Request for the direct suspension of marketing authorizations

Brussels, 2 oktober 2023

Dear Sir/Madam,

We, the undersigned Members of the European Parliament, want to convey our deep concerns regarding the safety and ineffectiveness of COVID-19 vaccines and we believe it is imperative that immediate and resolute actions should be taken.

We therefore request the direct suspension of the marketing authorizations of the following COVID-19 vaccines:
- Conditional Marketing Authorisation Pfizer (Comirnaty) dated 21 December 2020.[1]
- Conditional Marketing Authorisation Moderna (Spikevax) dated 6 January 2021.[2]
- Renewal of Marketing Authorisation Pfizer (Comirnaty-tozinameran) dated 31 August 2023.[3]
- Renewal Marketing Authorisation Moderna (Spikevax-elasomeran) dated 15 September 2023.[4]

In this letter, we aim to provide a comprehensive, though not exhaustive, rationale for our urgent plea.

Nevertheless, we request you, as a governing body that is legally obligated to take a careful consideration, to broaden your perspective beyond the issues and deficiencies we have cited. The discourse surrounding COVID-19 vaccines has been marked by a disconcerting upsurge in reported side effects, and, astonishingly, there have even been alarming reports of excess mortality. All of this has unfolded beneath a veil of unwarranted secrecy.

Vaccines not authorised for transmission control As per Article 4.1 of the marketing authorization issued by the European Commission on August 31,
2023, Pfizer-BioNTech's (Comirnaty) vaccines are exclusively approved for active immunization.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Comirnaty 30 micrograms/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older.

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

5

According to article 4.1 of the marketing authorisation by the European Commission dated 15 September 2023 Moderna (Spikevax-elasomeran) vaccinations are also only authorised for active immunisation only.

[1] https://ec.europa.eu/health/documents/community-register/2020/20201221150522 /dec_150522_en.pdf
[2] https://ec.europa.eu/health/documents/community-register/ 2021/20210106150575/ dec_150575_en.pdf
[3] https://ec.europa.eu/health/documents/community-register/2023/202308311 60389/dec_160389 _en.pdf
[4] https://ec.europa.eu/health/documents/community-register/2023/2023091 5160561/dec_160561_en.pdf
[5] https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older.

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

[6]

It can be concluded that these therapeutic indications do not align with the fact that these vaccines are being promoted by pharmaceutical companies, politicians, and health professionals due to their potential for transmission control.

As a medicines agency, you are supposed to be well-versed in the intended medical uses of these vaccines. This essentially means that these medicines, including vaccines, should only be administered to individuals who seek personal protection, and they are not authorized for the purpose of reducing transmission or infection rates (transmission control).

As a medicines agency adhering to the principles of good administration and good medical practice, your duty entails the dissemination of this information to healthcare professionals, especially physicians. This enables them to incorporate it into their conversations during the informed consent process, as mandated by both national medical disciplinary laws and medical ethics. It is essential to emphasize that any off-label prescribing must always be performed with the informed consent of the patient.

Clinical trials Clinical trials for XBB.15 have commenced only recently and are scheduled for completion in 2024. Therefore, it is premature to consider renewing a license at this stage, especially when there is currently no international public health emergency of concern (PHEIC).[7]

Pfizer clinical trial (XBB) 10.08.23 to 28.06.24 (phase 2/3)

Study Overview

Brief Summary:
The purpose of this clinical protocol is to learn about the safety, tolerability, and immunogenicity of new BNT162b2 RNA-based vaccine candidates targeting new variants of SARS-CoV-2 in healthy people.

Substudy A:

- This study will evaluate the safety, tolerability, and immunogenicity of BNT162b2 (Omi **XBB**.1.5) given as a single 30 µg dose,
  - in people who are 12 years of age and older,
  - who previously received at least 3 doses of a US-authorized mRNA COVID-19 vaccine, with...

+ Show more

OFFICIAL TITLE

A PHASE 2/3 PROTOCOL TO INVESTIGATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF BNT162b2 RNA-BASED VACCINE CANDIDATES FOR SARS-CoV-2 NEW VARIANTS IN HEALTHY INDIVIDUALS

CONDITIONS

SARS-CoV-2 Infection | COVID-19

INTERVENTION / TREATMENT

Biological: BNT162b2 (Omi **XBB**.1.5)

