PELS RIJCKEN

North Netherlands District Court, Leeuwarden location
Session of Jan. 10, 2024
Case number/role number C/17/190788 / HA ZA 2023-172

Conclusion of Reply

regarding

1. The State of the Netherlands
whose registered office is at The Hague
2. Everhardus Ite Hofstra
3. Jaap Tamino van Dissel
4. Maria Petronella Gerarda Koopmans
5. Mark Rutte
6. Sigrid Agnes Maria Kaag
7. Hugo Mattheus de Jonge
8. Ernst Johan Kuipers
9. Diederik Antonius Maria Paulus Johannes Gommers
10. Wopke Bastiaan Hoekstra
11. Cornelia van Nieuwenhuizen
12. Feike Sijbesma
electing alien domicile at The Hague

Lawyers: mr. R.W. Veldhuis and mr. M.E.A. Mohring

and

13. Albert Bourla
lawyer: mr. D. Roessingh

14. Giselle Jacqueline Marie-Therese Van Cann
15. Paul Edwin Jansen
attorney at law: mr. L. Broers

16. William Henry Bill Gates III
lawyer: mr. W.H. Heemskerk

17. Agnes Catharina van der Voort-Kant
lawyer: mr. A.H. Ekker

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against

1. [redacted]
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5.
6.
7.

plaintiffs

attorneys: mr. P.W.J. Stassen and mr. A.G.W. van Kessel

1 Introduction

1.1 The Covid-19 pandemic was an eventful period, during which various, sometimes drastic, measures were needed to protect public health and society. protect. These included curfews, mandatory closures of various sectors and schools, the advice to stay home as much as possible, the obligation to keep 1.5 meters distance from others and lockdowns. Normal social life was thus suddenly - and for an extended period of time - completely turned upside down.

> In doing so, the State's policy was always based on three pillars: (i) an acceptable burden of care - hospitals must be able to provide quality care to both covid-19 patients and patients within regular care, (ii) protecting vulnerable people in society, and (iii) maintaining visibility and understanding of the spread of the virus, at a time when little known about the virus.

1.2 The State realizes that this has led to a period of uncertainty among people, and that in such a situation people rightly ask questions about the handling of the pandemic and the measures taken in that regard. There is ample room for such questions.

> Against this background, the Dutch Safety Board (OVV) also conducted extensive research into the government's handling of the corona crisis. Its purpose was to reconstruct, understand and where possible explain the events and actions during the corona crisis. This has resulted in three comprehensive sub-reports.'

1.3 The core contention of plaintiffs in these proceedings is that there would be intentional and unlawful deception in that the Dutch population (and thus plaintiffs) would have been called upon by defendants to be vaccinated against Covid-19, while defendants would have known that the vaccine was not safe and not effective. Plaintiffs also seek a declaratory judgment to that effect.

1.4 This contention of plaintiffs is false, and lacks any factual basis. That contention and claim are based entirely on plaintiffs' theory that there is allegedly a worldwide conspiracy, of which defendants are allegedly a part. That conspiracy is allegedly aimed, among other things, at carrying out the "Great Reset. The 'Great Reset' implies, according to plaintiffs, that after Covid-19, "a lot of things in the world will have to change forever!" because Covid-19 would expose contractionary errors and lead to a "new normal." All "factors determining human life" would thereby be made "objects of forced change. "[4] What this really

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' Available at: https://www.onderzoeksraad.nl/nl/page/20666/aanpak-coronacrisis.
Subpoena, para. 117.
° Subpoena, par. t22.
Subpoena, par. 186.

What this means in concrete terms (and why this should lead to the claims being allowed) cannot be deduced from the **writ of summons**. However, the subpoena does take the position that in order to bring about the "Great Reset," it would be pretended that there were major crises, when in reality they apparently did not .[S] Part of the "Great Reset" would thus include the "project Covid-19," which would involve a "pretended Sars-Cov-2 virus."!
Covid-19 would therefore not actually exist and the 'Covid-19 injections' would lead to (serious) injury and death." The vaccinations against Covid 19 are, according to plaintiffs, "crucial" to the implementation of the "Covid-19 project."! Thus, according to plaintiffs, there is mentally) mistreatment of the population, a medical experiment on the population," wanting to overthrow the State" and even genocide."[2] WÓÓ why all this would happen, by the way, remains unclear after reading the summons.

1.5 According to plaintiffs, this conspiracy was allegedly initiated by NGOs (particularly the WEF[2']), and financed by the World Bank.'[4] According to plaintiffs, the State - and several other defendants - would be under the direction of the WEF and implementing the Great Reset and the Covid 19 project.

1.6 The concrete reason for these plaintiffs' theories is apparently the book "The Great Reset," which outlines what the authors believe the world *might* look like after Covid-19. This book was written, among others, by Mr. Schwab, the president of the WEF." The WEF is initiating the sharing of insights and information on a global response to the social and economic crisis following the pandemic under the banner of 'The Great Reset.'!

> On this, see Jean Dohmen, "How the Great Reset was hijacked," *FD* Jan. 22, 2022, pp. 17-18 **(production 1)** and Nieuwsuur, "The Great Reset: the recurring fabrications," July 14, 2022. "*

1.7 Plaintiffs' theory is apparently that this book or WEF's initiative based on it is a plan, which the State (and the other defendants) are implementing at the behest of WEF. That theory has no factual basis whatsoever.

Subpoena, par, 186.
^ Subpoena, paras. 41, 109.
Subpoena, par. 109."
D69-aarciing, par, 4B.
" Subpoena, para. 277.
'° Subpoena, par. 273. "
Subpoena, par. 275. " ,
par. 2Bt.
" **Further** opk GAV} is **, and** zijcielings the UN well. '* Subpoena,
para. 114.
' **Klaus Schwab &** Thierry Malleret, *Covid)9. The* grea£ *reset,* **Zurich: ISBN** Agentur Schweiz 2020. '*
***Appendix Proceedings** If* **2021/22, 2541, answer** to question 4.
" NIS, "The Great Reset: the steecis recurring fabrications",
httos /ynos nl/newsuur/Collectie/ 13903/video/2436700-the-oreat-reset-the-ever-terrifying-

PehFMckenBDœDghmverFonui]nNv

1.8 The WEF is nothing more than an organization aimed at establishing international cooperation. WEF aims to be an independent and impartial international consultative body and to provide a platform for public-private cooperation. WEF, as a private-law foundation under Swiss law, does not have the authority to, and does not, give orders to the State or its ministers. State policy is not determined by the WEF, but by the Cabinet - is controlled by the States General.

1.9 Nor is the State in any way committed to the goals of the WEF (or of its president), or to the ideas of "The Great Reset.

> Thus, see also the answers to various Parliamentary questions by Member of Parliament Van Houwelingen on this :
>
> *"The WEB objectives as such are not objectives.*
> *The Cabinet is not committed to Mr. Klaus Schwab."*[®]
>
> *"(...) The Dutch government has no affiliation with the Great Reset Initiative, and, apart from publicly available information about it from the WEF, has no documents about it. (...) "**

1.10 Plaintiffs then unfold theories about the "Covid-19 project" - which would be part of the "Great Reset. Those theories are plainly objectionable. Without any factual basis, or even beginnings of substantiation, it is claimed that Covid-19 (a disease that has cost many people their lives, led to great health damage and also caused much other suffering) would not exist, but would have been invented in order to subsequently - deliberately and willfully - administer vaccinations to the population that would lead to (serious) injury and death. These accusations are not only serious, but also false and unsubstantiated. There is no question of a conspiracy or of a 'Covid-19 project'" the coronavirus Covid-19 does exist, and the vaccines have been found to be safe and ePective.*° The plaintiffs' statements run counter to the worldwide scientific consensus and are hung together with unsubstantiated suggestions and speculations. Also in other ways these statements defy the laws of logic, since it cannot be seen (and plaintiffs do not explain) why vaccinations would be given to the population that would lead to (serious) injury and death.

1.11 The subpoena thus involves nothing more than (complot) theories without any factual basis, with those theories then being used to make far-reaching, quaint and completely unsubstantiated accusations. The subpoena is based on quicksand. There is no conspiracy aimed at a "Great

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[®] *Appendix Acts* II 2021/22, 1164, p. 5.
* *Appendix Handelingen* II 2021/22, 2541, p. 11, answer to question 53.
*^ See below in par. 5.

Reset" or a "Covid-19 project" and plaintiffs have not yet presented the beginnings of any evidence to that effect. This removes any ground from plaintiffs' claims.

1. 12 The State is keen to emphasize that the consequences of the theories formulated in the subpoena not innocuous. The narrative used with those theories of an evil elite targeting the population may ultimately undermine the democratic rule of law. It already provides a group of people with legitimacy for online hate messages, (death) threats and worse.

1.13 To the latter, it is fitting that the subpoena in this case is directed not only against the State, but also against several individuals who have worked tirelessly as administrators, OMT members or otherwise to combat the pandemic.
These people - many of whom already have to contend with hate messages and (death) bed re threats, and in some cases also needing security - have been summoned in private, and at their home address, 9to then have to read in the summons far-reaching accusations against their person. Also - by the foundation apparently behind this subpoena[2°] - banners about these proceedings have been hung along the (snel) roads (and offered for sale on their website), on which these persons are mentioned by name **{production 2).** Both the summons and photos of the banners were widely shared with the media22 and on the Internet,'[3] with accompanying texts such as *"Sharing people, the scum responsible are finally coming to justice!!!"* and *"There must retribution!"* **production 3).** On the first-serving day of these proceedings, several people also gathered in front of the court with such banners, and, in addition, a truck was parked right in front of the court with pictures of some individual defendants on it, with the text "Warirec/" above it and around it, among other things, the texts *"corana vaccine -- poison," "37a,000 needlestick deaths in EU"* and *"Vaccinazi power vri)!!!"* **(production 4).**

1. 14 And all this while there is no legally respectable interest in involving these persons privately in these proceedings. After all, the accusations made against these persons in the summons relate to their work for the State. It is settled case law that the conduct of these persons must therefore be attributed to the State.[2°] This means - as (the lawyers of) plaintiffs know very well - that the accusations are wrongfully directed to these persons in private and must be addressed to the State. Insofar as the plaintiffs' claims are

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[z1] See: hctos://law online/. For the record, daE does not mean that this proceeding is (or can be) a class action. There is no such thing, if only because the requirements of Art. 3: 305a Bw. Therefore, to the extent that the plaintiffs argue in the subpoena that these proceedings also serve "the interest of fellow human beings" 'par. 19 subpoena) or make contentions about the vaccination of minors (par. 34 subpoena), it is true that they cannot defend those interests in these proceeding.

[22] See on this also: httos //chrisklomo nl/a-canceless-carona-suit/. See further have Fllmpje at httos //rechtoDrecht online/ lawsuit.

[23] hLtDs 7/law

[24] HR 1 October 1, 1991, ECLI NL:HR: 1991:ZC0360, N3 1993/165, para. 3.3. See also Court of Appeal of The Hague July 18, 2017, ECM: :GNDHA:20L7 :2033, para. t0.

directed against these individuals, plaintiffs' claims should therefore be dismissed on this ground alone.

> The State also expressly requests your court to decide oo this defense. The reason for this is that the State is increasingly confronted with subpoenas which, without any legally respectable interest, are directed against individual directors in private and other persons who are 9elated to the State. The State wishes to put a stop to this, in order to protect the interests of these persons.

1.15 That plaintiffs' claims cannot succeed is already by the foregoing. It is therefore only for the sake of completeness that the State will elaborate on the defense below. The defense in this statement of reply will always be put forward not only by the State but also by the other defendants on behalf of whom this statement is made (defendants sub 1 tim 10 and 14).

2 The Covid-19 pandemic

2.1 The discovery of the virus

2.1.1 In early January 2020, a new type of coronavirus was identified in Wuhan, China, which had caused a cluster of severe pneumonia,[2]* The newly discovered virus was called "SARS-Coronavirus-2," and the respiratory disease resulting from the virus "Covid-19".[2]!

2.1.2 Infection with the Covid-19 virus can lead to (very) serious symptoms. These include high fever, shortness of breath, pneumonia and septic shock. A significant proportion of people who contract longitis9 due to Covid-19 require ventilation, and for this reason must be admitted to the ICU. The virus has also killed a large number of people.[2]7

> It is now also known that the virus can lead to long-term health damage, such as the so-called "post-covid, "[2]

2.1.3 On January 22, 2020, the Minister for Medtsche Zorg informed the House of about the new virus.'° At that time, the virus had not yet reached the Netherlands. Among other things, the minister wrote that the RIVM would establish an Outbreak /-1anagement Team (OMT).

Opinion n. a. v. ONT 20t9-nCoV (wuhan), Jan. 27, 2020. The ONT opinion can be accessed here : httns://www.rivm.nl/corona/cavid-19/adviezen.

[26] **Research Council** for Safety, *Addressing corona crisis.* Oee/ 1: *to September 202a,* The Hague: Research Council 2022, p. 40, accessed via: https //www rijksoverheid nl/documents/reports/2022/02/ T 6/aanoak-corona.crisis part- 1-tat-seotember-2020.

[27] RIVI-I, *Covld-19 Guideline', httDS'//Ici rivm nl/guidelines/covid- t9.

[28] Central government, "Post-Covid (long-term complaints after corona). hctos //www rl1ksoverheld ni/subject/coronavirus-covid -19/airweovirUssen-zoais-orieo-en-corona/east-covid.

[29] **Parliamentary Papers II 2019/20, 25295, no. 75.**

organize: a team of experts who would advise on the virus and any further measures to be taken. At the time, there was much uncertainty about the virus:30

> *"It is well established that human-to-human transmission has been described, but essential data on how easily it occurs are lacking. The incubation period is probably a minimum of 3 to a maximum of 14 days. The extent of human-to-human infectivity and the conditions of transmission* are not *yet fully understood. Current data indicate transmission via droplets released during coughing and sneezing.*
> *Transmission by virus in droplets can occur over a range of 1.S to 2 meters. When a person carrying the virus becomes infectious, and how long the infectiousness persists during illness, is still unknown."*

2.1.4 At that time, the European Centre for Disease Prevention and Control (ECDC) still estimated the risk of introducing the virus into Europe as moderate and the risk of further spread within Europe as small!" The RIVM announced at the time that the virus did not look very contagious,[3'] and that the likelihood of the virus coming to the Netherlands was considered small.[*3]

2.1. 5 These estimates were soon outdated.

2.2 The global spreadina of the virus

2.2.1 On Jan. 30, 2020, the World Health Organization (WHO) - part of the United Nations - noted that the virus had to several countries on several continents. Consequently, the WHO declared "a *public health emergency of international concern over the global outbreak of a novel* coronavirus. "[3°]

2.2.2 Then things moved quickly with the global spread of the virus. The number of infections and rapidly , not only in the Netherlands (where the first person tested positive on February 27, 2020) but also worldwide!' Worldwide (as far as is known), nearly 100,000 people had already been infected with the by the end of February 2020.3*

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*° Opinion following ONT 2019-nCoV (wuhan), Jan. 27, 2020. " **Opinion** following ONT 2019-nCoV (Wuhan), Jan. 27, 2020.
^' RIVN, Jan. 24, 2020, httDS"//twitter.com/rivm/status/ 7 220717B15340158978
" **RIVM, "Patients** with pulmonary inflammation of **unknown** cause in **China," January 10, 2020, hLtps://www.rivm** .disease-in-china.
" WHO, *WHO Director-General's Statement on InR Emergency Committee on Novel Coronavirus (2019- nCoV}', January 30, 2020, httos'//www who int/director-oeneral/soeeches/detail/who-director-oeneral-s.- statement-on-ihr-emeroencv-committee-on-novel-caranavirus-f 2019-ncov).
" Oncler research raacl for the veiJighe'icl, *Addressing corona crisis. Vol. 1,* p. 43. '* **Opinion** following 58* OI Covid-19, B March 2020.

2.2.3 On March 11, 2020, the WHO formally declared a pandemic.[3']

2.2.4 At that time, there were (as far as is known) 11B,000 infections in 114 countries worldwide, and 4,291 people had died as a result of the virus. WHO expected that in the following days and weeks, the number of infections, the number of countries affected and the number of deaths would increase. The decision to classify the Covid-19 outbreak as a pandemic was not taken lightly, the WHO stressed:

> *"Pandemic is not a word to use lightly or carelessly. it is a word that,* if *misused, can cause unreasonable fear, or unjustified acceptance that the fight* is *over, leading to unnecessary suffering and death.*
>
> *Describing the situation as a pandemic does not change WHO's assessment of the threat posed by this virus. it doesn't change what WHO is doing, and it doesn't change what countries should do.*
>
> *We have never before seen a pandemic sparked by a coronavirus. This is the first panâemic caused by a coronavirus.*
>
> *And we have never before seen a pandemic that can be controlled, at the same time."*

2.2.5 Against this background, on March 12, 2020, WHO sent an open letter on the severity of the pandemic. letter calls on all countries to protect public health while ensuring economic and social stability and respecting human rights.'°

2.3 The first wolf in the Netherlands

2.3.1 The virus also spread in the Netherlands starting in February 2020. As shown in the chart below, the virus quickly took hold in a short period of time and the number of infectious people ran high:[40]

" WHO, "WHO Director-General's opening remąrks at the media briefing on COvfD-19," March 11, 2020, https://www.who.int/direcŁor-Qeneral/soeeches/cletail/who-ciirector-oenerai-s-ooenina-remarks-at-the-meclla-briefina-on-covid-19-- I 1-march-2020.

^ WI-IO, "WHO Director-General's **opening** remarks at **the media briefing on COV7D-19,"** March 11, 2020.

°° In this brier - unlike plaintiffs argue (writ of summons, para. 11) - nothing is yet mentioned about (the need for) vaccination.

⁴° **Central Government,** "Corona Dashboard: infectious **people.** https //coronadashboard riiksoverheid

Number of infectious people through time

This graph iates estimated number of infectedlixe people through the tiid.



2.3.2 This soon made it impossible for the RIVM and the GGD to trace the source of infection for every person infected with the virus. The pressure on care increased (regionally), and concerns about available IC capacity also began to arise.[4]! Overall, this created an uncertain situation in the Netherlands ,(42)

2.3.3 f let from March 12, 2020, therefore, the State took the first drastic measures: everyone with complaints had to stay at home, meetings with more than a hundred people were cancelled and everyone had to stay at home as much as possible. From March 15, 2020, the Netherlands was in an lockdown-43 in addition to the measures taken earlier, the hospitality industry, schools and childcare centers were closed and everyone in the Netherlands was asked to 1.5 meters distance. Practicing contact professions was not allowed. On March 19, 2020, nursing homes were closed to visitors. Furthermore, on March 26, 2020
grain formation on the streets was no longer allowed. The goal was to thus slow the spread of the virus, and thus also keep the burden of care and ICU manageable.°4

Testing was of great in this regard. On March 16, 2020, the WHO called on all countries to test persons with symptoms of Covid-19.°' However, the Netherlands, like many other countries, struggled with a shortage of testing materiaal.[4*] The House of Representatives also emphatically requested that the minister further classify the acquisition of needed protective and testing materials and respirators as a top priority, as the minister also wrote in his letter.[47] It was necessary to

" Research Council for cie safeheiçl, *Addressing coronacri'sis. Volume 1, p.* 46.
°' Opinion following 59° ONT, March 12, 2D20.
4* Board, *Addressing corona crisis. Volume 1,* p. 50, 59.
Research Council, *Addressing corona crisis.* Oee/ *J, p.* 50.
-* WHO, "WHO Director-Generai's opening remarks at the media briefing on COvID-19," March 16, 2020, https: //www. who. int/rlirector general/spee "hes/detail/wh'n-dïrertn<-oeneral-s-o0 in r

'* Parliamentary Papers ïf 20t9/20, 25295, no, 179.
Parliamentary Papers II 2019/2D, 25295, no. 179.

prioritize. Therefore, at first only patients in hospitals and certain health care providers were tested.

Inde the meantime, several measures were taken to solve the shortage of testing equipment. One was the creation of the National Coordination Structure for Testing Capacity (LCT) and the establishment of the Diagnostics Task Force to address the available testing capacity. increase,[4]

To the extent plaintiffs argue that there was no shortage of testing capacity,[4]! that is incorrect. There was indeed a shortage of testing, and not only in the Netherlands. In support of their contrary assertion, plaintiffs refer to the World Integrated Trade Solutions (WITS) database of the World Bank. This, according to plaintiffs, would show that there was trade in Covid-19 tests as early as 2017. However, this does not follow from the productions submitted by plaintiffs. Indeed, the WITS webpage in question states (emphasis added): *"The data here track previously existing medical devices that are now classified by the Wold Customs Organization as critical to tackling Covid-19."*

2.3.4 The State's policy was always based on three pillars: (i) an acceptable burden of care - hospitals must be able to provide quality care to both covid-19 patients and patients within regular care, (ii) protecting vulnerable people in society, and (iii) maintaining visibility and insight into the spread of the . In addition to these three pillars, the societal perspective was also an important starting point in the considerations to be made by the State. That starting point focused on limiting social and economic damage in the short , paying attention to structural social and economic damage, and preventing a disproportionate incidence of burden on certain groups.

2.3.5 In its policy making, the State has continued to be advised by the OUT. The OMT provides medical epidemiological advice and consists of experts and representatives from various professional organizations who advise from their own areas of expertise. The OMT therefore has specific expertise to the best possible epidemiological advice. S* In addition, the State also relied on advice from RIVM, WHO and ECDC. In addition, the Social Cultural Planning Office (SCP) advised on the social effects of the crisis and possible measures, and the Ministries of EZK, SZW and Finance (the Troika) advised on the economic social and financial effects. Until

[-B] Research Council *for* Safety, *Addressing coronacr1sis.* oee/ *3: January 2020 - September Zo22,* Den Hague: Onclerzoeksraacl 2023, p. S6, accessed via: hLtps //www.ri1ksoverhe id.nl/documents/raoporten/2023/10/25/aëtFIDü k-COFOFÏäCF SiS.

[-S] Subpoena, § 1B8.

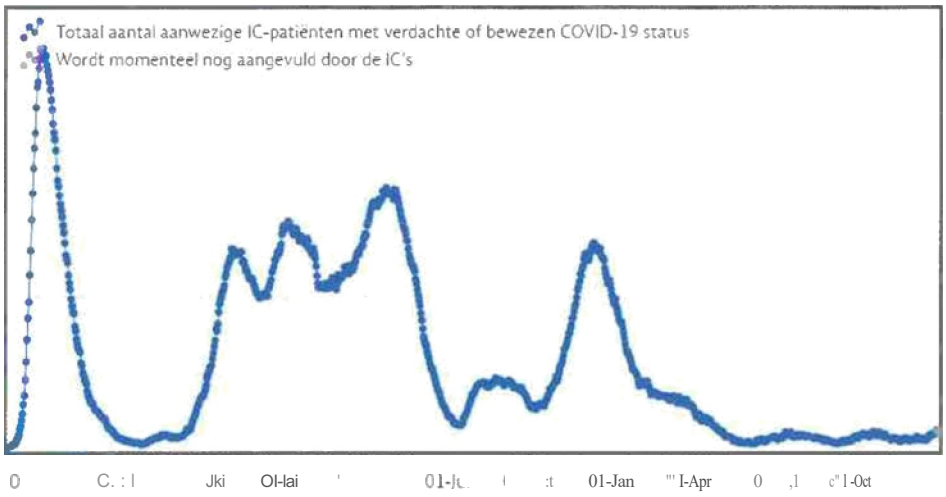
Website WITS, "Nedical Diagnostic Test insEruments and apparatus (902780) exports by Country in 2017," hI:tas //wits worldbank oro/traaelcomtrade/en/country/ALL/vear/20i 7/tradeflow/Exoorts/oartner/WLD/nom en/hS/prod uct/902?80.

[5i] See, inter alia, Gerechtshof Den Haag February 26, 2021, ECLI:NL:GHDHA:2021 :2B5, para. 6.8; District Court of The Hague April 3, 2020, ECM:NL: RBDHA:2020:3013, rpv. 4.8; Parliamentary Papers It 2000/01, 25295, no. 3 (letter from the Ninister of VwS of 22 j uni 2001).

