects against severe COVID-19, though these events were rare in the study, and statistically certain conclusion cannot be drawn. It is presently not known if the vaccine protects against asymptomatic infection, or its impact on viral transmission. The duration of protection is not known.

The CHMP considers the following measures necessary to address the missing efficacy data in the context of a conditional MA:

- The final clinical study report will be submitted no later than December 2023 and is subject to a specific obligation laid down in the MA. This will provide long-term data.

Regarding missing data to confirm efficacy in subpopulations that were not studied or whose data are limited please refer to sections 2.7 and 3.3.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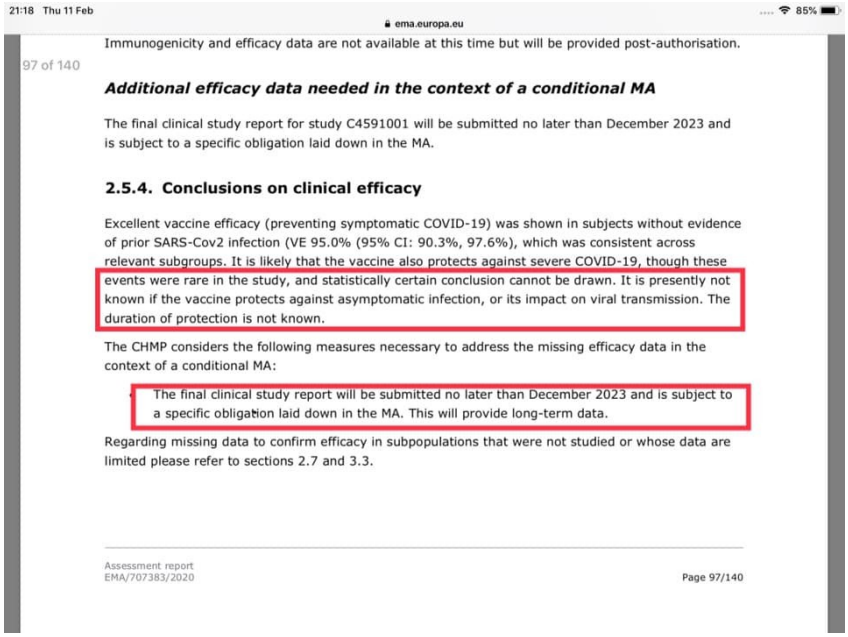
84%

***Specific Obligation to complete post-authorisation measures for the conditional marketing authorisation***

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

| Description | Due date |
|---|---|
| In order to complete the characterisation of the active substance and finished product, the MAH should provide additional data. | July 2021. Interim reports: 31 March 2021 |
| In order to ensure consistent product quality, the MAH should provide additional information to enhance the control strategy, including the active substance and finished product specifications. | July 2021. Interim reports: March 2021 |
| In order to confirm the consistency of the finished product manufacturing process, the MAH should provide additional validation data. | March 2021 |
| In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0315. | July 2021. Interim reports: January 2021, April 2021. |
| In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0159. | July 2021. Interim reports: January 2021, April 2021. |
| In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591001. | December 2023 |

Kazkaip is sito parasymo, itariu, kad kai kurie galbut gauna placebo, nes parasyta, kad atsitiktiniu budu vykdoma, vadinasi tikimybe egzistuoja, kad vakcinos ne visos vienodos sudeties.... ko pasekoje ir matome, vienus su ryskiais simtomais, kitus be jokiu..... vadinasi konkretus klinikinis tyrimas vykdomas su visais.....naglumui nera ribu.....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85%

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