STUDY START (ACTUAL)
2023-08-10

PRIMARY COMPLETION (ESTIMATED)
2024-06-28

STUDY COMPLETION (ESTIMATED)
2024-06-28

ENROLLMENT (ESTIMATED)
700

STUDY TYPE
Interventional

PHASE
Phase 2
Phase 3

OTHER STUDY ID NUMBERS
C4591054

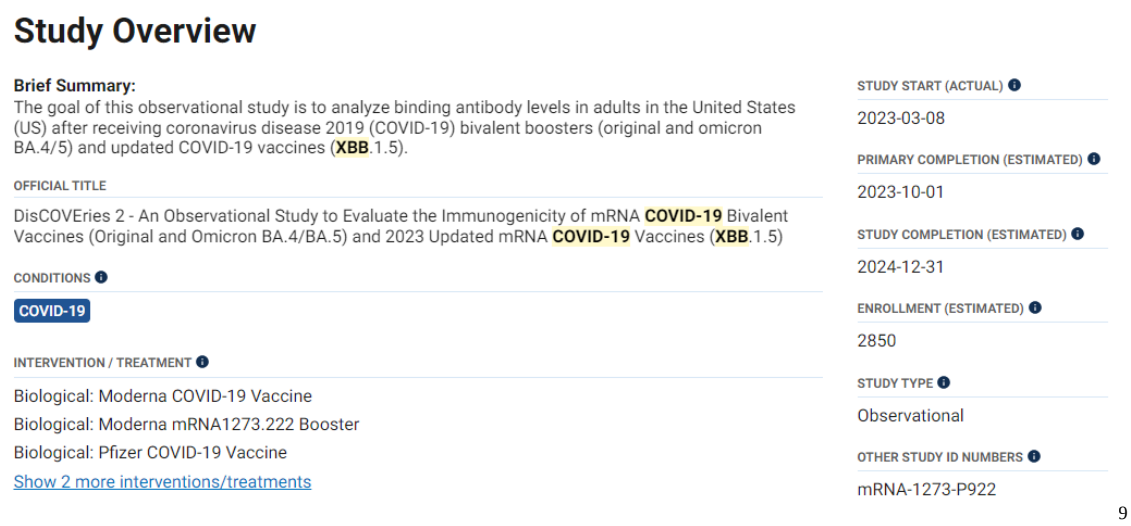
[8]

[6] www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf

[7] https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic

[8] https://www.clinicaltrials.gov/study/NCT05997290

Moderna: 08.03.23 to 31.12.24 (observational phase)



Study Overview

Brief Summary:
The goal of this observational study is to analyze binding antibody levels in adults in the United States (US) after receiving coronavirus disease 2019 (COVID-19) bivalent boosters (original and omicron BA.4/5) and updated COVID-19 vaccines (**XBB**.1.5).

OFFICIAL TITLE

DisCOVEries 2 - An Observational Study to Evaluate the Immunogenicity of mRNA **COVID-19** Bivalent Vaccines (Original and Omicron BA.4/BA.5) and 2023 Updated mRNA **COVID-19** Vaccines (**XBB**.1.5)

CONDITIONS

COVID-19

INTERVENTION / TREATMENT

Biological: Moderna COVID-19 Vaccine
Biological: Moderna mRNA1273.222 Booster
Biological: Pfizer COVID-19 Vaccine
Show 2 more interventions/treatments

STUDY START (ACTUAL)
2023-03-08

PRIMARY COMPLETION (ESTIMATED)
2023-10-01

STUDY COMPLETION (ESTIMATED)
2024-12-31

ENROLLMENT (ESTIMATED)
2850

STUDY TYPE
Observational

OTHER STUDY ID NUMBERS
mRNA-1273-P922

9

Main rule for authorisation of GMOs[SEP]The main rules for allowing genetically modified organisms (GMOs) in the environment can be found in Articles 6 to 11 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.[10] It makes perfect sense that the rules for this are enormously strict as it can have a major impact on humans and the environment.

However, an unusual occurrence transpired on July 15, 2020. In response to the COVID-19 pandemic, a new Regulation was hastily introduced and became effective on July 18, 2020 (refer to Article 5). The key provisions of significance are found in Articles 2(1) together with (2) and 4(1) of Regulation 2020/1043/EU. This regulation pertains to the conduct of clinical trials involving medicinal products designed for human use that contain or consist of genetically modified organisms and are intended for the treatment or prevention of coronavirus disease (COVID-19), as well as the supply of such medicinal products.[11]

Article 4

1. This Regulation shall apply as long as WHO has declared COVID-19 to be a pandemic or as long as an implementing act by which the Commission recognises a situation of public health emergency due to COVID-19 in accordance with Article 12 of Decision No 1082/2013/EU of the European Parliament and of the Council (7) applies.

Article 2

1. All operations related to the conduct of clinical trials, including packaging and labelling, storage, transport, destruction, disposal, distribution, supply, administration or use of investigational medicinal products for human use containing or consisting of GMOs intended to treat or prevent COVID-19, with the exception of the manufacturing of the investigational medicinal products, shall not require a prior environmental risk assessment or consent in accordance with Articles 6 to 11 of Directive 2001/18/EC or Articles 4 to 13 of Directive 2009/41/EC when these operations relate to the conduct of a clinical trial authorised in accordance with Directive 2001/20/EC.