Finally, implementation tests were conducted by the behavioral unit of the RIVM, the National Police, the security regions and the Association of Netherlands Municipalities, among others.

2.3.6 Despite the measures taken, the number of infections fast and high. There was great pressure on care, which meant that other forms of care had to be scaled down (including for life-threatening diseases, such as cancer and heart disease).'[2] Defense was called in to support care. Staffing not only increased rapidly with respect hospital beds, but also ICU staffing increased rapidly. Every effort was made during that period to scale up ICU capacity and maximize utilization of existing capacity." However, the ICU wards of hospitals became so full that patients had to be moved to ICU wards of other hospitals, and eventually even to Germany.'[4] For an overview of ICU occupancy, see: [SS]

The total number of pasiënï and present with verdac how or bewe zen L "OV1Ü- 19 on re IC by daq 2020 - 2022



2.3.7 On April 21, 2020, the figures regarding hospitals and ICUs were hopeful, but the pressure on care was still tremendously high (for example, regular care was still scaled down to a large extent). The situation in nursing homes was still very worrisome. There were many uncertainties. Because the measures were reducing the spread of the virus and the pressure on care was decreasing,

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RIVH, "Impact of the first COVID-19 wave on regular care and health," 2020, : iher 0 1 3 f.

Parliamentary Papers]ï 2020/21, 25295, no. 1063.

[S4] Research Council for veïlipity, *Aenpak corona crisis.* oee/ *z, p.* 58. On April 7, 2020, ICU occupancy peaked. There were then 1,424 corona patients in the , 46 of whom were in Germany. Therefore, plaintiffs *äat* there has never been a shortage of TC beds (par. g4 subpoena), is incorrect.

[55] National Intensive Care Evaluation, "COVID-19 infections in ICUs 2020 - 2022," h

however, some relaxations could be announced. For example, elementary school reopened from May 11, 2020, and more was also possible in the area of sports. The explanation of these decisions showed how far-reaching the pandemic was, and how much cabinet struggled to find a balance between implementing restrictive measures and keeping society open.'[6]

2.3.8 At the May 6, 2020 press conference, it was stressed that the Netherlands had to learn life with the as long as there was no vaccine. Dm to allow daily life to continue as normal as possible until then, testing was of utmost importance. As of June 1, 2020, anyone in the Netherlands with symptoms could therefore get tested.^' Because everyone could get tested, had to stay home after a positive test, there was some room for relaxation of measures from then on.

2.4 The second wolf in the Netherlands

2.4. 1 In the summer of 2020, the reproduction number (the average number of people infected by someone with the coronavirus) was again. It became clear that a second wave was coming to the Netherlands.' This led to more measures being taken again in September 2020.'!

2.4.2 Nevertheless, infections continued to rise. The president of the Federation of Medical Specialists qualified this second wave as a "tsunami. "[60] The number of infections and is shown in the chart below:[61]

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^ Rfjksoverheicl, *Lel:ten ijke text press conference Prime Minister /dark Rutte and Director Jaap van Dissel (Center lnÏ'ectionz1ektebestrijding) following **crlsis consultation cabinet',** April 21, 2020, https minister oresident mark-ruLte and-director-ïaao-of-dissel-center-infectious-sicknessEebestri'dinQ-after-aFlpop-of-criSiSberaad-kabinet.

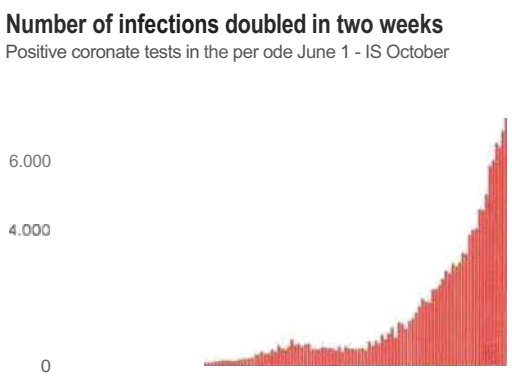
(5)' **Central Government,** '**Literal teksL** press conference **Prime Minister Rutte and Minister De 3onge after the end of 'Cabinet** crisis council**',** 6 mel Z02O, httDS"//www rijksoverheid n|/documents/ media texts/2020/0 S/19/let:ter1ijke-tekst-DersconferenLie-minister-oresiclent-rul:te-and-minister-the-1onoe-na-afio.oo-of-cr'sistjg_raad-kabine.t.

^ Parliamentary Papers II 2020/21, 2529S, no, 613.

*" See also **Research Council** for Safety, ***Tackling coronacnsis. Deet 1,*** **p.** 80; Central government, 'Tightened measures to spread of virus', Sept. 28, 2020, hLtos //www ri1ksoverhe'iä **ni/actual/news/2O2O/09/2B/aanaescherote-measures-to-drlnaen-the-versorei0!***nct-*of-the-virus-teruo -.

*° **Peter Paul van Benthem, "Blog: Tsunami *genaamä* COVIO-19," October 13, 2020,** httos //demed ischsoecial ist

°' NOS, *The coronaweek in graphs: verplee9*uis increasingly väker source of infection," October 13, 2020, httos //nos nl/arts .



In two weeks, hospital bed occupancy had doubled. The number of ICU admissions also a continued upward trend, and all this while pressure on care was already high. The expectation of the DMT was that hospital and ICU occupancy rates would double from March 2020 if no measures were taken and previous measures proved ineffective. Against this background, the DMT recommended the implementation of new, additional, measures.[6]!

2.4.3 On Oct. 13, 2020, the Cabinet decided on a partial lockdown.[6]!

2.4.4 By early November 2020, there was a stabilization in the number of hospital and ICU admissions. However, there were many signs that the burden of care was too high. The reproduction rate was also high in certain areas. To ensure that a downward trend would be initiated, the OMT recommended a brief tightening of measures.** The Cabinet followed this advice, instituting - on top of the partial lockdown - additional measures for a period of two weeks.!' It then returned to the partial .

2.4.5 However, the partial lockdown could not sufficiently prevent further spread of the virus. f4ed mid-December, there were nearly 200 new hospital admissions and over 25 new ICU admissions every day, and that number was rising slightly. The pressure on care was further increased, and the stacking of regular care and increasing Covid- 19 care would not be sustainable if further increases occurred. An increase in the number of infections was set to be higher than in March 2020,[66]

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*' Opinion following 80° ONT, Oct. 13, 2020.
*' Central government, "Partial lockdown to infections," Oct. 13, 2020, https: //www rijksnveTr-id .n!/arti hel*news/2020 10/13/oedeelteliii e-incbr'own-nm-bee *m* *n* *riso-*t drinoe9.
^* Opinion following 83 and 84' ONT, November 3, 2020.
^^ Central government, *Temporary aggravation of partial lockdown," November 3, 2020, jus /*www r_i kso*zerhei l 9nder p-nen_/gg_grnaviru itr4liÎn/news/2020/11/03/ti'delijke- aggrainq- of-the-rjer1e=lr+-li]t<e-lorkdnwn.
°° Aclvies n.a. 91* ONT, t4 December 202D.

Therefore, the Netherlands went into lockdown again as of December 16, 2020, which was explained as follows:[6']

> "The point is: we as humans have to be alert the day, dozens or hundreds of times, to the virus at bay. The virus only has to get lucky once to jump over, and we have to get lucky on every contact.
>
> That is an unequal struggle. And it is exactly what we are looking at now. Because the virus jumps over - and far too often. Every day, an average of 60 people die from corona. Every day we record an average of about 9,000 new infections. That's a full Kuip in less than 6 days. The numbers are also rising in hospitals and nursing homes. More people end up in the hospital in the 2nd wave than in the first wave.
>
> I know: numbers are abstract. And they certainly don't tell the whole story, either. But the reality is that more than a million regular hospital treatments have now been postponed. It will happen to you if you are waiting for treatment.
> The reality is that people in hospitals and nursing homes have been running on their gums for another three months. The stretch is really out.
>
> Meanwhile, about 30,000 people with corona were hospitalized, 6,000 of whom were in intensive care. Of those 6,000, the group under 50 was 2.5 times larger than the group over 80,
>
> The hard truth is that almost all of these 6,000 people would have died had not been treated in intensive care. And that, almost without exception, they are still dealing with shortness of breath, extreme fatigue and other symptoms long after their discharge from the hospital.
> That's what corona does. That's why it's so important that care remains accessible. That there is a bed for you when you it.
>
> So much, in brief, for the background of the lockdown. We have no choice: the number of contacts between people must go down. That is what everything must now be focused on."

2.5 Start of vaccination cam paone and the third ool in the Netherlands

2.5.1 This was the situation in the Netherlands when the first Covid-19 vaccination was given on Jan. 6, 2021.*®

°' Rijksoverheiȼl, *Tv speech by Prime Minister Nark Rutte on the lockdown', Dec. 14, 2020, ht:tas'//www .rliksoverheid nl/documents/toesoraken/2020/ 12/ 14/tv-toesoraak-of-minister-oresident- mark-rutte.

^ Oncierzoeksraad voor de veiligheid, *Aanpak coranacrisis. Volume* 7: *September* 2070 *to)uli 202,* The Hague: Research Council 2022, p. 165. Available at: hrtos://www rijksoverheid nl/docu menrenyraoooorten/2022/ 10/t2/aanoak-coronacrisis.

2.5.2 The scarcity of vaccines at that time made it necessary to prioritize vaccine provision. **In doing so,** the goal **was** to reduce serious illness and death due to Covid -19 as much as possible.[6]! For this reason, most **vulnerable** people were vaccinated **first**: those aged 60 or older (from old to young), and those with underlying health problems.' In addition, medical personnel with direct patient contact, such as nurses in nursing homes, were also vaccinated on a priority basis,*1 so that staff turnover in overburdened care could be avoided as much as possible. Then the vaccine would be by age group (from old to young).'! In this way, everyone in the Netherlands was offered the opportunity to I get vaccinated, with the State informing the population as well and completely as possible.

2.5.3 By the end of February 2021, nearly 800,000 people had received their first Covid-19 vaccination. Just over 200,000 people had also received a second dose of the vaccine,[7]! These included (some of) the most vulnerable people (people aged 80-plus, residents of care facilities) and healthcare workers.

2.5.4 In late March 2021, a third wave began to be visible in the number of infections.'[4] The third wave was expected to peak around mid-April 2021.'[5] The lockdown remained in effect for that reason.

2.5.5 On April 13, 2021, the Cabinet that certain restrictions (such as the curfew) could be lifted from the end of April 2021, in part because of increased vaccination rates - particularly among the elderly and vulnerable :[76]

> *"With all the vaccinations we're putting in place, we will - as far as we can tell right now - reach a point in the second half of May that we're all looking forward to incredulously. Then all the people over 60 and those at high medical risk will have had their first vaccine. If they are protected, then very* v'*ee/fewer people will become seriously ill from corona* infection*. And together with the people who have already been sick and have thus built up protection, this ensures that the virus can take up much less space. And who are seeing that even . It is for this reason that we will soon dare to let go of measures in a number of steps."*

---

*° **Research Council vpor** safety, *Addressing **corona crisis. Volume 2,*** **p,** 147.
Health Council, Strategies for COVID-19 vaccination No. **2020/23, The** Hague: t9 November 2020. Available at: https //www oezonciheidsraad nï/documents/advices/2020/11/ 19/sLrateoieen-vooF- covid-19-vaccination.

" Board, *Addressing corona crisis. Volume 2,* p, 147.

'° Parliamentary Papers II 2020/2a, 25 295, no. 745, p. B.

" RIVN, 'First figures vaccination rate in view', Feb. 23, 2021', https //www rfvm

Central Government, *Literal text press conference Prime Minister Rul:te and Minister de jonge', March 23, 2021, hl?tDS"//www rl ksoverheid nl/cidocumenten/ meäiateksten/2021/03/23/ierteriïï ke-teksE-oersconference-minister-oreside'nt-rutte-and-minister de-ianqe-23-march-202 1.

'* Research Council for Safety, ***Addressing** coronacrlsis. Volume 2,* p. 67.

'° Central Government, *Letter text press conference Prime Minister Rutte and Minister *ae* Jonge,' April 13, 2021, hl:tas //www rijksoverheid nl/documents/meaiaEeksten/2021/04/t3/letter.lJike-teks£-oersconference-minister- oresident-rutte-and-minister-de-joy-13-a pril-202 1.

2.5.6 The effects of the launch of the vaccination campaign were therefore evident during the third wave. The RIVf-J signaled in the third wave that the number of hospitalizations of people under sixty years of age (who generally had not yet been vaccinated) increased sharply, but by contrast the number of hospitalizations of people over eighty (a large proportion of whom had been vaccinated) decreased - probably due to the vaccinations."

2.5. 7 By mid-May 2021, more than 6 million people in the Netherlands had been vaccinated with a first dose of the Covid-19 vaccine. Nearly 2.5 million people had been 9vaccinated against the virus with two doses.'!

Total participation COVID-t9 vaccination.

Tabel 1: Aantal personen bij wie een eerste en/of t[illegible]de dosis COVID-19-vaccin toegediend is, week 1 t/m week 20, 2021, per type uitvoerder.

Doelgroep en/of uitvoerder	Start-datum[2]	Vaccin[1]	Eerste dosis	Tweede dosis	Totaal aantal vaccinaties
Leeftijdsgroepen (inclusief zorgmedewerkers)		COpAüf			
85-89-jarigen	29-01-2021		188.8 90	17+.689	363.5 79
80 - 6sja ngen	05-02-2021		3 74. 89B	34 7. 6 6S	7 2 2. 56Z
75 - 79 -hanging	06-03-2021		563.578	460.534	1.024.112
70-74-jarigen	06-04-2021		81369S))6,600		i S0Z95
65-69-jarigen	19-04-2021		3*7.B66	40.202	RSB068
55-59-jarigen	27-04-2021				
45-49-jarigen			5Z5.395	5E .648	E7? 042
35-39-jarigen			140.507	32.300	17 2.807
			8ï 18T	20. RD.	i II. 76*
2s 's-;an9en			ls.o31	ia.6 o	sa.6
2o z't-;ar'gen			7-.soo	2-.'e6	98.8-s
<y0 her			34.°ît2	jD.4¥4	4-t 756
ieen.jd onöexena			eaz	toy	sg0
sevar inee-o by nuis.aMen estimated''		Az	t.2zs.sum	7Zs.z37	I.4ss.33g
GevxrcnmnOOoP m "e "ge oiv0e<de*igescDat'''' 06-01.1021		) S	8JO.697	3t6JP1	I |9708B
Totaal			6.153.355	2.304.562	8.457.917

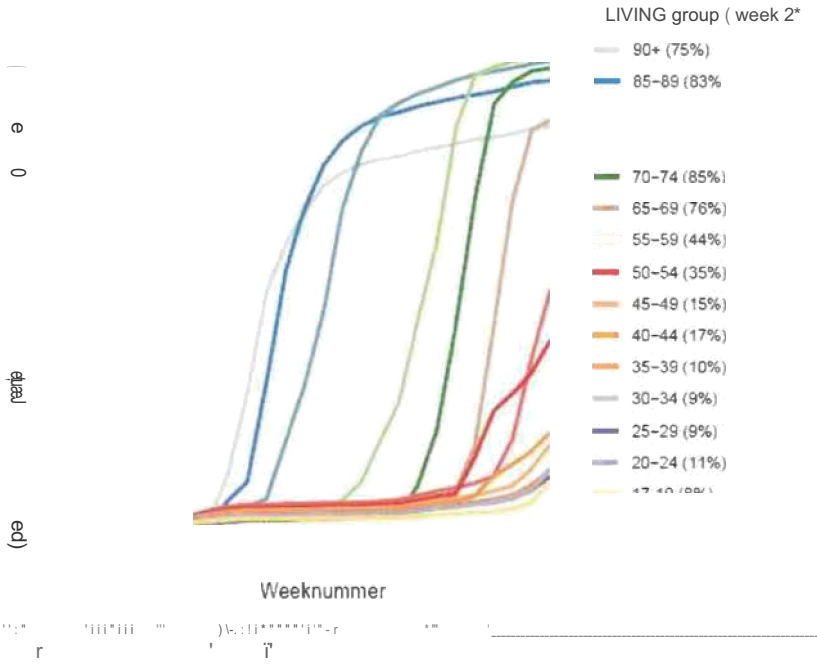
2. 5.8 Further relaxations were (then) announced as of May 19, 2021, and then again as of May 28, 2021. In principle, all sectors, including secondary education, could reopen under conditions. Here, too, vaccination played a major role: *"And it will take some time, but the end of this crisis is coming closer with every prickbi). "**

" R4VM, *in third wave sharp rise in hospitalizations younger age groups," May 4, 2021, httos //www rivm nï/news/news/third-wave-strong-stiioina-hospitaloona mes-ionoere-ïeeftiidsoroepen.

® RïVIfl, "Participation COvID-19 vaccination ín the Netherlands," May 25, 2O21, httos //www rivm ni/sites/dera.u! 'f'iesy202 a03/wekel ikse°zo20rapnortaoe9620COV1D-I9t620vaccinatleoraacl 25 05 202 ï Ddf.

^ Rijksoverheid, "Letter1ijke tekst persconferentie minister-president Rutte en minister de Jonge," May 28, 2021, httos //www rijksoverheid nl/documents/ mediateksLen/202t/05/28/letter1teksL_. Dersconference-minister-oresident-rutte-and-minister-cie-ionoe-Z8- May-202 1.

2. 5.9 Society reopened at the end of June 202 1 (subject to the 1.5m measure). By that time, 9.9 million people in the Netherlands had been vaccinated with their first dose of the Covid vaccine, and 5.3 million had also received their second dose :[8]'



2.6 A high vaccinq rate and abandonment of the latest measureregele n

2.6. 1 By the summer of 2021, the epidemiological picture was stable. The vacci nation rate was now at 85.6°/o among adults. AI 81.7% of adults were thereby valled ig vaccinated and thus highly protected.® [2] This also allowed the 1.5m measure to be released in September 2021.® '

2.6. 2. When the number of infected ngen rose again in the fall of 2021, it again showed how effective the vaccine was. The OL11 wrote:® [4]

> *"The inflow and occupancy on nursing wards and ICU i'n the hospital is increasing slightly. The average daily number of admissions to nursing wards in the past week averaged 42 compared to 34 the week: before, and 10 versus 7 in the ICU (source. LCPS). Also öe*

Rijksov°rhe id, 'Literal text press con*erenrie minisLer president R Ete and mirJ iste- the J--9th', t8 Jun 202 1, httn //'wwvv r *nver held.¿.l/ orum -yn mediatek en/2 n2 ¿0¿/ 18/.etterli ke-ted r-perccs nfere ntde- minisre r- oresideiJt -rurte-en- .ini eter-de -'or ne- 1s-iuni -202 1.

[81] RIVE, 'Declnamc vacci naLit in Nedcr la md', 29 un:' 202 J , htt¿¿:// www'. ri v nI/Si \e /hefg u/t/'iles/ 202 t n6/FCvID- R Vaer ina"'n 7r l'ar1 nse ri r a apne 2n 2 l n6 Zn t 05^ aa nueoa s: .cdf.

[82] Ka me-stu kker' II 2020/21, 252 95, no, 1422.

[83] Ka mer0rief Stund of cases COVfD - 1 9 d . dated 14 SepN2m ber 202 1, Ka merstukken II 2020/2 1, 25295, no. 14 22.

[84] Adv es n. a. v. 127° OMT, 11 uktuber 2021.

> *incidence of hospitalization is much higher in the unvaccinated population than* in *the vaccinated . In September, this incidence in all age groups was at least 10 times higher in the unvaccinated population compared with the fully vaccinated population. The previously very high vaccine effectiveness found against both hospitalization and XC admissions in the Netherlands persists in the most recent data* {95% *and 98%)."*

2.6.3 As a result of increased vaccination rates, the peak in the number of infections was lower. Nevertheless, the peak was higher than the cabinet deemed responsible, partly in view of the resulting pressure on health care. ' That led to the reintroduction of several restrictive measures. In addition, the campaign for booster vaccinations for 60-plusers also began.® * The booster vaccines proved to be very effective against further infection and in other countries at that time. '

2.6.4 In December 2021, the more contagious Omikron variant emerged. The severity of disease progression in this variant was not known at the time. Therefore, a hard lockdown was decided at the end of that month!!! In addition, the booster campaign was further expanded!!!

2.6.5 Despite the high number of infections, the cabinet, after advice from the 0/ JT, on January 25, 2022, considered it justified to relax measures. [0] A major reason for this was the high vaccination rate. The vaccines protected well against hospitalizations, and othereby relieved the burden of care. The unvaccinated group was clearly overrepresented in the number of hospitalizations:!'

Parliamentary Papers II 2020/21, 25295, no, 1468.

*° Rijksoverheid, "Literal Eekst press conference corpnavirus minister-president Rutte and minister de Jonge," November 12, , httos //www rijksoverheid nl/documents/mediatexts/2021/11/12/ietterliÏke-text-Dersconference-coronavirus- minister-president-rul:te-and-minister-de-1onoe-12-november-20zt.

^' **Health Council,** Opinion-Booster-vaccination-against-COV1D-19-in-person-of-18-to-60-years, 2S November 2021. Available : httos //www. oezondheidsraad nl/documents/advices/2021/1 1/25/boostervaccination-teoen-covid-19-bii-oersonen- from-18-to-60-years-old.

** **Parliamentary Papers II 2D20/2** 1, **25295,** no. t672.

^ Health Council, Opinion-Booster-vaccination-against-COViD-19-in-people-18-to-60-years-old, Nov. 25, 2021. Available at: httos //www oezondheidsraad nl/documents/aaviezen/202t/1 T/2 S/boostervaccination-teoen-cov1d- t9-bii- oersonen-van-IB-toE-60 iaar

*° Opinion following 139' ONT, Z4 January 2O22.

"" Central Government, **"Literal text press conference cpronavirus minister-pres dent** Rutte and minister Kuipers," 2S January 2022, httos //www riiksoverheTd nl/documents/medïatexts/2022/01/25/letterJiike-text- press-conferenLie-coronavirus-minister-presloenL-rutLe-and-minister-kuioers.



2,6.6 On Feb. 15, 2022, the press conference began with the words "*opens again."* The number of virus infections was higher than ever, but the number of hospitalizations remained stably low. Thanks in part to vaccines, the Netherlands was more resistant to the virus.*'

> *"Fortunately,* we are in *a different phase now. You see here that very, very many people are* öesmeC *right now, more than ever. You also see that after the* last two press conferences *on January* 1 *and January 25, where we* requests, *the number of infections continued to rise. And if you look at how hospital occupancy is doing now, it* öee/d *totally different from the past two)aar. Hospital occupancy always increased along with* ele *infections. To now zia* ye *that it is almost stable, despite* those *high infection ci)fers. What we hoped for and* 'eruded, *has turned* out to *be true. Thanks to" vaccines and booster shots. And thanks to"* the *immunity* cf/e *people have gained from infected. And besides, that omikron variant is less pathogenic."*

2.6.7 In March 2022, virtually all corona measures were abandoned.

> However, there was still an obligation to wear a face mask at airports. This measure expired on May 21, 2022!!!

