

PELS RIJCKEN

District Court of the Northern Netherlands,
Leeuwarden branch. Hearing of 10 January 2024
Case number/roll number C/ 17/ 190788 / HA ZA 2023-172

Statement of defence

concerning

1. The State of the Netherlands
whose registered office is situated in The Hague
 2. Everhardus Gte Hofstra
 3. 3aap Tamino van Dissel
 4. Maria Petronelia Gerarda Koopmans
 5. Mark Rutte
 6. Sigrid Agnes Maria Kaag
 7. Hugo Mattheüs de Jonge
 8. Ernst Johan Kuipers
 9. Diederik Antonius Maria Paulus
Zotiannes Gommers
 10. Wopke Bastiaan Hoekstra
 11. Cornelia van Nieuwenhuizen
 12. Feike Sijbesma
- all residing in The Hague

solicitors: Mr R. W. Veldhuis and Mr M. E.A.
Möhring

and

13. Albert Bourla, solicitor:
Mr D. Roessingh

14. Giselle Jacqueline Marie-Thérèse Van
Cann

15. Pauï Edwin Zansen
solicitor: Mr L. Broers

16. William Henry Bill Gates III
solicitor: Mr W.H. Heemskerk

17. Agnes Catharina van der Voort-Kant,
solicitor: Mr A.H. Ekker

Defendants

against

1. [REDACTED]
2. [REDACTED]
2. [REDACTED]
4. [REDACTED]
5. [REDACTED]
6. [REDACTED]
7. [REDACTED]

claimants

solicitors: P.W.J. Stassen, LL.B., and A.G.W.
van Kessel, LL.B.

1 Introduction

- 1.1 The Covid-19 pandemic was a turbulent period, during which various, sometimes far-reaching, measures were necessary to protect public health and society. These included, for example, a curfew, mandatory closures of various sectors and schools, advice to stay at home as much as possible, the requirement to maintain a distance of 1.5 metres from others, and lockdowns. As a result, normal social life was suddenly — and for a prolonged period — turned completely upside down.

The Government's policy in this regard has always been based on three pillars: (i) ensuring that the healthcare system could cope within acceptable limits — hospitals must be able to provide high-quality care to both COVID-19 patients and those receiving routine care, (ii) protecting vulnerable members of society, and (iii) monitoring and understanding the spread of the virus, at a time when little was yet known about it.

- 1.2 The Government realises that this has led to a period of uncertainty for people, and that, in such a situation, people are right to ask questions about the approach to the pandemic and the measures taken in that regard. There is every scope for such questions.

Against this background, the Dutch Safety Board (OVV) also conducted an extensive investigation into the government's handling of the coronavirus crisis. The aim was to reconstruct, understand and, where possible, explain the events and actions that took place during the coronavirus crisis. This has resulted in three comprehensive interim reports.

- 1.3 The central claim of the claimants in these proceedings is that there was deliberate and unlawful misrepresentation, in that the Dutch population (and therefore also the claimants) were urged by the defendants to be vaccinated against Covid-19, whilst the defendants were allegedly aware that the vaccine was neither safe nor effective. The claimants are also seeking a declaration to that effect.

- 1.4 This assertion **by the claimants** is incorrect and lacks any factual basis. That assertion and claim are based entirely on the claimants' theory that there is a global conspiracy, of which the defendants are said to be a part. Among other things, that conspiracy is said to be aimed at implementing the 'Great Reset'. According to **the claimants**, the 'Great Reset' means that, following Covid-19, 'many things in the world will have to change forever',* because Covid-19 has exposed flaws in the system and is said to lead to a 'new normal'.* All 'factors affecting human life' are said to be made 'subject to forced change' as a result.⁴ What this actually

⁴ Available at: <https://www.onderzoeksraad.nl/nl/oaoe/20666/aanoak-coronacrisis>.
⁵ Summoning, para. 117.
 Summons, para. 122.
 Summons, para. 186.

It cannot be inferred from the writ of summons what this means in concrete terms (and why this should lead to the upholding of Oe's claims). However, the writ of summons does take the view that, in order to bring about the 'Great Reset', it would be pretended that major crises were taking place, whilst in reality these apparently did not occur.⁵ Part of the 'Great Reset' would thus also be the 'Covid-19* project', which allegedly involves a "faked SARS-CoV-2 virus".!

'Covid-19 therefore does not actually exist, and the "Covid-19 injections" would lead to (serious) injury and death.' According to the claimants, the Covid-19 vaccinations are "crucial" to the implementation of the 'Covid-19 project'! According to the claimants, this constitutes (psychological) abuse of the population,⁹ a medical experiment on the population,¹ an attempt to "overthrow the State" and even genocide.² Why all this is allegedly taking place, however, remains unclear even after reading the summons.

- 1.5 According to the claimants, this conspiracy was initiated by NGOs (in particular the WEF*), and is funded by the World Bank.⁴ The State — and various other defendants — are, according to the claimants, under the leadership of the WEF and are implementing the 'Great Reset' and the 'Covid-19 project'.
- 1.6 The specific basis for these theories put forward by the claimants appears to be the book *The Great Reset*, which outlines what the authors believe the world *might* look like after Covid-19. This book was co-authored by Mr Schwab, the chairman of the WEF.*' Under the banner of 'The Great Reset', the WEF is promoting the sharing of insights and information on a global approach to the social and economic crisis following the pandemic,¹⁶

See Jean Dohmen, 'How the Great Reset was fabricated', *FD* 22 January 2022, pp. 17–18 (**Exhibit 1**) and Nieuwsuur, 'The Great Reset: the ever-recurring fabrications', 14 July 2022."

- 1.7 The plaintiffs' theory appears to be that this book, or the WEF initiative based on it, constitutes a plan which the State (and the other defendants) are implementing on the WEF's instructions. That theory has no factual basis whatsoever.

[^] Summon, para. 186.

[^] Statement of Claim, paras. 41, 109. ' Statement of claim, para. 109.

" Summoning, para. 48. "

Summoning, para. 277.

[^] Summoning, para. 273. "

Summoning, para. 275. "

Summoning, para. 281.

" Furthermore, GAVI is also mentioned, and, incidentally, the UN as well, " Subpoena, para. 114.

⁵ Klaus Schwab & Thierry Pélissier, *Covid 19. The Great Reset*, Zurich: ISBN Agentur Schweiz 2020.

¹⁶ **Appendix to Proceedings II** 2021/22, 2541, answer to question 4. "

NOS, 'The Great Reset: the ever-recurring myths', <https://nos.nl/nieuwsuur/collectie/13903/video/2436700-the-great-reset-ae-steeds-teruokerencie-verzinsels>.

1.8 The WEF is nothing more than an organisation dedicated to fostering international cooperation. The WEF aims to serve as an independent and impartial international consultative body and to provide a platform for public-private partnership. The WEF, as a private-law foundation under Swiss law, does not have the authority to issue instructions to the State or its ministers, nor does it do so. The State's policy is not determined by the WEF, but by the Cabinet — which is subject to scrutiny by the States General.

1.9 Nor is the State in any way committed to the objectives of the WEF (or its chairman), nor to the ideology of 'The Great Reset'.

See also the responses to various parliamentary questions raised by MP Van Houwelingen on this subject:

"The WEF objectives as such are not the Government's objectives. The government is not committed to Mr Klaus Schwab."

"(...) The Dutch government has no affiliation with the Great Reset Initiative and, apart from publicly available information on this subject from the WEF, has no documents on the matter. (...)"⁹

1.10 The claimants then go on to put forward theories about the 'Covid-19 project' — which they claim forms part of the 'Great Reset'. These theories are unquestionably reprehensible. Without any factual basis, or even the slightest shred of evidence, it is claimed that Covid-19 (a disease that has cost many people their lives, has caused significant damage to health and much other suffering) does not actually exist, but was invented in order to subsequently — deliberately and maliciously — administer vaccines to the population that would lead to (serious) injury and death. These allegations are not only serious, *but* also incorrect and unfounded. There is no question of a conspiracy or a 'Covid-19 project'. The Covid-19 coronavirus does indeed exist, and the vaccines have been found to be safe and effective.*[^] The **claimants'** assertions run counter to the global scientific consensus and are based on unfounded suggestions and speculation. Furthermore, these assertions defy the laws of logic, as it is impossible to see (and the claimants fail to explain) why vaccinations would be administered to the population that would lead to (serious) injury and death.

1.11 The summons therefore concerns nothing more than (conspiracy) theories without any factual basis, whereby those theories are subsequently used to make far-reaching, malicious and entirely unfounded accusations. The summons is built on quicksand; there is no question of a conspiracy based on a 'Great

¹⁰ Appendix Proceedings II 2021/22, 1 164, p. 5.

Appendix to Proceedings II 2021/32, Z541, p. 11, answer to question 53.

²⁰ See paragraph 5 below.

Reset’ or a ‘Covid-19 project’, and the claimants have not yet provided even the slightest evidence to that effect. Consequently, the claimants’ claims are entirely without merit.

- 1.12 The State wishes to emphasise that the consequences of the theories set out in the summons are by no means harmless. The narrative, fuelled by these theories, of a malevolent elite acting against the population may ultimately undermine the democratic rule of law. It already provides a group of people with justification for online hate speech, (death) threats and worse.
- 1.13 In line with this, the summons in this case is directed not only against the State, but also against various individuals who, as government ministers, members of the DMT or in other capacities, have worked tirelessly to combat the pandemic. These people – many of whom are already having to cope with hate messages and (death) threats, and in some cases also require security – have been summoned in their private capacity and at their home addresses, only to then be forced to read far-reaching personal accusations against them in the summons. Furthermore, the foundation apparently behind this summons* has – banners regarding these proceedings have been hung along the (side) roads (and offered for sale on their website), on which these individuals are named by name (**Exhibit 2**). Both the summons and photographs of the banners have been widely shared with the media** and on the internet,²³ accompanied by captions such as *“Share this, everyone: the responsible party is finally appearing in court!!”* and *“There must be retribution!”* (Exhibit 3). On the first day of these proceedings, several people also gathered outside the court holding similar banners, and a lorry was parked directly in front of the court displaying photographs of some of the individual defendants, with the text *“Wanted”* above them and, surrounding this, texts including *“corona vaccine — poison”, ‘375,000 vaccine deaths in the EU’* and *‘Vaccinazi power unleashed!!!’* (**Exhibit 4**).
- 1.14 And all this despite the fact that there is no legally valid interest in involving these individuals in their private capacity in these proceedings. After all, the allegations made against these individuals in the writ of summons relate to their work for the State. It is settled case law that the conduct of these individuals must therefore be attributed to the State.²⁴ This means – as (the lawyers for) the claimants are well aware – that the allegations are wrongly directed at these individuals in their private capacity and should instead be directed at the State. In so far as the claimants’ claims are

²¹ See: <https://rechttoprecht.online/>. For the record: this does not mean that these proceedings are (or can be) a collective action. That is not the case, not least because the requirements of Article 3:30Sa of the Dutch Civil Code have not been met. Insofar as the claimants assert in the writ of summons that these proceedings also serve ‘the interests of fellow human beings’ (paragraph 19 of the writ of summons) or put forward arguments regarding the vaccination of minors (paragraph 34 of the writ of summons), they cannot, therefore, represent those interests in these proceedings.

²² See also on this subject: <https://chrisklomo.nl/een-kansioze-corona-aan-kiacht/>. See also the video at <https://rechttoprecht.online/rechtszaak>. <https://rechttoprecht-online/index>

²⁴ Supreme Court 11 October 1991, ECM:NL:HR: 1991 :ZC0360, NJ 1993/165, para. 3.3. See also The Hague Court of Appeal 18 July 2017, ECLI:NL:GHDHA-20 L7 -2033, para. 10.

As the claims are directed against these individual persons, the claimants' claims must therefore be dismissed on this ground alone.

The State also expressly requests this court to rule on this defence. The reason for this is that the State is increasingly faced with summonses directed, without any legally justifiable grounds, against individual government ministers in their private capacity and other persons associated with the State. The State wishes to put a stop to this, in order to protect the interests of these persons.

1.15 It is already clear from the foregoing that the claimants' claims cannot succeed. It is therefore merely for the sake of completeness that the State will set out its defence in more detail below. The defence set out in this statement of defence is put forward not only by the State but also by the other defendants on whose behalf this statement is made (defendants 1 to 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 cases of pneumonia. The newly discovered virus was named 'SARS-Coronavirus-2', and the respiratory disease resulting from the virus was named 'COVID-19'.

2.1.2 An infection with the Covid-19 virus can lead to (very) severe symptoms. These include, for example, high fever, shortness of breath, pneumonia and septic shock. A significant proportion of people who develop pneumonia as a result of Covid-19 require ventilation and must therefore be admitted to the ICU. The virus has also proved fatal for a large number of people.*⁷

It is now also known that the virus can lead to long-term health complications, such as so-called 'post-Covid'.*

2.1.3 On 22 January 2020, the Minister for Medical Care briefed the House of Representatives on the new virus.²⁵ At that time, the virus had not yet reached the Netherlands. The Minister wrote, amongst other things, that the RIVM would set up an Outbreak Management Team (OMT)

²⁵ Advice following OMT 2019-nCoV (Wuhan), 27 January 2020a. The OMT reports can be consulted here: <https://www.rivm.nl/corona/covid-19/advice>.

²⁶ Dutch Safety Board, *Response to the coronavirus crisis. Part 1 – up to September 2020*, The Hague: Dutch Safety Board 2022, p. 40, available at <https://www.rijksoverheid.nl/documenten/rapporten/2022/02/16/adddak-caronacr.isis-deel-1-tot-september-2020>.

²⁷ RIVM, 'COVID-19 Guidelines', <https://ici.rivm.nl/richtlijnen/covid-19>.

²⁸ Central Government, 'Post-Covid (long-term effects after Covid)', <https://www.rijksoverheid.nl/onderwerpen/coronavirus-covid-19/luchtweovirussen-zoais-uried-en-corona/post-covid>.

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

organise: a team of experts to advise on the virus and any further measures to be taken. At that time, there was still a great deal of uncertainty about the virus;³⁰

*'It is established that human-to-human transmission has been reported, but key **data** on how easily this transmission occurs are lacking. The incubation period is likely to be between a minimum of 3 and a maximum of 1 days. The extent of human-to-human transmissibility and the circumstances **under which** transmission occurs are not yet fully understood. Current evidence suggests transmission via droplets released when coughing and sneezing.*

*Transmission via viral droplets can occur over a range of 1.5 to 2 metres. It is **not** yet **known** when a person carrying the virus becomes infectious, nor how long infectiousness persists during illness."*

- 2. 1.4 At that time, the European Centre for Disease Prevention and Control (ECDC) still assessed the risk of the virus being introduced into Europe as moderate and the risk of further spread within Europe as low.** The RIVM stated at the time that the virus did not appear to be highly contagious,³² and that the likelihood of the virus reaching the Netherlands was considered low.³³
- 2.15 These assessments were soon rendered obsolete.
- 2.2 The global spread of the virus
- 2.2. 1 On 30 January 2020, the World Health Organisation (WHO) — part of the United Nations — noted that the virus had spread to various countries on different continents. The WHO therefore declared that there was 'a *public health emergency of international concern regarding the global outbreak of a novel coronavirus*'.*
- 2.2.2 The virus then began to spread rapidly across the globe. The number of infections rose sharply, not only in the Netherlands (where the first person tested positive on 27 February 2020) but also worldwide.³⁵ Worldwide, by the end of February 2020, there were already (as far as is known) nearly 100,000 people infected with the virus,³⁶

³⁰ Advice regarding ONT 2019-nCoV (Wuhan), 27 January 2020. "

³¹ Advice regarding ONT 2019-nCoV (Wuhan), 27 January 2020.

³² R4VN, 24 January 2020, <https://twitter.com/rtvm/status/1220717815340158978>.

³³ RIVM, 'Patients with pneumonia of unknown cause in China', 10 January 2020, <https://www.rivm.nl/nieuws/nieuwe-ontziekte-in-china>,

³⁴ WHO, 'WHO Director-General's statement on the IHR Emergency Committee on the Novel Coronavirus (2019-nCoV)', 30 January 2020, <https://www.who.int/director-general/soeche.s/detail/who-director-general-s-statement-on-ihr-emergency-committee-on-novel-coronavirus-2019-ncov>.

³⁵ Dutch Safety Board, *Response to the coronavirus crisis. Part 1*, p. 43. '*'

³⁶ Advice following 58° ONT Covid-19, 8 March 2020.

223 On 11 March 2020, the WHO formally declared that a pandemic was underway.³⁷

2.2.4 At that time, there were (as far as was known) 118,000 cases worldwide across 114 countries, and 4,291 people had died as a result of the virus. The WHO expected that in the coming days and weeks, the number of infections, the number of affected countries and the death toll would continue to rise. The decision to classify the Covid-19 outbreak as a pandemic was not taken lightly, the WHO emphasised:

“Pandemic is not a word to be used lightly or carelessly. It is a word which, if misused, can cause unreasonable fear, or an unjustified assumption that the fight is over, leading to unnecessary suffering and death.

Describing the situation as a pandemic does not alter the WHO’s assessment of the threat posed by this virus. It does not change what the WHO is doing, nor does it change what countries should do.

We have never before seen a pandemic caused by a coronavirus. This is the first pandemic 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 backdrop, on 1–2 March 2020, the WHO sent an open letter regarding the severity of the pandemic. In that letter, all countries are called upon to protect public health, whilst taking into account economic and social stability and respecting human rights.⁴⁰

2.3 The first case in the Netherlands

2.3.1 From February 2020 onwards, the virus also spread in the Netherlands. As shown in the graph below, the virus spread rapidly within a short period of time and the number of infected people rose sharply:⁴⁰

³⁷ WHO, ‘WHO Director-General’s opening remarks at the media briefing on COVID-19’, 11 March 2020, https://www.who.int/director-general/speeches/5/@yE5jg_yihpi@rector I gg,qntq,a-re.mar.ig\$ g= media-briefing-on-covid-19 -----11 March 2020

³⁸ WNO, ‘WHO Director-General’s opening remarks at the media briefing on COVID-19’, 11 March 2020. ³⁹ Contrary to the claimants’ assertion (summons, para. 11), this letter does not yet mention anything regarding (the

obligation to be vaccinated.

⁴⁰ Central Government, ‘Corona Dashboard: infectious people’, <https://coronadashboard.rliksoverheid.nl/landell1k/besmettelijke-mensen>

Number of infectious people over time

This graph shows the estimated number of infectious people over



2.3.2 As a result, it soon became impossible for the RIVM and the GGD to trace the source of infection for every person infected with the virus. Pressure on the healthcare system increased (regionally), and concerns also began to arise about the available ICU capacity. Overall, this created an uncertain situation in the Netherlands,^{4 *}

2.3.3 Consequently, with effect from 12 March 2020, the government introduced the first far-reaching measures: anyone with symptoms had to stay at home, gatherings of more than one hundred people were cancelled, and everyone was asked to stay at home as much as possible. From 15 March 2020, the Netherlands was in lockdown:^{4*} in addition to the measures taken previously, the hospitality sector, schools and childcare centres closed, and everyone in the Netherlands was asked to maintain a distance of 1.5 metres. People working in contact-intensive professions were not permitted to work. On 19 March 2020, care homes were closed to visitors. Furthermore, on 26 March 2020, gathering in groups on the street was no longer permitted. The aim was to slow the spread of the virus and, in doing so, keep the strain on the healthcare system and intensive care units manageable,⁴⁴

Testing was of great importance in this regard. On 16 March 2020, the WHO called on all countries to test people with symptoms of Covid-19.⁵ However, like many other countries, the Netherlands faced a shortage of testing materials.^{4*} The House of Representatives also expressly urged the Minister to make the procurement of necessary protective and testing materials and ventilators an even higher priority, as the Minister also noted in his letter.^{4 *} It was necessary to

^{4*} Dutch Safety Board, *Handling the coronavirus crisis. Part 1*, p. 46. ^{*} Advice in response to 59th ONT, 12 March 2020.