2. Sponsors shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the investigational medicinal product into the environment.

12

[9] https://www.clinicaltrials.gov/study/NCT05765578 Moderna clinical trial (XBB)
[10] https://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-0baaf0518d22.0004.02/DOC_1&format=PDF
[11] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1043
[12] Ibidem

This Regulation allowed for a temporary derogation from the very strict rules of Directive 2001/18/EC.[14]

Of particular significance are Articles 6 and 9 of the Directive. These articles pertain to the authorization procedure and public consultation and information. It's worth noting that these provisions align with the Aarhus Convention, which focuses on access to information, public participation in decision-making, and access to justice in environmental matters. The Aarhus Convention became effective in the Netherlands on March 29, 2005.[15]

Article 9

Consultation of and information to the public

1. Member States shall, without prejudice to the provisions of Articles 7 and 25, consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.

2. Without prejudice to the provisions of Article 25:

— Member States shall make available to the public information on all part B releases of GMOs in their territory;

— the Commission shall make available to the public the information contained in the system of exchange of information pursuant to Article 11.

[13] Ibidem

[14] https://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-0baaf0518d22.0004.02/DOC_1&format=PDF

[15] https://wetten.overheid.nl/BWBV0001700/2005-03-29

Article 6

Standard authorisation procedure

1. Without prejudice to Article 5, any person must, before undertaking a deliberate release of a GMO or of a combination of GMOs, submit a notification to the competent authority of the Member State within whose territory the release is to take place.

2. The notification referred to in paragraph 1 shall include:

(a) a technical dossier supplying the information specified in Annex III necessary for carrying out the environmental risk assessment of the deliberate release of a GMO or combination of GMOs, in particular:

  (i) general information including information on personnel and training,

  (ii) information relating to the GMO(s),

  (iii) information relating to the conditions of release and the potential receiving environment,

  (iv) information on the interactions between the GMO(s) and the environment,

  (v) a plan for monitoring in accordance with the relevant parts of Annex III in order to identify effects of the GMO(s) on human health or the environment,

  (vi) information on control, remediation methods, waste treatment and emergency response plans,

  (vii) a summary of the dossier;

(b) the environmental risk assessment and the conclusions required in Annex II, section D, together with any bibliographic reference and indications of the methods used.

The main rule is however that a GMO can only receive authorization in the European Union once a technical dossier, which includes seven specified documents, has been submitted, along with an environmental risk assessment.
Recently, a report titled "Resilient Biotechnology Policy: Lessons from the COVID-19 Crisis and Opportunities for Enhancing Resilience in Biotechnology Policy" was issued by the Committee on Genetic Modification (COGEM) on October 11, 2022, and made public on December 16, 2022.[16]

Chapter 3 of this report shows that Regulation 2020/1043/EU is void because it is not based on the correct legal basis. Articles 114 or 168(4)(c) of the Treaty on the Functioning of the European Union (TFEU) cannot be invoked in this case. This means that the rules of Directive 2001/18/EC continued to apply in full and that a technical dossier and an environmental report should therefore have been submitted. Having failed to do so, all the permits issued were thus unlawfully granted to the pharmaceutical companies.

For the 2 extensions, it also applies that even if Regulation 2020/1043 would not be void, then at least according to Article 4(1) of the Regulation, a technical dossier and an environmental risk assessment should have been submitted for the extensions, since the PHEIC was terminated by the WHO on May 5, 2023.

[16] https://cogem.net/app/uploads/2022/12/CGM-2022-05-Veerkrachtig-biotechnologiebeleid.pdf

Furthermore, it is imperative that the public be informed and consulted in compliance with Article 9 of the Ordinance. Given that none of these procedures were followed, it highlights the presence of significant procedural errors, making the granted authorisations invalid. Consequently, seeking an extension of the existing license was not the appropriate course of action; instead, a new license application should have been submitted. This underscores the necessity for an immediate suspension of the issued marketing authorizations.

It's worth noting that the same issue also pertains to Regulation 2019/5/EU. This regulation is also based on the wrong legal ground, namely: Articles 114 and 168(4)(c) TFEU. Consequently, this Regulation is also considered void.

Quality of the vaccines It is evident that vaccines failing to meet quality standards should not be granted marketing authorization. Concerning the development of vaccines, there have been disconcerting reports about their quality. In brief, and without covering all the issues, the following deficiencies can be highlighted.