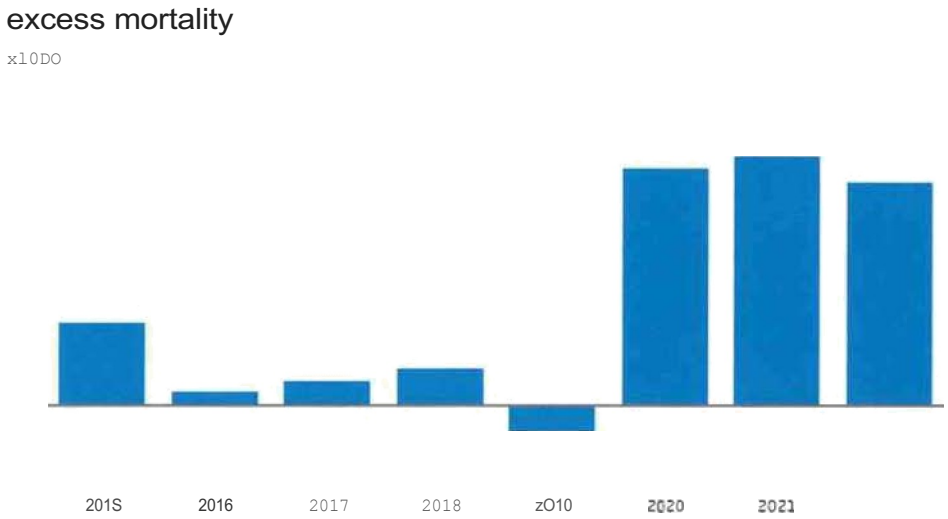
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^ Rljksoverheld, "Literal text press conference coronavirus mlnister-president Rutte and minister Kuipers," 25 Januarl 2022, https'//www.n'keverhefd.nl/documents/medtatetexts/2022/0s/Zs/letterirli'e-text press conference- rqnav rus-mini<tsr-oresldent-rutte-and-minlster-kufoers.

°° R9Moverheid, "Nond caps and vliee : Dutch rules change as of May 21, 2022," May 13, 2022, *.https* JAy. "t riÊsov member *en/actual/newyts/ZO22yO5/i8j* mouth-cap1es-and-viieoen-nedertandswreoets-. change-from-21.-mvi-20'22...

2.7 The impact of the Covid-19 pandemic: excess mortality and morbidity

2.7.1 Over 48,000 people died from Covid-19 in the Netherlands through 2022!° In the years 2020, 2021 and 2022 - during the Covid-19 pandemic - there was also a clear (and substantial) excess mortality in the Netherlands. Dft is evident from CBS figures:*



It is therefore incorrect that, as plaintiffs argue, there was no excess mortality during the pandemic.

In support of that position, the plaintiffs submitted as production 4 a table, which the plaintiff claims came from CBS. However, that table cannot be found on the CBS website. Moreover, the data that can be found on the CBS website show that the figures included in the table submitted as production 4 are incorrect. For example, production 4 states that the number of deceased in 2020 was 162,348, while according to CBS it 168,678! Further, production 4 states that the population of the Netherlands in 2020 was 17.47 million, while according to CBS it was (rounded) 17.41.*® Thus, the percentages included in production 4 are also incorrect. Anyway: the position of

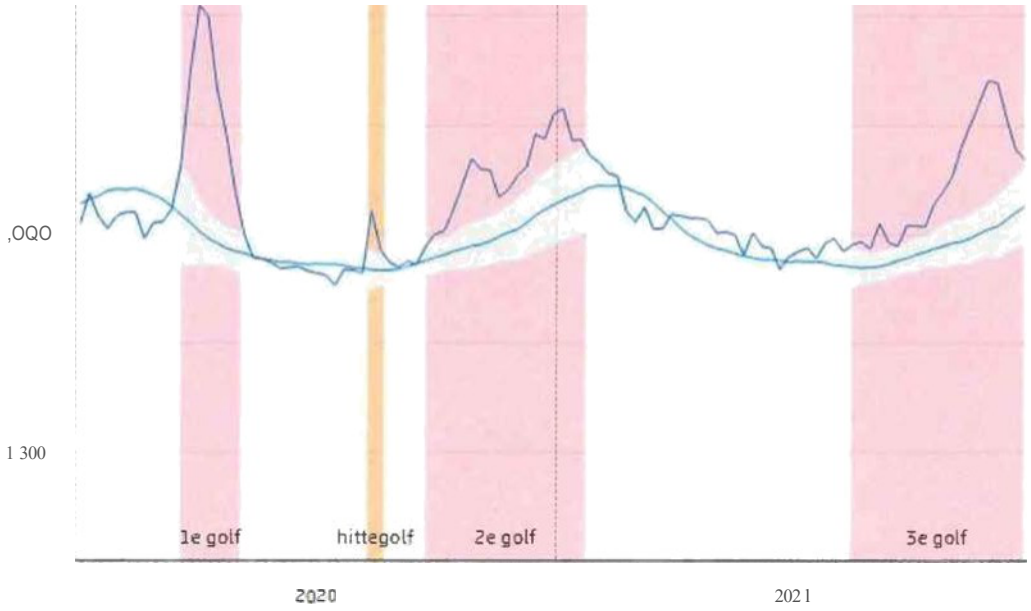
*4 CBS, "Health in Coronati *a,"* September 1, 2023*,* https:/Lwww.rhs nlml-nl lv isiiniisations/w lvaar -ïn-ggronaLi nndhoir1-in-rnrona ,
°' CBS, *2022 third consecutive year of excess mortality', Jan. 25, 2023, has nl*nieuws/2023/04/202.2-derde-iaar-np-ni-met-c'versterfre.,.
** Subpoena, para. 29.
Staü ine, "Population development; month and year," (production 5). See also: w rhs in n kinrt$groF"/nverli'rlen.
^* CBS, ' Population Census' (via 'show table'), hVps * ^/www cbs nl/en -r'!/visualisati-g/dash r

plaintiffs that according to CBS there were no excess deaths in 2020 contradicts what CBS itself concludes about this: *"In 2020 and 2021, a total of 340 thousand people died. That is 30 dutzend (10 percent) more people than vermakh had there no COV7D-1 9 epidemic. The total* deaths *from COVfD-1 9 based on the Causes of Death Statistics in this)aren betraf 40 thousand. The three waves of excess mortality that were visible in 2020 and 2021 coincide with the periods when many people suffered from COVID-1 9 violations. Notably, the rise, peak and then fall* in *excess mortality and COV/D-1 9 mortality occur at" about the same time at"* each *wave."*

2.7.2 That there was excess mortality during the Corona pandemic is also evident in the chart below:'[00]

Z.2.1Past "

.'(hTbieu;i ' C P5} !m|c'vai



offeden'n Deceased n, vzrwa cht

°* CBS, "Stellte, oversLerRe and COvID-19 sterile in 2020 and 2021," June 23, 2022, httos //www cbs nf/nI-nl/Ionaread/statistical-trend.s/2022/mortality-over-mortality-and-covid-19-setting-in-2020-and-2021.

'°° CBS, *SterRe, excess mortality and COVID-19 mortality in 202ß and 2021', 23 Jun 2022.

2.7.3 Against that background, CBS concludes that the excess mortality in the 2020-2022 period will be - and particularly in 2020 and 2021 - is related to Covid-19 mortality. Whereas the excess mortality during that period was 45,800, over 48,000 people died from Covid-19 during the same period. In doing so, CBS also reports - citing a study by RIVM' - that vaccination against Covid-19 is associated with a reduced risk of death from Covid -19.'[0°]

2.7.4 Infection with the coronavirus, apart from the risk of death, can also serious and long-term physical consequences. For example, a large number of people have been hospitalized or admitted to the ICU.'°! Research shows that nine out of ten patients who have been hospitalized still have symptoms a year later.'[04] However, even without hospitalization, Covid-19 can have consequences in the form of long-term symptoms after a passed infection (post-covid). Commonly described long-term complaints are fatigue, shortness of breath, headaches, forgetfulness and difficulty concentrating, loss of smell, palpitations, muscle pain, and anxiety and mood symptoms.[10'] In the first five months of 2022, over 700 people with long-term Covid complaints reported to the UWV. In 62"/o of the cases, the Covid complaints were so severe and so long-lasting that those affected were declared completely disabled.'[06]

2.7.5 The social consequences of the corona crisis are also significant. In the corona years there has been a lot of delayed care, which affects the number of healthy years of life people . In that context, it is also important to note that waiting times in care are still high. This applies not only to physical care, but also to mental care - where an increase in referrals has been noted since the corona crisis (especially among young people). Furthermore, young people have suffered educational disadvantages. The economic effects of the corona crisis have also significant, despite the dampening effect on those effects of the from-the-government support for businesses.°°*

' RIVN, 'vaccination verïaagC odds of COVID-19 mortality and does not increase odds of mortality from other causes,' June 23, 2022. Available at: httos.'//www rivm .nl/news/vaccination-lowers-oD-covid -19- mortality-chances-and-increases-chances-of-a-covid-19-mortality-from-other-causes-not.

'°2 CBS, "Mortality and causes of death in 2020 through 2022," December 11, 2O23. Available at: hrtDS*//www cbs nl/nl- nl/ionoread/¢6D0OLtaoes/2023/overmortality-and-death-causes-in-2020-until-and-with-0 2.

'°' Health Council, Long-term complaints after Covid-19. Contours of the post-Covid syndrome, No. 2022/04, The Hague: 2022. Available at: httos //www gezondheidsraad nl/oDderwerpen/zoro/.alle-adviezen- ove.r-zoroylanodUci¢re-complaints-after-covid-19.

'°' Erasmus NC, '9 in 10 patrons hold long-term symptoms after Hospitalization for coyid-19', httos //amazingerasmusmc nl/infection/9-on-the-10-DatienEs-hold-long-term-complaints-nd- sickh uisooname-for-covid-19/.

'°* Healthraaci, Langciurig powers after Covid-19. Contours of the post-Cov'ia syncirome, No. 202Z/04, The Hague: 2022

'"^ UWV, "UWV: Most clients with long-term corona complaints valled ig incapacitated," June 28, , httos //www uwv nl/ni/oersberichten/uwv-most-chenten-with-Janadurloe-corona complaints-volïedia- incapacitated.

'°' See also Social Impact Team, 'Social impact of the coronacri5is, Presentation for the Technical Briefing in the House of Representatives, December 13, 2022, https://www rilksoverhei0.nl/binaries/riiksoverheid/dacuments/oub1ications/2022/12/23/oresentatix-chairman- mit-technical-brleflno- 13-12-2022/Presentation+chair+NIT+technical+brieFinn+13+december+2022.nrIF.

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2J.6 The consequences of Covid-19 are therefore serious. The plaintiffs' theories - to the effect that Covid-19 would not exist - do not do justice to the people who died as a result of Covid-19 and their loved ones, the people who were (or are) long-term ill as a result of Covid-19, and the people who were otherwise harmed as a result of Covid-19.

3 Plaintiffs' claims

3.1 In these proceedings plaintiffs claim a declaratory judgment that defendants (as a group and each for themselves) acted unlawfully towards plaintiffs *"by unlawfully misleading them opzefteliyk and thereby inducing them to have Covid-1 9* injections *of which defendants knew, or at least should have known, that these injections not safe and effective".* In addition, the plaintiffs claim to order the defendants to pay damages, to be made out in state.

3.2 This proceeding thus involves a far-reaching claim, making serious against the defendants. The State notes at this point that **the plaintiffs**' accusation that the defendants individually or as a group have deliberately misled plaintiffs and thereby induced them to take the Covid-19 vaccination is completely insufficiently explained. Plaintiffs have not even explained - and have not made plausible - 1) that they had themselves vaccinated, 2) which vaccine was involved, 3) at what time or times this took place, and 4) which information from which defendant was leading for each of them in doing so. In the absence these explanations and substantiation, the State disputes that plaintiffs were vaccinated as a result of information by defendants.

3,3 f laar in any : of oozetteliik and oo unlawful wfize misleading plaintiffs, in order to induce them to take a Covid-19 vaccine while oedaaods knew or should have known that those vaccines were not veilio and effective. as is in the claimed declaratory judgment, there is no question. The State will explain this in more detail below. In doing so, the State first and foremost argues that plaintiffs have not met their burden of proof, and that for that reason alone the claims should be dismissed.

4 Protecting public health

4.1 The State has a positive obligation to protect public health. This follows from art. 22 of the Constitution, which provides that the State shall take measures to promote public health, and also from art. 2 and art. 8 ECHRf1. This also means that the State is bound to prevent epidemic, endemic and other diseases as much as possible and to combat outbreaks thereof®

'^ See also Gerechtshof Den Haag 14 December **2021, ECLI:**NL:**GHDHA:2021:2453,** para. 6.10 **and Gerechtshof** Den Haag t4 December **202 1, ECLI:NL:GHDHA.'** 2021**:2452,** para. 6.15. **See further Bunschoten, in:** 7"&C **Constitution and** Statute, Commentary on Art. 22 Gw

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4.2 Therefore, given the severity of the Covid-19 pandemic and the (possible) consequences of that pandemic for the health of the Dutch population,'[0] the State was plainly obliged to take measures to combat the Covid-19 pandemic.

4.3 The State fulfilled this positive obligation by taking various, sometimes far-reaching, measures - after carefully weighing up all the interests involved. Furthermore - after vaccines became available - the State made vaccines against Covid-19 available (free of charge and informed) to anyone in The Netherlands who wanted them, and recommended the population to make use of this possibility.

4.4 As will be explained in more detail below, these vaccines were admitted to the European market after evaluation by the European Medicines Agency (ElflA), and the Health Council gave a positive opinion on their inclusion in the National Vaccination Program. The authorization procedure did not deviate from the regular substantive requirements for the authorization of new drugs. Therefore, the State was able to decide without further ado to include these vaccines in the National Vaccination Program, and to call upon the population to be vaccinated. In doing so, the State did not act unlawfully, but rather fulfilled its positive obligation to protect public health.

5 The development and authorization of vaccines against Covid-19

5.1 The verkriioen of a tradeverounnino fEMAJ

5.1.1 A medicine, such as a vaccine, may only be marketed in the Netherlands if it has been granted a marketing authorization by the national or European medicine authority. "[0] The national medicine authority is the College ter Beoordeling van Geneesmiddelen (CBG)."! The European medicines authority is the EMA. "[2]

51.2 For drugs that protect against viral diseases, such as Covid-19, the required to obtain a marketing authorization the central procedure""

'^^ See par. 2 above.
' Art. 40 para. 1 Medicines Act.
'' Art. 2 and Art. 9, opening words and under f, Medicine Act.
'' Art. 1 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicinal Products Agency.
" CBG, 'Central Procedure,' httos:y/www .cbq-meb nl/topics/hv-central-procedure.

with the EMA. [21]* If the marketing authorization is subsequently granted by the EMA (and thus: under the responsibility of the European Commission), then that authorization is valid at once for the entire European Union - and thus also for the Netherlands.'"

5.1.3 That central procedure at the ENA essentially the following.

5. 1.4 There is a special committee within the ENA that focuses on medicinal products for human use!![6] - the Committee for Pledicinal Products for Human Use (C/1PH),

> The CMPH coordinates the scientific evaluation of the quality, safety and efficacy of medicinal products for human use.'
>
> Eac h lidstaat appoints a member and a deputy who sits on the CMPH,1'® and in beg insel represents the competent national authorities. The Dutch representatives in the CMPH both work at the MEB. In this way, the national medic nauthorities have a say in the decision-making of the CMPH and the EMA.

5.1.5 Each application for authorization of a medicinal product for human use must be accompanied by the data and documents referred to in Art. 6 Regulation (EC) 726/2004 (the drug dossier). The drug dossier consists of five parts (administrative data, data on the manufacturing process and quality, characteristics of the drug, results of laboratory tests and results of tests with subjects).[1]!*

5.1. 6 The basic principle is that this information must be submitted at the time the application is . However, there is also the possibility of an accelerated procedure, a so-called 'rolling review'.'°0 In this process, information is already shared (and assessed) with the EMA while the clinical trial is still in progress. In this way, the review can start earlier. This considerable time, without compromising the assessment of the quality, safety and efficacy of the vaccine. [12]◦

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*4 Regulation (EC) No. 726/2004, Annex 1, Art. 3 (as amended May 20, 2008, see Recital 8).
Art. 13(1) Regulation (EC) No. 726/20O4.
115 Art. 5(1) and Art. 56(1) Regulation (EC) No. 726/2004. Art.
116 57(1)(b) Regulation (EC) No. 726/2004.
Art. 61 of Regulation (EC) No. 726/2004.
CBG, 'CBG annual report 202O: procedures am a drug the markE Le',
119 hLtps //www cbgiaawerslaq.nl/cbo-'aarverslao/2020/01/0rocedures-to-bring-a-medicine-m'iaaei-or-vaccine-oo- the-markL.
CBG, "CBG Annual Report Z020: Procedures To Market a Drug," 2020; See also: ENA, "COVID-19
120 guidance: evaluation *anä* marketing authorization.
betas://www ema eurooa eu/en/human-reoulatorv/overview/DUblic-health-threats/coronavirus-äiSease-covid-19/covid-19-nublic-health-emeraency-international-concern-2020-23/ouidance-deveiooers-comoanieS/covid-t9-auidance-evaluation- marketina-authorization.
EI-łA, "Start of rolling review for adapted Comirnaty COVID-19 vaccine," IS June 2022,
hlżDS"//www ema eurona euyen/oe start-rollinQ-review-adaoted-comirnatv-covid-19-vaccine.

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5.1.7 The CMPH assesses whether the conditions for granting a marketing authorization are met. For this purpose, the CMPH appoints one of its members (from one of the member states) as rapporteur.'2^ This reporter is in charge of coordinating the assessment. The committee concerned may appoint a second member (from another member state) as co-rapporteur. The task of the co-rapporteur is to criticize the rapporteur's report or to a second report independently."!

5.1.8 The rapporteurs both prepare a scientific report, summarizing the data from the authorization application, giving their opinion on the effectiveness of the drug and their views on possible uncertainties from the data. The CMPH then meets in plenary to discuss the reports and adopt a final opinion.° 2(4) In this plenary session, all member states and national medicines authorities are represented by their experts serving on the CMPH. The final opinion is sent to the European Commission within 15 days.'2' The European Commission ultimately decides whether to actually grant a marketing authorization based on the CMPH's opinion.!'*

5.1.9 Based on Art. 14-bis (1) Regulation (EC) No. 726/2004, a conditional authorization may be granted - prior to the submission of complete clinical data - if the benefit of immediate availability of the medicinal product on the market outweighs the risk associated with the need to submit additional data. The marketing authorization may be granted on this basis only if the balance of benefits and risks of the drug is favorable and it is likely that the applicant will be able to provide comprehensive data (Art. 14-bis (3)). Specific obligations may thereby be attached to a marketing authorization (art. 14-bis para. 4). In any case, the licensee is required to complete ongoing studies or conduct new studies to confirm that the benefit-risk balance is favorable (art. 14-bis para. 5). The period of validity of a marketing authorization granted under this article is one year (and may be renewed thereafter).

5. 1. 10 Regulation (EC) No. 507/2006 lays down detailed rules for obtaining a conditional marketing authorization for medicinal products for human use.'2' Article 4 of that Regulation the following:

"* Art. 62 Regulation (EC) 726/2004
'^^^ Art. 6 Rules of procedure Comm tLtee for Nedicinal Products for Human U se. See: EMA, 'Rules of ', httDS"//www ema eurpoa eu/en/documents/other/chmo-rules-procedure and Ddf.
'^(4) ENA, 'Fro m laboratory to patient: the journey of a medicine assessed by ENA', httDS //www ema euroDa eu/en/documents/other/laboratory-oatienL-iournev-centrallv-authorized-medicine en odf.
'*5 Art. 5 paragraph 2 jo. art. 9 licl 3 regulation (EC) 7 26/2004. '°* Art. 10 Mld 2 regulation (EC) 726/2004.
'°' Commission Regulation (EC) No. 507/2006 of March 29, **2006 on** conditional marketing authorizations for medicinal products for human use falling the scope of Regulation (EC) No. 726/2004.

1. A conditional authorization may be granted when the Committee determines that, although complete clinical data on the safety and efficacy of the drug have not been provided, all of the following requirements have been met:

   a) the risk-benefit balance of the medicinal product as defined in Article 1(28a) of Directive 2001/83/EC is positive;

   b) it is likely that the applicant can provide that full clinical data;

   c) unmet medical needs are met;

   d) the public health benefits of the immediate availability of the drug on the market outweigh the risk associated with having to provide additional data.

5.2 Admission of Covid-19 vaccines to the European market

5.2. 1 A number of Covid-19 vaccines have used the rolling review procedure mentioned above. In a rolling review, as mentioned above, the same documents must be submitted and the same steps are taken as in the normal procedure, but the process is accelerated by parts. In a rolling review, the vaccine is also assessed according to the usual standards of quality, safety and effectiveness.°' Corona vaccines are, in short, tested against the same (very) stringent criteria as vaccines against other infectious diseases. The assessment, due to the rolling review, can only take place earlier (and thus faster):'[2]!

'*® EMA, "EMA starts second rolling review of a COVID-19 vaccine," October 6, 2020, httos://www.ema.eurooa eu/en/news/ema-starts-second-roittno-review-covld-E9-vacclne.

"* ENA, 'COVID-19 vacclnes: development, evaluation, approval and monitoring', httos://www ema euroDa eu/en/human-reoulatorv-overview/oubtic-health-threats/coronav\rus-disease-covid-19/covid-19-Oublic-health-emeroencv-international-concern-z020-23/covid-19-vaccines-develoDment-evaluatlon-aDDL€iVal-and-monitorlna.

Figure 5: Standard evatuaGon process compared **with rolling revieu/ of** COvID-19 **vaccines**



5.2.2 Based on a rolling review and pursuant to the procedure of Art. 14-bis of Regulation No. 726/2004, a positive opinion was given by the EMA for the four vaccines against Covid-19 used in the Netherlands, and a (conditional) marketing authorization was granted for these vaccines by European Commission:

i. BioNTech/Pfizer's vaccine (Comirnaty) is conditionally licensed on Dec. 21, 2020.'![0]
ii. The vascin of Moderna (Spikevax) is conditionally admitted on Jan. 6, 2021.˚3'
AstraZeneca's vaccine (Vaxzevria) is conditionally licensed on Jan. 29, 2021.'3'
iv. Janssen's vaccine (3covden) is conditionally licensed on March 11, 2021.'*3

5.2.3 Said vaccines have therefore been admitted to the European market subject to conditions. These conditions imply that the manufacturers are obliged to provide additional information during the following two years, as soon as this additional data becomes available. For example, further research still needs to be conducted into (among other) the duration of

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130 Ef4A,'Comimaty **(COvjo-1g mRNA** Vacclne (nucleosidc mo4ified): An overview of Comimaty, including Its adapted vaccines, and why it 1s **authorized** in **me EU' (productle 6).** For fret full assessment report tie: httos'/ywww.+ma.euroȼ'a.eu/en/documenrs/assessment-reportYcomlrnaty-eoar-oubltc-assessment- regort gn Qgf.

i3i EHA, '5plkevax1 (COVID-19 mRNA Vaccine (nucicosida modified): and overview of **Spikevax,** Including Its adapted vaccines, and why it **is authorized in** the **' (ptoductia 7).** for fret full assessment **report** see: httos //www ema eurooa eu/en/dc'cuments/assessment-reoott/soikevax-orevfoustv-covid-19-vacctne-modeme-eoar-oublic-assessment-report and odr.

132 EMA, "Vaxzevrial (COvzD-:t9 vaccine **(ChAdOx1-S** [recombinant])}: An overview of vexzovria and why It is **authorized in the EU," (production 8}. For** the **fulllge assessment** report zfe: htt0s-/rwww ema eurooa eu/en/documentsYassessment-reoortYvzxzevda-prgvlogSly-Covid-G9-yaCCiny-ysttayeneca-eoar-ouDlic-assessment-reoort eF\ Ddf.

t33 ENA, '3covden1 **(COVTD-19 vaccine** 'Ad26.COv2-S (recombinant}j) M overview or 4covden and why it . **authorized in the EU* (productte 9).** For **the full assessment report** see: **httos-//www ema** euroDa eu/en/documents/assessment-reoorUcovid-t9-vaccine-fanssen-eoar-oublic-assessment-report and odf,

protection of the vaccines, how well the vaccines prevent serious COVID-19, how well it protects people with a less-functioning immune system, children and pregnant women, and whether the vaccine also prevents coronas. A conditional authorization is given only if (among other things) the benefit of immediate availability of the drug on the market outweighs the risk associated with the fact that additional data still need to be provided (see above in Sections 5.1.9-5.1.10).

5.3 The Health Council's advice

5.3.1 After the (conditional) approval of the vaccines by the European Commission for admission to the European market, the vaccines can be offered in the Netherlands.