Dutch Safety Board, *Response to the coronavirus crisis. Part 1*, pp. 50, 59.

^{4*} Dutch Safety Board, *Response to the coronavirus crisis. Part 1*, p. 50.

^{4 *} WHO, "WHO Director-General's opening remarks at the media briefing on COVID-19", 16 March 2020, https://www.who.int/director-general/soerhes*detafi/whc-cllrer*nr-aenera!-s-on n nQ-*e may nl,

^{**} Parliamentary Papers 71 2019/20, 25295, No. 179.

^{*} Parliamentary Papers M 2019/20, 25295, no. 179.

prioritise. For this reason, initially only patients in hospitals and certain healthcare providers were tested.

In the meantime, various measures were taken to resolve the shortage of testing materials. One of these was the establishment of the National Coordination Structure for Testing Capacity (LCT) and the setting up of the Diagnostics Task Force to expand.⁴ !

In so far as the claimants argue that there was no shortage of testing capacity,⁴ this is incorrect. There was indeed a shortage of tests, and not only in the Netherlands. In support of their contrary assertion, the claimants refer to the World Bank's World Integrated Trade Solutions (WITS) database. According to the claimants, this allegedly shows that trade in Covid-19 tests was already taking place in 2017. However, this does not follow from the evidence submitted by the claimants. The relevant WITS webpage states (underlining added): *"The data here track previously existing medical devices that are now classified by the World Customs Organisation as critical to tackling Covid-19."* **

2.3.4 The Government's policy in this regard was consistently based on three pillars: (i) ensuring that the healthcare system could cope — hospitals must be able to provide high-quality care to both COVID-19 patients and those receiving routine care, (ii) protecting vulnerable members of society, and (iii) monitoring and understanding the spread of the virus. In addition to these three pillars, the social perspective was also an important guiding principle in the Government's decision-making. This principle focused on limiting short-term social and economic damage, addressing structural social and economic damage, and preventing the disproportionate burden from falling on certain groups.

2.3.5 Furthermore, the Government has consistently sought advice from the DI JT in its policy-making. The OMT provides medical and epidemiological advice and comprises experts and representatives from various professional organisations who offer advice based on their own areas of expertise. The DMT therefore possesses the specific expertise required to provide the best possible epidemiological advice." In addition, the Government also relied on advice from the RIVM, the WHO and the ECDC. Furthermore, the Netherlands Institute for Social Research (SCP) provided advice on the social impacts of the crisis and possible measures, whilst the Ministries of Economic Affairs and Climate Policy (EZK), Social Affairs and Employment (SZW) and Finance (the Troika) advised on the economic, social and financial impacts. Until

¹¹⁸ Dutch Safety Board, *Response to the coronavirus crisis. Part 3. January 2020 – September 2023a*, The Hague: Dutch Safety Board 2023, p. 56, available at: <http://www.rijksoverheid.nl/documenten/rapporten/2023/10/25/aanpak-coronacrisis>.

⁴⁹ Summon, § 1B8.

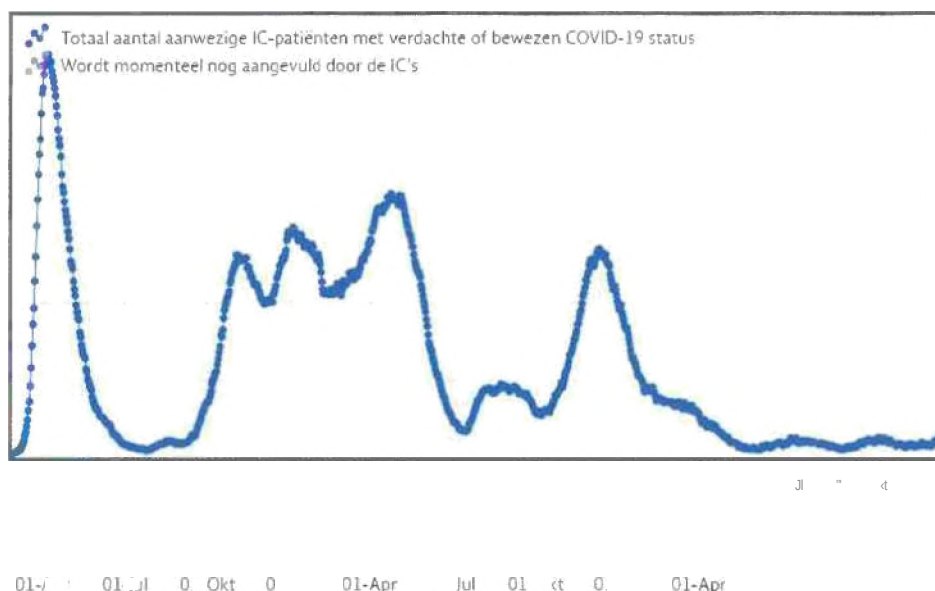
WITS website, 'Medical Diagnostic Test Instruments and Apparatus (9027g0) exports by country in 2017', <https://wits.worldbank.org/trade/comtrade/en/country/ALL/year/2017/tradehow/Exports/Dartner/WLD/nom/en/h5/product/902780>.

See: inter alia, The Hague Court of Appeal, 26 February 2021, ECLI:NL:GHDHA:2021:285, para. 6.8; The Hague District Court 3 April 2020, ECLI:NL:RBDHA:2020.3013, para. 4.8; Parliamentary Papers II 2000/01, 25295, no. 3 (letter from the Minister for Health, Welfare and Sport dated 22 June 2001).

Finally, implementation assessments were carried out by, amongst others, the RIVM's Behavioural Unit, the National Police, the safety regions and the Association of Netherlands Municipalities.

- 2.3.6 Despite the measures taken, the number of infections rose rapidly and reached high levels. This placed considerable pressure on the healthcare system, forcing a scaling back of other forms of care (including for life-threatening conditions such as cancer and heart disease).⁵² The Ministry of Defence was called in to support the healthcare system. Not only did hospital bed occupancy rise rapidly, but ICU occupancy also increased rapidly. During that period, every effort was made to scale up ICU capacity and make maximum use of existing capacity.⁵³ However, hospital ICUs became so full that patients had to be transferred to ICUs in other hospitals, and ultimately even to Germany.⁵⁴ For an overview of ICU occupancy: 5'

Het totaal aantal aanwezige patiënten met verdachte of bewezen COVID-19 op de IC per dag 2020 – 2022



- 2.3.7 On 21 April 2020, the figures relating to hospitals and ICUs were encouraging, but the pressure on the healthcare system remained extremely high (for example, routine care was still largely scaled back). The situation in care homes remained very worrying. There were many uncertainties. As the measures had slowed the spread of the virus and the pressure on the healthcare system was easing,

⁵² RIVM, 'Impact of the first COVID-19 wave on routine healthcare and health', 2020, [Gv.../radio18lof](#).

⁵³ Parliamentary Papers If 2020/2 1, 25295, No. 1063.

⁵⁴ Dutch Safety Board, *Handling of the coronavirus crisis*. Vol. 1, p. 58. On 7 April 2020, ICU occupancy peaked. At that time, there were 1,424 COVID-19 patients in ICUs, 46 of whom were in Duijsland. The claimants' assertion that there was never a shortage of ICU beds (para. 94 of the writ of summons) is therefore incorrect.

⁵⁵ National Intensive Care Evaluation, 'COVID-19 infections in ICUs 2020–2022',

it was, however, possible to announce some easing of restrictions. For example, primary schools reopened from 11 May 2020, and more was also permitted in the area of sport. The explanatory notes accompanying this decision-making process revealed just how far-reaching the pandemic was, and how much the government struggled to strike a balance between implementing restrictive measures and keeping society functioning.⁶

- 2.3.B During the press conference on 6 May 2020, it was emphasised that the Netherlands would have to learn to live with the virus until a vaccine became available. To enable daily life to continue as normally as possible in the meantime, testing was of the utmost importance. From 1 June 2020, anyone in the Netherlands with symptoms was therefore able to get tested.⁷ As everyone could get tested and was required to stay at home following a positive test, there was some scope for easing the measures from that point onwards.

2.4 The second wave 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) rose again. It became clear that a second wave was heading for the Netherlands. This led to further measures being introduced in September 2020.⁸

- 2.4.2 Nevertheless, the number of infections continued to rise. The chair of the Federation of Medical Specialists described this second wave as a 'tsunami'.⁹ The number of infections is shown in the graph below:¹⁰

⁶ Central Government, 'Verbatim transcript of the press conference given by Prime Minister Mark Rutte and Director Jaap van Dissel (Centre for Infectious Disease Control) following the cabinet's crisis meeting', 2 April 2020, <https://www.rijksoverheid.nl/documenten/mediateksten/2020/04/21/letterlijke-tekst-oersconferentie-minister-mark-rutte-en-director-jaap-van-dissel-centre-for-the-control-of-infectious-diseases-following-the-conclusion-of-the-cabinet-crisis-meeting>.

⁷ Central Government, 'Verbatim transcript of the press conference by Prime Minister Rutte and Minister De Jonge following the conclusion of the Cabinet's crisis meeting', 6 May 2020, <https://www.rijksoverheid.nl/documenten/mediateksten/2020/05/19/letterlijke-tekst-persconferentie-minister-oreSident-rutte-en-minister-de-jonge-na-arloos-van-crisissheraad-kabine.r>.

⁸ Parliamentary Papers II 2020/21, Z529S, No. 613.

⁹ See also: Safety Investigation Council, *Tackling the coronavirus crisis*. Oeel I, p. 80; Central Government, 'Stricter measures to curb the spread of the virus', 28 September 2020, <https://www.rijksoverheid.nl/actueel/nieuws/2020/09/28/aanbevelingen-maatregelen-om-de-verspreiding-van-het-virus-terug-te-dringen>.

¹⁰ Peter Paul van Benthem, 'Blog: A tsunami called COVID-19', 12 October 2020, <https://demedischsoecialist.nl/news-overview/news/bjoo-tsunami-oenaa-md-covid-19>.

¹¹ NOS, 'The coronavirus week in charts: care homes increasingly the source of infection'. 13 October 2020, <https://nos.nl/artikel/2352186-de-coronaweek-in-grafieken-verpleeghuis-steeds-vaker-bron-van-besmetting>.

Coronavirus cases have doubled in two weeks

Positive coronavirus tests in the period 1 June – 13 October



Within two weeks, hospital bed occupancy had doubled. The number of admissions to ICUs also showed a sustained upward trend, all whilst pressure on the healthcare system was already high. The OMT predicted that occupancy rates in hospitals and ICUs would be twice as high as in March 2020 if no measures were taken and the previous measures proved ineffective. Against this backdrop, the Of JT advised that new, additional measures be introduced,⁶¹

2.4.3 On 13 October 2020, the government decided to impose a partial lockdown.**

2.4.4 In early November 2020, the number of hospital and ICU admissions began to stabilise. However, there were many indications that the strain on the healthcare system was too high. The reproduction number was also high in certain areas. To ensure that a downward trend would be established, the OMT recommended a brief tightening of the measures.⁶⁴ The government followed this advice and — in addition to the partial lockdown — for a period of two weeks.⁶⁵ After that, the partial lockdown was reinstated.

2.4.5 However, the partial lockdown was insufficient to prevent the virus from spreading further. By mid-December, there were nearly 200 new hospital admissions and over 25 new ICU admissions every day, and that figure was rising slightly. The pressure on the healthcare system increased further, and the backlog of routine care combined with the rising demand for Covid-19 care would become unsustainable if cases continued to rise. The outlook was for an increase in the number of infections higher than in March 2020.!!

**Advice following B0⁶⁶ OMT, 13 October 2020.

*⁶⁷ Central Government, 'Partial lockdown to reduce infections', 13 October 2020, <https://www.rijksoverheid.nl/nieuws/2020/10/13/partiel-lockdown-to-reduce-infections-gb.html>

*⁶⁸ Advice pursuant to Articles 83 and 84⁶⁹ OMT, 3 November 2020.

Central Government, 'Temporary tightening of partial lockdown', 3 November 2020, <https://www.rijksoverheid.nl/nieuws/2020/11/03/tijdelijke-verbetering-van-de-maatregelen-tegen-coronavirus>

⁶⁹ *hāyies n.a.* v. 91⁷⁰ OMT, 14 December 2020.

Consequently, the Netherlands went back into lockdown from 16 December 2020, which was explained as follows: 6'

"The point is: as people, we must remain vigilant throughout the day, dozens or hundreds of times, to keep the virus at bay. The virus only needs to get lucky once to spread, and we must be lucky with every contact."

That's an uneven battle, and it's exactly what we're seeing right now. Because the virus is spreading — far too often. Every day, an average of 60 people die from Covid-19. Every day, we record an average of around 9,000 new cases. That's a full Kuip stadium in less than six days. The figures are also rising in hospitals and care homes. In the second wave, more people are being admitted to hospital than in the first wave.

I know: numbers are abstract. And they certainly don't tell the whole story. But the reality is that more than a million routine hospital treatments have now been postponed. Imagine if that happened to you whilst you were waiting for treatment.

The reality is that staff in hospitals and care homes have been running on empty for three months now. They've really reached their limit.

To date, around 30,000 people with COVID-19 have been hospitalised, 6,000 of whom were in intensive care. Of those 6,000, the group aged under 50 was 2.5 times larger than the group aged over 80.

The harsh reality is that almost all of these 6,000 people would have died had they not been treated in intensive care. And that, almost without exception, they continue to suffer from shortness of breath, extreme fatigue and other symptoms long after their discharge from hospital.

That is what COVID-19 does. That is why it is so important that healthcare remains accessible. That there is a bed for you when you need it.

(...)

So much for a brief overview of the background to the lockdown. We have no choice: the number of contacts between people must be reduced. Everything must now be focused on that."

2.5 Start of the vaccination campaign and the third wave in the Netherlands

2.5.1 This was the situation in the Netherlands when the first Covid-19 vaccination was administered on 6 January 2021.*®

⁰¹ Central Government, 'TV address by Prime Minister Mark Rutte on the lockdown', 14 December 2020, <https://www.rijksoverheid.nl/documenten/toespraken/2020/12/14/tv-toespraak-van-minister-president-mark-rutte>.

⁰² Dutch Safety Board, 'Handling the coronavirus crisis. Part 2 – September 2020 to July 2021', The Hague: Dutch Safety Board 2022, p. 165. Available at: <https://www.rijksoverheid.nl/documenten/rapporten/2022/10/12/aanpak-coronacrisis>.

- 2.12 The shortage of vaccines at that time made it necessary to set priorities when administering vaccines. The aim was to minimise serious illness and death from Covid-19 as much as possible.⁶¹ For this reason, the most vulnerable people were vaccinated first: those aged 60 or over (from oldest to youngest), and those with underlying health conditions.⁶² In addition, healthcare staff in direct contact with patients, such as carers in care homes, were also given priority for vaccination,⁶³ so that staff absences in the overburdened healthcare sector could be prevented as far as possible. The vaccine would then be offered by age group (from oldest to youngest).⁶⁴ In this way, everyone in the Netherlands was given the opportunity to be vaccinated, with the State providing the population with as accurate and comprehensive information as possible.
- 2.5.3 By the end of February 2021, nearly 800,000 people had received their first dose of the Covid-19 vaccine. Just over 200,000 people had also received a second dose of the vaccine.⁶⁵ These included (some of) the most vulnerable people (those aged 80 and over, residents of care homes) and healthcare workers.
- 2.54 By the end of March 2021, a third wave was beginning to become apparent in the number of infections.⁶⁶ The third wave was expected to peak around mid-April 2021.⁶⁷ For this reason, the lockdown remained in force.
- 2.5.5 On 13 April 2021, the government announced that certain restrictions (such as the curfew) could be lifted from the end of April 2021, partly due to the increased vaccination rate — particularly among the elderly and vulnerable.⁶⁸

“With all the vaccinations we are administering, we will – as far as we can tell at present – reach a point in the second half of May that we are all incredibly looking forward to. By then, people over the age of sixty and those at high medical risk will have received their first dose. Once they are protected, far fewer people will become seriously ill from a COVID-19 infection. And, together with those who have already been ill and have thus built up immunity, this will ensure that the virus has much less scope to spread. We are already seeing evidence of this. That is why we will soon have the confidence to ease restrictions in a number of stages.”

⁶⁰ Dutch Safety Board, **Approach to the COVID-19 crisis. Part 2**, p. 147. Health Council of the Netherlands, *Strategies for COVID-19 Vaccination* No. 2020/23, The Hague: 1 November 2020. Available at: <https://www.gezondheidsraad.nl/documenten/adviezen/2020/1u19/strategieën-voor-covid-19-vaccinatie>.

Dutch Safety Board, **Tackling the coronavirus crisis. Part 2**, p. 147.

⁷² Parliamentary Papers II 2020/21, 25295, No. 745, p. 8.

RIVM, ‘First figures on vaccination coverage’, 23 February 2021, <https://www.rivm.nl/nieuws/eerste-cnfers-vaccinatieaard-in-beeld>. Central Government, ‘Verbatim transcript of the press conference by Prime Minister Rutte and Minister De Jong’, 23 March 2021, <https://www.rijksoverheid.nl/documenten/media-teksten/2021/03/23/letterlijke-tekst-persconferentie-minister-president-rutte-en-minister-de-jong-23-maart-2021>.

⁷⁵ Safety Investigation Council, **Tackling the coronavirus crisis. Part 2**, p. 67. Central Government, ‘Verbatim transcript of the press conference by Prime Minister Rutte and Minister de Jonge’, 3 April 2021, <https://www.rijksoverheid.nl/documenten/media-teksten/2021/04/L3/Literal-text-of-press-conference-by-Prime-Minister-Rutte-and-Minister-de-Jonge-3-April-2021>.