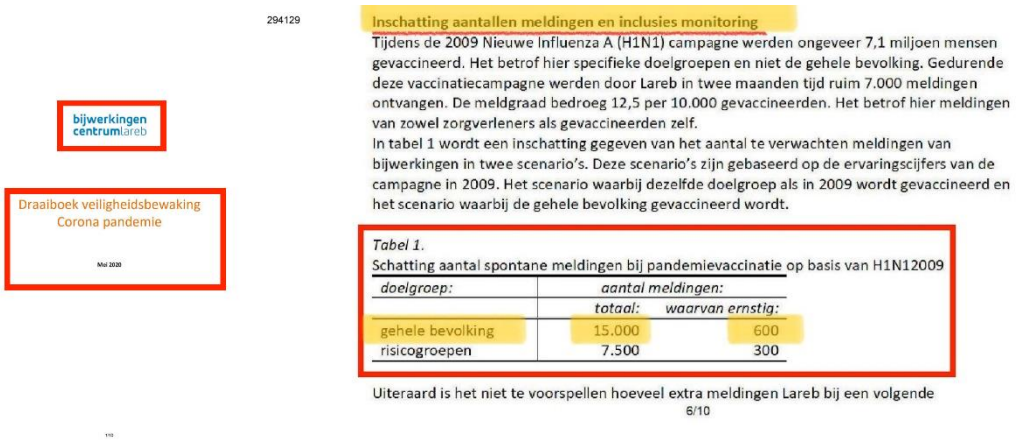
a. The vaccines are harmful

It is evident that the vaccines carry health risks, as substantiated by the substantial volume of reports on adverse reactions received in the Netherlands by the Centre for National Registration and Evaluation of Adverse Reactions (LAREB), as outlined in their report dated September 17, 2023.

able ducer/Tradename	Total number of reports*	Number of adverse reactions reported	Number of reports with a serious adverse reaction**	Deceased
Pfizer (Comirnaty)	125.746	518.269	3.764	506
Pfizer herhaalprik	2.214	10.413	54	13
Moderna (Spikevax)	49.909	286.598	934	91
Moderna herhaalprik	3.592	17.791	88	12
AstraZeneca (Vaxzevria)	38.033	223.424	997	79
Janssen (Jcovden)	15.101	78.337	291	17
Novavax (Nuvaxovid)	60	277	-	-
Merk onbekend	584	2.439	95	33
Total	**235.239**	**1.137.548**	**6.223**	**751**

This is serious considering that in May 2020, the LAREB prepared a "Corona pandemic safety monitoring plan" in which it assumed that 15,000 reports would be received -600 of which were serious- if the entire population were vaccinated (see page 6 of 10 of the plan).[17]

[17] https://voorwaarheid.nl/wp-content/uploads/2022/03/2022-03-09-Tuchtklacht-Pels-Rijcken-bijlage-2-WOB-Draaiboek-LAREB-Veiligheidsbewaking-Corona-pandemie-mei-2020.pdf



bijwerkingen centrumlareb

Draaiboek veiligheidsbewaking Corona pandemie

Mei 2020

294129

Inschatting aantallen meldingen en inclusies monitoring

Tijdens de 2009 Nieuwe Influenza A (H1N1) campagne werden ongeveer 7,1 miljoen mensen gevaccineerd. Het betrof hier specifieke doelgroepen en niet de gehele bevolking. Gedurende deze vaccinatiecampagne werden door Lareb in twee maanden tijd ruim 7.000 meldingen ontvangen. De meldgraad bedroeg 12,5 per 10.000 gevaccineerden. Het betrof hier meldingen van zowel zorgverleners als gevaccineerden zelf.
In tabel 1 wordt een inschatting gegeven van het aantal te verwachten meldingen van bijwerkingen in twee scenario's. Deze scenario's zijn gebaseerd op de ervaringscijfers van de campagne in 2009. Het scenario waarbij dezelfde doelgroep als in 2009 wordt gevaccineerd en het scenario waarbij de gehele bevolking gevaccineerd wordt.

Tabel 1.
Schatting aantal spontane meldingen bij pandemievaccinatie op basis van H1N12009

doelgroep:	*aantal meldingen:*	
	totaal:	*waarvan ernstig:*
gehele bevolking	15.000	600
risicogroepen	7.500	300

Uiteraard is het niet te voorspellen hoeveel extra meldingen Lareb bij een volgende

6/10

This implies that the volume of reports has exceeded LAREB's initial projections by a factor of approximately 16 (235,239 / 15,000 = 15.68) for all adverse reactions and by a factor of roughly 10.5 (6,223 / 600 = 10.37) for serious adverse events. It is perplexing that the Marketing Authorisation Holder (MEB) did not take the step of suspending the marketing authorizations much earlier, given these substantial discrepancies.

Moreover, it's worth noting that the package leaflet of Pfizer's Comirnaty explicitly mentions side effects such as myocarditis and pericarditis, with this term appearing 20 times. These adverse effects pose a particular risk for boys and young men. Additionally, there have been reported cases of fatalities.