5.3.2 The Health Council then advises the Cabinet on the use of vaccines by the State.'!° The Health Council assesses whether there is a significant disease burden and whether vaccination is effective, safe, acceptable and efficient. In doing so, the Health Council bases itself on *,peer-review'ed* and published scientific articles on the safety and efficacy of the vaccines studied, and on Ef-JA and data. The Health Council also advises on whether a vaccination should have a place in a public vaccination program. get, and on whether vaccination can be classified as essential care or individual care."!

> The recent report of the Research Council for Safety shows that the Health Council: 'has conscientiously followed its statutory task in its advice. The Advisory Board has been guided primarily by the state of science in its opinions."![6]

5.3.3 On December 24, 2020, the Health Council concluded that vaccination with Pfizer's vaccine is effective, sufficiently safe and acceptable, and recommended that the vaccine be used in public vaccination programs against Covid-19 **(production** 10)". The Health Council notes that although the vaccine has side effects, they are predominantly mild, short-lived and transient, and therefore the health benefits of vaccination outweigh the side effects.

'^ Research Council for Safety, *Addressing '::orona crisis. Volume Z,* p. 147, p. 131.

'°* Health Council, *The individual, collective and public interest of vaccination* (No. 2O13/21), The Hague, 2013, httos //www oezondheidsraad nl/documents/advice.iezen/2013/ T0/03/the-individual -yol1ecCi v n_ oublic-belano-of-vaccination.

"° Dutch Board, *Addressing corona crisis. Volume z,* p. 136

'' The production is the Health Council's summary. The full Health Council report can be accessed at." httos //www aealthcouncil nl/binaries/healthcouncil/documents/opinions/2020/l2/24/"ovid-19-vaccination-biontech-pfizer/Advice-COVID-19-vaccination-BioNTech-Pfizer *oat.*

534 The Health Council reached similar conclusions regarding the use of the Moderna vaccine (opinion dated January 11, 2021, **production 11)!", the** AstraZenecd vaccine (opinion dated February 4, 2021, **production** 12)[*3*], and the Janssen vaccine (opinion dated March 17, 2021, **production 13)."**[4]

5.3.5 Thus, the Health Council has advised positively on the use of BioNtech/Pfizer, f loderna, AstraZeneca and Janssen vaccines in the Netherlands.

> For completeness, the State points out the following.
>
> Between March 14 and March 22, 2021, the Netherlands stopped vaccinating with AstraZeneca's vaccine as a precautionary measure. Norway and Denmark reported adverse reactions. Thrombosis developed in six people under the age of 50, along with a reduced platelet count. However, the EMA concluded on March 18, 2021 that the vaccine's benefits outweighed the risk of rare side effects.'[4]'
>
> In early April 2021, the Lareb side effect center foundation reported that a Dutch woman had died after vaccination with AstraZeneca, due to thrombosis along with a lowered platelet count. A further five reports had been received about women between 25 and 65 years of age suffering these side effects after vaccination with AstraZeneca."[4]! These reports were similar to reports in other European countries.'[4]' As a precautionary measure, the Netherlands subsequently decided - partly in response to an advisory issued by the Health Council on June 2, 2021 - to no longer administer AstraZeneca's vaccine in the Netherlands to persons under the age of 60.'°°

5.3.6 Al therefore, only vaccines that - after review by the competent authorities - have been admitted (subject to conditions) to the European market have been used in the Netherlands. This means that the EMA considers the vaccines safe and effective. The Health Council has also advised positively about offering the vaccines in The Netherlands. Only then were the vaccines offered to the Dutch population by the State. The State

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'°® The production is the Health Council's summary. The full Health Council report can be accessed at: httos://www ohealthcouncil .**nl/Dinaries/healthcouncil/documents/opinions/2021/01/11/covid-j** 9-vaccination-moderna-vaccine-and-the-vaccinationstrateoie/Advice-COVID-19-vaccinati€'Naderna-vaccine-and-the-vaccinationstrateoie odf.

'°* Production is ele summary of **the Health Council.** The full Health Council report can be accessed at: httov//wvvw.oehealthcouncil nfbinaries/healthcouncil/documents£aäÜezen£2O2l/O2/04/cov -19-vaccination-astrazeneca-vaccine7Advice-COvlD-19-vaccination-AstraZeneca-vaccine *odf*.

'°^ **The production is the Health Council's summary. The full** Health Council report can be accessed at: hl:tas //www oezpndheidsraad nl/binaries/health sraad/documents/advice/2021/03/J7/covid -19-vaccination-Janssen-vaEcin/Advice-COVID-19-vaccination-Janssen-vaccine odf.
EI'4A, 'COVID-19 Vaccine AstraZeneca: benefits stili outweigh the **risks** ciespJte **possible link to** rare blood clots with low *blooa* p1atelets', httos //www ema euroDa eu/en/news/covid-1g-vaccine-astrazeneca-benefits-still-outweigh-risks-desoJte-possible-link-rare-bJood-clots.

'°' Research Council for Safety, *Addressing coronacrlsis. Volume 2,* p. 67.

'*' Lareb, 'Update reports of thrombosis with a low bleed plate count after corona vaccination,' May 2, 2022, httos //www lareb nl/news/uodate-reports-of-thrombosis-with-a-laao -aantai-bloedolate-after- corona vaccination.

'°^ Research Council for Safety, *Tackling coronacrlsis. Volume* 2,' p. 67; Health Council, Deployment of vaccines in current phase COVID-19 vaccination program (No. Z021/28), The Hague: 2021.

was allowed to rely on the review of the State-independent EMA and the advice of the State-independent Health Council.

6 No unlawful acts

61 Introduction

6.1.1 Despite the foregoing, plaintiffs take the position that the vaccines are not safe or effective. With this position, plaintiffs go against the scientific consensus that the vaccines are safe and effective. Only vaccines that have been tested and assessed by competent authorities, and found safe and effective by those authorities, have been used in the Netherlands.

These vaccines have also been used in the rest of the European Union (and beyond). Also globally, the approach of different countries in terms of vaccination policy is largely similar to the Dutch approach.

6.1.2 In the subpoena, plaintiffs - in defiance of the scientific consensus - take up the far-reaching and unsubstantiated contention that the State and several other defendants, moreover, would have known that the vaccines were neither safe nor effective, and yet would have called on the population to be vaccinated. This allegation again lacks any factual basis. As explained above, the vaccines are safe and effective and the State was entitled to assume the same. Moreover: plaintiffs do state a few things about what certain persons would have known at certain moments, but subsequently do not substantiate these statements. Where plaintiffs do make more concrete assertions about the safety and effectiveness of the vaccines, these are assertions based on incorrect information or assertions that legally inconclusive.

6.13 The State below.

6.2 "3rd does it for ee' other"

6.2.1 According to plaintiffs, the vaccines against Covid-19 would not prevent transmission. The motto "you're doing it for someone else" would be for that reason, plaintiffs said.

6.2.2 First and foremost, the State argues that this assertion of plaintiffs cannot in any case result in granting plaintiffs' claims. After all, even if hell would be the case that the motto 'you are doing it for someone else' would be incorrect (which is not the case), this does not mean that there is unlawful action. At most, that would mean that plaintiffs have taken a vaccine that helps only themselves (and not others). It is hard to see why that would be unlawful - let alone that it could support the claimed declaratory judgment, which speaks of "deliberately and on

unlawfully misleading" plaintiffs by inducing them to take vaccines against Covid-19 "which defendants knew, or at least should have known, were not safe and effective."

6.Z.3 Anyway: it is true that taking a vaccine against Covid-19 helps not only yourself, but also others.

6.2.4 Taking a vaccine contributes to increasing the vaccination rate, Increasing the vaccination board has the effect of reducing the chances of the virus . This is because after vaccination, humans develop antibodies against Covid- 19, and as such are protected against the . The chance that someone who has been vaccinated against Covid-19 will still be infected with the virus is less than for someone who has not been vaccinated, and also the chance that someone who has been vaccinated will infect another is less than for someone who has not been vaccinated. In this way, the spread of the virus is also dampened.

6.25 Thus, the more people have vaccinated against Covid-19, the less chance the virus has to spread. In this way, taking a vaccine helps protect others, including the vulnerable and those who cannot be vaccinated (e.g., for medical reasons) or do not want to be. Increasing vaccination rates and thereby dampening the spread of the virus also helps to reduce pressure on health care. In addition, persons who become infected with Covid-19 despite vaccination generally become less seriously ill and require less hospitalization. This leaves more care capacity available for those who do (urgently) need it. Furthermore, increasing the vaccination rate and thus reducing the spread of the virus contributes to the fact that restrictive and drastic measures to combat the virus (with all their), are not - or at least less - . This is in the interest of the functioning of society as a whole.

6.2.6 Vaccination against Covid-19 is thus - regardless of whether the vaccine prevents transmission - not only in your own interest, but also in the interest of others, for several reasons.

6.2.7 Moreover, it is true that the WHO, the ECDC, the OMT, the RIVN and the Health Council - experts who base their reports and opinions on scientific research - all endorse to a greater or lesser extent that Covid-19 vaccinations do help to9 coronavirus transmission. In this regard, the State refers to the following sources:

> ECDC's March 29, 2021 report ("Risk of SARS-CoV-2 transmission from newly-infected individuals with documented previous infection or vaccination*), which states, *"There is evidence that*

vaccination significantly reduces viral load and symptomatic/asymptomatic infections in vaccinated individuals, which could translate into reduced transmission, although the vaccine elTicacy varies by vaccine product and target group. in light of this , the total number of infections is expected to decrease significantly as vaccination coverage increases, provided that there is a match between the vaccine strains and the circulating virus strains. This will lead to decreased transmission overall.".''*

ECDC's report "Interim guidance on benefits of full vaccination against COVID-19 for transmission and implications for non-pharmaceutical interventions," dated April 21, 2021, which states*, "In summary, based on the limited evidence available, the likelihood of an infected vaccinated person transmitting the disease is currently assessed to be very low to low."^*

- The May 20, 2021 Health Council opinion "Transmission after vaccination," in which the Health Council concluded that vaccination protects the vaccinated against (severe) morbidity and mortality and contributes to a greater or lesser extent to the prevention of infections in others. [14]7

- The Of4T's opinion of May 24, 2021,[14]! in which the Oï'4T endorsed the Health Council's opinion and expected that the actual effect of vaccination in preventing transmission was itself underestimated. The OUT further emphasized - both the opinion of August 11, 2021'[4]! and in the opinion of September 13, [2021°S0] - that the probability of a vaccinated person carrying infectious virus is low. In its opinion of November 1, 2021, the ONT further writes that the prevalence of infection and is higher in unvaccinated persons and that the probability of transmission in an infection after vaccination is lower,[15°] Finally, it also follows from the OMT's opinion of November 11, 2021 that, according to the OMT, the residual risk of transmission and infection after vaccination is significantly reduced and even smaller than after a negative test. TS2

" See: ECDC, "Risk of SARS-Cov-2 transmission From newly-infected individuals with documented previous infection or vaccination," httgs y/www ecdc.europa.eu/en/oubhcations-dataysars-cov-2-transmission-newly-infected-inciividuatS-Drevious- Infection,

'4' See ECDC, 'Intern m guidance on the benefits oF full vaccination **against** COVfD-19 for transmission and implications for non-pharmaceutical interventions' 2I April 2021, p 9, accessed vla: httos'//www.ecdc euroDa eu/sltes/default/flles/documents/Interim-guidance-benefits-of-full-vaccination- against-COVID-19-for-transmission-and-implications-for-non-pharmaceutical- interventions odf.

'^' Health Council, **"Advice on** transmission after vaccinaEy," May 20, 2021, available at httos'//www oezondheidsraad nJ/documents/advice/2021/0S/zO/transmission-after-vaccination.

"° AdvJes n . a. of 114° ONT (part 2), May 24, 2021.

"^ Opinion n a v. 123- and 124° OMT, August 13, 2021 p. 5.

' Opinion n a v. 126th ONT, Sept. 13, , p. 6-7. '^' Opinion n a v. 128' OMT, November 1, 2021, p. 7.

°** Opinion following 130^ OMT, 'I1 November 2021, p. 7.

- RIVM I research also shows that vaccines against Covid -19 inhibit transmission of the Alpha variant of the virus.!'[3] That research shows (i) that transmission from vaccinated to vaccinated is 40% less than transmission from unvaccinated to vaccinated and (ii) that transmission from vaccinated to unvaccinated is 63"/o fTlinder than transmission from unvaccinated to unvaccinated.'!°

  The September 1, 2021 ECDC report ("Interim public health considerations for the provision of additional COVID-19 vaccine doses") points to another study that supports RIVM's findings, [1S']

- Research by the RIVf I on the "transmission pairs" in the period July and August 202:t, shows that in those months unvaccinated people in the Netherlands in particular caused further infection and - and that in the process they mainly infected other unvaccinated people. [15'6]

- RIVM has also been conducting a large-scale study of the langij ne effects of vaccination against Covid-19 since May 2021.![S'] That study, which includes surveys through March 14, 2023, indicates that the V'aCc/ne *Effectiveness against Transmission* (VET) for both the Delta and Omikron variants is 64°/o.'!

- In a news release dated December 1, 2023, the EMA confirmed, based on a large of scientific studies, that vaccines prevent transmission.°'! RIVM also points to a review of international research on the effect of vaccination on transmission, which shows that vaccination reduces the risk of further infection.'[60]

6.2.8 The State may base its policy on the opinions of these experts. This is settled case law.

['5'] De Gier et al, "Vaccine effectiveness against 5ARS-Cov-2 transmission and inrections among household and other close contacl:s of conFtrmed cases, the Netherlands, February to Nay 2021," *Eurosurveitlance* 31 2O21.

['5'] Other research also concludes clat vaccination prevents transmission, cf: D. W. Eyre et al, The impact of SARS-Cov-2 vaccination on Alpha & Delta variant transmission, available at: httos //www.ne m .oro/doi/full/ 70 1056/ne moa2116597.

[' 5] ECDC, 'Interim public health considerations for the proviS1on of aciditiona[COVID-19 vaccine aoses,' p. 14, *available for* consultation at: httos //www ecdc europa eu/en/publïcations-data/covtd-19-DUbliC-health-considyrations-additio¿ai-yaccjne-doses, p. 14. See also: EDC, 'Interim quidance on the benefits of full vaccination against COV1D-19 for transmission and implicatians for non-pharmaceutical interventions. "21 April 2D2 1

["] https //www tweedekamer nl/debat en vergadenno/committeeveroaderlnoen/detaiis?id= 2021AOS298.

['*'] RJvN, *The national immunization program in the Netherlands: surveillance and developments in 2022-. 2023 (RIvN report 2023-0330)', Bilthoven : RtVN 2023, p. 293-294. Available at: httos //www rivm.nl/library/raooorten/2023-0330 odf.

['®] RIVN, "The national immunization program In toe Netherlands: surveillance and developments in 2022-. 2023 {'RIVI'4 report 2023-0330}', Biithoven : RïVI*I 2023, p. 273-274.

['*^] EI IA, *COVID-19 vaccines key facts', updaret December 1, 2023, httos //www ema eurooa eu/en/human-reoulatorv-overview/Oublic-health-threats/coronavirus-diseaSe-covid-19/covid-19-medicines/covid-19-vaccines-kev-facts, with further references.

[*°] RIVN, The national immunization program in the Netherlands: surveillance and developments in 2021- 2022 (RIVN report 2022-0342), Bilthoven: RTVN 2022, p. 281 "In all sEudies where vaccination status was included it was observed Lhat vaccination of the Index reduced the SAR [secondary attack rate].", with further references there. Available at: httos //www rivm nl/library/raooorten/ 2022-0042 odf.

See, for example:

Court of Appeal of The Hague December 14, 2021, ECLI:NL:GHDHA: 2021: 2452, para. 6.17;
The Hague Court of Appeal Feb. 26, 2021, ECLI: NL:GHDHA:2021:285, para. 6.9;
- Rb. The Hague April 3, 2020, ECLI: NL:RBDHA:2020:3013, para. 4.8;
- Rb. The *Hague* July 24, 2020, ECLI: NL:RBDHA:2020: 6856, para. 4.12.

6.2.9 In conclusion, therefore, the State could have reasonably made the call for citizens to be vaccinated, and to do so not only for themselves but also for another person.

6.3 Graphene oxide

6.3.1 Plaintiffs still argue that the vaccines would be harmful to health because Pfizer and Moderna's Mrna vaccines allegedly contain Graphene oxide,'[6]' which plaintiffs claim would be highly toxic.'°°

6.3.2 The CBG's drug information database shows what substances are present in Pfizer°![3] and Moderna'*[4] vaccines. It shows that no graphene oxide is present in these vaccines. Nor have plaintiffs made it at all plausible that graphene oxide would be present in the vaccines of l-toderna and Pfizer.

On this, see also the fact check conducted by Reuters: Fact Check - No evidence graphene oxide is present in available COVID-19 vaccines via lipid nanoparticles.'! This also discusses the Karen Kingston video cited by plaintiffs and the (unrelated) patent number CN 11220919A cited by plaintiffs.

6.4 Pfizer-rannnrt

6.4.1 Plaintiffs further contend that Pfizer's vaccine would be dangerous.'** They base that contention on a report. That report, according to plaintiffs, would be a report of a clinical trial conducted by Pfizer in which subjects were vaccinated with the vaccine. In this trial, according to plaintiffs, 29,914 women, 9,182 men and Z,990 children participated. During this trial, 1,223 subjects allegedly died and 11. 36t subjects suffered serious permanent physical injuries, plaintiffs allege.

'*' Subpoena, paras. 151, 265; '°'
Subpoena, para. 154.
'°' CBG, 'Medicines Information Bank Com irnaty',
https:/*www gpnpes'nformationbank mini/rp17 774 7.
'°° CBG, "Drug infarmaEiebank Spikeva r",
n °l-ninfnrmationbank nl/nico12 7630.
Reuters, 'No evidence graphene pxide is present in available COVID-19 vaccines via lip'icl nanoparticles',
hfts< //www reut r< com/art n h n
a-lin ;L-nos-idf!Sf 1N2PI* XM/.
'*° See Report (productle 40 attached to subpoena) and Subpoena, paras. 143 - 144.

6.4. 2 However, a reading of this report submitted by plaintiffs reveals something different.

643 The report is not a clinical trial, but an analysis of vaccine side effects reported to Pfizer by various agencies from different countries.![6'] A total of 42,086 side effects were reported.1*

6.4.4 The numbers cited by plaintiffs of reports of 1,223 deaths and of 11,361 persons with serious permanent injuries, should not be contrasted with the ¢otaa/ *number of bij "actions* (42,086), as plaintiffs do, but with the *total number of doses shipped worldwide.* 3uisthe total number of doses worldwide, however, is omitted from the report submitted by plaintiffs as production. The number of doses shipped worldwide is critical to the interpretation of the report and the stated number of deaths and persons with serious permanent injuries.

> In that regard, the State also points to a report from the EMA showing that over 97 million doses of Pfizer's vaccine were shipped in the period December 21, 2020 to April 29, 2021.[6*] Although this period is longer than the period covered by the report cited by plaintiffs, it lows to the fact that the number of reported deaths and the number of reported persons with serious permanent physical injuries - compared to the total number of doses - is very limited, and also significantly smaller than plaintiffs make it appear. It should also be kept in mind that these are reports to Pfizer of deaths and persons with serious permanent physical injuries following vaccination. This does not mean that the death of these persons, or the suffering of serious permanent physical injury by these persons, is actually due *to* vaccination. This is all the more true since in the early days of vaccination - which is the subject of this report - the elderly and vulnerable in particular were vaccinated.

6.4.5 Therefore, it cannot be inferred from the report submitted by plaintiffs that the Pfizer vaccine would be dangerous.°'[O] Moreover, fs the Pfizer vaccine has been approved by the EMA, and the use of the vaccine in the Netherlands has been assessed by the Health Council. The State was entitled to rely on this.

6.4.6 Finally, neither has it been stated nor shown that plaintiffs have taken a vaccine from Pfizer. Thus, without further explanation, it is impossible to see what interest they have in these assertions and how that can lead to granting the requested declaratory judgment.

'[^7] Subpoena, production 40, p. 5.

'[^®] Of which 25,379 were *medically confirmed* and 16,707 *were non-medicaiiy confirmea.* Subpoena, production

'** ENA, "Assessment report on the annual renewaJ of the conditional marketing authorization," p. 16, hI?tDS'ilwww ema.euroDa eu/en/documents/variation-reDort/comirnatY-h-c-S735-r-0046-eDar-assessment-reoort-renewai and odr.

' In this Sentence, see also: NOS, 'Sources at #uproar over Pfizer papers,' July 31, 2022, httos 7/nos nl/news hour)collectle/13903/artikel/2438923-sources- bii-ooher-over-the-pfizer-oaoers.

6.5 Aarhus Convention

6.5.1 The plaintiffs further argue that the "Temporary Regulation on Different Treatment of Permit Applications for Gene Therapy in Connection with Combating COVID-19'°" would have violated the Aarhus Convention."[7]!

6.5.2 With the Temporary Regulation it was arranged that for the application for a permit for clinical trials with genetically modified organisms aimed at combating Covid-19, not the uniform public preparation procedure from the Awb was followed, but the regular preparation procedure. In any event - whatever else may be said of the plaintiffs' contentions - it is impossible to see that, had the uniform public preparation procedure been followed, the plaintiffs would not have laten vaccination, let alone that the failure to follow the uniform public preparation procedure could justify the conclusion that the plaintiffs were "deliberately and unlawfully misled by the defendants in order to induce them to laten Covid-19 vaccinations, which the defendants knew ... were not safe and effective." Therefore, the plaintiffs' argument about the Aarhus Convention in these proceedings lacks relevance.

6.5.3 There also no violation of the Aarhus Convention.

6.5.4 The basis for the Temporary Regulation!*! is the Environmental Management Act. Section 9.2.2.1 of the Environmental Management Act states that regulations are to be laid down by order in council with respect to, in brief, genetically modified organisms if a reasonable suspicion has arisen that actions involving them will result in undesirable effects on human health or the environment. If, in the opinion of the Minister, the expected or apparent effects for human health or the environment make it urgently necessary that a regulation be made and the making of an order in council cannot be awaited, the Minister may make a regulation (art. 9.2.2.6 Environmental Management Act).

6.5.5 The Temporary Regulation made use of the latter possibility. Because of the pandemic, the Minister deemed it necessary to introduce a ministerial regulation, thereby speeding up the licensing procedure. This was because it was of great importance that a vaccine could be developed as quickly as possible to combat the pandemic. This was also consistent with the wishes of the House of Representatives, which

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" StCrt. 2O20, 18941.
"* Subpoena, para. 132.
"^ This ministerial regulation in force between March 3t 202O and October 29, 2020. On October 292020, the regulation was repealed, because from that momenL the subject of the regulation was regulatedcl in Eu regulation 2020/1043. that ordinance was implemented mIddei of the introduction of **a new regulation,** again **pursuant** to art. 9.2.2.6 of the Environmental Management Act (Stcrt. 2020, 18941 and Stcrt. 2020, 54619. See also the Decree of 20 October 2D22 amending the Decree on genetic modified organisms environmental management 20 i 3 (implementing regulation {EU) 2019, 13B1 and (EU) 2020, 1043}, Stb. 2022, **407).** Plaintiffs mention **this new regulation** in the subpoena nlet.

had asked the minister to accelerate the licensing process so that new treatments and technologies, such as the vaccine against the new coronavirus, could be developed and tested more quickly."° That acceleration was accomplished in that the uniform preparation procedure was not followed with respect to the permit, but rather the regular preparation procedure. The arrangement did not compromise safety.[1]"5 Indeed, contrary to plaintiffs' claims, the requirement of doing an environmental risk assessment for licensing remained in place.

> Nor is this a marketing authorization for Covid-19 vaccines, "[6] as plaintiffs seem to believe, but an authorization to conduct clinical trials of in-development Covid 19 vaccines.