- 2.5.6 The effects of the start of the vaccination campaign were therefore clearly visible during the third wave. During the third wave, the RIVM noted that the number of hospital admissions among people under the age of sixty (who, in general, had not yet been vaccinated) rose sharply, whilst the number of hospital admissions among those aged eighty and over (a large proportion of whom had been vaccinated) fell – probably as a result of the vaccinations.”
- 2.5.7 By mid-May 2021, more than 6 million people in the Netherlands had received a first dose of the Covid-19 vaccine; nearly 2.5 million people had been vaccinated against the virus with two doses.’*

De COVID-19-vaccinatie

persoon die een eerste en/of tweede dosis COVID-19-vaccinatie heeft ontvangen op 20 mei 2021, per type uitvoerder.

groep	uitvoerder	Start-datum	Vaccinatie	Eerste dosis	Tweede dosis	Totaal	antallen
Leeftijdsgroep	Leeftijdsgroep	Leeftijdsgroep	Leeftijdsgroep	Leeftijdsgroep	Leeftijdsgroep	Leeftijdsgroep	Leeftijdsgroep
evacuatie door GGD	evacuatie door GGD	evacuatie door GGD	evacuatie door GGD	evacuatie door GGD	evacuatie door GGD	evacuatie door GGD	evacuatie door GGD
85-89-jarigen	85-89-jarigen	85-89-jarigen	85-89-jarigen	85-89-jarigen	85-89-jarigen	85-89-jarigen	85-89-jarigen
80-84-jarigen	80-84-jarigen	80-84-jarigen	80-84-jarigen	80-84-jarigen	80-84-jarigen	80-84-jarigen	80-84-jarigen
75-79-jarigen	75-79-jarigen	75-79-jarigen	75-79-jarigen	75-79-jarigen	75-79-jarigen	75-79-jarigen	75-79-jarigen
70-74-jarigen	70-74-jarigen	70-74-jarigen	70-74-jarigen	70-74-jarigen	70-74-jarigen	70-74-jarigen	70-74-jarigen
65-69-jarigen	65-69-jarigen	65-69-jarigen	65-69-jarigen	65-69-jarigen	65-69-jarigen	65-69-jarigen	65-69-jarigen
60-64-jarigen	60-64-jarigen	60-64-jarigen	60-64-jarigen	60-64-jarigen	60-64-jarigen	60-64-jarigen	60-64-jarigen
55-59-jarigen	55-59-jarigen	55-59-jarigen	55-59-jarigen	55-59-jarigen	55-59-jarigen	55-59-jarigen	55-59-jarigen
50-54-jarigen	50-54-jarigen	50-54-jarigen	50-54-jarigen	50-54-jarigen	50-54-jarigen	50-54-jarigen	50-54-jarigen
45-49-jarigen	45-49-jarigen	45-49-jarigen	45-49-jarigen	45-49-jarigen	45-49-jarigen	45-49-jarigen	45-49-jarigen
40-44-jarigen	40-44-jarigen	40-44-jarigen	40-44-jarigen	40-44-jarigen	40-44-jarigen	40-44-jarigen	40-44-jarigen
35-39-jarigen	35-39-jarigen	35-39-jarigen	35-39-jarigen	35-39-jarigen	35-39-jarigen	35-39-jarigen	35-39-jarigen
30-34-jarigen	30-34-jarigen	30-34-jarigen	30-34-jarigen	30-34-jarigen	30-34-jarigen	30-34-jarigen	30-34-jarigen
25-29-jarigen	25-29-jarigen	25-29-jarigen	25-29-jarigen	25-29-jarigen	25-29-jarigen	25-29-jarigen	25-29-jarigen
20-24-jarigen	20-24-jarigen	20-24-jarigen	20-24-jarigen	20-24-jarigen	20-24-jarigen	20-24-jarigen	20-24-jarigen
<20 jaar	<20 jaar	<20 jaar	<20 jaar	<20 jaar	<20 jaar	<20 jaar	<20 jaar
Totaal	Totaal	Totaal	Totaal	Totaal	Totaal	Totaal	Totaal

- 2.5.8 On 19 May 2021, and subsequently again on 28 May 2021, further easing of restrictions was announced. In principle, all sectors, including secondary education, were allowed to reopen subject to certain conditions. Here too, vaccination played a major role: “*And although it will take a little while yet, the end of this crisis is drawing closer with every jab.*”

RIVM, ‘Third wave sees sharp rise in hospital admissions among younger age groups’, 4 May 2021, <https://www.rivm.nl/nieuws/in-derde-oom-sterke-stijging-ziekenhuisopnames-100-jaar-leeftijdsgroepen>.

⁷⁸ RIVM, ‘Participation in COVID-19 vaccination in the Netherlands’, 25 May 2021, <https://www.rivm.nl/sites/default/files/2021-05/rapportage-2020COVID-19-199620Vaccinatieadvies-2021-05-2021-Dat>.

⁷⁹ Central Government, ‘Verbatim transcript of the press conference by Prime Minister Rutte and Minister De Jong’, 28 May 2021, <https://www.rijksoverheid.nl/documenten/mediateksten/2021/05/28/lettertietekst-oersconferentie-minister-president-rutte-en-minister-de-jong-28-mei-2021>.

- 2.5.9 At the end of June 2021, society reopened (in compliance with the 1.5-metre social distancing rule).⁸⁰ At that time, 9.9 million people in the Netherlands had been vaccinated with their first dose of the Covid-19 vaccine, and 5.3 million people had also already received their second dose.⁸¹

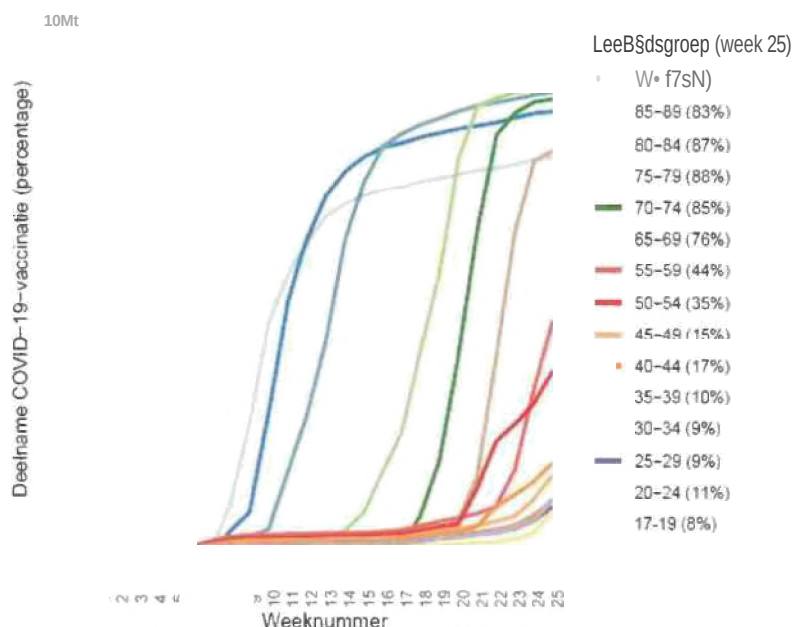


Figure 1: Cumulative percentage of COVID-19 vaccination by age group in the Netherlands, week 25.

2.6 A high vaccination rate and the lifting of the latest measures

- 2.6.1 In the summer of 2021, the epidemiological situation remained stable. The vaccination rate among adults stood at 5,696. Of these, 8,796 adults were fully vaccinated and therefore highly protected. As a result, the 1.5-metre social distancing rule was also lifted in September 2021.⁸²

- 2.6.2 When the number of infections rose again in the autumn of 2021, it once more became clear just how effective the vaccine was. The OMT wrote the following on this subject:⁸³

“Admissions and occupancy rates in nursing wards and intensive care units in hospitals are falling slightly. The average daily number of admissions to nursing wards over the past week was 42, compared with 3 the week before, and 10 versus 7 the week before that (source: LChS). Also, the

⁸⁰ Government Press Office, ‘Verbatim transcript of the press conference by Prime Minister Rutte and Minister De Jonge’, 18 June 2021, <http://www.rijksoverheid.nl/documenten/media/2011/06/18/letterlijke-tekst-persconferentie-minister-president-Rutte-en-minister-van-de-Zonghe-18-juni-2021>

⁸¹ RIVM, ‘Public participation in the Netherlands’, 29 June 2021, https://www.rivm.nl/sites/default/files/2021-06/COVID-19_Vaccination_Estimates_website_report_38210629_t059_a_noeoast.pdf

⁸² Hamer 5LJ kker II 2020/21, 2529S, rtf. 1422.

⁸³ Parliamentary Document: Status of COVID-19 as at 1 September 2021, Parliamentary Papers II 2020/21, 25z95, no. 1•t22.
Advice following 127• Ot•FT, 1 October 2021,

The incidence of hospitalisation is much higher in the unvaccinated population than in the vaccinated population. In September, this incidence was at least 10 times higher in the unvaccinated population compared with the vaccinated population across all age groups. The previously observed very high vaccine effectiveness against both hospitalisation and ICU admission in the Netherlands is confirmed by the most recent data (95% and 98%).'

- 2.6.3 The peak in the number of infections was lower as a result of the increased vaccination coverage. Nevertheless, the peak was higher than the government deemed justifiable, partly in view of the pressure this was placing on the healthcare system.^{!*} This led to the reintroduction of various restrictive measures. In addition, the campaign for booster vaccinations for the over-60s was launched.^{® 6} At that time, booster vaccines were proving to be highly effective against further infections in other countries.^{® 7}
- 2.6.4 In December 2021, the highly contagious Omicron variant began to spread. At the time, the severity of the illness caused by this variant was not yet known. Consequently, a strict lockdown was imposed at the end of that month. In addition, the booster campaign was further expanded.!!
- 26.5 Despite the high number of infections, the government, following advice from the ONT, deemed it justifiable on 25 January 2022 to ease the measures.^{!0} A key reason for this was the high vaccination rate. The vaccines provided good protection against hospital admissions, thereby relieving the pressure on the healthcare system. The unvaccinated group was clearly over-represented in the number of hospital admissions:g

^{!"} Kame<slutken II 2D2Of2t, ZS29S, no. 1468.

^{!"^} Central Government, 'Transcript of the coronavirus press conference by Prime Minister Rutte and Minister de Jonge', 12 November 2021, <https://www.rijksoverheid.nl/documenten/media-teksten/2021/11/12/transcript-of-the-coronavirus-press-conference-by-Prime-Minister-Rutte-and-Minister-de-Jonge-2-November-2021>.

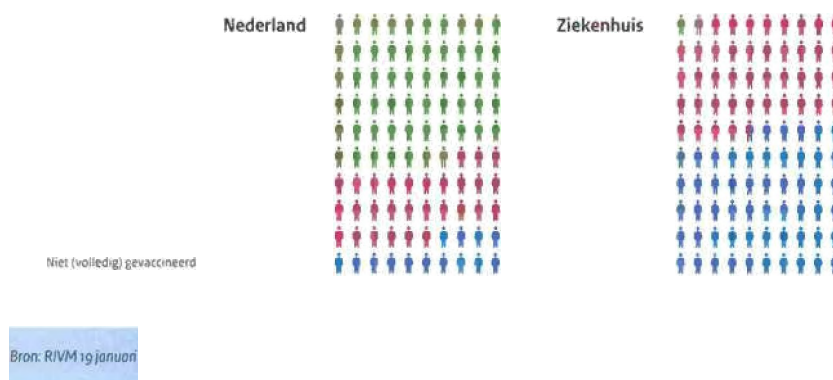
[^] Health Council, Advice on COVID-19 booster vaccinations for people aged 18 to 60, 25 November 2022. Available at: <https://www.gezondheidsraad.nl/documenten/adviezen/2021/11/25/boostervaccinatie-tegen-covid-19-bij-personen-van-18-tot-60-jaar>.

^{° *} Parliamentary Papers II 2020/21, 25295, no. 1672.
Health Council of the Netherlands, Advice on booster vaccination against COVID-19 for people aged 18 to 60, 25 November 2021. Available at: <http://www.gezondheidsraad.nl/documenten/adviezen/2022/25/boostervaccinatie-tegen-covid-19-bij-personen-van-18-tot-60-jaar>.

Advice pursuant to 139° ONT, 24 January 2022,
"Central Government, 'Verbatim transcript of the coronavirus press conference by Prime Minister Rutte and Minister Kuipers', 25 January 2022, <https://www.rijksoverheid.nl/documenten/materiaalteksten/2022/01/25/letterlijke-tekst-persconferentie-coronavirus-minister-president-rutte-en-minister-kuipers>.

Vaccins bieden nog steeds hoge bescherming

Very few people in the Holy Mass with a booster vaccination



- 2.6.6 On 15 February 2022, the press conference began with the words ‘the country is opening up again’. The number of virus infections was higher than ever, but the number of hospital admissions remained stable and low. Thanks in part to the vaccines, the Netherlands was better able to withstand the virus.*

“Fortunately, we are now in a different phase. You can see here that a great many people are currently infected, more than ever before. You can also see that following the last two press conferences on 14 January and 25 January, at which further easing of restrictions was announced, the number of infections rose further. It now appears that we may have passed the peak. And if you look now at how hospital occupancy is faring, the situation is completely different from the Over the past two years, hospital occupancy rates have risen in line with infection rates. It now appears, however, that they have remained virtually stable, despite those high infection figures. What we had already hoped and suspected therefore appears to be true. We are more resistant to the virus. Thanks to vaccines and booster jabs. And thanks to the immunity people have built up from having been infected. What’s more, the Omicron variant causes less severe illness.”

- 2.6.7 In March 2022, virtually all COVID-19 restrictions were lifted,

although the requirement to wear a face mask at airports remained in place. This measure was lifted on 21 May 2022.!

* Rijksoverheid, ‘Transcript of the press conference on the coronavirus by Prime Minister Rutte and Minister Kluivers’, 25 January 2022, <https://www.rijksoverheid.nl/documenten/mededelingen/2022/01/25/full-text-of-the-press-conference-on-the-coronavirus-by-prime-minister-rutte-and-minister-kluivers>.

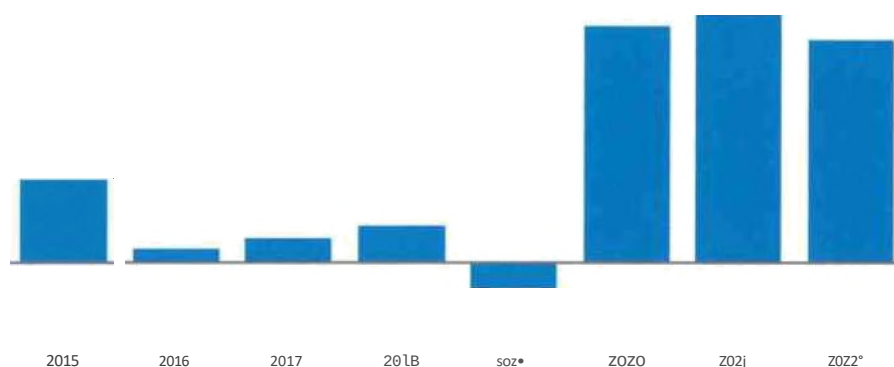
* Rijksoverheid, ‘Face masks and hand sanitiser: Dutch rules to change from 2 May 2022’, 13 May 2022, <https://www.rijksoverheid.nl/actueel/nieuws/2022/05/13/face-masks-and-vaccines-dutch-rules-change-from-21-may-2022>.

2.7 The consequences of the Covid-19 pandemic: excess mortality and illness

2.7.1 Up to and including 2022, more than 48,000 people in the Netherlands have died from Covid-19.¹⁴ In 2020, 2021 and 2022 — during the Covid-19 pandemic — there was also a clear (and significant) excess mortality in the Netherlands. This is evident from figures from Statistics Netherlands (CBS):¹⁵

Excess mortality

per 1,000



* voorlopige cijfers

It is therefore incorrect to claim, as the claimant does, that there was no excess mortality.⁹⁶

In support of that position, the claimants have submitted, as Exhibit 4, a table which, according to the claimant, is said to originate from Statistics Netherlands (CBS). However, that table cannot be found on the CBS website. Furthermore, the data that can be found on the CBS website shows that the figures included in the table submitted as Exhibit 4 are incorrect. For instance, Exhibit 4 states that the number of deaths in 2020 was 162,348, whereas according to the CBS it was 168,678.¹⁷ Furthermore, Exhibit 4 states that the population of the Netherlands in 2020 was 17.47 million, whereas according to the CBS (rounded) it was 17.41.¹⁸ The percentages included in Exhibit 4 are therefore also incorrect. In any case: the position of

¹⁴ CBS, 'Health in the Time of Corona', 1 September 2023, <https://www.cbs.nl/nl-nl/visualisaties/waarschijnlijkheden-in-2023-2024>.

¹⁵ CBS, '2022: third consecutive year of excess mortality', 25 January 2023, <https://www.cbs.nl/nl-nl/2022-2023-2024-2022-third-year-in-a-row-with-excess-mortality>, Daily Report, para. 29.

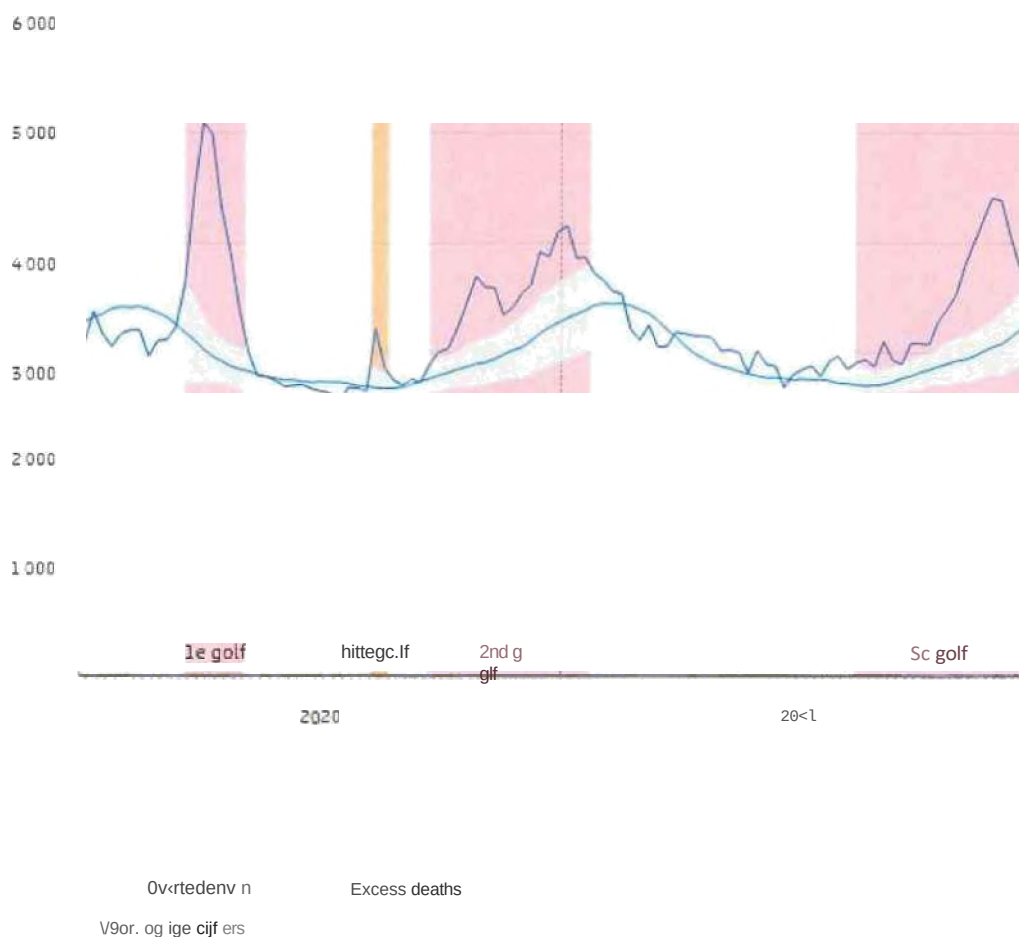
¹⁷ Statistics Netherlands, 'Population trends: month and year', (publication 15 May 2023). See also: www.ris.nl.

¹⁸ CBS, 'Population statistics' (via 'show table'), <https://www.cbs.nl/nl-nl/visualisaties/waarschijnlijkheden-in-2023-2024>.