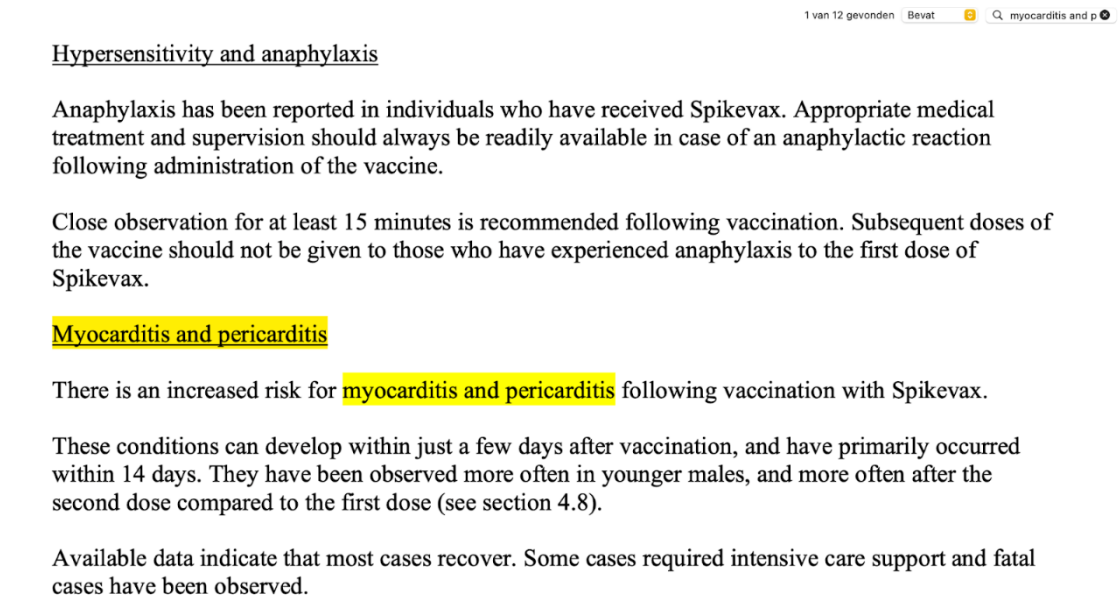
Myocarditis and pericarditis

There is an increased risk of myocarditis and pericarditis following vaccination with Comirnaty. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males (see section 4.8). Available data indicate that most cases recover. Some cases required intensive care support and fatal cases have been observed.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.

Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

The package leaflet for Moderna's Spikevax similarly highlights the risk of myocarditis and pericarditis, with this term appearing 12 times. Moreover, there have also been documented cases of fatalities,



*b. Lack of therapeutic efficacy and unacceptable risks of side effects*A fundamental requirement for a vaccine is to stimulate long-term immunity.[18] If a vaccine only offers protection for less than a year, it falls short of this crucial criterion. Immunity entails establishing a durable defense, which is not achieved in such cases.

c) Lack of declared qualitative and quantitative properties.
In terms of quality, it is important to emphasize that the vaccines do not effectively prevent transmission, rendering the slogan "You're doing it for someone else" inapplicable. Consequently, these drugs are prescribed off-label, necessitating informed consent that explicitly outlines the risk of mortality and the fact that the medication is not approved for transmission prevention.

In quantitative terms, it should be noted that the vaccines have not met the claim that vaccination would render 70% to 95% of individuals immune to infection.[19]

c. The documents submitted are incorrect
Due to irregularities and illegalities in altering the categorization of medicines, drugs that have undergone inadequate safety research have erroneously been introduced to the market. Changes in the rolling review and conditional marketing authorization procedures, as well as modifications to the definitions of vaccines and immunity, have rendered the criteria inadequate. Furthermore, significant irregularities have been identified in clinical trial data, and these concerns have been reported multiple times in the British Medical Journal (BMJ).[20]

d. Inserts do not meet requirements
The Summary of Product Characterisations (SMPCs also called leaflets for *professionals*) submitted by Pfizer and Moderna are so voluminous that they have become de facto illegible for both doctors and citizens making informed consent impossible.

In addition, it is not allowed to create 1 package leaflet for different products. The XBB.15 boosters qualify as a new medicine, for which a separate leaflet should therefore be designed. The pharmacist

[18] https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm#diseases
[19] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9115787/
[20] https://www.bmj.com/content/375/bmj.n2635

cannot expect the doctor and the patient to figure out for themselves which part of such extensive SMPCs (package leaflets), namely 574 pages or 224 pages is about the XBB.15 booster, as shown below.

SMPC Pfizer (574 pages)[21]
SMPC Moderna (224 pages)[22]

The information must be clear and also easily accessible. It is not permissible to lump everything together in the proverbial "big heap", even if the same excipients are used. A separate leaflet should be prepared for each variation. After all, even a small change in sequence can have major consequences. (such as thalidomide where the stereoisomer is teratogenic)

The current leaflets list the variants interchangeably. This is insufficiently specific and therefore not permitted under medical law and medical ethics.

d. There was a breach of good manufacturing practices
Emails sent within the EMA show that there were 3 problems shortly before authorisation. These problems were mainly related to good manufacturing practices.