6. 5.6 The ministerial regulation does not violate the Aarhus Convention, which deals with access to information, public participation in decision-making and access to justice in environmental matters1. The purpose of the Aarhus Convention is to contribute to the protection of the right of persons to live in an environment adequate to their health and well-being (Art. 1). While the Aarhus Convention does provide, inter alia, for a system of public participation in decisions on the release into the environment of genetically modified organisms, it provides that, within the framework of national legislation, States Parties shall*, so far as possible and appropriate,* apply that system of public participation (Art. 6(11)).

6.5.7 The ministerial regulation significantly shortened the authorization process for conducting clinical trials. This fits within the possibilities offered by Art. 6(11) of the Aarhus Convention.

> The Hague Court of Appeal also previously ruled that the State had complied with its information obligations under the Aarhus Convention (ECLI: NL:GHDHA:2021:1094, para. 5.9).

6.5.8 Based on the ministerial regulation, four permits were issued - within the applicable legal frameworks - to conduct clinical trials with the Janssen vaccine.'[77] The granting of the permit was published in the Government Gazette and was to the possibility of objection and appeal.°* Plaintiffs did not avail themselves of that opportunity.

6.5.9 The Janssen vaccine was subsequently (i.e., after completion of the clinical trials) admitted to the European market after evaluation by the EMA and approved by the Health Council (see Section 5.2 above). The assessment of the safety and

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"[4] Parliamentary Papers II 2020/21, 25295, no. 180.
"[S] 2ie also the notes to this decision, Stcrt. 2021, 38878.
"° Indeed, that is what the ENA was about, as above. " Stcrt. 2020, 38A21.
'^ Stcrt. 2020, 38421.

effectiveness of this vaccine by these agencies took place after completion of the clinical trials for which a license had been granted. Thus, there is no question that by taking a vaccine against Covid-19, the plaintiffs participated in a clinical trial, as they claim."!!!

6.5.10 The State notes in this regard that it has neither been stated nor shown that plaintiffs have taken a Janssen vaccine. It is therefore impossible to see what interest plaintiffs have in their position on this point.

To the extent plaintiffs' contentions still refer to the Pfizer vaccine, they also lack relevance. The ministerial regulation does not apply to the Pfizer vaccine, because of the absence of genetically modified organisms in that vaccine. Again, moreover, it has neither been stated nor shown that plaintiffs took a Pfizer vaccine.

6.6 Oe three "excesses" alleged by plaintiffs

6.6.1 In the subpoena, plaintiffs cite three more somewhat surprising "examples of excesses" to which "the State's extremely reprehensible and objectionable acts and omissions" are alleged to have led.

6.6.2 As a first example, plaintiffs argue that Mr. Gates has made an investment in Heineken, and that Heineken has aired an advertisement in which the slogan *"the night belongs to the vaccinated"* is heard. This should have been countered by the State to protect its citizens, plaintiffs argue.'![0] However, plaintiffs do not make clear why this is the case and why bfailure to do so constitutes unlawful conduct by the State. The State is not responsible for Mr. Gates' investments or manifestations of Heineken.

6.6.3 The second example cited by plaintiffs is that there would be crimes of which ann officials should have aang iRe.'[®] * However, as explained above iS no crime has been committed, so this contention by plaintiffs fails.

Insofar as plaintiffs in that regard still point to communications to the municipality of Haaksbergen, for the sake of completeness the State notes that the municipality of Haaksbergen is not part of the public-law legal entity the State of the Netherlands.

6.6.4 Then, as a third example, plaintiffs accuse the State of having "threatened its citizens with death" via national television. To this end, the State allegedly made two "horrific video messages" and broadcast them through Postbus 51.'!!! The videos referred to by plaintiffs are not the State, and are

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"* Subpoena, par. 133.
'®° Subpoena, par. 258. '® ' Subpoena, par. 259. '*' Subpoena, par. 262.

also not broadcast through Postbus 51 (which, by the way, has not existed for a few years either). The first video was broadcast by the program "The Society," and is a reference to the Netflix series "Squid Game."® ! The second video was aired by the program 'Plakshot',°!° and is a variation on a drill rap.

On these videos, see also the answer to Van Houwelingen's parliamentary questions, Appendix Proceedings II 2021/22, 823.

6.6.5 Thus, of any unlawful han¢iels of the State, in view of the foregoing, there is no discussion.

6.7 The individual reproaches

6.7.1 It also follows from the foregoing that there is no question of wrongful conduct on the part of the various natural persons (wrongly) involved in these proceedings, who, as government officials, O/'4T members or otherwise, have in fact worked tirelessly to combat the pandemic. The - far-reaching - accusations made against these individuals are malicious and unfounded.

6.7.2 For the sake of completeness, the following is noted per person regarding the individual reproaches made. Here the order from the summons is followed.

6.7.3 *Hofstra.* Where plaintiffs refer to "Hofstra's opinions" (which would apparently be something different from ONT's opinions), it is not clear what they are referring to. Next, plaintiffs claim that Hofstra would have known that "the capacity of care not at risk." [6] It is not clear on what the plaintiffs base this contention. While it is claimed by plaintiffs that care capacity was scaled down from 1972, this is - whatever else is said about it - irrelevant to the question of what the care capacity during the corona pandemic actually was (and whether it was compromised). It has been explained in detail above that hospital and ICU staffing levels were under **(very) severe** pressure on several occasions during the pandemic, and that in an overall sense the pressure on care was high.'! Moreover, because of the exponential manner in which the number of infections and increases, ICU capacity would be without measures even at higher capacity for the foreseeable future. What plaintiffs' (bare) assertion about the PCft test has to do with the capacity of care is impossible to see. Further, plaintiffs point to pandemic drills that Hofstra supervised and the call for people to get vaccinated (including through an open letter and the vaccination campaign). That is not unlawful

'® * NPO, *The SpciëteiE', httD'2'//naa. nl/startYseries/de-societeit/season-2021/ele-societeit 35/afsoeien, from **38:34.**
'** **Subpoena,** production 90, second 00:05 - 00 :10 #plakshot Jn image appears.
'8' Subpoena, para. 29.
'® * Subpoena, par. 3D. ""
See par. 2.
®®Subpoena, paras. 31-32, 34.

- to the contrary. Plaintiffs' follow-up assertion that Hofstra knew in April 202t that (batches of) the vaccines were life-threatening and did not offer any protection against the virus,®is unsubstantiated and lacks any factual basis. Even it has not been explained which batches would have been involved, and that plaintiffs would have been vaccinated with those batches. Hofstra is not a "participant" in "the Covid-19 project."'[0] Plaintiffs then go on to argue that Hofstra should have , in short, the GGD's deployment of the "prophylactic bus" at schools.'[9]' These buses were deployed to an accessible way of vaccinating, including in areas with low vaccination g board.'

The assertion (without any explanation or substantiation) made by plaintiffs that these buses were deployed with the intention of persuading young people as young as 12 years of age to I get vaccinated without parental consent is incorrect. Moreover, this contention lacks relevance in these proceedings, as plaintiffs are adults.

6.7.4 *Van Dissel.* The plaintiffs claim that the OMT's opinions are "manifestly unlawful" and "wrong and harmful," but do not substantiate that at all (either). Moreover, these are opinions of the OMT, for which Van Dissel is not personally liable. Unsubstantiated and objectionable is the plaintiffs' claim that Van Dissel would have intentionally defended the Of-1T's opinions in "the knowledge that these opinions wrong and harmful. "[9]! AI equally unsubstantiated is plaintiffs' contention that Van Dissel is "connected to the bigger picture. "[9]° That Van Dissel ziCh has spoken out in favor of the vaccination policy and called on people to let themselves be vaccinated,!!!' is not unlawful - on the contrary - has been explained in detail above.

6.75 *Koopmans.* Plaintiffs suggest that Koopmans' appointment to a WHO investigation team was terminated because she served on the CDC in Guandong, China.[1]![6] The answers to earlier Parliamentary questions on this issue,°!* show that termination of Koopmans' appointment does not mean that there were questions about Koopmans' integrity. Illustratively, Koopmans continued to serve on other committees at WHO as usual and was a member of the OMT throughout the Covid-19 pandemic. It is incorrect (that Koopmans knew) "that Moderna had already started its Covid-19 vaccine trials in 2017" or that Covid-19 was "a project and not a disease," as plaintiffs - without even substantiation - state!!!! Plaintiffs further contend - also without any substantiation - that Koopmans had the aforementioned report from

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° Subpoena, par. 33. '°
Subpoena, par. 31. '^' ,
par. 34.
"" RJVM, "Influence of prods on vaccine coverage," Sept. 12, , hLLDS"//www rivm nl/aedraoson¢ierzoek/invloed-arikbussen-oo-vaccinationoraad.
' Subpoena, para. 36.
'*4 Subpoena, para. 36.
'**° Subpoena, par, 3B.
'°° Subpoena, par, 40.
'^' AppendixJ Proceedings II 2020/21, No. 1372.
'*® Subpoena, para. 41.

Pfizer,'!!! but also do not substantiate that at all, leaving aside that it does not follow from that report what plaintiffs read in it (see par. 6.4 above). Furthermore, the claim that *the defendants* concealed important information from the or spread incorrect information is unfounded. There is also no question of Koopmans "concealing" her role in the Disinformation Think Tank, as plaintiffs claim! - leaving aside the question of why that would unlawful. It is further factually incorrect that the vaccines were harmful. It is also factually incorrect that Koopmans would have possessed information from which it would have followed that the vaccines harmful, as plaintiffs - qualitatively enough - claim.![10]'

6.7.6 *Rutte.* Rutte is not a "prominent member" of the WEF!!!! He is listed as an author on the WEF's website (plaintiffs' production 11) because he once wrote an article published on the WEF's website.![03] Exactly what plaintiffs intend to suggest with the two photos of Rutte and Mr. Schwab (also production 11) remains unclear, as does why those photos would " the relationships between Rutte" and Schwab. Incorrect is that Mr. Schwab would be "the superior" of Rutte, as plaintiffs stellen![O°] - but only substantiated by reference to a letter (plaintiffs' production 12) which, according to plaintiffs, would show that the president of the WEF "instructs" Rutte to ensure that the Netherlands leads the reforms to be implemented in Europe as part of the "Great Reset. That is not what that letter says. Nor is there any mention of Rutte accepting an assignment from the WEF on Covid-19, which Rutte executes on behalf of the WEF. It has been further explained in detail in the foregoing that - and why - calling on the population to get vaccinated against Covid-19 is not unlawful, but rather that the positive obligation of the State to protect public health was thereby fulfilled. This applies unreservedly to Rutte's statements cited by plaintiffs - and, for that matter, to the statements of all other defendants.![05] It is damaging - and factually incorrect - for plaintiffs to argue that Rutte knew that "the narrative regarding the so-called Covid-19 pandemic was untrue and that the Covid-19 injections - particularly certain batches - cause serious bodily harm." This claim is also not substantiated at all, as is the subsequent claim that Rutte allegedly misled the bevolki-9.[206] The other accusations made against Rutte (such as propagating that taking a vaccine also helps someone else) have been discussed at length in the above.

'"' Subpoena, para. 42.
'^^' Subpoena, par. 45. '°'
, par. 4'i. '°' , par. 47.
[2^'] hrtos y/www.teforum.oro/agenda/2017701/water-shaoed-mv-countrvs-oast-it-wili-shaDe-the-future-for-all of-us/.
^^^ Subpoena, para. 48.
[2^] Subpoena, paras. 49-54.
[2°"] Subpoena, para. 55.

6.7.7 *Kaag.* Kaag is not a "prominent member" of the WEF,!0* did not "go to work for the WEF," was not part of a WEF think tank in which "plans [were] devised for implementing an Eotal realignment of, among other things, Dutch society,",° is not working on (devising or implementing) "the Great Reset" or "the Covid-19 project" and is not making a case for its implementation.[2] * AI these assertions by plaintiffs are not substantiated in any way. The video clip that plaintiffs cite in that regard (plaintiffs' production 16) has an unclear origin and appears to have been taken out of context (moreover, it lappears to have been cut). : Kaag is not 9ecommitted to the "Build Back Better commissioned by the WEF and the UN" not to mention that not being explained what that would entail and why that would be unlawful. The letter that plaintiffs submit in that regard (plaintiffs' production 17) is addressed to WHO and concerns a letter in which Kaag states that she is no longer available to serve on 's Global Prepared ness Monitoring Board. Thus, this cannot support plaintiffs' contentions. Factually incorrect is that (Kaag knew that) "many people died at Pfizer trials and thousands of people suffered grievous bodily harm", as plaintiffs - again: without any substantiation - state."!O Where plaintiffs still talk about the "exchange of information" between the Ministry of Finance and the WEF,[2]" in fact it concerns the sending of invitations by the WEF and the answering of those invitations, as appears from the production 20 submitted by plaintiffs themselves. Finally, it is also incorrect that Kaag "knows that there is a false narrative. "[2 2°]

6.7.8 *De Jonge.* De Jonge is not a "prominent member" of the WEF. Nor can this be inferred from the (single) circumstance that De Jonge is mentioned on the WEF website, as plaintiffs seem to think.!'[3] Nor is there any question of De Jonge carrying out a task 'assigned' by the WHO or WEF.[214] Plaintiffs' assertion that there would have been 'military psychological behavioral influencing tactics', aimed at arousing great fear and with the purpose of misleading the population, lacks any fact1y basis. Nor does anything of the sort follow from the quotes cited by plaintiffs, which, incidentally, have nothing to do with vaccination either.'[1]' Nor does follow from plaintiffs' production 22, which piece, incidentally, does not come from De Jonge (but is part of the Catshuis briefing of November 1, 2020, and has been made public as an appendix to the December 8, [20202'6] parliamentary letter). That calling on the population to I get vaccinated is not unlawful has been extensively discussed above

*°' She did serve, among other things, on the Giobaï Action Group and was a member of *ae* Niclclie East and Africa stewardship board. On this, see Appendix Handelinqen U 202l/22, 2541 (response to questions 20 and 68, and ppk the response to question 14).
'°® Subpoena, para. 61.
' °° Subpoena, paras. 61-64.
'" Subpoena, par. 66.
" Subpoena, paras. 67-69.
" Subpoena, para. 69.
"* Subpoena, par, ?3.
2'° , par. 73-74.
"° Subpoena, paras. 74-76.
'*° Status letter COVID-19 dated December 8, 2020, reference 179235 3-215138- PDC19.

explained. Plaintiffs' claim that De Jonge deliberately misled many people and deliberately endangered their lives and health!"[7] is objectionable, especially since any substantiation for this claim is lacking. Furthermore, as early as June 2020, the Netherlands, Italy, France and Germany (the Inclusive Vaccine Alliance) made agreements with vaccine developers to supply vaccines to Europe if vaccine development went well!'! Later, the European Commission adopted this, and entered into so-called 'advance payment agreements' on behalf of all European Union member states with providers of a promising candidate vaccine against Covid-19.![1]! To the extent plaintiffs argue that De Jonge wrongly stated that money was invested (by the Netherlands) in the development of vaccines,'![0] that is therefore incorrect. Finally, the plaintiffs' accusation that De 3onge's comparison to frikandells (to illustrate that people not know exactly what is in them, but do eat them) "is unworthy of a minister and in flagrant violation of the fundamental provision of Article 7 ICCPR "[22]' (the prohibition on torture) is indicative of the line of reasoning in the subpoena, and is self-contradictory.

6.7.9 *Kuipers.* It has already been explained in the foregoing that there indeed a shortage of ICU beds, and that care came under great . Plaintiffs' accusations against Kuipers in this regard (and with which they deny it) are therefore unfounded!!!! It is further factually incorrect that Kuipers directed to vaccinate people with a vaccine that was not !!![3] This is also not at all evident from what plaintiffs state in this regard, nor from production 27 of plaintiffs. At the time of the alleged expressions (December 30, 2021), Pfizer's vaccine had already been authorized by the EI'-1A, and the Health Council had also already given a positive opinion about that vaccine (see par. 5 above). It is also regrettable that plaintiffs state that "Under the responsibility of Kuipers, these injections are still being administered to mostly defenseless people without any form of informed-consent, and the harmful effects of the Covid-19 injections are being concealed by Kuipers. "[224] It has already been explained above that this is incorrect, leaving aside the fact that any form of substantiation of this claim is lacking.

6.7.10 *Gommers.* Plaintiffs' contentions about Gommers largely amount to a repetition of the aforementioned already refuted - unsupported - contentions. Reference is made to that earlier refutation. What is new is that plaintiffs state that Gommers "adjusted his tactics of influencing behavior" and would have pretended to have a critical attitude in order to influence people.

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[217] Subpoena, paras. 78 and 85.
[218] Central government, "I lagged corona vaccine contracted for Europe," 1Z June 2020, https //www.rijksoverheid.nl/onderweroen/coronavirus-tiidliin/nieuws/2020/06/ 3/mooeInk- corona vaccine-pre-eurooa contracted.
[219] Parliamentary Papers Al 2020/21, 25295, no. 565.
Dagvaard Ing, par. 83.
Dagvaard Ing, par. 84.
Subpoena, para. 94.
[223] Subpoena, paras. 95-97.
[224] Subpoena, para. 99.

affect.[22]' This is nothing more than plaintiffs' own theory, which no substantiation. It is incorrect (that Gommers knew) "that what he was doing would lead to enormous harm to the Dutch population."[226] The same is true of the serious suggestion that Gommers would have had the intention that people in care would be , so that care capacity would be further reduced. "* These - evil - assertions are also not substantiated at all.

6.7.11 *Hoekstra.* It is also incorrect with respect to Hoekstra that he is a "prominent member" of the WEF, as plaintiffs claim.°° This also does not follow from the image of the WEF website submitted as production 31. Nor is Hoekstra a proponent of "the project Covid -19: The Great Reset." Nor is this assertion substantiated other than by reference to a letter. That Hoekstra was invited to a meeting of the WEF,[2°]! is obviously not illegitimate. Nor was this correspondence conducted "in secret." The inferences that plaintiffs make on the basis of this letter about the hierarchical relationships between them are based on nothing more than the circumstance that Mr. Schwab in another letter addresses Hoekstra with "Dear Minister," while conversely Hoekstra addresses Mr. Schwab with "Your Excellency, "[30] and are thus far-fetched. Oe far-reaching inferences that plaintiffs
attach to this letter are incorrect and find no support in the text of that letter. There is no question of an unconditional commitment by Hoekstra to cooperate with "the Covid 19: The Great Reset project. "[3]' Why the corona support package that plaintiffs still cite'!!! would be unlawful is impossible to . It is further incorrect that (HoeMtra would have known that) the vaccines would not safe or effective, and any substantiation for that claim is also lacking. The claim that Hoekstra would have abused his office as Nlinister of Finance is incorrect and malicious.

6. 7.12 *Van Nieuwenhuizen.* In fact, the plaintiffs' accusation against Van Nieuwenhuizen refers only to the plaintiffs' alleged violation of the Aarhus Convention. There no such violation, any more than there is participation in a clinical trial by taking a Covid-19 vaccine, as explained above {par. 6.5). In any event, that mere allegation cannot support the declaratory judgment sought against it - in : that there was intentional deception, with knowledge that the vaccines were not safe cannot carry.

6.7.13 *Sijbesma.* Sijbesma was asked by the cabinet to lend a helping hand as special envoy corona, and began his work on March 26, 2020

" Subpoena, para. 106.
22a , pars. 108 and 109.
" Subpoena, par. 109."®
Subpoena, par. 112. "' ,
par. MS.
*'° Subpoena, par. 113. "'
Subpoena, par. 124. "'
Subpoena, par, 12s.

commenced, As special envoy corona, Sijbesma (i) focused on exploring the options for testing capacity; and (ii) brought the developments surrounding possible corona vaccines into kdart (so that the Netherlands would the option of possible vaccines available).'°° Sijbesma fulfilled the role of special envoy corona in a personal capacity, voluntarily, unpaid and without reimbursement of expenses. Sijbesma functioned as an advisor, scout and connecting link between the State and the (international) business community. He had no authority on behalf of the State to determine or implement the testing or vaccination policy, or to enter into contracts on behalf of the State, as also appears from the news item about **Sijbesma**'s role on rijksoverheid.nl that plaintiffs themselves submit (as production 56). Nor did Sijbesma have any role related to vaccine safety. Sijbesma was special envoy through September 2020. Thus, by the time the Netherlands started vaccinating (in January 2021) and plaintiffs were faced with the choice of whether or to do so, Sijbesma was no longer an envoy for quite some time. Contrary to plaintiffs' suggestion, the role of special envoy corona had![4] no direct connection to Sijbesma's capacity at that time as a (former)
)director of several companies and involved in several international organizations. As stated above, he fulfilled that role in a personal capacity. Nor was Sijbesma appointed as special envoy corona in the capacity of representative of a "non-governmental organization such as (NGO, WEF)" (or of the WBG), as plaintiffs apparently believe. It is incorrect that Sijbesma is an outspoken advocate of a "total realignment" as plaintiffs claim.[2]![5] This contention is also not substantiated by plaintiffs. The plaintiffs' position that ties to Sijbesma's WEF (and the other defendants) were intentionally disregarded in Sijbesma's appointment as special envoy!!° lacks factual basis.'3* Nor is Sijbesma a "global plan." To the extent plaintiffs argue that there was no shortage of testing (and reproach Sijbesma in that regard),[2°®] the incorrectness of that assertion(s), including assertions about the WITS database with which Sijbesma also has nothing to do, nor had access to, is already apparent from the foregoing (see Section 2.3.3). Thus, Sijbesma did not, as plaintiffs call it, participate in a "lie" or hea presentation of facts in the April 12, 2020 Buitenhof-external that would have "demonstrably false." This yet tbs' of it that that contention(s) of plaintiffs about testing are irrelevant to the claim
eh of , which after all pertain to vaccinating. The connection between the Rothschild patent cited by plaintiffs, connecting "everything, and beforehand @ bodies of people, via the 5G and 6G Internet technology",[2]'! and this , remains guess after reading the subpoena unclear. These contentions, or rather theory,

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°'°See also hÈtps://www,rijksoverheid.nl/documents/pubiications/2O20/0B/13/explanation-role-feike-sijbesma-as-special-authority-corona.
'^° Subpoena, pa r. 1B5. '^'
Subpoena, para 186. [2]^^
Subpoena, para 187.
'^' There is also no question that **this was concealed. The** WEF website lists which individuals in what ways are involved in the wEF and that Sijbesma has been a member of the Board of Trustees since 2019.
[2]'° Subpoena, par. IB?-194.
"° Subpoena, para. 196.

are (also) unsubstantiated and unsupported. Sijbesma has (had) no involvement in this. It is also untrue (that Sijbesma would know) that Covid-19 is a project and not a disease, and is "fully and completely familiar with and involved in the Covid-19 project that is to to the Great Reset" and that this would be the real reason he would have been made a coronagezant.![4]° Again, any factual substantiation for these assertions is lacking. Plaintiffs' suggestion that Sijbesma received instruction, direction or otherwise from the WEF is incorrect and lacks any factual basis, nor is there any question of Sijbesma implementing "The Great Reset. The same applies to plaintiffs' assertion that Sijbesma would have acted unlawfully by making or failing to make statements in the Buitenhof broadcast mentioned above. Therefore, plaintiffs' assertions that Sijbesma would have put on a "play", widely reported in the media,^([4])' are incorrect and lack any factual foundation, let alone that there would have been any deception by Sijbesma.

6.8 SIOt5OITi

6.8.1 Concluding from the above, there is no question that plaintiffs were intentionally and unlawfully misled in order to thereby induce them to have Covid -19 injections of which defendants knew, or at least should have known, that these injections not safe and effective. Therefore, the claimed declaratory judgment cannot be granted. There is no question of any wrongful act - let alone of any form of group liability pursuant to Section 6:166 of the Dutch Civil Code.

6.8.2 It also follows from the above that there is no violation of art. 97a Sr (leaving aside that the question of whether that is the case is not for the civil court). None of the defendants has associated themselves in any way with a person or body established abroad with the aim of (i) inducing such a person or body to provide support for the preparation, promotion or bringing about of revolution, or to reinforce such a or body in the intention drawn up for this purpose, to promise assistance or to provide such assistance, or with the aim of (ii) preparing, promoting or bringing about such a revolution.