The claimants' assertion that, according to Statistics Netherlands (CBS), there was no excess mortality in 2020 contradicts the CBS's own conclusions on the matter: "In 2020 and 2021, a total of 150 thousand people died. That is 30 thousand (10 per cent) more people than would have been expected had there been no COVID-19 pandemic." The total number of deaths from COVID-19, based on the Causes of Death Statistics for these years stood at 40,000. The three waves of excess mortality observed in 2020 and 2021 coincide with the periods in which many people died from COVID-19. In particular, the rise, the peaks and subsequent decline in excess mortality and COVID-19 mortality occur at roughly the same time in each wave."**

- 2.7. 2 The fact that there was excess mortality during the COVID-19 pandemic is also clearly shown in the graph below:!!

2.2.1 Deaths per week*



** CBS, 'Mortality, excess mortality and COVID-19 deaths in 2020 and 2021', 23 June 2022, <https://www.cbs.nl/en-gb/indicators/mortality-in-2020-and-2021>.

*** CBS, 'Mortality, excess mortality and COVID-19 mortality in 2020 and 2021', 23 June 2022.

- 2.7.3 Against this background, the CBS concludes that excess mortality in the period 2020–2023 — and particularly in 2020 and 2021 — is linked to deaths from Covid-19. Whilst excess mortality during that period stood at 45,800, more than 48,000 people died from Covid-19 in the same period. The CBS also reports — citing a study by RIVM¹⁰⁶ — that vaccination against Covid-19 is associated with a reduced risk of death from Covid-19.¹⁰⁷
- 2.7.4 Infection with the coronavirus can also have serious and long-term physical consequences, quite apart from the risk of death. For example, a large number of people have been admitted to hospital or to the ICU.¹⁰⁸ Research shows that nine out of ten patients who were admitted to hospital still have symptoms a year later.¹⁰⁹ However, even without hospitalisation, Covid-19 can lead to long-term symptoms following infection (post-Covid). Commonly reported long-term symptoms include fatigue, shortness of breath, headaches, forgetfulness and difficulty concentrating, loss of smell, palpitations, muscle pain, and anxiety and mood disorders.¹¹⁰ In the first five months of 2022, more than 700 people with long-term Covid symptoms registered with the UWV. In 62% of the cases, the Covid symptoms were so severe and prolonged that those affected were declared completely unfit for work.¹¹¹
- 2.7.5 The social consequences of the coronavirus crisis are also significant. During the pandemic, there has been a great deal of deferred care, which has an impact on the number of healthy years people have. In this context, it is also important to note that waiting times in healthcare remain high. This applies not only to physical healthcare but also to mental healthcare — where an increase in the number of referrals has been observed since the COVID-19 crisis (particularly amongst young people). Furthermore, young people have fallen behind in their education. The economic effects of the COVID-19 crisis have also been significant, despite the mitigating effect of government support provided to businesses.¹¹²

RIVM, 'Vaccination reduces the risk of COVID-19 mortality but does not increase the risk of mortality from other causes', 23 June 2022. Available at: <https://www.rivm.nl/nieuws/vaccinatie-verlaagt-kans-oo-covid-19-sterfte-en-verhoogt-kans-oo-sterfte-door-andere-oorzaken-niet>.

CBS, 'Excess mortality and causes of death in 2020 to 2022', 11 December 2023. Available at <https://www.cbs.nl/lonoread/r60DOrtaoes/2023/excess-mortality-and-causes-of-death-in-2020-to-2022>.

Health Council of the Netherlands, Long-term symptoms following COVID-19. Outline of the post-COVID syndrome, No. 2022/D4, The Hague: 2022. Available at: <https://www.gezondheidsraad.nl/onderwerpen/zorg/alle-adviezen-over-zorg/langdurige-klachten-na-covid-19>.

Erasmus MC, '9 out of 10 patients had long-term symptoms following hospitalisation for Covid-19', <https://www.erasmus.nl/infection/9-out-of-10-patients-experience-long-term-symptoms-after-hospitalisation-for-covid-19/>.

Health Council of the Netherlands, Long-term symptoms following COVID-19. Outlines of post-COVID syndrome, No. 2022/04, The Hague: 2022

¹⁰⁶ UWV, 'UWV: most clients with long-term COVID-19 symptoms are fully unfit for work', 18 June 2022, <https://www.uwv.nl/nl/oersDerichten/uwv-meeste-clienten-met-lanoooriae-coronaklachten-volledio-arbeidsongeschikt>.

See also the Social Impact Team, 'Social Impact of the COVID-19 crisis, Presentation to the Technical Committee in the House of Representatives', 13 December 2022,

<https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/overheidspublicaties/2022/12/23/presentatie-chairman-MIT-technical-briefing-t3-t2-2022/Presentation+for+the+future+of+the+Technical+Briefing+3+December+2022+odf>.

- 2.7.6 The consequences of Covid-19 are therefore serious. The plaintiffs' theories — which effectively claim that Covid-19 does not exist — do not do justice to those who have died as a result of Covid-19 and their loved ones, those who have been or are still suffering from long-term illness as a result of Covid-19, and those who have otherwise suffered harm as a result of Covid-19.

3 The claimants' claims

- 3.1 In these proceedings, the claimants seek a declaration that the defendants (as a group and individually) acted unlawfully towards the claimants *"by deliberately and unlawfully misleading them and thereby inducing them to receive Covid-19 injections which the defendants knew, or at least ought to have known, that these injections were not safe and effective"*. In addition, the claimants seek an order requiring the defendants to pay damages, to be determined at a later stage.

- 3.2 These proceedings therefore concern a far-reaching claim, in which serious allegations are levelled against the defendants. The State notes at this stage that the plaintiffs' allegation that the defendants, either individually or as a group, deliberately misled the plaintiffs and thereby induced them to receive a Covid-19 vaccination has not been substantiated to any significant extent. The claimants have not even explained — nor have they made it plausible — 1) that they were vaccinated, 2) which vaccine was involved, 3) at what time or times this took place, and 4) which information from which defendant was decisive for each of them in this regard. In the absence of such explanation and substantiation, the State disputes that the claimants were vaccinated as a result of information provided by the defendants.

- 3.3 In any event: there is no question of the plaintiffs having been misled in a deliberate and unlawful manner, with a view to persuading them to take a Covid-19 vaccine, whilst the defendants knew or ought to have known that those vaccines were neither safe nor effective, as set out in the application for a declaration of law. The State will explain this in more detail below. The State maintains, first and foremost, that the claimants have failed to fulfil their duty of care, and that the claims must therefore be dismissed on that ground alone.

The protection of public health

4

- 4.1 The State has a positive obligation to protect public health. This follows from Article 22 of the Constitution, which stipulates that the State shall take measures to promote public health, and also from Articles 2 and 8 of the ECHR. This also means that the State is obliged to prevent epidemic, endemic and other diseases as far as possible and to combat outbreaks thereof.⁴ ®

⁴ See also The Hague Court of Appeal, 14 December 2021, ECLI:NL:GHDHA:2021:2453, para. 6.10, and The Hague Court of Appeal, 14 December 2021, ECLI:NL:GHDHA:2021:2452, para. 6.15. See also Bunschoten, in: 7th ed. Constitution and Charter, commentary on Article 22 of the Constitution

- 4.2 In view of the severity of the Covid-19 pandemic and the (potential) consequences of that pandemic for the health of the Dutch population, the State was therefore unquestionably obliged to take measures to combat the Covid-19 pandemic.
- 4.3 The State has fulfilled this positive obligation by implementing various, sometimes far-reaching, measures — after carefully weighing up all the interests involved. Furthermore, once vaccines became available, the State made Covid-19 vaccines available (free of charge and with full information) to everyone in the Netherlands who wished to have them, and recommended that the population make use of this opportunity.
- 4.4 As will be explained in more detail below, these vaccines have been authorised for the European market following an assessment by the European Medicines Agency (EMA), and the Health Council has issued a favourable recommendation regarding their inclusion in the National Immunisation Programme. The authorisation procedure did not deviate from the standard substantive requirements applicable to the authorisation of new medicinal products. The State was therefore fully entitled to decide to include these vaccines in the National Immunisation Programme and to urge the public to get vaccinated. In doing so, the State did not act unlawfully, but rather fulfilled its positive obligation to protect public health.

5 The development and authorisation of the Covid-19 vaccines

5.1 Obtaining a marketing authorisation (EIA)

- 5.1.1 A medicinal product, such as a vaccine, may only be placed on the market in the Netherlands if a marketing authorisation has been granted by the national or European medicines authority.¹⁰⁰ The national medicines authority is the Medicines Evaluation Board (CBG).¹¹ The European medicines authority is the EMA.¹²
- 5.1.2 For medicinal products that protect against viral diseases, such as Covid-19, it is mandatory to follow the centralised procedure^{*1}

¹⁰⁰ See paragraph 2 above.

¹¹¹ Section 40(1) of the Medicines Act.

¹¹ Article 2 and Article 9, preamble and point (f), of the Medicines Act.

¹⁰⁰ Article 1 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

¹¹ CBG, 'Centralised procedure', <https://www.cbqmeb.nl/onderwerpen/hvcentrale-procedure>.

to be followed at the EMA.¹¹⁴ If the marketing authorisation is subsequently granted by the EMA (and thus under the responsibility of the European Commission), that authorisation is valid throughout the European Union in one go — and therefore also in the Netherlands.¹¹⁵

5.1.3 This centralised procedure at the EMA essentially entails the following.

5.1.4 Within the EMA, there is a special committee that focuses on medicinal products for human use — the Committee for Medicinal Products for Human Use (CPMH).

The CPMP coordinates the scientific evaluation of the quality, 'the safety and efficacy of medicinal products for human use.' Each Member State appoints a member and an alternate to sit on the CPMP,¹¹⁶ who, in principle, represent the competent national authorities. The Dutch representatives on the CPMP both work at the CBG. In this way, the national medicines authorities have a say in the decision-making of the CPMP and the EMA.

S. 1.F Every application for a marketing authorisation for a medicinal product for human use must be accompanied by the data and documents referred to in Article 6 of Regulation (EC) No 726/2004 (the medicinal product dossier). The medicinal product dossier consists of five sections (administrative data, data on the manufacturing process and quality, characteristics of the medicinal product, results of laboratory tests and results of clinical trials).¹¹⁷

5.1.6 The basic principle is that this information must be submitted at the time the application is made. However, there is also the option of an accelerated procedure, known as a 'rolling review'.¹¹⁸ Under this procedure, information is shared with the EMA (and assessed) whilst the clinical trial is still in full swing. This allows the assessment to begin earlier. This results in significant time savings, without compromising the assessment of the vaccine's quality, safety and efficacy.¹¹⁹

¹¹⁴ Regulation (EC) No 726/2004, Annex 1, Article 3 (as amended on 20 May 2008; see the recitals under BJ. Article 13(1) of Regulation (EC) No 726/2004.

¹¹⁵ Article 5(1) and Article 56(1) of Regulation (EC) No 726/2004.

Article 57(1)(b) of Regulation (EC) No 726/2004.

Article 61 of Regulation (EC) No 726/2004.

¹¹⁹ CBG, 'CBG Annual Report 2020: Procedures for placing a medicinal product on the market', <https://www.cbg.nl/taarverslag/2020/01/procedures-op-een-geneesmiddel-of-vaccin-op-de-markt-le-brengen>.

¹²⁰ CBG, 'CBG Annual Report 2020: procedures for placing a medicinal product on the market', 2020; 2nd edition: EMA, 'COVID-19 guidance: evaluation and marketing authorisation', <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-intervention-concern-2020-23/guidance-for-developers-and-companies/covid-19-guidance-evaluation-market-authorisation>.

¹²¹ EMA, 'Start of rolling review for adapted Comirnaty COVID-19 vaccine', 1 June 2022, <https://www.ema.europa.eu/en/news/comirnaty-covid-19-vaccine>.

- 5.1.7 The CMPH assesses whether the conditions for granting a marketing authorisation have been met. To this end, the CMPH appoints one of its members (from one of the Member States) as rapporteur.¹² This rapporteur is responsible for coordinating the assessment. The committee concerned may appoint a second member (from another Member State) as co-rapporteur. It is the co-rapporteur's task to critique the rapporteur's report or to draw up a second report independently.¹³
- 5.1.8 Both rapporteurs draw up a scientific report in which they summarise the data from the marketing authorisation application, give their assessment of the medicine's efficacy and set out their views on any uncertainties arising from the data. The CMPH then meets in plenary session to discuss the reports and adopt a final opinion.¹⁴ In this plenary session, all Member States and national medicines authorities are represented by their experts who sit on the CMPH. The final opinion is sent to the European Commission within 15 days.¹⁵ The European Commission ultimately decides, on the basis of the CMPH's opinion, whether a marketing authorisation is actually granted.¹⁶
- 5.1.9 Pursuant to Article 14a(1) of Regulation (EC) No 726/2004, — prior to the submission of full clinical data — a conditional marketing authorisation may be granted if the benefit of the immediate availability of the medicinal product on the market outweighs the risk associated with the need to provide additional data. The marketing authorisation may only be granted on this basis if the balance of benefits and risks of the medicinal product is favourable and it is likely that the applicant will be able to provide comprehensive data (Article 14a(3)). Specific obligations may be attached to a marketing authorisation (Article 14-bis(4)). In any event, the marketing authorisation holder is required to complete ongoing studies or carry out new studies to confirm that the balance of benefits and risks is favourable (Article 14-bis(5)). The period of validity of a marketing authorisation 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 authorisation for medicinal products for human use.¹⁷ Article 4 of that Regulation provides as follows:

¹² Article 62 of Regulation (EC) No 726/2004

¹³ Article 6 of the Rules of Procedure of the Committee for Medicinal Products for Human Use. See: EMA, 'Rules of Procedure', <https://www.ema.europa.eu/en/documents/other/chmo-rules-procedure-and-dof>.

¹⁴ EMA, 'From laboratory to patient: the journey of a medicine assessed by EMA', <https://www.ema.europa.eu/en/documents/other/laboratory-to-patient-journey-centrally-authorized-medicine.pdf>.

¹⁵ Article 5(2) in conjunction with Article 9(3) of Regulation (EC) No 726/2004.
Article 10(2) of Regulation (EC) No 726/2004.

¹⁶ Commission Regulation (EC) No 507/2006 of 29 March 2006 concerning conditional authorisations for the placing on the market of medicinal products for human use falling within the scope of Regulation (EC) No 726/2004.

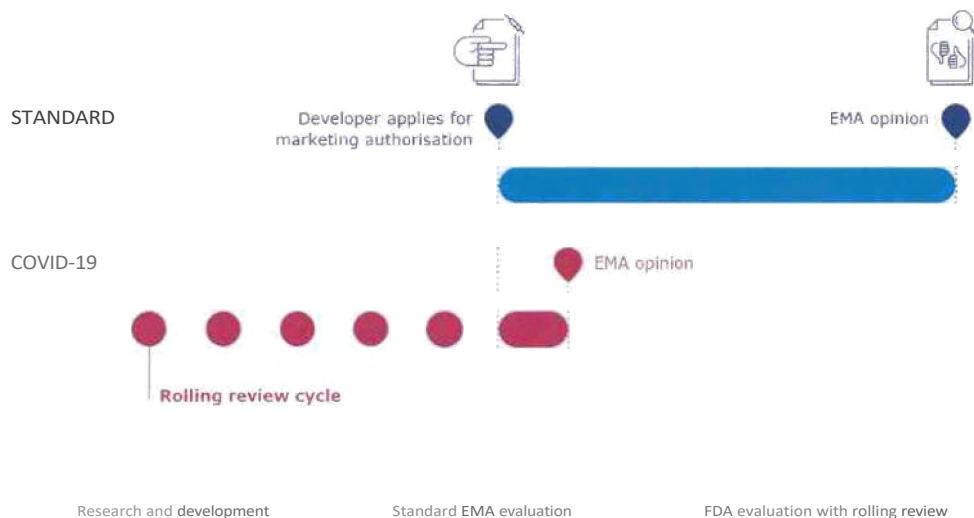
1. A conditional marketing authorisation may be granted where the Committee determines that, although complete clinical data on the safety and efficacy of the medicinal product have not been provided, all the following requirements are met:
 - a) the benefit-risk balance of the medicinal product, as defined in Article 1(28)(b) of Directive 2001/83/EC, is positive;
 - b) it is likely that the applicant will be able to provide complete clinical data;
 - c) unmet medical needs are addressed;
 - d) the public health benefits of the immediate availability of the medicinal product on the market outweigh the risk associated with the fact *that* further data *still* needs to be provided.

5.2 The authorisation of Covid-19 vaccines on the European market

- 5.2.1 The rolling review procedure mentioned above has been used for a number of Covid-19 vaccines. As stated, a rolling review requires the submission of the same documents and the completion of the same steps as the standard procedure, but the process is accelerated by overlapping certain stages. In a rolling review, the vaccine is also assessed according to the usual standards for quality, safety and efficacy.¹⁰ In short, coronavirus vaccines have been assessed against the same (very) strict criteria as vaccines against other infectious diseases. Thanks to the rolling review, the assessment can simply take place earlier (and therefore more quickly):¹¹

¹⁰ ENA, 'EMA announces second rolling review of a COVID-19 vaccine', 6 October 2020, <https://www.ema.europa.eu/en/news/ema-statement-said-cp-covid-19-vaccine>.
¹¹ EMA, 'COVID-19 vaccines: development, evaluation, approval and monitoring', <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-of-international-concern-2020-237-covid-19-vaccines-development-evaluation-approval-and-monitoring>.

Figure 3: Standard evaluation process compared with rolling review of COVID-19 vaccines



52.2 Based on a rolling review and in accordance with the procedure set out in Article 14a of Regulation No 726/2004, the EMA has issued a positive opinion on the four Covid-19 vaccines used in the Netherlands, and the European Commission has granted a (conditional) marketing authorisation for these vaccines:

- i. The BioNTech/Pfizer vaccine (Comirnaty) was granted conditional authorisation on 21 December 2020.¹³⁰
- II. Ploderna's vaccine (Tspikevax) was granted conditional authorisation on 6 January 2021.¹³¹
- II. The AstraZeneca vaccine (Vaxzevria) was granted conditional authorisation on 29 January 2021.¹³²
- iv. The Janssen vaccine (Jcovden) was granted conditional authorisation on 3 March 2021.¹³³

5. K3 The vaccines mentioned have therefore been authorised for the European market subject to certain conditions. These conditions mean that the manufacturers are obliged to provide EMA with additional information every two years, as soon as such data becomes available. For example, further research is to be carried out into (among other things) the duration of

¹³⁰ EMA, 'Comirnaty (COVID-19 mRNA vaccine (nucleoside-modified)): An overview of Comirnaty, including its adapted vaccines, and why it is authorised in the EU' (Production 6). For the full assessment report, see: <http://www.ema.europa.eu/en/documents/assessment-report/comirnaty-eoar-ouhpc-assessments-report-and-dcf>.

¹³¹ EMA, 'Sputnik V (COVID-19 mRNA Vaccine (genetically modified))' An overview of Sputnik V, including its adapted vaccines, and why it is authorised in the EU' (product no. 7). For the full assessment report see: <http://www.ema.europa.eu/en/documents/assessment-report/sputnik-v-previous-covid-19-vaccine-modern8WDBP-ouhpc-assessment-report.pdf>.

¹³² EMA, 'Vaxzevria (COVID-19 vaccine (mAdOx1-S [recombinant])): An overview of Vaxzevria and why it is authorised in the EU (product information)'. For the full assessment report: <http://www.ema.europa.eu/en/documents/assessment-report/vaxzevria-eoar-ouhpc-assessment-report-and-dcf>.