Wathion Noel
Mon 11/16/2020 12:42 PM
Inbox
Time for decision-making at EU; tomorrow phone call with Olga et al to prepare for EU Exe SG on Wednesday.
Wednesday EU Exe SG with HoAs.
Thursday TC with Commissioner.
The feasibility to "adapt" the CMA to these extraordinary circumstances will be key for determining the approach.
Classified as internal/staff & contractors by the European Medicines Agency

This email argues that the ability to amend the terms of a conditional marketing authorisation is important to the approach.[23]

Nolte Alexis
Mon 23/11/2020 10:48
Sent Items
To:
Korakianiti Evdokia;
Evdokia,
One way to understand how the lower mRNA level in the finished product translates to efficacy would be to measure whether it affects significantly levels of protein expression. It could be that the level of antigenic protein expressed is not significantly affected. However, I don't know whether there is a test that would allow to predict impact on efficacy without clinical trial for comparability.
Alexis
Classified as internal/staff & contractors by the European Medicines Agency

[21] https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_nl.pd
[22] https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_nl.pdf
[23] https://voorwaarheid.nl/wp-content/uploads/2022/12/E-mail-4.png

This e-mail states that the lower amount of intact mRNA in the *finished* product might translate into lesser efficacy, thus making the 95% claim underlying the media statements a priori misleading.[24]

Boone Hilde

ma 23/11/2020 14:26

Dear Marco & Irene,

In the EC table, CHMP opinion is presented for 21 December, whereas this morning 23rd was mentioned as per current timetable, I understand.

But, indeed we agreed trying to bring Opinion forward by a few days eg to 21 or even 18 Dec.

So, what response should we give back to EC now:

Current EMA planning is 23 Dec for Opinion, but we are looking into bringing adoption forward?

Or

Do we already say that 21 Dec for Opinion, as listed in the EC table, is correct, but that we are looking into bringing adoption forward even more?

I take it that the Eudralink TT request that we just received, replaces Olga's question below (as it is in essence the same).

Best, Hilde

In this email, it is clear that rather than being guided by thorough research to arrive at an opinion, the EMA is interfering in the substantive process and indicating that approval should be given sooner. This did happen, the Conditional Marketing Authorisation was awarded to Pfizer on 21 December 2020.[25]

Conclusions: a number of major concerns remain that impact the benefit/risk of the vaccine (efficacy/safety) most notably the comparability issue around % mRNA integrity. These concerns are shared by most member states. **An approval by the end of the year could potentially be possible, if these concerns + GMP will be resolved**. Any remaining Quality issues will need to be considered in the context of overall B/R (& could potentially be addressed via specific obligations/Annex II conditions/recommendations).

The BWP report reflecting these conclusions is undergoing written adoption today.

With thanks to Ton, Brian and Claudio,

Kind regards,

Veronika

Veronika Jekerle, PhD

Head of Pharmaceutical Quality Office

Quality and Safety of Medicines

Office: 09-N-02

Extension: 8438

On 24 November 2020, there was still talk of 3 Major Objections;
1. The mRNA integrity depends on Good Manufacturing Practices (GMP). A problem was identified with mRNA integrity.
2. The *clinical batches* used for the *clinical trials* differed significantly from the *commercial batches*.
3. Finally, there was also a lot of difference between different production facilities.[26]

The batch homogeneity did not appear to be in order. That this in turn affected the benefit/risk ratio, aka efficacy/safety ratio was shown in the publication: Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine, Maniche et al, 30 March 2023.[27]
In this publication, reports of adverse events depend on batch number. This correlation is significant. 4% of doses account for 70% of reports.