6.8.3 The relevant means of proof available to the State to plaintiffs' contentions are attached to this conclusion as exhibits. The State offers - in so far as the burden of proof may rest on it pursuant to Section 150 Rv and in the context of any rebuttal evidence - to prove all its contentions by all means in law.

+[4]^ Dagvaard Ing, par. L99.
**' Subpoena, paras. 188 and 184.

7 Causation and the alleged injury

7.1 For the sake of brevity, the State nop notes the following about causation and the damages alleged by plaintiffs.

7.2 Plaintiffs claim to have (letsel) damages. In support, plaintiffs refer to "diagnoses" by "medical specialists. "[242] However, these appear to be seven documents signed by the same doctor. These documents read more like an indictment of Dutch vaccination policy than a medical statement. For example, in several of the statements, the following - similar passage to : Ê43

> *"Given the concealment of side effects and the giving of* v'acc/ris *that have not yet been fully tested and investigated, under the guise that there was an emergency, confidence in the government about the vaccines and the message the government was delivering has completely disappeared. Given the IFR figure, there was never a medical emergency and the mortality rate of*
> *Corona compliant influenza. This figure by itself does not justify any action taken by the government and does not justify the need to administer vaccines. Nen got over this entirely. There was no ex post medical necessity and therefore no crisis situation and therefore no pandemic posing a danger to humanity worse than the annual flu."*

Such a passage has no place in a medical statement. The doctor who signed the statements evidently adheres to the same theories as plaintiffs,[2°4] That alone detracts from the neutrality, objectivity and reliability of the statements. For this reason alone, the statements cannot be given the value that plaintiffs attach to them.

7.3 Moreover, it is even questionable whether these are statements of a doctor, and not statements of plaintiffs themselves. After all, the opening sentence of these statements reads *"Hereby follows a medical statement <u>of the above-mentioned patient</u> about his health and his situation (...)"* (emphasis added). No medical or special authority can therefore be attributed to these statements either.

7.4 Plaintiffs claim that they suffered physical injuries as a result of the graphene oxide allegedly contained in the Covid vaccines.'°'

7.5 According to plaintiffs' contentions, there would be graphene oxide in the mRNA vaccines (the vaccines from Pfizer and Moderna). That plaintiffs have been vaccinated with such a vaccine

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'*' Subpoena, para. 265.
*◦ ' Subpoena, production 91, p. 1, 3, 5, 9 8 J3.
2ie also the "I Ïanifesto of Alexander van Walraven to all doctors of the Netherlands," available at <u>httos:/ywww .youtube corru'watch?v=sOoNZOaa mU.</u>
'" Subpoena, para. 265.

(and if so, with wełke then), is not explained or substantiated. This already stalls. The State has already explained above that the vaccines do not contain graphene oxide (para. 6.3). Graphene oxide from the vaccines therefore cannot be the cause of the damages alleged by plaintiffs. But even apart from that, the alleged damages are insufficiently plausible.

Plaintiffs 1 tim 3 and 5 acknowledge that there are currently no external physical signs of serious physical injury. They do, however, allege that there are minor complaints. This assertion is not concretized or substantiated in any way. Even the statement does not mention any concrete physical complaint. On the contrary, that statement implies that these plaintiffs have üone complaints ("He himself has no complaints yet"). Thus, according to their own statements, these plaintiffs have no injury.

Plaintiffs 4, 6 and 7 allege that they suffered serious physical injuries as a result of the Covid vaccines!!![4]! However, the statements submitted - whatever else they may be, see above in paras. 7.2-7.3 - do not show that the alleged bodily injury was the result of the Covid vaccines. Plaintiffs do claim that, but any form of (medical) substantiation for that claim is lacking - in fact, it is only bare assertions by plaintiffs themselves.

- Plaintiffs 4 and 6 allegedly developed Parkinson's as a result of the vaccine. In this regard, the State points out that the determinants of Parkinson's are largely unknown. The statement provides no substantiation for the claim that the vaccine would the cause of Parkinson's. It is incorrect that Parkinson's would on the side effect list for the mRNA vaccines,[24]' Nor is this evident from the Lareb side effect list.'[4]!

- With respect to Claimant 7, the statement identifies the vaccine as the cause of a TIA. It is stated in that regard that "the vaccines" cause clotting problems. This is not evident from the list of side effects in the package inserts for the mRNA vaccines.[2°]! The comment in the statement that a TIA is a side effect of the vaccine

---

^°^ Subpoena, para. 265.
'°' ENA, 'Appendix 1: summary of proäuct characteristics **Comirnaty',**
httos //www ema eurooa eu/nï/documents/oroduct- information/comirnatv-eoar-oroduct-infarm ation nl odf.
ENA, ' Appendix 1: summary of product characteristics **Spikevax',**
httDS'//www ema eurooa eu/en/documents/oroduct-information/soikevax-oreviouslv-covid-t9-vaccine-moderna-eoar-product-information en odf.
'°® Lareb, 'Side effects coronavaccines', httos //www lareb nl/bi\werkinoen-coronavaccinesaofizer
[4]° EI'4A, 'Appendix 1: summarylnq of product characteristics Comirnaty'.
EI-)A, 'Appendix 1: summary of product characteristics Spikevax'.

is "until proven otherwise," does not hold up either scientifically or legally.

7.6 Claimants further allege that they have suffered immaterial damages (apparently: mental injury within the meaning of Art. 6:106 BW°50). Although all seven plaintiffs claim to have suffered mental injury, only five of the declarations mention this. For the other two plaintiffs even that form of substantiation is lacking. But even where the statements do mention mental harm, it is insufficient. These statements are hardly concrete, and completely (or nearly) identical. Therefore, these statements are insufficient substantiation for even the plausibility of the alleged immaterial damage.

7.7 All in all, plaintiffs have not made it sufficiently plausible that they have suffered damages as a result of the vaccine. The State recalls that plaintiffs have not even made it plausible (i) that they have left themselves to be vaccinated, (ii) which vaccine is involved, (iii) at what time or times this place, and (iv) what information from which defendant guided each of them in doing so. Already with that, they have also failed to make it plausible that they were induced to take a Covid-19 vaccination by "intentional deception" on the part of defendants.

7.8 Finally, in this regard, the State points out that everyone in the Netherlands has always been free to make their own considerations with regard to whether or not to take a vaccine, to form their own opinions about the usefulness and necessity of vaccination, and to choose not to laten vaccination. Some twenty percent of the adult population has also chosen not to I get vaccinated. Plaintiffs have also had that choice.

8 Conclusion

The State et al. conclude:

i) rejecting the claim;

ii) jointly and severally order the plaintiffs to pay the costs of the proceedings, with the stipulation that statutory interest shall be payable on this order for costs from the fifteenth day after the date of the judgment to be rendered in this matter;

iii) ordering the plaintiffs jointly and severally to pay the follow-up costs in accordance with the liquidation rate budgeted at€ 173 or, in the case of service, C 271;

iv) with declaration oat these cost orders are enforceable.



handled by R. W. Veld huis and M.E,A. Möhring P.O.
correspondent e Box 11756, 2502 AT The Hague
teefoOn +31 70 515 3793
e-maii reimer.veldhuis@pelsrijcken.nl
case no. 11020625

it, ';cwe :B D-ouglocve' -oruqn> v

State/je.s. C/17/190788 / HA ZA 2023-172

Inventory productions conclusion of reply

1 Jean Dohmen, "How the Great Reset was hijacked," *FD* Jan. 22, 2022

2 Images of the banners hung

3 Various screenshots of posts on X (formerly Twitter)

4 a. 4an Westera, "In vain to court for case against Bilt Gates," *Leeuw.arder Courant* Nov. 23, 2023

b. Image truck from aforementioned article

c. Screenshot of a message on X (formerly Twitter)

5 Screenshot from StatLine website 'Population trends; month and year'

6 EMA, "Comirnaty(COVIO-19 mRNA Vaccine (nucleoside modified): An overview of Comirnaty, including its adapted vaccines, and why it is authorized in the ',

7 EI' tA, 'Spikevax 1 (COVID-19 mRNA Vaccine (nucleoside modified): An overview of Spikevax, including its adapted vaccines, and why it is authorized in the ",

8 EMA: 'Vaxzevria 1 (COVID-19 Vaccine (ChAdOx1-S recombinant]): An overview of 'Vaxzevria and why it is authorised in the '

9 EMA, "Jcovden1 (COVID-19 vaccine (Ad26.COV2-S [recombinant]). An overview of Jcovden and why it is authorized in the '

10 Health Council, BioNTech/Pfizer summary Dec. 24, 2020

11 Health Council, Moderna vaccine summary and vaccination strategy Jan. 11, 2021

12 Health Council, AstraZeneca vaccine summary Feb. 4, 2021

13 Health Council, Janssen vaccine summary March 17, 2021

1



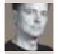
BE5TUR

Hoe de Great Reset werd gekaapt

Gomplot thinkers hijacked World Eoonomio Forum boss Klaus Hohwabs idea for a Great Reset. Faotcheckers have been tiirling their fingers blue for a year and a half to debunk all the uomplot stories. 'That term werlite like a red rag to a bull.'

O Read ver der on pag'iila lö

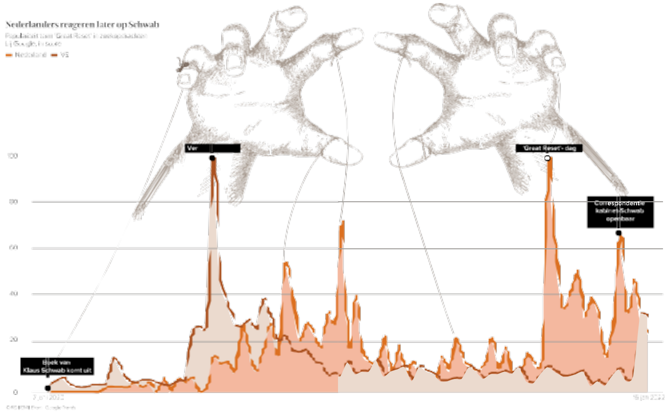




Jean Dohmen is redacteur economie van Het Financieele Dagblad

Vervolg van pagina 17

Geen complottheorie is zo hardnekkig als die over de Great Reset. Anderhalf jaar houden complotdenkers zich vast in de gedachte dat de 'woke' elite ...



'De echte angst van complotdenkers is misschien wel dat er géén complot is'

Maarten van Rossem

KANAAL OP TRUMP

PUINHOPEN

In het kort

Complotten: geplande pandemie, massa-onteigening en uitroeiing

Wetenschappers hebben al decennia gewaarschuwd voor het groeiende gevaar van pandemieën

VERSPREIDING NEPNIEUWS

2


FEIKE SIJBESMA
(WEF)
In Friesland gedagvaard
RechtOprecht.online


SIGRID KAAG
(WEF)
In Friesland gedagvaard
RechtOprecht.online


MARION KOOPMANS
(Viroloog / OMT)
In Friesland gedagvaard
RechtOprecht.online


DIEDERIK GOMMERS
(OMT)
In Friesland gedagvaard
RechtOprecht.online


HUGO de JONGE
(WEF)
In Friesland gedagvaard
RechtOprecht.online
VERBODEN
TOEGANG


MARK RUTTE
(WEF)
In Friesland gedagvaard
RechtOprecht.online
Dit is een openbare mededeling inzake een gerechtelijke procedure voor de rechtbank (art. 121 Grondwet)

3

Sharing people, the responsible tuïg is finally coming to !!!

Translate pestilence

Together For Holland

The first media canvases have been posted. And these cannot be censored or ignored by the media. For more info, visit www.RechtOprecht.online









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Lawyers from the "Right to " foundation have DAVIDED Rutte, Kaag & Marion Koo pmans, among others, on behalf of victims of vacci nation damage! There must retribution!

Do a & RT aJs you can't wait to them!

Translate post



7:48 PM Aug 8, 2023 5s Vie'.vs.

216 801 2.3K 5

4a

Leeuwarder Courant, 23 november 2023, pagina 22.

Vergeefs naar rechtbank voor zaak tegen Bill Gates

JAN WESTERA

LEEUWARDEN The **Recht Oprecht lawsuit drew a handful of sympathizers to the Zaailand, in front of the court building in Leeuwarden, on Wednesday.**



Sympathizers of Straight Straight gathered Wednesday in the square in front of Leeuwarden District Court. FoTo. LC

Right on election day would be the af- kick of their lawsuit on behalf of ze- ven people who claim they were harmed after their vaccinations against Covid-19 and are still suffering.

According to the foundation's two lawyers, Peter Stassen and Arno van Kessel, one of the seven victims died in October. They reported this in their own news broadcast, without mentioning the cause of death. According to Stassen, it was a Si aged care employee who had had the vaccine "put on for someone else.

The Frisian foundation Recht Oprecht (Straight Straight Foundation) has been calling the what they see as seventeen far- causers of this and other scha- de in Leeuwarden sued.

Among them are American billionaire Bill Gates, Mark Rutte and Everhard Hofstra, who lives in Friesland. The latter was part of the so-called Outbreak Management Team that the Dutch government advice to.

The supporters of Recht Oprecht did not the courthouse on Wednesday. According to spokesman Anno Rijpkema of the District Court of Northern Netherlands, there was not much to there either. As Rijpkema explained, there was no question of a real sitting; it was a "role sitting".

In it, the role judge deals purely formally with how this process will have to proceed. "So the role judge deals with the procedures, not the content," Rijpkema points out. "And today the judge hasn't done anything."

However, Rutte, Gates and Hof-

Lawsuit on behalf of seventeen people over harm from covid vaccinations

stra and the other fourteen defendants were given an additional six weeks by the court to respond to the indictment issued to them by the Recht Oprecht Op i4 July foundation.

"The further handling by the judiciary will depend in part on the content of that answer," Rijpkema said. "And only then will the judge be appointed who will deal with the substance of the case. That may also be a plurality judge."

But, states Rijpkema, "at this moment we only have a summons with attachments" from Recht Op- recht. Lawyer Van Kessel tells in own newscast that the country's lawyer is acting on behalf of 12 defendants. He also says that Gates' own lawyer in Ame- rica took delivery of the subpoena. According to him, the billionaire has not yet hired a lawyer to defend himself in the Straight Up case.

Since the case against the seventeen is pending, the foundation has moved from a farm on the Warstienserdyk in Wergea to business premises on the Ceresweg in Leeuwarden. There are also changes within the board. Treasurer Jeroen Laurens Maximili- on Cornelis Evers and Secretary Marcel Johan de Haan are no longer active as directors, according to data from the Chamber of Commerce. Ritske Blom from Wergea is still a director from the very beginning, the only other director is currently Helena Hendrika de Vries.

4b


WANTED
Coronavaccin = vergif
Media = fakenews
We worden belazerd
375.000 prikdoden in EU
24 miljoen ernstige
bijwerkingen in EU
Het klopt niet
Media = schuldig
GGD's zijn medeplichtig
Kinderen zijn onze toekomst
en geen proefkonijnen
Vaccinazi macht vrij!!!

4c

Klaar voor morgen. Plein t Zaailand tegenover het gerechtsgebouw!

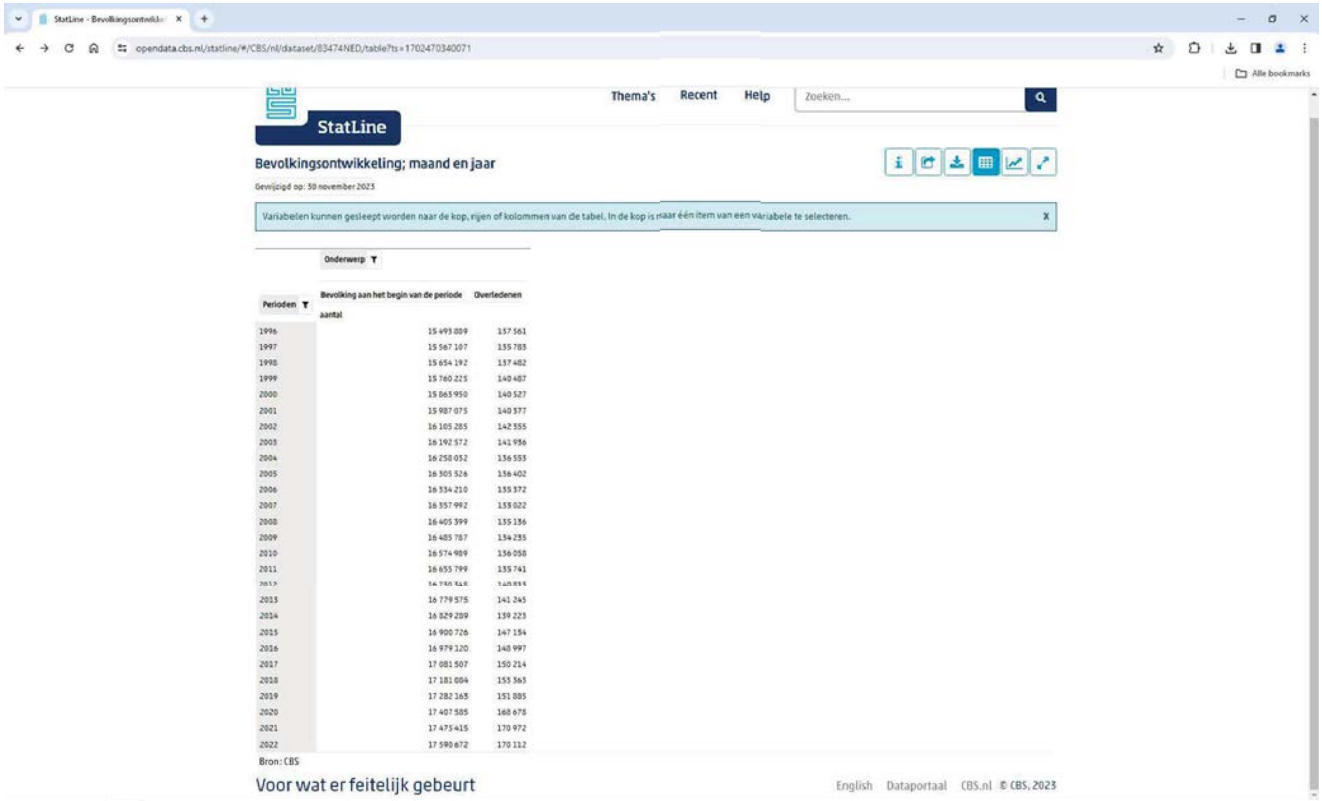
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9:40 PM · Nov 21, 2023 · **3,830** Views

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StatLine - Bevolkingsontwikk
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Bevolkingsontwikkeling; maand en jaar
Gewijzigd op: 30 november 2023
Variabelen kunnen gesleept worden naar de kop, rijen of kolommen van de tabel. In de kop is maar één item van een variabele te selecteren.
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Perioden
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1998 15 654 192 137 482
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2001 15 987 075 140 377
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2003 16 192 572 141 936
2004 16 258 052 136 553
2005 16 305 526 136 402
2006 16 334 210 135 372
2007 16 357 992 133 022
2008 16 405 399 135 136
2009 16 485 787 134 235
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2021 17 475 415 170 972
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Voor wat er feitelijk gebeurt
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EMA/392045/2023
EMEA/H/C/005735

Comirnaty (*COVID-19 mRNA Vaccine (nucleoside modified)*)

An overview of Comirnaty, including its adapted vaccines, and why it is authorised in the EU

What is Comirnaty and what is it used for?

Comirnaty is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people from the age 6 months.

The originally authorized Comirnaty contains tozinameran, a messenger RNA (mRNA) molecule with instructions for producing a protein from the original strain of SARS-CoV-2, the virus that causes COVID-19.

Comirnaty is also available as three adapted vaccines:

- Comirnaty Original/Omicron BA.1 contains tozinameran and riltozinameran, an mRNA molecule with instructions for producing a protein from the Omicron BA.1 subvariant of SARS-CoV-2;
- Comirnaty Original/Omicron BA.4-5 contains tozinameran and famtozinameran, an mRNA molecule with instructions for producing a protein from the Omicron BA.4 and BA.5 subvariants of SARS- CoV-2;
- Comirnaty Omicron XBB.1.5 contains raxtozinameran, an mRNA molecule with instructions for producing a protein from the Omicron XBB.1.5 subvariant of SARS-CoV-2.

Comirnaty does not contain the virus itself and cannot cause COVID-19.

How is Comirnaty used?

Adults and children from 5 years of age should receive a single dose injected into the muscle of the upper arm, regardless of their previous vaccination history.

Children from 6 months to 4 years of age who have completed a primary vaccination course or have had COVID-19 before should also receive a single dose, which can be injected into the muscle of the upper arm or thigh.

In children from 6 months to 4 years of age who have not completed a primary vaccination course and have not had COVID-19, the vaccine is given as three doses; the first two doses are given three weeks

Official address Domenico Scarlattilaan 6● 1083 HS Amsterdam● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go towww.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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separately, followed by a third dose given at least 8 weeks after the second . The injections can be given in the muscles of the upper arm or thigh.

An additional dose may be given to people with a severely weakened immune system.

The vaccines should be used according to official recommendations issued at national level by public health bodies.

For more information about using Comirnaty, including information about the adapted vaccines, doses for different age groups, see the package leaflet or consult a healthcare professional.

How does Comirnaty work?

Comirnaty works by preparing the body to defend itself against COVID-19. It contains a molecule called mRNA which has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells and can differ between variants of the virus.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person's immune system will then recognize the protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with SARS-CoV-2, their immune system will recognize it and be ready to defend the body against it.

The mRNA from the vaccine is broken down after vaccination and removed from the body.

Adapted vaccines are expected to maintain protection against the virus as they contain mRNA more closely matching circulating variants of the virus.

What benefits of Comirnaty have been shown in studies?

A very large clinical trial showed that Comirnaty, given as a two-dose regimen, was effective at preventing COVID-19 in people from 12 years of .

This main trial involved around 44,000 people aged 16 and above in total. Half received the vaccine and half were given a dummy injection. People did not know whether they received the vaccine or the dummy injection.

Efficacy in people aged 16 and above was calculated in over 36,000 participants (including people over 75 years of) who had no sign of previous infection. The study showed a 95% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (8 cases out of 18,198 got COVID-19 symptoms) compared with people who received a dummy injection (162 cases out 18,325 got COVID-19 symptoms). This means that the vaccine demonstrated a 95% efficacy in the trial.

The trial in people aged 16 years and older also showed around 95% efficacy in the participants at risk of severe COVID-19, including those with asthma, chronic lung disease, diabetes, high blood pressure or obesity.

The trial was extended to include 2,260 children aged 12 to 15 who had no sign of previous infection. It showed that the immune response to Comirnaty in this group was comparable to the immune response in the 16 to 25 age group (as measured by the level of antibodies against SARS-CoV-2).
Around 2,000 children received either the vaccine or a placebo (a dummy injection), without knowing which one they were given. Of the 1,005 children receiving the vaccine, none developed COVID-19 compared with 16 children out of the 978 who received placebo. This means that, in this , the

vaccine was 100% effective at preventing COVID-19 (although the true rate could be between 75% and 100%).

Another study showed that an additional dose of Comirnaty increased the ability to produce antibodies against SARS-CoV-2 in organ transplant adult patients with severely weakened immune systems.

A study in children aged 5 to 11 showed that the immune response to Comirnaty given at a lower dose (10 micrograms) was comparable to that seen with the higher dose (30 micrograms) in 16- to 25- year-olds (as measured by the level of antibodies against SARS-CoV-2). Of the 1,305 children receiving the , three developed COVID-19 compared with 16 out of the 663 children who received placebo. This means that, in this study, the vaccine was 90.7% effective at preventing symptomatic COVID-19 (although the true rate could be between 67.7% and 98.3%).

A main study in children from 6 months to 4 years of age evaluated the immune response triggered by the vaccine (given as 3 injections) by measuring the level of antibodies against SARS-CoV-2. The study showed that the immune response to the lower dose of Comirnaty (3 micrograms) was comparable to that seen with the higher dose (30 micrograms) in 16- to 25-year-olds.