¹³³ EMA, 'COVID-19 (COVID-19 vaccines (Ad26.COV2-s recombinant))' An overview of COVID-19 and why it is authorised in the EU (Publication 9). For the full assessment report, see: <http://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-janssen-eoar-public-assessment-report>.

the efficacy of the vaccines, how well they prevent severe COVID-19, how well they protect people with weakened immune systems, children and pregnant women, and whether the vaccine also prevents COVID-19 symptoms. Conditional authorisation is only granted if (among other things) the benefit of the medicinal product's immediate availability on the market outweighs the risk associated with the fact that additional data still needs to be provided (see paragraphs 5.1.9–5.1.10).

5.3 The advice from the Health Council

5.3.1 Following the (conditional) approval of the vaccines by the European Commission for authorisation on the European market, the vaccines may be made available in the Netherlands.

5.3.2 The Health Council then advises the Government on the State's use of the vaccines.¹³⁴ 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 its assessment on *peer-reviewed* and published scientific articles concerning the safety and effectiveness of the vaccines under investigation, as well as on data from the EMA and the FDA. The Health Council also advises on whether a vaccine should be included in a public vaccination programme, and on whether vaccination can be classified as essential care or as individual care.¹³⁵

The recent report by the Dutch Safety Board shows that the Health Council: “has conscientiously fulfilled its statutory duty in its advisory role. The advisory body has been guided primarily by the current state of scientific knowledge in its advice”.¹³⁶

5.3.3 On 24 December 2020, the Health Council concluded that vaccination with the Pfizer vaccine is effective, sufficiently safe and acceptable, and recommended that the vaccine be used in public vaccination programmes against Covid-19 (**publication 10**)¹³⁷. The Health Council notes that, whilst the vaccine does have side effects, these are predominantly mild, short-lived and transient, and that the health benefits of vaccination therefore outweigh the side effects.

¹³⁴ Dutch Safety Board, *Approach to the coronavirus crisis*. Oee/ 2, p. 147, p. 131.

¹³⁵ Health Council of the Netherlands, *The individual, collective and public interest of vaccination* (No. 2013/21), The Hague, 2013, https://www.oezondheidsraad.nl/documenten/adviezen/2013/10/03/hj2\individuele_collectisyn-gn-Dublieke-belano-van-vaccinatie.

¹³⁶ Dutch Safety Board, *'Handling the coronavirus crisis'. Part 2*, p. 136.

¹³⁷ This is a summary by the Health Council. The full report by the Health Council is

View the advice at:

<https://www.oezongheigsraaQnVmnaries/health-council-documents/advice/2020/L2E24Ycowl-19-variation-biontech-pfizer/Advice-on-COVID-19-vaccination-BioNTech-Pfizer.pdf>.

- 5.3.4 The Health Council has reached similar conclusions regarding the use of the Moderna vaccine (advice of 11 January 2021, **document 11**)¹⁴, the AstraZeneca vaccine (advice of 4 February 2021, **document 12**)¹⁵, and the Janssen vaccine (advice of 17 March 2021, document 13).¹⁶
- 5.3.5 The Health Council has therefore issued a positive recommendation on the use of the BioNTech/Pfizer, Moderna, AstraZeneca and Janssen vaccines in the Netherlands.

For the sake of completeness, the State would also like to point out the following.

Between 14 March and 22 March 2021, the Netherlands suspended the use of the AstraZeneca vaccine as a precautionary measure. This was because Norway and Denmark had reported side effects. Six people under the age of 50 developed thrombosis, accompanied by a low platelet count. However, on 18 March 2021, the EMA concluded that the benefits of the vaccine outweighed the risk of rare side effects.¹⁷

In early April 2021, the Lareb Adverse Reaction Centre reported that a Dutch woman had died following vaccination with AstraZeneca, as a result of thrombosis combined with a low platelet count. A further five reports had been received concerning women aged between 25 and 65 who experienced these side effects following vaccination with AstraZeneca.¹⁸ * These reports were similar to those in other European countries.¹⁹ * As a precautionary measure, the Netherlands subsequently decided — partly in response to advice from the Health Council of the Netherlands dated June 2021 — to no longer administer the AstraZeneca vaccine in the Netherlands to people under the age of sixty.²⁰

- 5.3.6 AI therefore uses only vaccines in the Netherlands that — following assessment by the competent authorities — have been authorised (subject to conditions) for the European market. This means that the EMA considers the vaccines to be safe and effective. The Health Council has also issued a positive recommendation regarding the provision of the vaccines in the Netherlands. Only then were the vaccines made available to the Dutch population by the State. The State

This is a summary of the Health Council's report. The full report from the Health Council can be consulted at: <https://www.gezondheidsraad.nl/binaries/gezondheidsraad/documenten/adviezen/2021/01/11/covid-19-vaccination-modern-vaccine-and-the-vaccination-strategy/Advice-COVJD-19-vaccination-Modern-vaccine-and-the-vaccination-strategy>.

This document is a summary of the Health Council's report. The full report by the Health Council can be accessed at:

<https://www.gezondheidsraad.nl/binaries/gezondheidsraad/documenten/adviezen/2021/02/04/covid-19-vaccinatie-astrazeneca-vaccin/Advies-COVID-19-vaccinatie-AstraZeneca-vaccin.pdf>.

This is a summary by the Health Council of the Netherlands. The full report by the Health Council of the Netherlands can be found at:

¹⁴⁰ <https://www.gezondheidsraad.nl/binaries/gezondheidsraad/documenten/adviezen/2021/02/17/covid-19-vaccination-janssen-vaccine/Advice-on-COVID-19-vaccination-with-the-Janssen-vaccine.pdf>.

EMA, 'COVID-19 Vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelet counts', <https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-to-rare-blood-clots>.

Dutch Safety Board, 'Tackling the coronavirus crisis'. Vol. 2, p. 67.

¹⁵² Lareb, 'Update on reports of thrombosis with a low platelet count following COVID-19 vaccination', 2 May 2022, <https://www.lareb.nl/news/update-reports-of-thrombosis-with-a-low-platelet-count-following-covid-19-vaccination>.

¹⁴⁴ Dutch Safety Board, 'Approach to the COVID-19 crisis. Part 2', p. 67; Health Council of the Netherlands, 'Use of vaccines in the current phase of the COVID-19 vaccination programme' (No. 2021/28), The Hague: 2021.

in doing so, it was entitled to rely on the assessment by the EMA, which is independent of the State, and the advice of the Health Council, which is independent of the State.

6 No unlawful conduct

6.1 Introduction

6.1.1 Notwithstanding the foregoing, the claimants take the view that the vaccines are neither safe nor effective. In making this assertion, the claimants are going against the scientific consensus that the vaccines are, in fact, safe and effective. In the Netherlands, only vaccines that have been tested and assessed by the competent authorities, and found by those authorities to be safe and effective, have been used.

These vaccines have also been used in the rest of the European Union (and beyond). Globally, too, the approach taken by various countries with regard to vaccination policy is largely comparable to the Dutch approach.

6.1.2 In the writ of summons, the claimants — contrary to the scientific consensus — make the far-reaching and unfounded assertion that the State and various other defendants were, moreover, aware that the vaccines were neither safe nor effective, and yet called on the population to be vaccinated. This allegation, once again, lacks any factual basis. As explained above, the vaccines are indeed safe and effective, and the State was entitled to assume as much. Furthermore, whilst the claimants make various assertions about what certain individuals are alleged to have known at specific times, they subsequently fail to substantiate these claims. Where the claimants do put forward more specific assertions regarding the safety and effectiveness of the vaccines, these are either based on incorrect information or are not legally conclusive.

6.1.3 The State explains this below.

6.2 “You do it for someone else”

6.2.1 According to the claimants, the Covid-19 vaccines do not prevent transmission. The slogan ‘you do it for others’ would therefore be incorrect, according to the claimants.

6.2.2 The State maintains, first and foremost, that this argument put forward by the claimants cannot, in any event, result in the claims being upheld. Even if it were the case that the slogan ‘you’re doing it for others’ were incorrect (which it is not), that would not in itself mean that there has been any unlawful conduct. At most, it would mean that the claimants have taken a vaccine that helps only themselves (and not others as well). It is not clear why that would be unlawful let alone that this could support the declaration sought, which refers to ‘the deliberate and

“unlawfully misleading” the claimants by persuading them to receive Covid-19 vaccines “which the defendants knew, or at least ought to have known, were not safe and effective”.

- 6.2.3 Be that as it may: it is true that having a Covid-19 vaccine not only helps you, but also others.
- 6.2.4 Getting vaccinated helps to increase the vaccination rate. Increasing the vaccination rate reduces the virus’s chances of spreading. After all, following vaccination, people develop antibodies against Covid-19 and are therefore protected against the virus. The likelihood of someone who has been vaccinated against Covid-19 still becoming infected with the virus is lower than for someone who has not been vaccinated, and the likelihood of someone who has been vaccinated infecting another person is also lower than for someone who has not been vaccinated. In this way, the spread of the virus is also curbed.
- 6.25 The more people who have been vaccinated against Covid-19, the less chance the virus has of spreading. In this way, getting vaccinated helps to protect others, *including* vulnerable people and those who cannot be vaccinated (for example, for medical reasons) or who do not wish to be. Increasing the vaccination rate and thereby curbing the spread of the virus also helps to reduce the pressure on the healthcare system. Furthermore, people who become infected with Covid-19 despite being vaccinated generally experience less severe symptoms and are less likely to require hospitalisation. This means there is more healthcare capacity available for those who do (urgently) need it. Furthermore, increasing the vaccination rate and thereby curbing the spread of the virus helps ensure that restrictive and far-reaching measures to combat the virus (with all the consequences that entail) are not or, at any rate, to a lesser extent. This is in the interests of the functioning of society as a whole.
- 6.2.6 Vaccination against Covid-19 is therefore — quite apart from the question of whether the vaccine prevents transmission — for various reasons not only in your own best interests, but also in the interests of others.
- 6.2.7 Furthermore, the WHO, the ECDC, the OMT, the RIVM and the Health Council of the Netherlands — experts who base their reports and advice on scientific research — all endorse, to a greater or lesser extent, the view that Covid-19 vaccinations do indeed help to prevent the transmission of the coronavirus. In this regard, the State refers to the following sources:

The ECDC report of 29 March 2021 (‘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 lead to reduced transmission, although vaccine efficacy 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 the vaccine strains match the circulating virus strains. This will lead to a reduction in transmission overall.”¹⁴

The ECDC report ‘Interim guidance on the benefits of full vaccination against COVID-19 for transmission and implications for non-pharmaceutical interventions’ dated 2 April 2021 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.”¹⁵**

The Health Council’s advisory report ‘Transmission following vaccination’ of 20 May 2021, in which the Health Council concluded that vaccination protects the vaccinated individual against (severe) illness and death and, to a greater or lesser extent, helps to prevent infections in others.¹⁶

- The OMT’s advice of 24 May 2021, ¹⁷ in which the OMT endorses the Health Council’s advice and expects that the actual effect of vaccination on preventing transmission is itself underestimated. The OMT has furthermore — both in its advice of 11 August 2021¹⁸ and in its advice of 13 September 2021¹⁹ — emphasised that the likelihood of a vaccinated person carrying a contagious virus is low. In its advice of 1 November 2021, the OMT also states that the prevalence of infections is higher among the unvaccinated and that the likelihood of transmission following infection after vaccination is lower.²⁰ Finally, it also follows from the OMT’s advice of 11 November 2021 that, according to the OJT, the residual risk of transmission and infection following vaccination is significantly reduced and is even lower than after a negative test.²¹

¹⁴ See: ECDC, ‘Risk of SARS-CoV-2 transmission from newly-infected individuals with documented previous infection or vaccination’, <https://www.ecdc.europa.eu/en/publications-daLa/sars-cov-2-transmission-newly-infected-in-individuals-with-previous-infection>.

¹⁵ See ECDC, ‘Interim guidance on the benefits of full vaccination against COVID-19 for transmission and implications for non-pharmaceutical interventions’, 21 April 2021, p. 9, available at <http://www.ecdc.europa.eu/sites/default/files/documents/Interim-guidance-benefits-of-full-vaccination-against-COVID-19-for-transmission-and-implications-for-non-pharmaceutical-interventions.pdf>.

¹⁶ Health Council of the Netherlands, ‘Advice on transmission following vaccination’, 20 May 2021, available at: <https://www.oezondheidsraad.nl/documenten/adviezen/z021/05/20/transmissie-na-vaccinatie>.

¹⁷ Advice in response to 114th OMT (Part 2), 24 May 2021.

¹⁸ Advice in response to 123rd and 124th OMT, 13 August 2021, p. 5.

¹⁹ Advice in response to 126th OMT, 13 September 2020, p. 6–7.

²⁰ Advice in response to 128th OMT, 1 November 2021, p. 7.

²¹ Advies, following the 130th OMT meeting, 1 November 2021, p. 7.

Research by the RIVM also shows that Covid-19 vaccines prevent transmission of the Alpha variant of the virus.^{75*} That research shows (i) that transmission from vaccinated people to other vaccinated people is 40 per cent lower than transmission from unvaccinated people to vaccinated people, and (ii) that transmission from vaccinated people to unvaccinated people is 63 per cent lower than transmission from unvaccinated people to unvaccinated people.^{76°}

- The ECDC report of 1 September 2021 ('Interim public health considerations for the provision of additional COVID-19 vaccine doses') refers to another study that supports the RIVM's findings.⁷⁵
- Research by the RIVM into 'transmission pairs' during July and August 2021 shows that, during those months, it was primarily unvaccinated people in the Netherlands who were responsible for further infections — and that they mainly infected other unvaccinated people.^{76**}
- Since May 2021, the RIVM has also been conducting a large-scale study into the long-term effects of vaccination against Covid-19.⁷⁷ That study, which includes survey data up to 14 March 2023, indicates that the *Vaccine Effectiveness against Transmission* (VET) for both the Delta and Omicron variants is 64 per cent.^{75°}
- In a press release dated 1 December 2023, the EMA confirmed, on the basis of a large number of scientific studies, that vaccines reduce transmission.^{75!} The RIVM also refers to a review of international research into the effect of vaccination on transmission, which shows that vaccination reduces the risk of further infection.^{76!}

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

⁷⁵ De Cfer et al., 'Vaccine effectiveness against SARS-CoV-2 transmission and infections among household and other close contacts of confirmed cases, the Netherlands, February to May 2021', *Eurosurveillance* 31 2021.

⁷⁶ Other studies conclude that vaccination prevents transmission; see: D.W. Eyre et al., 'The impact of SARS-CoV-2 vaccination on Alpha, Beta and Delta variant transmission', available at: <https://www.neim.orq/doi/full/10.10.56?pmoa2.1.1.6597>.

⁷⁷ ECDC, 'Interim public health considerations for the provision of additional COVID-19 vaccine doses', p. 14, available at: https://www.ecdc.europa.eu/en/publications-data/covid-19-public-health-considerations-additional-vaccine-doses_p.14. See also: ECDC, 'Interim guidance on the benefits of full vaccination against COVID-19 for transmission and implications for non-pharmaceutical interventions', 21 April 2021.

⁷⁸ <https://www.tweedekamer.nl/debat/en-veroaderinaYcommissieveraaderinoen/details?id=20z1A0S298> ⁷⁹ RIVM, 'The national immunisation programme in the Netherlands: surveillance and developments in 2022–2023 (RIVM report 2023-0330)', Utrecht, RIVM 2023, pp. 293–294. Available at: <https://www.rivm.nl/bibliotheek/rapporten/2023-0330.DdF>.

⁸⁰ RIVM, 'The national immunisation programme in the Netherlands: surveillance and developments in 2022–2023 (RIVM report 2023-0330)', Bilthoven: RIVM 2023, pp. 273–274.

⁸¹ EMA, 'COVID-19 vaccines: key facts', updated 1 December 2023, <https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/covid-19-vaccines-key-facts>, with further references.

⁸² RIVM, 'The national immunisation programme in the Netherlands: surveillance and developments in 2021–2022 (RIVM report 2022-0342)', Bilthoven: RIVM 2022, p. 2B1: "In all studies where vaccination status was included, it was observed that vaccination of the index case reduced the SAR [secondary attack rate]", with further references therein. Available at: <https://www.rivm.nl/bibliotheek/rapporten/2022-0342>.

See, for example:

Court of Appeal, The Hague, 14 December 2021, ECLI:NL:GHDHA:2021:2452, para. 6.17;
Court of Appeal, The Hague, 26 February 2021, ECLI:NL:GHDHA:2021:285, para. 6.9;
District Court of The Hague, 3 April 2020, ECLI:NL:RBDHA:2020:30 13, para. 4.8;
District Court of The Hague, 24 July 2020, ECLI:NL:RBDHA:2020:6856, para. 4.12.

6.2.9 It follows, therefore, that the State was entirely justified in calling on citizens to get vaccinated, not only for their own sake but also for the sake of others.

6.3 Graphene oxide

6.3.1 The claimants further argue that the vaccines are harmful to health because the mRNA vaccines from Pfizer and Moderna allegedly contain 'graphene oxide', which, according to the claimants, is highly toxic.¹ !*

6.3.2 The CBG's medicines information database shows which substances are present in the Pfizer¹ 6* and Moderna*6° vaccines. It shows that no graphene oxide is present in these vaccines. The claimants have also failed entirely to establish that graphene oxide is present in the Moderna and Pfizer vaccines.

See also the fact check carried out by Reuters: Fact Check — No evidence graphene oxide is present in available COVID-19 vaccines via lipid nanoparticles.^{°°s}
This fact check also addresses the video by Karen Kingston cited by the claimants and the (unrelated) patent with number CN 11220919A, which the claimants have just cited.

6.4 Pfizer report

6.4. 1 The claimants further argue that the Pfizer vaccine is dangerous.*6 * They base this claim on a report. According to the claimants, this report is an account of a clinical trial conducted by Pfizer, in which the trial participants were vaccinated with the vaccine. According to the claimants, 29,914 women, 9,182 men and 2,990 children took part in this trial. The claimants allege that 1,223 participants died during this trial and that 11,361 participants suffered serious, permanent physical injury.

Statement of claim, paras. 151,
265. ¹⁰⁰ Statement of claim, para.
1'14.

¹⁰¹ CBG, 'Comirnaty Medicines Information Bank',
È j2g;Y/www. .er'E'esmiddr'I•ntnf rmati•bank .n I/JrlI * p1 77 747. _____

¹⁰⁰ CBG, 'Spikevax Medicines Information Bank',
Medicines Information Bank n|in I/cp1 27 688.

" Reuters, 'No evidence that **graphene oxide** is present in available COVID-19 vaccines via lipid nanoparticles',
https://www.reu+++m oom la kann

n 6-vln- linir1- -it1U'2L1 N2 PI2X H/.

¹⁰⁰ See the report (Exhibit 40 to the writ of summons) and the writ of summons, paras. 143–144.

6.4.2 However, a reading of this report submitted by the claimants reveals something different.

6.4.3 The report is not a clinical trial, but an analysis of the adverse reactions to the vaccine reported to Pfizer by various authorities in different countries.¹⁹¹ A total of 42,086 adverse reactions were reported.¹⁹²

6.4.4 The figures cited by the claimants regarding reports of 223 deaths and of 11.36 The number of people with severe permanent injuries should not be compared with the total *number of 'adverse events'* (42,086), as the claimants do, but with the total *number of doses shipped worldwide*. However, it is precisely the total number of doses shipped worldwide that has been redacted from the report submitted by the claimants as an exhibit. The number of doses shipped worldwide is of great importance for the interpretation of the report and the stated number of deaths and people with serious permanent injuries.