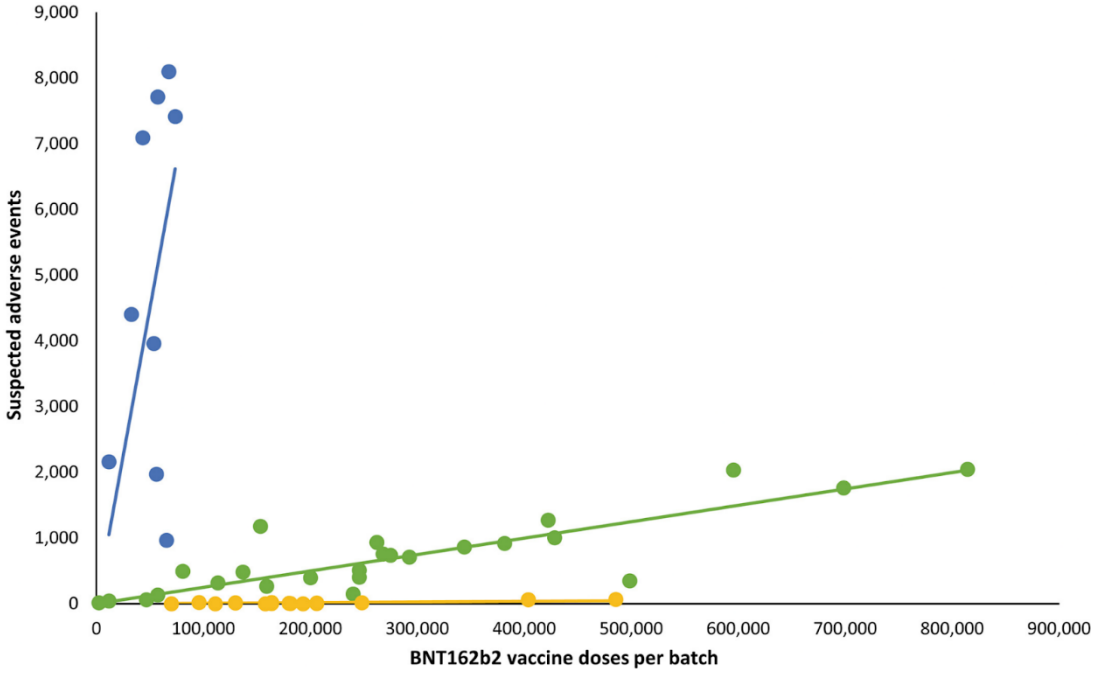
---

[24] https://voorwaarheid.nl/wp-content/uploads/2022/12/E-mail-7.png

[25] https://voorwaarheid.nl/wp-content/uploads/2022/12/E-mail-14.png

[26] https://voorwaarheid.nl/wp-content/uploads/2022/12/E-mail-9.png

[27] https://onlinelibrary.wiley.com/doi/10.1111/eci.13998



A drug so diverse in action cannot be authorised, if only because of the impossibility of informed consent. In addition, as a precautionary principle, the highest category of side effects must be assumed. This makes an effectiveness/safety trade-off negative for each specific target group.

Interim conclusion**:** As many as 6 out of 10 categories have not been met, which is why you should proceed to immediate suspension.

Union licence for Pfizer and Moderna The Conditional Marketing Authorisation for Pfizer and Moderna awarded on 21 December 2020 and 6 January 2021 do not meet the requirements as Regulation 2019/5/EU[28] & Regulation 2020/1043/EU[29] & Regulation 2021/756/EU[30] do not meet the framework laid down:

> On environmental risk assessment and reporting in Regulation2001/18/EC[31] & Directive 2009/41/EC[32]
>
> On safety for medicinal products laid down in Directive 2001/83/EC[33] & 2003/63/EC & 2007/1394/EC[34]
>
> Concerning the granting of a union licence laid down in Regulation 2004/726/EC & Regulation 2008/1234/EC[35]

The changes in Regulation 2019/5/EU should not be used to go outside the framework of existing classification and categorisation, only clarification is allowed, no categories can be added that conflict with the current system, full legislation is needed for that.[36]

---

[28] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32019R0005&qid=1695804802708

[29] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32020R1043

[30] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32021R0756

[31] https://eur-lex.europa.eu/resource.html?uri=cellar:303dd4fa-07a8-4d20-86a8-0baaf0518d22.0009.02/DOC_1&format=PDF

[32] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:125:0075:0097:EN:PDF

[33] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0083

[34] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32007R1394

[35] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1234-20130804

[36] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32019R0005&qid=1695804802708

The temporary suspension of the environmental risk assessment and reporting (2020/1043) appears to be null and void with this (see chapter 3 of the report Resilient Biotechnology Policy dated 11 October 2022 by COGEM published on 16 December 2022.[37] Particular reference is made to pages 36-38 of the report.

The changes in Regulation 2021/756/EU were done AFTER the first Conditional Marketing Authorisation grant. Article 19 of Regulation 2008/1234 clearly states that follow-up licences should be assessed according to the criteria of the first licence.[38]

CHAPTER IV

SECTION 1

Special procedures

Article 19

Extensions of marketing authorisations

1. An application for an extension of a marketing authorisation shall be evaluated in accordance with the same procedure as for the initial marketing authorisation to which it relates.

2. An extension shall either be granted a marketing authorisation in accordance with the same procedure as for the granting of the initial marketing authorisation to which it relates or be included in that marketing authorisation.