Additional data showed that subsequent doses, including boosters, lead to a rise in levels antibodies against SARs-CoV-2. Available data also indicate that vaccines adapted specifically to target circulating strains of the virus are expected to elicit a strong immune response against these strains.

Can children be vaccinated with Comirnaty?

The originally authorized Comirnaty, Comirnaty Original/Omicron BA.4-5 and Comirnaty Omicron XBB.1.5 are authorized for adults and children from 6 months of .

Comirnaty Original/Omicron BA.1 is authorized for adults and children from 12 years of .

Can immunocompromised people be vaccinated with Comirnaty?

Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.

Severely immunocompromised people may be given an additional dose of Comirnaty as part of their primary vaccination.

Can pregnant or breast-feeding women be vaccinated with Comirnaty?

Comirnaty can be used during pregnancy. A large amount of data from pregnant women vaccinated with Comirnaty during the second or third trimester of their pregnancy has been analyzed and showed no increase in pregnancy complications. Although data in the first trimester of pregnancy are more limited, no increased risk of miscarriage was seen.

Comirnaty can also be used during breast-feeding. Data from women who were breast-feeding after vaccination have not shown a risk of adverse effects in breast-fed babies.

No data are currently available regarding the use of the adapted vaccines in pregnant or breastfeeding women. However, based on similarity with the vaccine targeting the original strain, including a comparable safety profile, Comirnaty Original/Omicron BA.1 can be used during pregnancy and breast- feeding. In addition, based on the data available for the originally authorized Comirnaty and Comirnaty Original/Omicron BA.1, Comirnaty Original/Omicron BA.4-5 and Comirnaty Omicron XBB.1.5 can also be used during pregnancy and breast-feeding.

Can people with allergies be vaccinated with Comirnaty?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

Allergic reactions (hypersensitivity) have been seen in people receiving the vaccine. A very small number of cases of anaphylaxis (severe allergic reaction) have occurred. Therefore, as for all vaccines, Comirnaty, including its adapted vaccines, should be given under close medical supervision, with the appropriate medical treatment available. People who have a severe allergic reaction when they are given a dose of Comirnaty or its adapted vaccines should not receive subsequent doses.

How well does Comirnaty work for people of different ethnicities and genders?

The main Comirnaty trial included people of different ethnicities and genders. Efficacy of around 95% in the main trial was maintained across genders and ethnic groups.

What are the risks associated with Comirnaty?

For the full list of side effects and restrictions with Comirnaty, see the package leaflet.

The most common side effects with Comirnaty are usually mild or moderate and get better within a few days after vaccination. These include pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills, fever and diarrhea. They may affect more than 1 in 10 people. In children aged 6 to 23 months, the most common side effects also include irritability, sleepiness, loss of appetite, tenderness or redness at the injection site and fever. The most common side effects in children 2 to 4 years of age include pain or redness at the injection site, tiredness and fever.

Redness at the injection site, enlarged lymph nodes, nausea and vomiting may occur in up to 1 in 10 people. Itching at the injection site, pain in the arm where the vaccine was injected, enlarged lymph nodes, difficulty sleeping, feeling unwell, decreased appetite, lethargy (lack of energy), hyperhidrosis (excessive sweating), night sweats, asthenia (weakness), and allergic reactions (such as rash, itching, itchy rash, and rapid swelling under the) are uncommon side effects (affecting less than 1 in 100 people). Weakness in muscles on one side of the face (acute peripheral facial paralysis or palsy) occurs in less than 1 in 1,000 people.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) may occur in up to 1 in 10,000 people.

Very few cases of extensive swelling of the vaccinated arm, swelling of the face in people with a history of injections with dermal fillers (soft, gel-like substances injected under the skin), erythema multiforme (red patches on the skin with a dark red center and paler red rings) paraesthesia (unusual feeling in the skin, such as tingling or a crawling feeling) and hypoesthesia (decreased feeling or sensitivity in the skin) have occurred. Allergic reactions have also occurred with Comirnaty, including a very small number of cases of severe allergic reactions (anaphylaxis).

The safety of the adapted vaccines is similar to that of the originally authorized Comirnaty vaccine.

Why is Comirnaty authorized in the ?

Data show that Comirnaty causes the production of antibodies against SARS-CoV-2 that can protect against COVID-19. The main trials of Comirnaty showed that the vaccine has a high efficacy in all age groups. Most side effects are mild to moderate in severity and are gone within a few days.

The Agency therefore decided that the benefits of Comirnaty, including its adapted vaccines, are greater than its risks and that it can be authorised for use in the .

Comirnaty was originally given "conditional authorization" because there was more evidence to come about the vaccine. The company has provided comprehensive information, including data regarding its safety, efficacy, and how well Comirnaty prevents severe disease. In addition, the company has completed all requested studies on the pharmaceutical quality of the . As a result, the conditional authorisation has been switched to a standard one.

What measures are being taken to ensure the safe and effective use of Comirnaty?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Comirnaty have been included in the summary of product characteristics and the package leaflet.

A risk management plan (RMP) is also in place and contains important information about the vaccines' safety, how to collect further information and how to minimize any potential risks.

Safety measures for Comirnaty are implemented in line with the EU safety monitoring plan for COVID- 19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets Comirnaty will provide regular safety reports.

As for all medicines, data on the use of Comirnaty are continuously monitored. Suspected side effects are carefully evaluated and any necessary action taken to protect patients.

Other information about Comirnaty

Comirnaty received a conditional marketing authorisation valid throughout the EU on 21 December 2020. This was switched to a standard marketing authorisation on 10 October 2022.

More information about the COVID-19 vaccines is available on the COVID-19 vaccines key facts page.

Further information on Comirnaty, including its adapted vaccines, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/comirnaty

This overview was last updated in 08-2023.

EMA/404588/2023
EMEA/H/C/005791

Spikevax[1] (*COVID-19 mRNA Vaccine (nucleoside modified)*)

An overview of Spikevax, including its adapted vaccines, and why it is authorised in the EU

What is Spikevax and what is it used for?

Spikevax is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people from the age of 6 months.

The originally authorized Spikevax contains elasomeran, a molecule called messenger RNA (mRNA) with instructions for producing a protein from the original strain of SARS-CoV-2, the virus that causes COVID-19.

Spikevax is also available as three adapted vaccines:

- Spikevax bivalent Original/Omicron BA.1 contains elasomeran and an additional mRNA molecule, imelasomeran, with instructions for producing a protein from the Omicron BA.1 subvariant of SARS-CoV-2;
- Spikevax bivalent Original/Omicron BA.4-5 contains elasomeran and an additional mRNA molecule, davesomeran, with instructions for producing a protein from the Omicron BA.4 and BA.5 subvariants of SARS-CoV-2
- Spikevax XBB.1.5 contains andusomeran, an mRNA molecule with instructions for producing a protein from the Omicron XBB.1.5 subvariant of SARS-CoV-2.

Spikevax and its adapted vaccines do not contain the virus itself and cannot cause COVID-19.

How is Spikevax used?

The originally authorized Spikevax is given in people from the age of 6 months as two injections, usually into the muscle of the upper arm, or the thigh in infants and young children, 28 days apart. A booster dose may be given to adults and children from the age of 6 years, at least 3 months after primary vaccination with Spikevax, or another mRNA vaccine or an adenoviral vector vaccine.

[1] Previously known as COVID-19 Vaccine Moderna

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Spikevax bivalent Original/Omicron BA.1 may be given as a single injection to adults and children from the age of 6 years, at least 3 months after primary vaccination or a booster dose with a COVID-19 vaccine.

Both Spikevax bivalent Original/Omicron BA.4-5 and Spikevax XBB.1.5 are given as a single injection to adults and children aged 5 years and older, irrespective of their previous COVID-19 vaccination history. In children from 6 months to 4 years of age, they are given as a single injection in those who have completed a primary vaccination course or have had COVID-19 before, or as two injections 28 days apart in those who have not previously been vaccinated against COVID-19 or had COVID-19.

An additional dose of Spikevax, Spikevax bivalent Original/Omicron BA.4-5 or Spikevax XBB.1.5 may be given to adults and children aged 6 months and older with a severely weakened immune system.

The vaccines should be used according to official recommendations, issued at national level, by public health bodies.

For more information about using Spikevax, including information about the adapted vaccines and doses for different age groups, see the package leaflet or consult a healthcare professional.

How does Spikevax work?

Spikevax works by preparing the body to defend itself against COVID-19. It contains a molecule called mRNA which has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells and which can differ between variants of the virus.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person's immune system will then recognize this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with SARS-CoV-2, their immune system will recognize it and be ready to defend the body against it.

After vaccination, the mRNA from the vaccine is broken down and removed from the body.

Adapted vaccines work in the same way as the original vaccine and are expected to maintain protection against the virus as they contain mRNA more closely matching circulating variants of the virus.

What benefits of Spikevax have been shown in studies?

A very large clinical trial showed that Spikevax, given as a two-dose regimen, was effective at preventing COVID-19 in people from 18 years of . The trial involved around 30,000 people in total. Half received the vaccine and half were given dummy injections. People did not know whether they received the vaccine or the dummy injections.

Efficacy was calculated in around 28,000 people from 18 to 94 years of age who had no sign of previous infection. The trial showed a 94.1% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (11 out of 14,134 vaccinated people got COVID-19 with symptoms) compared with people who received dummy injections (185 out of 14,073 people who received dummy injections got COVID-19 with symptoms). This means that the vaccine demonstrated a 94.1% efficacy in the . The trial also showed 90.9% efficacy in participants at risk of severe COVID-19, including those with chronic lung disease, heart disease, obesity, liver disease, diabetes or HIV infection.

Another study showed that an additional dose of Spikevax increased the ability to produce antibodies against SARS-CoV-2 in organ transplant patients with severely weakened immune systems.

The effects of Spikevax were also investigated in a study involving over 3,000 children aged 12 to 17 years. The study showed that Spikevax produced a comparable immune response in 12- to 17-year- olds to that seen in young adults (aged 18 to 25 years), as measured by the level of antibodies against SARS-CoV-2. In addition, none of the 2,163 children who received the vaccine developed COVID-19, compared with four of 1,073 children given a dummy injection. These results allowed to conclude that the efficacy of Spikevax in children 12 to 17 years old is similar to that in adults.

An additional study involving three groups of children aged 6 months to under 2 years, 2 to 5 years and 6 to 11 years showed that Spikevax produced a comparable immune response in these age to that seen in young adults (aged 18 to 25 years), as measured by the level of antibodies against SARS-CoV-2. These results indicate that the efficacy of Spikevax in children 6 months to 11 years old is similar to that in adults.

Additional data showed that subsequent doses, including boosters, lead to a rise in levels of antibodies against SARS-CoV-2.

Based on available data, vaccines adapted specifically to target circulating strains of the virus are expected to elicit a strong immune response against these strains.

Can children be vaccinated with Spikevax?

Originally authorized Spikevax, Spikevax bivalent Original/Omicron BA.4-5 and Spikevax XBB.1.5 are authorized for adults and children from 6 months of age.

Spikevax bivalent Original/Omicron BA.1 is authorized for adults and children from 6 years of .

Can immunocompromised people be vaccinated with Spikevax?

Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.

Severely immunocompromised people may be given an additional dose of Spikevax as part of their primary vaccination.

Can pregnant or breast-feeding women be vaccinated with Spikevax?

Spikevax can be used during pregnancy.

A large amount of data from pregnant women vaccinated with Spikevax during the second or third trimester of their pregnancy has been analyzed and showed no increase in pregnancy complications. Although data in women in the first trimester of pregnancy are more limited, no increased risk of miscarriage was seen.

Spikevax can be used during breast-feeding. Data from women who were breast-feeding after vaccination have not shown a risk of adverse effects in breast-fed babies.

No data are currently available regarding the use of the adapted vaccines in pregnant or breast-feeding women. However, based on the similarity with the originally authorized Spikevax, including a comparable safety profile, the adapted vaccines can be used during pregnancy and breast-feeding.

Can people with allergies be vaccinated with Spikevax?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

Allergic reactions (hypersensitivity) have been seen in people receiving the vaccine. A very small number of cases of anaphylaxis (severe allergic reaction) have occurred. Therefore, as for all vaccines, Spikevax, including the adapted vaccines, should be given under close medical supervision, with the appropriate medical treatment available in case of allergic reactions. People who have a severe allergic reaction when they are given a dose of Spikevax or its adapted vaccines should not receive subsequent doses.

How well does Spikevax work for people of different ethnicities and genders?

The main clinical trials for Spikevax included people of different ethnicities and genders. The high efficacy was maintained across genders and ethnic groups.

What are the risks associated with Spikevax?

For the full list of side effects and restrictions with Spikevax, see the package leaflet.

The most common side effects with Spikevax are usually mild or moderate and get better within a days after vaccination. These include redness, pain and swelling at the injection site, tiredness, chills, fever, swollen or tender lymph nodes under the arm, headache, muscle and joint pain, nausea (feeling sick) and vomiting. They may affect more than 1 in 10 people. In infants under 3 years of age, irritability, crying, sleepiness and loss of appetite are also very common side effects (affecting more than 1 in 10 infants).

Hives and rash at the injection site, sometimes occurring more than a week after injection, rash affecting areas other than the injection site and diarrhea may affect less than 1 in 10 people. Itching at the injection site, dizziness and abdominal pain may affect less than 1 in 100 people. Swelling of the face, which may affect people who had facial cosmetic injections in the past, weakness in muscles on one side of the face (acute peripheral facial paralysis or palsy), paraesthesia (unusual feeling in the skin, such as tingling or a crawling feeling) and hypoaesthesia (reduced sensation to touch, pain and temperature) may affect less than 1 in 1,000 people.

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the) may occur in up to 1 in 10,000 people.

A very small number of cases of erythema multiforme (red patches on the skin with a dark red center and paler red rings) have occurred. Allergic reactions have also occurred in people receiving the vaccine, including a very small number of cases of severe allergic reactions (anaphylaxis).

The safety of the adapted vaccines is comparable to that of the originally authorized Spikevax vaccine.

Why is Spikevax authorized in the ?

Data have shown that originally authorised Spikevax and its adapted vaccines cause the production of antibodies against SARS-CoV-2 that can protect against COVID-19. The main trials showed that the originally authorised vaccine has a high efficacy in all age groups. Most side effects are mild to moderate in severity and are gone within a few days.

The European Medicines Agency therefore decided that the benefits of Spikevax, including its adapted vaccines, are greater than its risks, and it can be authorised for use in the EU.

Spikevax was originally given 'conditional authorization' because there was more evidence to come about the vaccine. The company has provided comprehensive information, including data regarding its safety, efficacy, and how well Spikevax prevents severe disease. In addition, the company has completed all requested studies on the pharmaceutical quality of the vaccine. As a result, the conditional authorisation has been switched to a standard one.

What measures are being taken to ensure the safe and effective use of Spikevax?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Spikevax and its adapted vaccines have been included in the summary of product characteristics and the package leaflet.

A risk management plan (RMP) is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimize any potential risks.

Safety measures for Spikevax and its adapted vaccines are implemented in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets Spikevax will provide regular safety reports.

As for all medicines, data on the use of Spikevax and its adapted vaccines are continuously monitored. Suspected side effects are carefully evaluated and any necessary action taken to protect patients.

Other information about Spikevax

COVID-19 Vaccine Moderna received a conditional marketing authorisation valid throughout the EU on January 6, 2021. This was switched to a standard marketing authorisation on 3 October 2022.

The name of the vaccine was changed to Spikevax on June 22, 2021.

More information about the COVID-19 vaccines is available on the COVID-19 vaccines key facts page.

Further information on Spikevax and its adapted vaccines can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/spikevax.

This overview was last updated in 09-2023.

EMA/863593/2022
EMEA/H/C/005675

Vaxzevria[1] *(COVID-19 Vaccine (ChAdOx1-S [recombinant]))*

An overview of Vaxzevria and why it is authorised in the EU

What is Vaxzevria and what is it used for?

Vaxzevria is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older.

Vaxzevria is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein from SARS-CoV-2, the virus that causes COVID-19.

Vaxzevria does not contain the virus itself and cannot cause COVID-19.

How is Vaxzevria used?

Vaxzevria is given as two injections, usually into the muscle of the upper arm. The second dose should be given between 4 and 12 weeks after the first dose.

A booster dose may be given at least 3 months after the second dose. A booster dose of Vaxzevria can also be given to adults who have had two doses of an authorized mRNA COVID-19 vaccine. The vaccines should be used according to official recommendations issued at national level by public health bodies.

For more information about using Vaxzevria, see the package leaflet or consult a healthcare professional.

How does Vaxzevria work?

Vaxzevria works by preparing the body to defend itself against COVID-19. It is made up of another virus (adenovirus) that has been modified to contain the gene for making the SARS-CoV-2 spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.

[1] Previously known as COVID-19 Vaccine AstraZeneca

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Once it has been given, the vaccine delivers the SARS-CoV-2 gene into cells in the body. The cells will use the gene to produce the spike protein. The person's immune system will then recognize this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with SARS-CoV-2, their immune system will recognize it and be ready to defend the body against it.

The adenovirus in the vaccine cannot reproduce and does not cause disease.

What benefits of Vaxzevria have been shown in studies?

Combined results from 4 clinical trials in the United Kingdom, Brazil and South Africa showed that Vaxzevria was safe and effective at preventing COVID-19 in people from 18 years of age. These studies involved around 24,000 people altogether. Half received the vaccine and half were given a control injection, either a dummy injection or another non-COVID vaccine. People did not know if they had been given the test vaccine or the control injection.

The Agency based its calculation of how well the vaccine worked on the results from study COV002 (conducted in the UK) and study COV003 (conducted in Brazil). The other two studies had fewer than 6 COVID-19 cases occurring in each, which was not enough to measure the preventive effect of the vaccine. In addition, as the vaccine was to be given as two standard doses, and the second dose should be given between 4 and 12 weeks after the first, the Agency concentrated on results involving people who received this standard regimen.

These showed a 59.5% reduction in the number of symptomatic COVID-19 cases in people given the vaccine (64 of 5,258 got COVID-19 with symptoms) compared with people given control injections (154 of 5,210 got COVID-19 with symptoms). This means that the vaccine demonstrated around a 60% efficacy in these clinical trials.

Another study conducted in the United States, Peru and Chile involved around 26,000 people, of whom 21% were above 65 years of . The participants received the second dose 4 weeks after the first one. The study showed a 74% reduction in the number of symptomatic COVID-19 cases in people given the vaccine (73 of 17,662 got COVID-19 with symptoms) compared with people given control injections (130 of 8,550 got COVID-19 with symptoms). The study also showed that the vaccine efficacy of Vaxzevria in older people is comparable to that seen in younger people.

Further data showed a rise in antibody levels when a booster dose was given after the second dose of Vaxzevria or after two doses of an mRNA vaccine in adults aged 30 years and above with a normal immune system.

Can children be vaccinated with Vaxzevria?

Vaxzevria is not currently authorized for use in children. EMA has agreed with the company on a plan to conduct trials involving children at a later stage.

Can immunocompromised people be vaccinated with Vaxzevria?

There are limited data on immunocompromised people (people with weakened immune systems). Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.

Can pregnant or breast-feeding women be vaccinated with Vaxzevria?

Preliminary animal studies do not show any harmful effects in pregnancy, however data on the use of Vaxzevria during pregnancy are very limited. Although there are no studies on breast-feeding, no risk during breast-feeding is expected.

The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks.

Can people with allergies be vaccinated with Vaxzevria?

People who already know they have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

Allergic reactions (hypersensitivity) have been seen in people receiving the vaccine. Cases of anaphylaxis (severe allergic reaction) have also occurred. As for all vaccines, Vaxzevria should be given under close medical supervision, with the appropriate medical treatment available in case of allergic reactions. People who have a severe allergic reaction when they are given the first dose of Vaxzevria should not receive the second dose.

How well does Vaxzevria work for people of different ethnicities and genders?

The clinical trial included people of different ethnicities and genders. The efficacy was maintained across genders and ethnic groups.

What are the risks associated with Vaxzevria?

The most common side effects with Vaxzevria are usually mild or moderate and get better within a few days after vaccination. When compared with the first dose, side effects reported after the second dose are milder and reported less frequently. People receiving Vaxzevria may experience more than one side effect at the same time.

The most common side effects are tenderness, pain and bruising at the injection site, headache, tiredness, muscle pain, general feeling of being unwell, chills, fever, joint pain and nausea (feeling sick). They may affect more than 1 in 10 people.

Thrombocytopenia (low levels of blood platelets), vomiting, diarrhea, pain in legs or arms, swelling and redness at the injection site, flu-like illness and asthenia (weakness) may affect up to 1 in 10 people. Lymphadenopathy (enlarged lymph nodes), decreased appetite, dizziness, sleepiness, lethargy (lack of energy), hyperhidrosis (excessive sweating), abdominal (belly) pain, muscle spasms, itching, rash and urticaria (itchy rash) may affect up to 1 in 100 people.

Weakness in muscles on one side of the face (facial paralysis or palsy) may affect up to 1 in 1,000 people.

Thrombosis (formation of blood clots in the blood vessels) in combination with thrombocytopenia (thrombosis with thrombocytopenia syndrome, TTS) and Guillain-Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells) may affect up to 1 in 10,000 people.

A very small number of cases of angioedema (rapid swelling under the skin), capillary leak syndrome (fluid leakage from small blood vessels causing tissue swelling and a drop in blood pressure) and transverse myelitis (a neurological condition characterized by an inflammation in the spinal cord) have

occurred with Vaxzevria. A very small number of cases of immune thrombocytopenia (a condition in which the immune system mistakenly targets blood platelets, reducing their levels and affecting normal blood clotting) and cerebrovascular venous and sinus thrombosis (formation of blood clots in the vessels draining blood from the brain) have also occurred.

Allergic reactions have occurred in people receiving the vaccine, including some cases of severe allergic reactions (anaphylaxis). As for all vaccines, Vaxzevria should be given under close supervision with appropriate medical treatment available.

Vaxzevria must not be given to people who have had thrombosis with thrombocytopenia syndrome (TTS) after receiving the vaccine. Vaxzevria must also not be given to people who have previously had capillary leak syndrome.

Why is Vaxzevria authorized in the ?

Vaxzevria offers a good level of protection against COVID-19 which is a critical need in the current pandemic. The main trials showed that the vaccine had around 60% efficacy against the main strain of SARS-CoV-2 in circulation at the time. Most side effects are mild to moderate in severity and are gone within a few days.

The European Medicines Agency decided that Vaxzevria's benefits are greater than its risks and it can be authorized for use in the EU.

Vaxzevria was originally given "conditional authorization" because there was more evidence to come about the vaccine. The company has provided comprehensive information, including data regarding its safety and efficacy, confirming the findings from earlier studies previously submitted. In addition, the company has completed all requested studies on the pharmaceutical quality of the . As a result, the conditional authorisation has been switched to a standard one.

What measures are being taken to ensure the safe and effective use of Vaxzevria?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Vaxzevria have been included in the summary of product characteristics and the package leaflet.

A risk management plan for Vaxzevria is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimize any potential risks. A summary of the RMP is available.

Safety measures for Vaxzevria are implemented in line with the EU safety monitoring plan for COVID- 19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets Vaxzevria will provide regular safety reports.

As for all medicines, data on the use of Vaxzevria are continuously monitored. Suspected side effects reported with Vaxzevria are carefully evaluated and any necessary action taken to protect patients.

Other information about Vaxzevria

COVID-19 Vaccine AstraZeneca received a conditional marketing authorization valid throughout the EU on January 29, 2021. The name of the vaccine was changed to Vaxzevria on 25 March 2021.The conditional marketing authorisation was switched to a standard marketing authorisation on 31 October 2022.

More information about the COVID-19 vaccines, such as the use of adapted vaccines and boosters, is available on the COVID-19 vaccines key facts page.

Further information on Vaxzevria can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/vaxzevria.

This overview was last updated in 11-2022.