In this regard, the State also refers to a report by the EMA which shows that, in the period from 21 December 2020 to 29 April 2021, over 97 million doses of the Pfizer vaccine were shipped.¹⁹³ Although this period is longer than the period covered by the report cited by the claimants, it shows that the number of reported deaths and the number of reported cases of people with serious permanent physical injury — relative to the total number of doses — is highly exaggerated, and also significantly smaller than the claimants make it out to be. It must also be borne in mind that this relates to reports made to Pfizer of deaths and cases of people suffering serious permanent physical injury following vaccination. This does not, however, mean that the deaths of these individuals, or the serious permanent physical injuries they sustained, were actually caused *by* vaccination. This is all the more true given that, during the initial phase of the vaccination programme — to which this report relates — it was primarily the elderly and vulnerable who were vaccinated.

6.4.5 It cannot therefore be inferred from the report submitted by the claimants that the Pfizer vaccine is dangerous.¹⁹⁴ Furthermore, the Pfizer vaccine has been approved by the EMA, and its use in the Netherlands has been assessed by the Health Council. The State was entitled to rely on this.

6.4.6 Finally: it has neither been alleged nor established that the claimants received a Pfizer vaccine. Without further explanation, it is therefore not clear what interest they have in these assertions and how this could lead to the granting of the declaration sought.

¹⁹¹ Summons, Exhibit 40, p. 5.

¹⁹² of which 25,379 were **medically** confirmed and 16,707 were *non-medically confirmed*. Summons, Exhibit 40, p. 6.

¹⁹³ EMA, 'Assessment report on the annual renewal of the conditional marketing authorisation', p. 16, <https://www.ema.europa.eu/en/documents/variation-reDort/comirnat-hs-5735-r-0046-eDar-assessment-report-renewal-and-odf>.

¹⁹⁴ See also in this context: NOS, 'Sources speak out about the Pfizer papers', 31 July 2022, <https://nos.nl/nieuwsuur/collectie/13903/artikel/24ZB923-bronnen-achter-de-ophef-over-de-pfizer-papers>.

6.5 Aarhus Convention

- 6.5.1 The claimants further argue that the ‘Temporary scheme for the exceptional processing of gene therapy licence applications in connection with the fight against COVID-19’* constitutes a breach of the Aarhus Convention.’⁷²
- 6.fi.2 The Temporary Regulation provided that, for applications for authorisation to conduct clinical trials involving genetically modified organisms aimed at combating Covid-19, the standard preparatory procedure under the General Administrative Law Act (Awb) was to be followed rather than the uniform public preparatory procedure. In any event — whatever the merits of the claimants’ arguments may be — it is impossible to see how, had the uniform public preparatory procedure been followed, the claimants would not have been vaccinated, let alone that the failure to follow the uniform public preparatory procedure could justify the conclusion that the claimants were “deliberately and unlawfully misled them in order to induce them to undergo Covid-19 vaccinations, which the defendants knew (...) were neither safe nor effective.” The claimants’ arguments regarding the Aarhus Convention in these proceedings are therefore also irrelevant.
- 6.5.3 Moreover, there is no question of a breach of the Aarhus Convention.
- 6.5.4 The basis for the Temporary Regulation!⁷ is the Environmental Management Act. Article 9.2.2.1 of the Environmental Management Act stipulates that regulations may be laid down by order in council concerning, in short, genetically modified organisms if there is a reasonable suspicion that handling them will result in undesirable effects on human health or the environment. If, in the Minister’s opinion, the expected or actual effects on human health or the environment make it urgently necessary to adopt regulations and it is not possible to wait for a general administrative order to be issued, the Minister may adopt regulations (Article 9.2.2.6 of the Environmental Management Act).
- 6.5.5 This latter option was utilised in the Temporary Regulation. Due to the pandemic, the Minister deemed it necessary to introduce a ministerial regulation and, in doing so, to expedite the authorisation procedure. It was, in fact, of the utmost importance that a vaccine could be developed as quickly as possible to combat the pandemic. This was also in line with the wishes of the House of Representatives, which

⁷² Stcrt. 2020, 1991.

⁷³ Summons, para. 132.

⁷⁴ This ministerial regulation **was in force** between 31 March 2020 and 29 October 2020. **On 29 October 2020, the regulation was repealed, as the subject matter of the regulation was**, from that date onwards, governed by EU Regulation 2020/1043. That Regulation was **implemented by** means of the introduction of a new regulation, again pursuant to Article 9.2.2.6 of the Environmental Management Act (Government Gazette 2020, 18941 and Government Gazette 2020, 546 **19**. **See also the Decree of 20 October 2022** amending the Decree on the environmental management of genetically Organisms Environmental Management Decree 2013 (implementing Regulations (EU) 2019, 13B1 and (EU) 2020, 1043), Stb. 2022, **407**). The claimants refer **to this new** scheme in the writ of summons.

the Minister had requested that the authorisation procedure be expedited, so that new treatments and technologies, such as the vaccine against the novel coronavirus, could be developed and tested more quickly.”⁹ This acceleration was achieved by the fact that, with regard to the licence, the standard preparatory procedure was followed rather than the uniform preparatory procedure. The scheme did not compromise safety.”¹⁰ After all, the requirement to carry out an environmental risk assessment prior to the granting of a licence remained in force, contrary to the claimants’ assertions.

Nor is this a matter of a marketing authorisation for Covid-19 vaccines,¹¹ as the claimants appear to believe, but rather an authorisation to conduct clinical trials on Covid-19 vaccines currently under development.

6.5.6 The ministerial regulation does not conflict with the Aarhus Convention, which concerns access to information, public participation in decision-making and access to justice in environmental matters. The aim of the Aarhus Convention is to contribute to the protection of the right of individuals to live in an environment that is conducive to their health and well-being (Article 1). Whilst it is true that the Aarhus Convention provides, amongst other things, for arrangements for public participation in decisions concerning the release of genetically modified organisms into the environment, the Convention also stipulates that the Contracting Parties must, within the framework of national legislation, apply those arrangements for public participation *to the extent possible and appropriate* (Article 6(U)).

6.5.7 The ministerial regulation significantly streamlined the authorisation process for conducting clinical trials. This is in line with the possibilities provided for in Article 6(11) of the Aarhus Convention.

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

6.5.8 On the basis of the ministerial regulation — within the applicable legal **frameworks** — four authorisations were granted to conduct clinical trials with the Janssen vaccine,¹ “The granting of the authorisations was published in the Government Gazette, and the possibility of lodging an objection or appeal was open.” The claimants did not make use of that possibility.

6.5.9 The Janssen vaccine was subsequently (i.e. following the completion of clinical trials) authorised for the European market following assessment by the EMA and approved by the Health Council (see paragraph 5.2 above). The assessment of the safety and

⁹ Parliamentary Papers II 2020/21, 25295, No. 180.

¹⁰ See also the explanatory notes to this decision, Government Gazette 2021, 38878.

¹¹ This concerns the ENA, as explained above. ”” Government Gazette 2020, 3842a

¹² Government Gazette 2020, 38421

The assessment of the effectiveness of this vaccine by these authorities took place after the completion of the clinical trials for which authorisation had been granted. It is therefore not the case that the claimants, by receiving a Covid-19 vaccine, took part in a clinical trial, as they allege.**!

- 6.5.10 In this regard, the State notes that it has neither been alleged nor established that the claimants received a Janssen vaccine; it is therefore difficult to see what interest the claimants have in raising this point.

Insofar as the claimants' arguments still relate to the Pfizer vaccine, these are likewise irrelevant. The ministerial regulation does not apply to the Pfizer vaccine, due to the absence of genetically modified organisms in that vaccine. Here too, incidentally, it has neither been alleged nor established that the claimants received a Pfizer vaccine.

6.6 The three 'excesses' cited by the claimants

- 6.6.1 In the writ of summons, the claimants cite a further three somewhat puzzling 'examples of excesses', to which 'the highly reprehensible and xwa1ike acts and omissions of the State' are alleged to have led.

- 6.6.2 As a first example, the claimants argue that Mr Gates made an investment in Heineken, and that Heineken broadcast an advert featuring the slogan '*the night belongs to the vaccinated*'. The State should have prevented this in order to protect its citizens, the claimants contend. However, the claimants do not make clear why this is the case or why, in the absence of such action, the State's conduct constitutes unlawful conduct. The State is not responsible for Mr Gates' investments or for Heineken's communications.

- 6.6.3 The second example cited by the claimants is that criminal offences were allegedly committed which civil servants should have reported.*® ° However, as explained above, no criminal offence has been committed, so this argument by the claimants falls flat.

In so far as the claimants still refer in this context to statements made to the municipality of Haaksbergen, the State notes, for the sake of completeness, that the municipality of Haaksbergen is not part of the legal entity under public law known as the State of the Netherlands.

- 6.6.4 Thirdly, the claimants accuse the State of having 'threatened its citizens with death' via national television. The State is alleged to have produced two 'horrific video messages' for this purpose and broadcast them via Postbus 51.' The videos referred to by the claimants do not originate from the State, and they n

[^] Statement of Claim, para. 133. [®] Statement of Claim, para. 258, ^{^1} Statement of Claim, para. 259. ^{*/} Statement of Claim, para. 262.

nor was it broadcast via Postbus 51 (which, incidentally, has not existed for a few years now). The first video was broadcast by the programme 'De Sociëteit', and is a reference to the Netflix series 'Squid Game'.¹⁶ * The second video was broadcast by the programme 'Plakshot',¹⁷ and is a variation on a drill rap.

See also the response to the parliamentary questions from Van Houwelingen regarding these videos, Annex to the Proceedings II 2021/22, 823.

6.6.5 In view of the foregoing, there is therefore no question of any unlawful conduct on the part of the State.

6.7 The individual allegations

6.7.1 It also follows from the foregoing that there has been no unlawful conduct on the part of the various natural persons (wrongly) involved in these proceedings, who, as government ministers, members of the OMT or in other capacities, have in fact worked tirelessly to combat the pandemic. The — far-reaching — allegations levelled against these individuals are reprehensible and unfounded.

6.7.2 For the sake of completeness, the following comments are made regarding the individual allegations levelled against each person. The order set out in the summons is followed here.

6.7.3 *Hofstra*. When the claimants refer to 'Hofstra's recommendations' (which are apparently distinct from those of the OMT),¹⁸ it is unclear what they are referring to. The claimants go on to argue that Hofstra must have known that 'healthcare capacity was not under threat'.¹⁹ It is not clear on what basis the claimants make this assertion. The claimants do state that healthcare capacity was scaled back from 1972 onwards, but — whatever the case may be — this is not relevant to the question of what the actual healthcare capacity was during the COVID-19 pandemic (and whether it was under pressure). It has already been explained at length above that occupancy rates in hospitals and on ICUs were repeatedly under (very) severe pressure during the pandemic, and that, in general terms, the pressure on the healthcare system was high.²⁰ Moreover, given the exponential rate at which the number of infections is rising, ICU capacity would, even with a higher capacity, come under strain within the foreseeable future if no measures were taken. It is not clear what the claimants' (mere) assertion regarding the PCR test has to do with healthcare capacity. Furthermore, the claimants refer to pandemic drills supervised by Hofstra and to the call for people to get vaccinated (including through an open letter and the vaccination campaign).²¹ That is not unlawful

¹⁶ NPO, 'De SoCietëit', <https://npo.nl/Start/serie/de-societeit/seizoen-2021/aflevering-35/afspeelen>, from 38:34.

¹⁷ 'Dagvaarding', scene 90, at 00:05–00:10, #plakshot appears on screen. ¹⁸ 'Dagvaarding', paragraph 29.

¹⁹ Summons, para. 30.

²⁰ See para. 2.

²¹ Summons, paras. 31–32, 34.

— on the contrary. The claimants’ further assertion that ‘Hofstra knew in April 2021 that (batches of) the vaccines were life-threatening and offered no protection whatsoever against the virus,’⁸ is unsubstantiated and lacks any factual basis. Indeed, it has not even been explained which batches these were supposed to be, nor that the claimants were vaccinated with those batches. Hofstra is not a ‘participant’ in ‘the Covid-19 project’.⁹ The claimants further argue that Hofstra should have opposed, in short, the GGD’s deployment of the ‘vaccination bus’ at schools.¹⁰ These buses were deployed to provide an accessible means of vaccination, including in areas with low vaccination rates.¹¹ The claim made by the claimants (without any explanation or substantiation) that these buses were deployed with the intention of vaccinating young people aged 12–17 is incorrect. It is incorrect to suggest that it takes 1–2 years to persuade someone to be vaccinated without parental consent. Moreover, this argument is irrelevant to these proceedings, as the claimants *zijn* adults.

6.7.4 *Van Dissel*. The claimants argue that the OMT’s recommendations are “manifestly unlawful” and “erroneous and harmful”, but they do not substantiate this at all. Moreover, these are recommendations from the OMT, for which Van Dissel is not personally liable. It is unfounded and reprehensible for the claimants to allege that Van Dissel deliberately defended the OMT’s recommendations ‘in the knowledge that these recommendations were erroneous and harmful’.¹² Equally unfounded is the claim by the claimants that Van Dissel is “part of the bigger picture”.¹³ The fact that Van Dissel spoke out in favour of the vaccination policy and called on people to get vaccinated,¹⁴ is not unlawful — on the contrary —, as has already been explained in detail above.

6.7.5 *Koopmans*. The claimants suggest that Koopmans’ appointment to a WHO investigation team was terminated because she sat on the CDC in Guangdong, China.¹⁵ It is apparent from the answers to parliamentary questions previously raised on this matter¹⁶ that the termination of Koopmans’ appointment does not imply that there were any doubts about her integrity. This is illustrated by the fact that Koopmans continued to serve on other committees at the WHO and that she has been 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 *the claimants* — without providing any form of substantiation — allege. The claimants further allege — again without any evidence — that Koopmans had access to the aforementioned report from

⁸ * Summons, para. 33. ⁹ Summons, para. 31. ¹⁰ Summons, para. 34.

¹¹ RIVM, ‘Impact of vaccination buses on vaccination rates’, 12 September 2022, <https://www.rivm.nl/aeëraosonderzoek/invloea-van-prikbussen-oo-vaccinatieoraad>.

¹² Summons, para. 36. ¹³ * Summons, para. 36. ¹⁴ Summons, para. 38. ¹⁵ Summons, para. 40.

¹⁶ Appendix to Proceedings 11 2020/21, No. 1372.

¹⁷ Summons, para. 41.

Pfizer, but they do not substantiate this at all, quite apart from the fact that the report does not support what the claimants read into it (see paragraph 6.4 above). Furthermore, the assertion that *the defendants* allegedly withheld important information from the public or disseminated incorrect information is unfounded. Nor is there any question of Koopmans having ‘concealed’ her role in the DesinfOFMätt’e think tank, as the claimants allege¹⁹⁹ — quite apart from the question of why that would be unlawful. It is also factually incorrect that the vaccines were harmful. It is also factually incorrect that Koopmans allegedly had access to information suggesting that the vaccines were harmful, as the claimants — regrettably — allege.²⁰⁰

6.7.6 Rutte. Rutte is not a “prominent member” of the WEF.²⁰¹ He is listed as an author on the WEF’s website (Exhibit 11 of the claimants) because he once wrote an article that was published on the WEF’s website.²⁰² It remains unclear exactly what the claimants are seeking to suggest with the two photographs of Rutte and Mr Schwab (also Exhibit 11), just as it remains unclear why those photographs are said to illustrate “the relationship between Rutte” and Schwab. It is incorrect to claim that Mr Schwab is Rutte’s “superior”, as the claimants assert²⁰ — yet they substantiate this solely by referring to a letter (Exhibit 11 of the claimants) which, according to the claimants, shows that the Chairman of the WEF “instructed” Rutte ‘instructs’ Rutte to ensure that the Netherlands leads the reforms to be implemented in Europe as part of the ‘Great Reset’. That is not stated in that letter. Nor is there any mention of a mandate accepted by Rutte from the WEF on Covid-19, which Rutte is implementing on behalf of the WEF. It has been explained in detail above that and why — calling on the population to be vaccinated against Covid-10 is not unlawful, but rather fulfils the State’s positive obligation to protect public health. This applies in full to the statements by Rutte cited by the claimants — and, incidentally, also to the statements made by all the other defendants.²⁰ It is harmful — and factually incorrect — that the claimants assert that Rutte knew that ‘the narrative concerning the so-called Covid-19 pandemic was untrue and that the Covid-19 injections — in particular certain batches — cause serious physical injury’. This assertion is also completely unsubstantiated, as is the subsequent assertion that Rutte misled the public.² * The other allegations levelled against Rutte (such as claiming that getting vaccinated also helps others) have already been addressed in detail above.

¹⁹⁹ Summon, para. 42.

²⁰⁰ Summons, para. 45.

²⁰¹ Summons, para. 45.

²⁰² Summons, para. 47.

https://www.weforum.Org/agenda/2017/01/water-sha_oed-mv-countrys-oast-it-will-shaDe-the-future-for-all-of-us/

* Summons, para. A8.

¹⁹⁵ Statement of Claim, paras. 49–54.

¹⁹⁶ Summons, para. 55.

- 6.7.7 *Kaag*. Kaag is not a ‘prominent member’ of the WEF,^{* 7} has not ‘gone to work for the WEF’, was not part of a WEF think tank in which ‘plans were devised for the implementation of a total reorganisation of, amongst other things, Dutch society’,^{*!!} is not involved in (conceiving or implementing) “the Great Reset” or “the Covid-19 project” and does not advocate for their implementation.^{2 !!} None of these assertions by the claimants are substantiated in any way. The video clip cited by the claimants in this regard (Exhibit 16 of the claimants) has an unclear origin and appears to have been taken out of context (it also appears to have been edited). In any event: Kaag has not committed to the “Build Back Better mandate of the WEF and the UN” not to mention that no explanation is provided as to what that would entail or why it would be unlawful. The letter submitted by the claimants in this regard (Exhibit 17 of the claimants) is addressed to the WHO and concerns a letter in which Kaag states that she is not available to serve on the WHO’s Global Preparedness and Monitoring Board. It cannot, therefore, serve as evidence to support the claimants’ assertions. It is factually incorrect that (Kaag knew that) “many people died during Pfizer trials and thousands suffered serious physical injury”, as the claimants allege — once again, without any evidence.^{*’!} Where the claimants also refer to the “exchange of information” between the Ministry of Finance and the WEF,^{2 ’} this in fact concerns the WEF sending invitations and simply responding to those invitations, as is evident, notably, from Exhibit 20 submitted by the claimants themselves. It is not apparent why this would be unlawful. Finally, it is also incorrect that Kaag ‘knows that there is a false narrative’.^{^z’}
- 6.7.8 *De Jonge*. De Jonge is not a “prominent figure” of the WEF. Nor can this be inferred from the (mere) fact that De Jonge is listed on the WEF’s website, as the claimants appear to believe.^{2*3} Nor is it the case that De Jonge is carrying out a “task assigned” by the WHO or the WEF.^{**4} The claim by the claimants that there were “military psychological behaviour-manipulation tactics”, aimed at instilling great fear and with the objective of misleading the population, lacks any factual basis. Nor does anything of the sort follow from the quotations cited by the claimants, which, incidentally, have nothing to do with vaccination either.^{2 °5} Nor does this follow from the claimants’ Exhibit 22, which, incidentally, does not originate from De Jonge (but forms part of the Catshuis briefing of 1 November 2020, and was made public as an annex to the letter to Parliament of 8 December 2020^{*2 6}). That the call for the Whether it is lawful to require the population to be vaccinated has already been discussed at length

⁷⁰⁷ She was, amongst other things, a member of *the* Global Action Group and was a member of the Northern East Africa Stewardship Board. See Appendix Proceedings II 2021/22, 2541 (response to questions 20 and 68, and also the response to question 14).