In addition, the addition of 'codes/sequences' in Regulation 2021/756/EU conflicts with the classification and categorisation of Directive 2001/83/EC[39] & Directive 2003/63/EC[40] & Regulation 2007/1394.[41]

Regulation 2009/120/EC making change to Annex part IV namely art 2.1 *"Gene therapy medicinal products shall not include vaccines against infectious diseases"* offers no relief, the last rule should be seen as mutually exclusive. After all, vaccine is already defined by the regulations that appeared before.[42]

A vaccine must induce immunity appears from Article 1(4) Directive 2001/83/EC:[43]

[37] https://cogem.net/app/uploads/2022/12/CGM-2022-05-Veerkrachtig-biotechnologiebeleid.pdf
[38] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1234-20130804
[39] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0083
[40] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32003L0063
[41] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32007R1394
[42] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32009L0120&qid=1696174935335
[43] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32001L0083

4. *Immunological medicinal product:*

Any medicinal product consisting of vaccines, toxins, serums or allergen products:

(a) vaccines, toxins and serums shall cover in particular:

(i) agents used to produce active immunity, such as cholera vaccine, BCG, polio vaccines, smallpox vaccine;

(ii) agents used to diagnose the state of immunity, including in particular tuberculin and tuberculin PPD, toxins for the Schick and Dick Tests, brucellin;

(iii) agents used to produce passive immunity, such as diphtheria antitoxin, anti-smallpox globulin, antilymphocytic globulin;

(b) 'allergen product' shall mean any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent.

Article 1.4 (immunological medicine) of this Regulation says "immune response" , but immunity. These are two completely different things. Immunity is a specific immune response where infection is prevented in the future, in the current injections there is no evidence of that.

In addition, a vaccine must contain an antigen; this antigen requires its own registration in the Vaccine Antigen Master File (VAMF) laid down in Directive 2003/63/EC.[44] The reason for this method is that homogeneity and quality and active dose can be determined per treatment. This is not the case with coding sequences.

The recommendations for categorisation and interpretation of the law is reflected in the EMA's *guidelines*.

Reflection paper on classification of advanced therapy medicinal products 2015
According to this paper, and especially paragraph 2.3.3, mRNA is considered an example of gene therapy.[45]

Reflection paper on criteria to be considered for the 6 evaluation of new active substance (NAS) status of 7 biological substances 2023
According to this paper and especially 5.8 which states that any significant change in the sequence of mRNA requires a new application.[46]

Thereby, it must be established that parts of Regulation 2020/1043/EU[47] and Regulation 2021/756/EU[48] are contrary to the classification system and the security system, as argued in the COGEM report, they are thus contrary to Articles 141 and 168 TFEU.

In addition, 2019/5 was used in violation of Article 290(1) of the Treaty on the Functioning of the European Union ("TFEU"):

[44] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32003L0063

[45] https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-classification-advanced-therapy-medicinal-products_en-0.pdf

[46] https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-criteria-be-considered-evaluation-new-active-substance-nas-status-biological_en.pdf

[47] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32020R1043

[48] https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX:32021R0756

"A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act."

It is clearly stated that delegation of powers is not about legislative acts. If classification and categorisation acts and provision are in conflict with existing classification and categories it is WELL legislation, thus all such acts are null and void. In addition, the same line can be followed as the changes lead to a greater risk to public health (see Article 168 TFEU).

The issues are discussed in detail in this publication by Helene Banoun, 9 June 2023, International Journal of Molecular Sciences.[49]

Conclusion

Your role as a medicines agency carries an inherent commitment to the principles of good administration and good medical practice. Failing to suspend the marketing authorizations in question would not only be incongruent with these principles but may also implicate human rights considerations, given the gravity of the issues at hand.

The stakes involved encompass not only the well-being of our citizens but also the allocation of taxpayers' funds.

Therefore, it is imperative that immediate action is taken to suspend the following marketing authorizations:- Conditional Marketing Authorisation Pfizer (Comirnaty) dated 21 December 2020.;[50]

- Conditional Marketing Authorisation Moderna (Spikevax) dated 6 January 2021[51]
- Renewal of Marketing Authorisation Pfizer (Comirnaty-tozinameran) dated 31 August 2023;[52]
- Renewal Marketing Authorisation Moderna (Spikevax-elasomeran) dated 15 September 2023.[53]

We kindly request an acknowledgment of receipt and anticipate a comprehensive response to this request at your earliest convenience.

Marcel de Graaff (Member of European Parliament)

[49] https://www.mdpi.com/1422-0067/24/13/10514

[50] https://ec.europa.eu/health/documents/community-register/2020/20201221150522 /dec_150522_en.pdf

[51] https://ec.europa.eu/health/documents/community-register/ 2021/20210106150575/ dec_150575_en.pdf

[52] https://ec.europa.eu/health/documents/community-register/2023/202308311 60389/dec_160389 _en.pdf

[53] https://ec.europa.eu/health/documents/community-register/2023/2023091 5160561/dec_160561_en.pdf