EMA/234937/2023
EMEA/H/C/005737

Jcovden[1] (*COVID-19 vaccine (Ad26.COV2-S [recombinant])*)

An overview of Jcovden and why it is authorised in the EU

What is Jcovden and what is it used for?

Jcovden is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older. COVID-19 is caused by SARS-CoV-2 virus.

Jcovden is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein found on SARS-CoV-2.

Jcovden does not contain SARS-CoV-2 itself and cannot cause COVID-19.

How is Jcovden used?

Jcovden is given as an injection, usually into the muscle of the upper arm.

A booster dose may be given at least 2 months after the first dose of Jcovden in people aged 18 years and older. A booster dose may also be given after a primary vaccination course with an mRNA or adenoviral vector vaccine. The timing of a Jcovden booster dose depends on when a booster would normally be given for such vaccines.

The vaccine should be used according to official recommendations issued at national level by public health bodies. For more information about using Jcovden, see the package leaflet or consult a healthcare professional.

How does Jcovden work?

Jcovden works by preparing the body to defend itself against COVID-19. It is made up of another virus (an adenovirus) that has been modified to contain the gene for making the SARS-CoV-2 spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.

[1] Previously known as COVID-19 Vaccine Janssen

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The adenovirus passes the SARS-CoV-2 gene into the vaccinated person's cells. The cells can then use the gene to produce the spike protein. The person's immune system will recognize the spike protein as foreign and produce antibodies and activate T cells (white blood cells) to target it.

Later, if the person comes into contact with the SARS-CoV-2 virus, the person's immune system will recognize the spike protein on the virus and be ready to defend the body against it.

The adenovirus in the vaccine cannot reproduce and does not cause the disease.

What benefits of Jcovden have been shown in studies?

Results from a clinical trial involving people in the United States, South Africa and Latin American countries found that Jcovden was effective at preventing COVID-19 in people from 18 years of . This study involved over 44,000 people. Half received a single dose of the vaccine and half were given placebo (a dummy injection). People did not know if they had been given Jcovden or placebo.

The trial found a 67% reduction in the number of symptomatic COVID-19 cases after 2 weeks in people who received Jcovden (116 cases out of 19,630 people) compared with people given placebo (348 of 19,691 people). This means that the vaccine had a 67% efficacy.

Further data showed a rise in antibody levels when a booster dose was given after completion of a primary course with Jcovden, an mRNA vaccine, or another adenoviral vector vaccine in people from 18 years of age.

Can children be vaccinated with Jcovden?

Jcovden is not currently authorized for use in children.

Can immunocompromised people be vaccinated with Jcovden?

There are no data on immunocompromised people (people with weakened immune systems). Although immunocompromised people may not respond as well to the vaccine, there are no particular safety concerns. Immunocompromised people can still be vaccinated as they may be at higher risk from COVID-19.

Can pregnant or breast-feeding women be vaccinated with Jcovden?

Animal studies do not show any harmful effects of Jcovden in pregnancy. However, data on the use of Jcovden during pregnancy are very limited. There are no studies of Jcovden on breast-feeding but no risk from breast-feeding is expected.

The decision on whether to use the vaccine in pregnant women should be made in close consultation with a healthcare professional after considering the benefits and risks.

Can people with allergies be vaccinated with Jcovden?

People who have an allergy to one of the components of the vaccine listed in section 6 of the package leaflet should not receive the vaccine.

Allergic reactions (hypersensitivity) have occurred in people receiving the vaccine, including rare cases of anaphylaxis (severe allergic reaction). As for all vaccines, Jcovden should be given under close medical supervision, with the appropriate medical treatment available in case of allergic reactions.

How well does Jcovden work for people of different ethnicities and genders?

The clinical trials included people of different ethnicities and genders. The vaccine worked across genders and ethnic groups.

What are the risks associated with Jcovden?

For the full list of side effects and restrictions with Jcovden, see the package leaflet.

The most common side effects with Jcovden are usually mild or moderate and get better within 1 or 2 days after vaccination.

The most common side effects are pain at the injection site, tiredness, headache, muscle pain and nausea. They may affect more than 1 in 10 people.

Fever, chills, as well as redness and swelling at injection site may affect up to 1 in 10 people. Dizziness, shaking, coughing, mouth and throat pain, sneezing, diarrhea, vomiting, rash, joint pain, muscle weakness, backache, pain in the arms and legs, weakness and feeling generally unwell may affect up to 1 in 100 people. Rare side effects (which may affect up to 1 in 1,000 people) are lymphadenopathy (enlarged lymph nodes), itchy rash, hypersensitivity (allergy), paraesthesia (unusual sensations like numbness, tingling or pins and needles), hypoesthesia (reduced sensation to touch, pain and temperature), facial paralysis, tinnitus (ringing or buzzing in the ears), venous thromboembolism (formation of blood clots in veins) and sweating.

For booster vaccinations, the number and severity of reactions tend to be higher when people have previously been vaccinated with a vaccine other than Jcovden compared to people who have completed a primary course with Jcovden.

Thrombosis (formation of blood clots in the blood vessels) in combination with thrombocytopenia (low levels of blood platelets), known as TTS (thrombosis with thrombocytopenia syndrome), and Guillain-Barré syndrome (a neurological disorder in which the body's immune system damages nerve cells) may affect up to 1 in 10,000 people.

Allergic reactions, including anaphylaxis (severe allergic reaction), have occurred in people receiving the vaccine. As for all vaccines, Jcovden should be given under close supervision with appropriate medical treatment available.

A very small number of cases of immune thrombocytopenia (a condition in which the immune system mistakenly targets blood platelets, reducing their levels and affecting normal blood clotting), capillary leak syndrome (fluid leakage from small blood vessels causing tissue swelling and a drop in blood pressure), cutaneous small vessel vasculitis (inflammation of blood vessels in the skin), transverse myelitis (a neurological condition characterized by an inflammation in the spinal cord), myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane around the heart) have occurred with Jcovden.

Jcovden must not be given to people who have previously had capillary leak syndrome; it must also not be given to people who have had TTS following vaccination with any COVID-19 vaccine.

Why is Jcovden authorized in the ?

Jcovden offers a good level of protection against COVID-19 which is critical during the current pandemic. The main trial showed that the vaccine has around 67% efficacy. Most side effects are mild to moderate in severity and last only a few days.

The European Medicines Agency therefore decided that Jcovden's benefits are greater than its risks and it can be authorised for use in the EU.

Jcovden was originally given 'conditional authorization' because there was more evidence to come about the vaccine. The company has provided comprehensive information, including data regarding its safety and efficacy, confirming the findings from earlier studies previously submitted. In addition, the company has completed all requested studies on the pharmaceutical quality of the . As a result, the conditional authorisation has been switched to a standard one.

What measures are being taken to ensure the safe and effective use of Jcovden?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Jcovden have been included in the summary of product characteristics and the package leaflet.

A risk management plan (RMP) for Jcovden is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimize any potential risks. A summary of the RMP is available.

Safety measures for Jcovden are implemented in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets Jcovden will provide regular safety reports.

As for all medicines, data on the use of Jcovden are continuously monitored. Suspected side effects reported with Jcovden are carefully evaluated and any necessary action taken to protect patients.

Other information about Jcovden

COVID-19 Vaccine Janssen received a conditional marketing authorization valid throughout the EU on March 11, 2021. The name of the vaccine was changed to Jcovden on 28 April 2022. The conditional marketing authorisation was switched to a standard marketing authorisation on 9 January 2023.

More information about the COVID-19 vaccines is available on the COVID-19 vaccines key facts page.

Further information on Jcovden can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/jcovden

This overview was last updated in 06-2023.

COVID-19-vaccinatie: BioNTech/Pfizer

Nr. 2020/29, Den Haag, 24 december 2020

Samenvatting

Gezondheidsraad

Recently, the BNT162b2 vaccine against COVID-19 developed by BioNTech and Pfizer (brand name *Comirnaty)* reviewed by the European Medicines Agency (EMA) and approved by the European Commission. This means it can be used in the Netherlands to combat
the COVID-19 pandemic. The Minister of Health, Welfare and Sport has asked the Health Council to advise on the use of this vaccine in different target groups eligible for vaccination. The Medical Committee of COVID-19 evaluated the vaccine using the established criteria used by the Health Council when advising on vaccinations.

Disease burden of COVID-19 is large

The first criterion for deployment of vaccination is that there must be significant disease burden. This is clearly the case with COVID-19. Until mid-December, the GGD 628,577 cases of illness and 10,168 deaths were confirmed by COVID-19. The risk of a severe disease course increases in people with chronic conditions and with increasing age. The average age of patients in the nursing ward was 67 years and in the ICU was 64 years. The vast majority of deaths were among the elderly, many of whom lived in nursing homes.

Vaccine works well in adults, elderly and medical risk groups

The next criterion is that vaccination must workable and effective. The vaccine is administered in two doses about three weeks apart. The efficacy of the BNT162b2 vaccine against COVID-19 was determined in over 36,000 people, half of whom received the vaccine and half of whom received a placebo. From that revealed that the vaccination protects adults as well as the elderly and medical risk groups well. In all groups, efficacy was well above 90%.
It is still unknown how lang the protection lasts and to what extent vaccination can also prevent the spread of the virus.

Vaccine is sufficiently safe: side effects are generally mild

Vaccination safety is also an important criterion. The BNT162b2 vaccine is sufficiently safe and well tolerated. Like all drugs, vaccines have side effects. The purpose of vacci-
nation is to trigger an immune system response, and this is often accompanied by associated temporary symptoms. Vaccination with the BNT162b2 vaccine produced side effects in most people after both the first and second doses. The most common were

mild to moderate pain at the injection site and fatigue, headache and muscle pain. The reactions were more common in younger people and more frequent after the second dose.
Most of the side effects were gone within a few days.

Vaccination is acceptable: **benefits** outweigh disadvantages
The committee finds that the advantages of vaccination (health benefits from protection against COVID-19) outweigh the disadvantages (side effects that are usually mild and short-term). Thus, the criterion of acceptability is also met. The cost-effectiveness of vaccination cannot yet be assessed because no data are yet available.

Recommendation: vaccine deployment, primarily in the elderly
from 60 years
Vaccination with the BNT162b2 vaccine is work- able, sufficiently safe and acceptable for adults, the elderly and medical risk-groups. The committee therefore recommends the health harm when public vaccination programs targeting COVID-19. Because the vaccine has an above-expected high efficacy in the elderly and reduce the burden of disease. workers, as this is due to COVID-19 being greatest in this expectation early group, the committee recommends the BNT162b2- of 4.5 million vaccine to be used primarily for the elderly from 60 years, with the oldest. This is in line with vaccination strategy 1, as formulated in the Health Council's recent advice on vaccination strategies. With this strategy, the greatest health gains are achieved
and additionally stem the influx of COVID-19 patients to hospitals, will put pressure on care
reduce. According to the committee, the BNT162b2 vaccine should be used on a limited basis to vaccinate health care personnel in long-term care, namely as long as the medical risk groups they care for cannot be vaccinated themselves. Also, the vaccine be used very selectively in curative care to maintain care use of BNT162b2 vaccine at sites of acute occurs due to healthcare worker attrition. According to the committee, the vaccine from AstraZeneca could provide a solution for vaccination of all healthcare vaccine according to current 2021 in a large quantity doses could be delivered.

De Gezondheidsraad, ingesteld in 1902, is een adviesorgaan met als taak de regering en het parlement 'voor te lichten over de stand der wetenschap ten aanzien van vraagstukken op het gebied van de volksgezondheid en het gezondheids(zorg)onderzoek' (art. 22 Gezondheidswet).
De Gezondheidsraad ontvangt de meeste adviesvragen van de bewindslieden van Volksgezondheid, Welzijn en Sport; Infrastructuur en Waterstaat; Sociale Zaken en Werkgelegenheid en Landbouw, Natuur en Voedselkwaliteit. De raad kan ook op eigen initiatief adviezen uitbrengen, en ontwikkelingen of trends signaleren die van belang zijn voor het overheidsbeleid.
De adviezen van de Gezondheidsraad zijn openbaar en worden als regel opgesteld door multidisciplinaire commissies van – op persoonlijke titel benoemde – Nederlandse en soms buitenlandse deskundigen.

U kunt dit document downloaden van www.gezondheidsraad.nl.

Deze publicatie kan als volgt worden aangehaald:
Gezondheidsraad. COVID-19-vaccinatie: BioNTech/Pfizer.
Den Haag: Gezondheidsraad, 2020; publicatienr. 2020/29.

Auteursrecht voorbehouden

COVID-19-vaccinatie: Moderna-vaccin en de vaccinatiestrategie

Nr. 2021/01, Den Haag, 11 januari 2021

Samenvatting

Gezondheidsraad

Recently, the mRNA-1273 vaccine against COVID-19 developed by Moderna (brand name *COVID-19 Vaccine Moderna)* was positively evaluated by the European Medicines Agency (EMA) and registered by the European Commission. This means it can be used in the Netherlands to combat the COVID-19 pandemic.
The Minister of Health, Welfare and Sport asked the Health Council to advise on the use of this vaccine in different target groups eligible for vaccination. The Medical Committee of COVID-19 assessed the vaccine using the established criteria used by the Health Council when advising on vaccinations.

Disease burden of COVID-19 is large
The first criterion for deployment of vaccination is that there must be significant disease burden. This is clearly the case with COVID-19. Until early January, the GGD 834,064 cases of illness and 11,826 deaths confirmed by COVID-19. The risk of severe disease progression increases with age and in people with chronic conditions.
The average age of patients in the nursing ward was 67 years and in the ICU was 64 years. The vast majority of deaths were among the elderly, many of whom lived in nursing homes.

Vaccine works well in adults, elderly and medical risk groups
The next criterion is that vaccination must workable and effective. The vaccine is administered in two doses 28 days apart. The efficacy of the mRNA-1273 vaccine against COVID-19 was determined in over 28,000 people, half of whom received the vaccine and half of whom received a placebo. It showed that the vaccination protected adults as well as the elderly and medical risk groups well, during a follow-up period of about two months. In all groups, efficacy was well above 80%.
It is still unknown how long the protection lasts and to what extent vaccination can also prevent the spread of the virus.

Vaccine is sufficiently safe: side effects are usually mild Vaccine safety is also a important criterion. The mRNA-1273 vaccine is sufficiently safe and well tolerated.
Like all drugs, vaccines have side effects. The purpose of vacci- nation is to trigger an immune system response, and this is often accompanied by associated temporary symptoms. Vaccination with the mRNA-1273 vaccine causes side effects in people after both the initial and the

second dose. The most common were mild to moderate pain at the injection site and fatigue, headache and muscle pain. Reactions were more common in younger people and more frequent after the second dose.
Most of the side effects were gone within a few days.

Vaccination is acceptable: advantages outweigh disadvantages
The committee finds that the advantages of vaccination (health benefits from protection against COVID-19) outweigh the disadvantages (side effects that are usually mild and short-term). Thus, the criterion of acceptability met. The cost-effectiveness of vaccination cannot yet be assessed because no data are yet available.

Recommendation: vaccine deployment, primarily in the elderly The committee concludes that vaccination with the mRNA-1273 vaccine is effective, sufficiently safe and acceptable for adults, the elderly and medical risk groups.
Therefore, the committee recommends the use of this vaccine in public vaccination programs targeting COVID-19. Because the vaccine demonstrates very high efficacy I in the elderly, the burden of disease due to COVID-19 is greatest in this group, and the vaccine becomes available in a relatively small quantity, the recommends that the mRNA-1273 vaccine be used primarily for the elderly aged 60 years and older, starting with the oldest, regardless of whether they belong to a medical risk group or not.

Vaccinating the elderly, both those living independently and those living in long-term care facilities, will reduce the burden of disease in reduce this group and this will result in the pressure in care being reduced. It is therefore importance of using currently available vaccines to vaccinate the elderly and designing the vaccination program so that the chosen vaccination strategy can continue to be followed.

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De adviezen van de Gezondheidsraad zijn openbaar en worden als regel opgesteld door multidisciplinaire commissies van – op persoonlijke titel benoemde – Nederlandse en soms buitenlandse deskundigen.

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Deze publicatie kan als volgt worden aangehaald:
Gezondheidsraad. COVID-19-vaccinatie: Moderna-vaccin en de vaccinatiestrategie.
Den Haag: Gezondheidsraad, 2021; publicatienr. 2021/01.

Auteursrecht voorbehouden

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COVID-19-vaccinatie: AstraZeneca-vaccin

Nr. 2021/04, Den Haag, 4 februari 2021

Samenvatting

Gezondheidsraad

Recently, the ChAdOx1-S nCoV-19 vaccine against COVID-19 developed by the University of Oxford and pharmaceutical company Astra- Zeneca (brand name Covid-19 vaccine Astra- Zeneca) has been positively evaluated by the European Medicines Agency (EMA) and regulated by the European Commission. This means that it can be used in the Netherlands to combat the COVID-19 pandemic. The Minister of Health, Welfare and Sport has asked the Health Council to advise on the use of this vaccine in different target groups eligible for vaccination. The Committee on Medical Aspects of COVID-19 assessed the vaccine using the established criteria by the Health Council when advising on vaccinations.

Disease burden of COVID-19 is large

The first criterion for deployment of vaccination is that there must be a significant disease burden. This is clearly the case with COVID-19. Until the end of January, COVID-19 confirmed 956,867 cases of illness and 13,665 deaths at the GGD. The risk of a serious disease course increases with age and is increased in people with chronic conditions.

Vaccine works well

The next criterion is that vaccination must be workable and effective. The vaccine is administered in two doses 4 to 12 weeks apart. The efficacy of the ChAdOx1-S nCoV-19 vaccine against COVID-19 was determined in more than 10,000 people, half of whom received the vaccine and half of whom received a control vaccine.

During a follow-up period of approximately two months, the efficacy of the vaccine about 60% in adults and medical risk groups. In people 56 years of age and older, there are still too few data available to vaccine efficacy. Because the vaccine does induce an immune response in this group that is similar with those of 18-55-year-olds, the assumes that the vaccine will be effective.

It is still unknown how long the protection lasts and to what extent vaccination can also prevent the spread of the virus.

Vaccine is sufficiently safe: side effects are generally mild

The safety of vaccination is also an important criterion. The ChAdOx1 nCoV-19 vaccine is sufficiently safe and well tolerated.

Like all drugs, vaccines have side effects. The purpose of vacci- nation is to elicit a response from the immune system, and this is often accompanied by

associated temporary symptoms. Vaccination with the ChAdOx1-S nCoV-19 vaccine causes side effects in most people. These are milder after the second dose and are less common. The most common were sensitivity and pain at the injection site, fatigue and headache. The reactions were mostly mild to moderate in severity were usually gone within a few days.

Vaccination is acceptable: advantages outweigh disadvantages

The committee finds that the advantages of vaccination (health benefits from protection against COVID-19) outweigh the disadvantages (side effects that are usually mild and short-term). Thus, the criterion of acceptability is also met. The cost-effectiveness of vaccination cannot yet be assessed, as no data are yet available.

Recommendation: deploy vaccine, first in 60-64-year-olds

The committee recommends that the ChAdOx1-S nCoV-19 vaccine be used in public vaccination programs targeting COVID-19 because the vaccine is efficacious, sufficiently safe and acceptable. In people 56 years of age and older, efficacy cannot yet be calculated due to the small number of older participants in the phase 3 trial. However, the ChAdOx1-S nCoV-19 vaccine has been shown to elicit an immune response in the elderly. Therefore, the committee assumes that the vaccine is sufficiently effective in them as well.
Because the immune system goes down functioning with advancing age (immunosenescence), in the elderly from 65 years of age uncertain whether the vaccine is sufficiently efficacious. The committee therefore considers the vaccine usable in adults up to 65 years of age. To prevent as much serious illness and death as possible, the committee recommends that the first available doses of the ChAdOx1-S nCoV-19 vaccine to be in the elderly of 60 to 64 years of age, starting with the oldest. Modeling lates that with this, the burden of disease will be lower than if this group is vaccinated with an mRNA vaccine later, namely after all 65-plusers, in accordance with the current vaccination schedule. In addition, the committee recommends vaccinating specific medical high-risk groups with an extra high risk. In part, these patients can be vaccinated with the ChAdOx1-S nCoV-19 vaccine. The patients whose immune systems are severely compromised should preferably receive an mRNA vaccine.
Once all the elderly are vaccinated, the committee to proceed vaccination with the ChAdOx1-S nCoV-19 vaccine of two groups at similar increased risk of a severe disease course of COVID-19: medical risk groups up to 60 years of age and people in the 50 to 60 age group, both groups starting with the elders.

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Deze publicatie kan als volgt worden aangehaald:
Gezondheidsraad. COVID-19-vaccinatie: AstraZeneca-vaccin.
Den Haag: Gezondheidsraad, 2021; publicatienr. 2021/04

Auteursrecht voorbehouden

COVID-19-vaccinatie: Janssen-vaccin

Nr. 2021/13, Den Haag, 17 maart 2021

Samenvatting

Gezondheidsraad

Recently, the Ad26.COV2.S vaccine against COVID-19 developed by Janssen Pharmaceutica (brand name Covid-19 vaccine Janssen) was positively evaluated by the European Medicines Agency (EMA) and registered by the European Commission. This means that it can be used in the Netherlands to combat the COVID-19 pandemic. The Minister of Health, Welfare and Sport asked the Health Council to advise on the use of this vaccine. The Committee on Medical Aspects of COVID-19 assessed the vaccine using the established criteria used by the Health Council when advising on vaccinations.

Disease burden of COVID-19 is large

The first criterion for deployment of vaccination is that there must be significant disease burden. This is clearly the with COVID-19. Until early March 2021, there are at the GGD
1,128,202 cases of illness and 15,917 deaths were confirmed by COVID-19. The risk of severe disease progression increases with age and is increased in people with chronic conditions.

Vaccine works well

The next criterion is that vaccination must be workable and effective. The vaccination consists of one dose. The efficacy of the Ad26.COV2.S vaccine against COVID-19 is determined in over 39,000 people, half of whom received the vaccine and half of whom received a placebo. As of 28 days after vaccination, the efficacy of the vaccine was found to be 66% against disease (positive
PCR test in combination with symptoms) and 85% against severe disease. Still unknown is how lang the protection lasts and to what extent vaccination can also prevent the spread of the virus. The added value of a second dose of vaccine is also still being studied.

Vaccine is sufficiently safe

Vaccination safety is also an important criterion. The Ad26.COV2.S vaccine is sufficiently safe and well tolerated. Like all drugs, vaccines have side effects. The purpose of vaccination is
to trigger an immune system response, and this is often accompanied by associated temporary symptoms. Vaccination with the Ad26.COV2.S vaccine causes side effects in most people. The most common were pain at the injection site, fatigue, headache and muscle pain. The reactions were more common in younger people than in the elderly, but were in the
most cases disappeared within two days.

Vaccination is acceptable:

advantages outweigh disadvantages

The committee believes that the benefits of vaccination (health benefits from protection against COVID-19) outweigh the drawbacks (side effects that are usually short-lived).

This also the criterion of acceptability. The cost-effectiveness of vaccination cannot yet be assessed because no data yet available on this.

Opinion: vaccine deployment

The committee recommends that the Ad26.COV2.S vaccine be used in public vaccination programs directed against COVID-19 because the vaccine is effective, sufficiently safe and acceptable for adults, the elderly and medical risk groups. The committee also recommends that the Ad26.COV2.S vaccine be used for the time being in the elderly aged 60 years and older, and vaccinated from old to young, until everyone in this group has had the opportunity to be I vaccinated. Vaccinating this group will prevent as much serious morbidity and mortality caused by COVID-19 as possible.

De Gezondheidsraad, ingesteld in 1902, is een adviesorgaan met als taak de regering en het parlement 'voor te lichten over de stand der wetenschap ten aanzien van vraagstukken op het gebied van de volksgezondheid en het gezondheids(zorg)onderzoek' (art. 22 Gezondheidswet).
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Deze publicatie kan als volgt worden aangehaald:
Gezondheidsraad. COVID-19 vaccinatie: Janssen-vaccin.
Den Haag: Gezondheidsraad, 2021; publicatienr. 2021/13.

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