⁷⁰⁸ Summons, para. 61.

⁷⁰⁹ Summons, paras. 61–64.

⁷¹⁰ Summons, para. 66.

⁷¹¹ Summons, paras. 67–69. ⁷¹²

Summons, para. 69.

⁷¹² Summons, para. 73.

^{2’^} Summons, paras. 73–74. ⁷¹⁵

Summons, paras. 74–76.

COVID-19 status update of 8 December 2020, reference 1792353-215138-PDC19.

explained. The claim by the claimants that De Jonge deliberately misled many people and deliberately endangered their lives and health^{*7} is reprehensible, all the more so as there is no evidence whatsoever to support this claim. Furthermore, the Netherlands, Italy, France and Germany (the Inclusive Vaccine Alliance) had already reached agreements with vaccine developers in June 2020 regarding the supply of vaccines to Europe, provided that vaccine development proceeded smoothly.^{**} The European Commission subsequently adopted this, and on behalf of all Member States of the European Union so-called 'advance payment agreements' concluded with providers of a promising candidate vaccine against Covid-19.^{*1} Insofar as the claimants allege that De Jonge wrongly stated that money had been invested (by the Netherlands) in the development of vaccines,^{**0} this is therefore incorrect. Finally, the claimants' accusation that the comparison made by De Jonge with frikandellen (to illustrate that people do not know exactly what is in them, but eat them anyway) is "unworthy of a minister and in flagrant breach of the fundamental rights provision in Article 7 of the ICCPR"^{*21} (the prohibition of torture) is characteristic of the line of reasoning set out in the writ of summons, and is self-incriminating.

- 6.7.9 *Kuipers*. As explained above, there was indeed a shortage of ICU beds, and the healthcare system came under considerable pressure. The allegations made against Kuipers by the claimants in this regard (and by which they deny this) are therefore unfounded.^{***} It is also factually incorrect that Kuipers directed the vaccination of people with a vaccine that had not been authorised.^{**3} This is not at all evident from the claimants' arguments on this matter, nor from Exhibit 27 submitted by the claimants. At the time of the alleged statements (30 December 2021), the Pfizer vaccine had already been authorised by the EMA, and the Health Council had also issued a positive recommendation regarding that vaccine (see paragraph 5 above). It is also reprehensible that the claimants assert that "Under Kuipers's responsibility, these injections are, to this very day, being administered to largely defenceless people without any form of informed consent, and the harmful effects of the Covid-19 injections are being 'Kuipers concealed this'".²²⁴ It has already been explained above that this is incorrect, quite apart from the fact that there is no evidence whatsoever to support this claim.
- 6.7.10 *Gommers*. The claims made by the claimants regarding Gommers largely amount to a repetition of the arguments relating to the previously refuted — and unsubstantiated — claims. Reference is made to that earlier refutation. What is new is that the claimants allege that Gommers began to adjust "his tactics for influencing behaviour" and is said to have pretended to adopt a critical stance in order to

Statement of Claim, paras. 78 and 85,
²¹⁸ Central Government, "Unlikely coronavirus vaccine contracted for Europe", 13 June 2020, <https://www.rijksoverheid.nl/onderwerpen/coronavirus-informatie/nieuws/2020/06/13/moelrtk-coronavaccin-voor-euroDa-oecontra-cteert>.
²¹⁹ Parliamentary Papers II 2020/21, 25295, No. 565.
 Summon, para. 83.
²²¹ Statement of Claim, para. 84.
²²² Statement of claim, para. 94.
²²³ Summon, paras. 95–97.
²²⁴ Statement of claim, para. 99.

influence.^{2*} This is nothing more than a theory put forward by the claimants themselves, for which there is no evidence whatsoever. It is incorrect (that Gommers knew) “that what he did would lead to enormous harm to the Dutch population”.^{***} The same applies to the serious suggestion that Gommers intended for healthcare workers to sustain injuries, thereby further reducing healthcare capacity.^{**} These — malicious — allegations are also entirely unsubstantiated.

- 6.7.11 *Hoekstra*. It is also incorrect to claim that Hoekstra is a “prominent member” of the WEF, as the claimants allege.^{*2} ! Nor does this follow from the screenshot of the WEF website submitted as Exhibit 31. Nor is Hoekstra an advocate of ‘the Covid-19: The Great Reset project’. This assertion is not substantiated either, other than by reference to a letter. The fact that Hoekstra was invited to a WEF meeting,² ! is, of course, not unlawful. Nor did this correspondence take place ‘in secret’. The inferences drawn by the claimants regarding the hierarchical relationships between the parties, based on this letter, are founded on nothing more than the fact that Mr Schwab addresses Hoekstra as ‘Dear Minister’ in another letter, whilst, conversely, Hoekstra addresses Mr Schwab as ‘Your Excellency’,²³⁰ and are therefore far-fetched. The far-reaching conclusions drawn by the claimants
- The claims attached to this letter are incorrect and are not supported by the text of the letter. There is no question of an unconditional commitment by Hoekstra to cooperate with ‘the Covid-19: The Great Reset project’.^{**} It is not apparent why the coronavirus support package, which the claimants still refer to^{**}, would be unlawful. It is also incorrect that (Hoekstra would have known that) the vaccines were not safe or effective, and there is no evidence whatsoever to support that assertion. The claim that Hoekstra abused his office as Minister of Finance is incorrect and reprehensible.
- 6.7.12 *Van Nieuwenhuizen*. The claimants’ allegation against Van Nieuwenhuizen relates, in fact, solely to the alleged breach of the Aarhus Convention. There is no such breach, nor is there any question of participation in a clinical trial by receiving a Covid-19 vaccine, as has already been explained above (paragraph 6.5). In any event, that single allegation cannot support the declaration sought against her — namely, that there was deliberate deception, with the knowledge that the vaccines were not safe.
- 6.7.13 *Sijbesma*. Sijbesma was asked by the government to lend a helping hand as a special envoy for the coronavirus, and commenced her duties on 26 March 2020

^{***} Summons, para. 106.

^{**} Summons, paras. 108 and 109.

[^] Summons, para. 109. ^{22^}
Summons, para. 12.

Summons, para. 115.

² Summons, para. 113.

^{'''} Summons, para. 124.

[^] Summons, para. 125.

“As a special coronavirus envoy, Sijbesma (i) focused on exploring options for increasing testing capacity; and (ii) monitored developments regarding potential coronavirus vaccines (so that the Netherlands would have the option of securing any vaccines that became available).” Sijbesma fulfilled the role of special envoy for the coronavirus in a personal capacity, on a voluntary basis, without remuneration and without reimbursement of expenses. Sijbesma acted as an adviser, scout and liaison between the State and the (international) business community. He had no authority on behalf of the State to determine or implement testing or vaccination policy, or to enter into contracts on behalf of the State, as is also evident from the news article about Sijbesma’s role on rijksoverheid.nl, which the claimants themselves have submitted (as Exhibit 56). Sijbesma also played no role whatsoever with regard to vaccine safety. Sijbesma served as special envoy until September 2020. Consequently, by the time the Netherlands began its vaccination programme (in January 2021) and the claimants were faced with the choice of whether or not to be vaccinated, Sijbesma had not been an envoy for quite some time. Contrary to what the claimants suggest,^{2^4} had no direct connection with Sijbesma’s status at that time as (former-

}director of various companies and a person involved with various international organisations. As mentioned, he fulfilled that role in a personal capacity. Nor was Sijbesma appointed as a special envoy for the coronavirus in his capacity as a representative of a ‘non-governmental organisation (NGO, WEF)’ (or of the WBG), as the claimants apparently believe. It is incorrect to claim that Sijbesma is an outspoken advocate of a ‘total reorganisation’, as the claimants allege.³ Nor is this assertion substantiated by the claimants. The claimants’ position that, upon Sijbesma’s appointment as social envoy, Sijbesma’s (and the other defendants’) links with the WEF were deliberately disregarded,^{2^6} lacks any factual basis.^{**} Nor do they put forward

Sijbesma has set out a ‘global plan’. Insofar as the claimants allege that there was no shortage of tests (and make accusations against Sijbesma in that regard),^{***} it is clear from the foregoing that these assertions are incorrect (see paragraph 2.3.3), including those concerning the WITS database, with which Sijbesma, incidentally, had nothing to do and to which he had no access. Sijbesma therefore did not, as the claimants put it, participate in a ‘lie’ or present a version of events that was ‘demonstrably false’ in the Buitenhof programme broadcast on 12 April 2020. This is quite apart from the fact that the claimants’ assertions regarding testing are irrelevant to their claims, which, after all, relate to vaccination. The connection between the Rothschild patent referred to by the claimants, the interconnection of “everything, and in particular human bodies, via SG and 6G internet technology”,^{**9} and this case remains unclear even after reading the writ of summons. These assertions, or rather, theories,

^{***} See also <https://www.rijksoverheid.nl/documenten/publicaties/2020/08/13/toeihting-rol-feike-sijbesma-als-Special-Envoy-for-the-Coronavirus>. ^{2^4} Summons, para. 185. ^{***} Summons, para. 186. ^{2^4} Summons, para. 187.

^{2^5} Nor is there any question of this having been concealed. The WEF’s website states which individuals are involved with the WEF and in what capacity, and that Sijbesma has been a member of the Board of Trustees since 2019.

^{2^6} Summons, paras. 187–194

^{o/o} Summons, para. 196.

are (also) unfounded and unsubstantiated. Sijbesma has not (had) any involvement in this. It is also incorrect (that Sijbesma is said to know) that Covid-19 is a 'project' rather than a disease, and that he is 'fully and thoroughly familiar with and involved in the Covid-19 project intended to lead to the Great Reset', and that this is said to be the real reason he was appointed as a coronavirus envoy.^{***} Once again, there is no factual basis whatsoever for these assertions. The claimants' suggestion that Sijbesma received instructions, guidance 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 the claimants' assertion that Sijbesma acted unlawfully by making statements, or by failing to do so, in the aforementioned Buitenhof programme. The claimants' assertions that Sijbesma staged a 'charade', which was widely publicised in the media,^{**} are therefore incorrect and lack any factual basis, let alone any suggestion that Sijbesma engaged in any form of deception.

6.8 Conclusion

- 6.8.1 In conclusion, there is no evidence that the claimants were deliberately and unlawfully misled in order to induce them to receive Covid-19 injections which the defendants knew, or at least ought to have known, were neither safe nor effective. The declaration sought cannot therefore be granted. There has been no unlawful conduct — let alone any form of collective liability under Article 6:166 of the Dutch Civil Code.
- 6.8.2 It also follows from the above that there has been no breach of Article 97a of the Criminal Code (notwithstanding that the question of whether this is the case does not fall within the remit of the civil court). None of the defendants has in any way established contact with a person or body based abroad with the intention of (i) persuading such a person or body to provide support for the preparation, promotion or instigation of a revolution, or to strengthen such a person or body in their intention to that effect, thereby promising or providing such assistance, or with the intention of (ii) preparing, promoting or bringing about such a revolution.
- 6.B.3 The relevant evidence available to the State to rebut the claimants' arguments is attached to this submission as exhibits. The State offers — in so far as the burden of proof may rest with it pursuant to Article 150 of the Code of Civil Procedure and in the context of any rebuttal — to prove all its arguments by all lawful means.

⁺4 ° Summons, para. 199,

^{'''} Summons, paras. 188 and 194.

7 The causal link and the alleged damage

7.1 For the sake of completeness, the State further notes the following regarding the causal link and the damage alleged by the claimants.

7.2 The claimants allege that they have suffered (consequential) damage. In support of this, the claimants refer to 'diagnoses' made by 'medical specialists'.^{2*2} However, it appears that these relate to seven documents signed by one and the same doctor. These documents read more like an indictment of Dutch vaccination policy than a medical certificate. For instance, the following — identical — passage appears in several of the certificates:⁴³

"Given the concealment of the side" effects and the administration of vaccines that have not yet been fully "tested and investigated", under the pretext that there was an emergency, public confidence in the government has completely vanished with regard to the vaccines and the message conveyed by the government. Given the/FR-

According to the figures, there was never a medical emergency, and the mortality rate from Covid-19 was in line with that of flu. This figure alone does not justify any of the measures taken by the government, nor does it justify the need to administer vaccines. They have completely overlooked this. In hindsight, there was no medical necessity and, consequently, no crisis situation and therefore no pandemic that posed a threat to humanity worse than seasonal flu."

Such a passage has no place in a medical statement. The doctor who signed the statements evidently subscribes to the same theories as the claimants. That alone undermines the neutrality, objectivity and reliability of the statements. For that reason alone, the statements cannot be accorded the weight that the claimants attribute to them.

7.3 Moreover, it is even questionable whether these are in fact statements made by a doctor, rather than by the claimants themselves. After all, the opening sentence of these statements reads: *'The following is a medical statement by the above-mentioned patient regarding his health and his situation /...'* (emphasis added). For this reason alone, therefore, no medical or particular authority can be attributed to these statements.

7.4 The claimants allege that they have suffered physical injury as a result of the graphene oxide that is said to be present in the Covid vaccines.⁴⁴

7.5 According to the claimants' allegations, graphene oxide is present in the mRNA vaccines (the Pfizer and Moderna vaccines). That the claimants were vaccinated with such a vaccine

^{2*} Statement of claim, para. 265.

⁴ Statement of claim, Exhibit 91, pp. 1, 3, 5, 9 & 13.

⁴³ See also the 'Manifesto by Alexander van Walraven to all doctors in the Netherlands', available at [hCOs://www.youtube.com/watch?v=sOoRZOaomu](https://www.youtube.com/watch?v=sOoRZOaomu).

⁴⁴ Summoning, para. 265.

(and if so, which ones), has not been explained or substantiated. This alone is sufficient to invalidate the case. The State has already set out above that the vaccines do not contain graphene oxide (para. 6.3). Graphene oxide from the vaccines cannot therefore be the cause of the damage alleged by the claimants. But even setting that aside, the alleged damage is not sufficiently plausible.

Claimants 1 to 3 and 5 acknowledge that there are currently no external physical signs of serious bodily injury. However, they claim that there are less severe symptoms. This assertion is not substantiated or supported in any way. Even the statement makes no mention of any specific physical complaint. On the contrary, that statement implies that these claimants have no complaints (“He himself has no complaints yet”). According to the statements they themselves have submitted in the proceedings, these claimants therefore have suffered no damage.

Claimants 4, 6 and 7 allege that they have suffered serious physical injury as a result of the Covid vaccines.^{24 6} However, the statements submitted — whatever else may be said about them, see paragraphs 7.2–7.3 above — do not show that the alleged physical injury is the result of the Covid vaccines. The claimants do allege this, but there is no form of (medical) evidence to support that claim — in fact, these are merely unsubstantiated assertions by the claimants themselves.

- o Claimants 4 and 6 are said to have developed Parkinson’s as a result of the vaccine. In this regard, the State points out that the causes of Parkinson’s are largely unknown. The statement provides no evidence whatsoever to support the claim that the vaccine is the cause of Parkinson’s. It is incorrect to suggest that Parkinson’s is listed as a side effect of mRNA vaccines.²⁵ Nor is this evident from the Lareb list of side effects,²⁴ !
- o With regard to claimant 7, the statement identifies the vaccine as the cause of a TIA. In this context, it is claimed that ‘the vaccines’ cause clotting problems. This is not evident from the list of side effects in the package leaflets for the mRNA vaccines.²⁶! The remark in the statement that a TIA is a side effect of the vaccine

²⁴* Summons, para. 265.

²⁵ EMA, ‘Annex 1: Summary of Product Characteristics for Comirnaty’, <https://www.ema.europa.eu/nl/documents/zrggyt-in/gima-pn/ggmirnatv-eoqr-oroduct-information>,

EMA, ‘Annex 1: Summary of the product characteristics for Spikevax’, <https://www.ema.europa.eu/nl/documents/product-information/Spikevax-previous-covid-19-vaccine-moderna-eDar-product-information-nl-pdf>.

²⁶^ Lareb, ‘Side effects of COVID-19 vaccines’, <https://www.lareb.nl/side-effects-of-COVID-19-vaccines#Pfizer>

²⁷** EMA, ‘Annex 1: Summary of Product Characteristics for Comirnaty’. EMA, ‘Annex 1: Summary of Product Characteristics for Spikevax’.

The argument that ‘until proven otherwise’ holds no water, either scientifically or legally.

- 7.6 The claimants further allege that they have suffered non-pecuniary damage (apparently: mental injury within the meaning of Article 6:106 of the Dutch Civil Code*). Although all seven claimants allege to have suffered mental injury, this is mentioned in only five of the statements. For the other two claimants, even this form of substantiation is lacking. However, even where the statements do mention psychological harm, this is insufficient. These statements are vague and entirely (or almost entirely) identical. Consequently, these statements do not provide sufficient evidence to support even the plausibility of the alleged non-pecuniary damage.
- 7.7 Even so, the claimants have failed to establish a prima facie case that they have suffered damage as a result of the vaccine. The State points out that the claimants have not even established (i) that they were vaccinated, (ii) which vaccine was involved, (iii) at what time or times this took place, and (iv) what information from which defendant was decisive for each of them in that regard. On that basis alone, they have also failed to establish that they were persuaded to receive a Covid-19 vaccination as a result of ‘deliberate misrepresentation’ by the defendants.
- 7.8 Finally, in this regard, the State points out that everyone in the Netherlands has always been free to make their own assessments regarding whether or not to have a vaccine, to form their own opinion on the usefulness and necessity of vaccination, and to choose not to be vaccinated. Around twenty per cent of the adult population has also chosen not to be vaccinated. The claimants, too, had that choice.

8 Conclusion

The State et al. submit:

- i) that the claim be dismissed;
 - ii) that the claimants be ordered jointly and severally to pay the costs of the proceedings, on the understanding that statutory interest shall be payable on that order for costs from the fifteenth day following the date of the judgment to be delivered in this case;
 - (ii) with the claimants being jointly and severally liable for the subsequent costs, estimated in accordance with the liquidation rate at €173 or, in the event of service of process, €271;
-

- iv) with a declaration that these orders for costs are enforceable immediately.

Solicitor

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Case No.	11020625



State v Minks et al. C/17/190788 / HA ZA 2023-172

List of exhibits in the statement of defence

- 1 4ean Dohmen, 'How the Great Reset was hijacked', *FD* 22 January 2022
- 2 Images of the banners displayed
- 3 Various screenshots of posts on X (formerly Twitter)
- 4 a. Kan Westera, 'In vain: court case against Bill Gates', *Leeuwarder Courant*, 23
November 2023
- b. Image of a lorry from the aforementioned article
- c. Screenshot of a post on X (formerly Twitter)
- 5 Screenshot from the StatLine website 'Population trends; month and year'
- 6 EMA, 'Comirnaty (COVID-19 mRNA Vaccine (nucleoside modified)): An overview of
Comirnaty, including its adapted vaccines, and why it is authorised in the EU',
- 7 ENIA, 'Spikevax1 (COVID-19 mRNA Vaccine (nucleoside-modified)): An overview of
Spikevax, including its adapted vaccines, and why it is authorised in the EU',
- 8 EMA: 'Vaxzevria1 (COVID-19 Vaccine (ChAdox 1-S [recombinant])): An overview of
Vaxzevria and why it is authorised in the EU'
- 9 EMA, '3covden 1 (COVID-19 vaccine (Ad26.COV2-S [recombinant])): An overview of
Jcovden and why it is authorised in the EU'
- 10 Health Council of the Netherlands, summary on BioNTech/Pfizer, 24 December 2020
- 11 Health Council of the Netherlands, summary of the Moderna vaccine and the vaccination strategy, 11 January
2021
- 12 Health Council of the Netherlands, summary on the AstraZeneca vaccine, 4 February 2021
- 13 Health Council of the Netherlands, summary of the Janssen vaccine, 17 March 2021



TIME

Hoe de Great Reset werd gekaapt

Conspiracy theorists seized upon the idea put forward by World Economic Forum chief Klaus Schwab regarding the Great Reset. They claim that within a few years, a blue virus will be released to trigger a pandemic. ‘That’s exactly what we’re aiming for.’

Read more on page 18



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

Dit is een openbaar manifestatie en het is niet toegestaan het te kopiëren of te verspreiden.



HUGO de JONGE
(WEF)
In Friesland gedagvaard
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VERBODEN
TOEGANG

MARK RUTTE

(WEF)

In Friesland gedagvaard

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Dit is een openbare mededeling inzake een gerechtelijke procedure voor de rechtbank (art. 121 Grondwet)

People, the long-awaited verdict is finally coming from the court!!!

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Together for the Netherlands



The first media banners have been put up. And these cannot be censored or ignored by the media. For more information, visit www.RechtOprecht.online



12:11 p m - 8 August 2022? – 11.SK V:-ews

Lawyers from the 'Recht op Recht' foundation have served summonses on Rutte, Kaag and Marion Koo-Pmans, amongst others, on behalf of victims of vaccine-related harm! There must be retribution!

Please share & RT if you can't wait for them to be PUNISHED!



7:48 pm 8 August 2023 – BTX Vie.vs

Failed court appearance in case against Bill Gates

JAN WESTERA

LEEWARDEN The Recht Oprecht court case drew a handful of supporters to the Zaailand on Wednesday, outside the courthouse in Leeuwarden.

Election Day was supposed to mark the start of their proceedings on behalf of seven people who claim to have suffered harm following their Covid-19 vaccinations and to still be 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, though without specifying the cause of death. According to Stassen, the victim was a 7-year-old care worker who had 'had the vaccine administered on behalf of someone else'.

The Frisian foundation Recht Oprecht has identified what it considers to be seventeen cases of... Those responsible for this and other damage in Leeuwarden have been brought before the court.

Among them are, amongst others, the 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 advised the Dutch government during the pandemic.

The supporters of Recht Oprecht did not enter the courthouse on Wednesday. According to spokesperson Anno Rijkema of the North Netherlands District Court, there was little to see there anyway. As Rijkema explains, this was not a proper hearing, but a 'case management hearing'.

In such a hearing, the case manager deals purely with the formalities of how this trial is to proceed. "The case manager therefore deals with the procedures, not the substance," explains Rijkema. "And the judge has not taken any action as yet today."

However, Rutte, Gates and Hof-



Supporters of Recht Oprecht gathered on Wednesday in the square in front of the courthouse in Leeuwarden. Photo: LC

Lawsuit on behalf of seventeen people seeking compensation for damage caused by Covid vaccinations

stra and the other fourteen defendants have been granted a further six weeks by the court to respond to the charges that the Recht Oprecht Foundation served on them on 14 July.

"The court's further proceedings will depend in part on the content of that response," said Rijkema. "And only then will the judge be appointed who will hear the case on its merits. That could also be a panel of judges."

However, Rijkema points out, "at the moment we only have a summons with annexes" from Recht Oprecht. Lawyer Van Kessel states in

the organisation's own news broadcast that the Crown Solicitor is acting on behalf of twelve defendants. He also states that Gates's own lawyer in America received the summons. According to him, the billionaire has not yet engaged a lawyer to defend himself in the Recht Oprecht case.

Since the case against the seventeen began, the foundation has moved from a farm on the Warstienserdyk in Wergea to commercial premises on the Ceresweg in Leeuwarden. There have also been changes within the board. According to information from the Chamber of Commerce, treasurer Leroen Laurens Maximiliaan Cornelis Evers and secretary Peter Marcel Johan de Haan are no longer active as board members. Founder Ritske Blom from Wergea remains a board member from the very beginning; the only other board member at present is Helena Hendrika de Vries.



**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 medeplchtig**

**Kinderen zijn onze toekomst
en geen proefkonijnen
Vaccinazi macht vrij!!**

Klaar voor morgen. Plein t Zaailand tegenover het gerechtsgebouw!

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9:40 PM · Nov 21, 2023 · 3,830 Views



5



40



112



4



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StarLine

Bevolkingontwikkeling, maand en jaar

Gevolgact: 30 november 2023

Thema's Recent Help Zoeken...

Verzichten kunnen gesorteerd worden naar de kop, rijen of kolommet van de tabel. In de kop is naar één item van een tabelde te selecteren.

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Periode	Bevolking aan het begin van de periode	Overstroom
Jaar		
1990	15 945 309	157 291
1991	15 967 107	133 783
1992	15 964 162	137 463
1993	15 960 225	140 467
1994	15 945 590	140 327
1995	15 987 075	140 317
1996	16 105 285	142 355
1997	16 240 572	144 156
1998	16 210 002	144 335
1999	16 205 526	156 402
2000	16 314 218	133 872
2001	16 337 992	145 022
2002	16 405 399	133 136
2003	16 465 787	144 235
2004	16 574 969	156 025
2005	16 637 799	133 742
2006	16 690 004	144 004
2007	16 770 375	142 245
2008	16 829 039	159 223
2009	16 890 726	147 154
2010	16 979 125	148 997
2011	17 061 507	150 214
2012	17 183 084	153 365
2013	17 282 165	151 895
2014	17 467 095	166 450
2015	17 475 435	179 972
2016	17 560 672	170 112

Bron: CBS

Voor wat er feitelijk gebeurt

Engels: Bevolkingontwikkeling CBS.nl CBS 2023

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 aged 6 months and over.

The originally authorised Comirnaty contains tozinameran, a messenger RNA (mRNA) molecule containing 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 riltosinameran, an mRNA molecule containing instructions for producing a protein from the Omicron BA.1 subvariant of SARS-CoV-2;
- Comirnaty Original/Omicron BA.4-5 contains tozinameran and famtosinameran, an mRNA molecule containing instructions for producing a protein from the Omicron BA.4 and BA.5 subvariants of SARS-CoV-2;
- Comirnaty Omicron XBB.1.5 contains raxtosinameran, an mRNA molecule containing 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 aged 5 years and over should receive a single dose administered by injection into the upper arm muscle, regardless of their previous vaccination history.

Children aged 6 months to 4 years who have completed a primary vaccination course or have previously had COVID-19 should also receive a single dose, which can be administered by intramuscular injection into the upper arm or thigh.

In children aged between 6 months and 4 years who have not completed a primary vaccination course and have not had COVID-19, the vaccine is administered in three doses; the first two doses are given three weeks

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An agency of the European Union



separately, followed by a third dose given at least 8 weeks after the second dose. The injections can be administered into 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 in accordance with official recommendations issued at national level by public health authorities.

For more information on using Comirnaty, including details on the adapted vaccines and 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 carries instructions for producing the spike protein. This is a protein on the surface of the SARS-CoV-2 virus that the virus needs to enter the body's cells, and it can vary between different 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 recognise the protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, at a later date, the person comes into contact with SARS-CoV-2, their immune system will recognise 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 that more closely matches circulating variants of the virus.

What benefits of Comirnaty have been demonstrated in studies?

A very large clinical trial showed that Comirnaty, administered as a two-dose regimen, was effective at preventing COVID-19 in people aged 12 and over.

This main trial involved a total of around 44,000 people aged 16 and over. Half received the vaccine and half were given a placebo. The participants did not know whether they had received the vaccine or the placebo.

Efficacy in people aged 16 and over was calculated in over 36,000 participants (including people over 75 years of age) who showed no signs of previous infection. The study showed a 95 per cent reduction in the number of symptomatic COVID-19 cases among those who received the vaccine (8 out of 18,198 developed COVID-19 symptoms) compared with those who received a placebo (162 out of 18,325 developed COVID-19 symptoms). This means that the vaccine demonstrated 95 per cent efficacy in the trial.

The trial in people aged 16 and over also showed around 95 per cent efficacy in 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 showed no signs of previous infection. It showed that the immune response to Comirnaty in this group was comparable to that 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 had been given. Of the 1,005 children who received the vaccine, none developed COVID-19, compared with 16 children out of the 978 who received the placebo. This means that, in this study, the

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

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

A study in children aged 5 to 11 showed that the immune response to Comirnaty administered 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 who received the vaccine, three developed COVID-19, compared with 16 out of the 663 children who received a placebo. This means that, in this study, the vaccine was 90.7 per cent effective at preventing symptomatic COVID-19 (although the true efficacy rate could be between 67.7 per cent and 98.3 per cent).

A main study in children aged between 6 months and 4 years assessed the immune response triggered by the vaccine (administered as three 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 observed with the higher dose (30 micrograms) in 16- to 25-year-olds.

Additional data showed that subsequent doses, including boosters, lead to an increase in the levels of antibodies against SARS-CoV-2. Available data also indicate that vaccines specifically adapted 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 authorised Comirnaty, Comirnaty Original/Omicron BA.4-5 and Comirnaty Omicron XBB.1.5 are authorised for adults and children from 6 months of age.

Comirnaty Original/Omicron BA.1 is authorised for adults and children aged 12 years and over.

Can people with compromised immune systems 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.

People who are severely immunocompromised may be given an additional dose of Comirnaty as part of their primary vaccination course.

Can pregnant or breastfeeding women be vaccinated with Comirnaty?

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

Comirnaty can also be used whilst breastfeeding. Data from women who were breastfeeding after vaccination have not shown any risk of adverse effects in breastfed babies.

No data are currently available regarding the use of the adapted vaccines in pregnant or breastfeeding women. However, given the similarity to the vaccine targeting the original strain, including a comparable safety profile, Comirnaty Original/Omicron BA.1 can be used during pregnancy and breastfeeding. Furthermore, based on the data available for the originally authorised 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 breastfeeding.

Can people with allergies be vaccinated with Comirnaty?

People who already know they are allergic to any of the vaccine's components listed in section 6 of the package leaflet should not receive the vaccine.

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

How effective is Comirnaty for people of different ethnicities and genders?

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

What are the risks associated with Comirnaty?

For the full list of side effects and restrictions relating to Comirnaty, see the patient information leaflet.

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

Redness at the injection site, swollen 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, swollen lymph nodes, difficulty sleeping, feeling unwell, loss of appetite, lethargy (lack of energy), hyperhidrosis (excessive sweating), night sweats, asthenia (weakness) and allergic reactions (such as a rash, itching, an itchy rash and rapid swelling under the skin) are uncommon side effects (affecting fewer than 1 in 100 people). Weakness in the muscles on one side of the face (acute peripheral facial paralysis or palsy) occurs in fewer than 1 in 1,000 people.

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

Very few cases of extensive swelling of the arm where the vaccine was administered, swelling of the face in people with a history of dermal filler injections (soft, gel-like substances injected under the skin), erythema multiforme (red patches on the skin with a dark red centre and paler red rings), paraesthesia (unusual sensations in the skin, such as tingling or a crawling sensation) and hypoesthesia (reduced sensation or sensitivity in the skin) have been reported. Allergic reactions have also been reported with Comirnaty, including a very small number of cases of severe allergic reactions (anaphylaxis).

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

Why is Comirnaty authorised in the EU?

Data show that Comirnaty stimulates the production of antibodies against SARS-CoV-2 that can protect against COVID-19. The main trials of Comirnaty showed that the vaccine is highly effective across all age groups. Most side effects are mild to moderate in severity and resolve within a few days.

The Agency has therefore concluded that the benefits of Comirnaty, including its adapted vaccines, outweigh the risks and that it can be authorised for use in the EU.

Comirnaty was originally granted 'conditional authorisation' because further evidence regarding the vaccine was still to be provided. The company has provided comprehensive information, including data on its safety, efficacy and how well Comirnaty prevents severe disease. In addition, the company has completed all the required studies on the pharmaceutical quality of the vaccine. As a result, the conditional authorisation has been converted to a standard authorisation.

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 vaccine's safety, how to collect further information and how to minimise 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 with all medicines, data on the use of Comirnaty are continuously monitored. Suspected side effects are carefully evaluated and any necessary action is taken to protect patients.

Further information about Comirnaty

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

Further information on 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 August 2023.

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

Spikevax¹ (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 aged 6 months and over.

The originally authorised Spikevax contains elasomeran, a molecule known as messenger RNA (mRNA) that contains 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, which contains 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 containing 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 authorised Spikevax is administered to people aged 6 months and over as two injections, usually into the upper arm muscle, or the thigh in infants and young children, 28 days apart. A booster dose may be given to adults and children aged 6 years and over, at least 3 months after primary vaccination with Spikevax, or another mRNA vaccine or an adenoviral vector vaccine.

¹ Previously known as the Moderna COVID-19 vaccine

Spikevax bivalent Original/Omicron BA.1 may be administered as a single injection to adults and children aged 6 years and over, 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 administered as a single injection to adults and children aged 5 years and over, regardless of their previous COVID-19 vaccination history. In children aged between 6 months and 4 years, they are administered as a single injection to those who have completed a primary vaccination course or have previously had COVID-19, or as two injections 28 days apart to 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 over with a severely weakened immune system.

The vaccines should be used in accordance with official recommendations issued at national level by public health authorities.

For more information on using Spikevax, including details of 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 carries instructions for producing the spike protein. This is a protein on the surface of the SARS-CoV-2 virus that the virus needs to enter the body's cells, and which can vary between different variants of the virus.

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

If, at a later date, the person comes into contact with SARS-CoV-2, their immune system will recognise 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 that more closely matches circulating variants of the virus.

What benefits of Spikevax have been demonstrated in studies?

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

Efficacy was calculated in around 28,000 people aged between 18 and 94 who showed no signs of previous infection. The trial showed a 94.1 per cent reduction in the number of symptomatic COVID-19 cases among those who received the vaccine (11 out of 14,134 vaccinated people developed symptomatic COVID-19) compared with those who received placebo injections (185 out of 14,073 people who received placebo injections developed symptomatic COVID-19). This means that the vaccine demonstrated 94.1 per cent efficacy in the trial. The trial also showed 90.9 per cent 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 boosted 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 an immune response in 12- to 17-year-olds comparable to that seen in young adults (aged 18 to 25 years), as measured by the level of antibodies against SARS-CoV-2. Furthermore, none of the 2,163 children who received the vaccine developed COVID-19, compared with four out of 1,073 children who were given a placebo injection. These results led to the conclusion that the efficacy of Spikevax in children aged 12 to 17 is similar to that in adults.

A further 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 an immune response in these age groups comparable 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 aged 6 months to 11 years is similar to that in adults.

Further data showed that subsequent doses, including booster doses, lead to an increase in the levels of antibodies against SARS-CoV-2.

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

Can children be vaccinated with Spikevax?

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

Spikevax bivalent Original/Omicron BA.1 is authorised for adults and children aged 6 years and over.

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.

People who are severely immunocompromised may be given an additional dose of Spikevax as part of their primary vaccination course.

Can pregnant or breastfeeding women be vaccinated with Spikevax?

Spikevax can be used during pregnancy.

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

Spikevax can be used whilst breastfeeding. Data from women who were breastfeeding after vaccination have not shown any risk of adverse effects in breastfed babies.

No data are currently available regarding the use of the adapted vaccines in pregnant or breastfeeding women. However, given their similarity to the originally authorised Spikevax, including a comparable safety profile, the adapted vaccines can be used during pregnancy and breastfeeding.

Can people with allergies be vaccinated with Spikevax?

People who already know they are allergic to any of the vaccine's components listed in section 6 of the package leaflet should not receive the vaccine.

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

How effective is Spikevax 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 relating to Spikevax, see the package leaflet.

The most common side effects of Spikevax are usually mild or moderate and improve within a few 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, drowsiness and loss of appetite are also very common side effects (affecting more than 1 in 10 infants).

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

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane surrounding the heart) 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 centre and paler red rings) have been reported. Allergic reactions have also been reported 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 authorised Spikevax vaccine.

Why has Spikevax been authorised in the EU?

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

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

Spikevax was originally granted 'conditional authorisation' as further evidence regarding the vaccine was still to be provided. The company has provided comprehensive information, including data on its safety, efficacy and how effectively Spikevax prevents severe disease. In addition, the company has completed all the required studies on the pharmaceutical quality of the vaccine. As a result, the conditional authorisation has been converted to a standard authorisation.

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 gather further information and how to minimise any potential risks.

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

As with 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 is taken to protect patients.

Further information about Spikevax

The Moderna COVID-19 vaccine was granted conditional marketing authorisation valid throughout the EU on 6 January 2021. This was converted to a standard marketing authorisation on 3 October 2022.

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

Further information on 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 September 2023.

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

Vaxzevria¹ (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 over.

Vaxzevria is made up of another virus (from the adenovirus family) that has been modified to contain the gene for producing 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 administered as two injections, usually into the upper arm muscle. 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 authorised mRNA COVID-19 vaccine. The vaccines should be used in accordance with official recommendations issued at national level by public health authorities.

For more information on 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 consists of another virus (adenovirus) that has been modified to contain the gene for producing the SARS-CoV-2 spike protein. This is a protein on the surface of the SARS-CoV-2 virus that the virus needs to enter the body's cells.

¹ Previously known as the COVID-19 Vaccine AstraZeneca



Once it has been administered, 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 recognise this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

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

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

What benefits of Vaxzevria have been demonstrated in studies?

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

The Agency based its calculation of the vaccine's efficacy on the results from study COV002 (conducted in the UK) and study COV003 (conducted in Brazil). The other two studies each had fewer than six cases of COVID-19, which was not sufficient to assess the vaccine's preventive effect. Furthermore, as the vaccine was to be administered as two standard doses, with the second dose to be given between 4 and 12 weeks after the first, the Agency focused on results involving people who received this standard regimen.

These trials showed a 59.5 per cent reduction in the number of symptomatic COVID-19 cases among people who received the vaccine (64 out of 5,258 developed symptomatic COVID-19) compared with those who received placebo injections (154 out of 5,210 developed symptomatic COVID-19). This means that the vaccine demonstrated an efficacy of around 60 per cent in these clinical trials.

Another study carried out in the United States, Peru and Chile involved around 26,000 people, 21 per cent of whom were aged over 65. The participants received the second dose four weeks after the first. The study showed a 74 per cent reduction in the number of symptomatic COVID-19 cases among those who received the vaccine (73 out of 17,662 developed symptomatic COVID-19) compared with those who received placebo injections (130 out of 8,550 developed symptomatic COVID-19). The study also showed that the efficacy of Vaxzevria in older people is comparable to that seen in younger people.

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

Can children be vaccinated with Vaxzevria?

Vaxzevria is not currently authorised for use in children. The 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 is 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 breastfeeding women be vaccinated with Vaxzevria?

Preliminary animal studies do not indicate any harmful effects during pregnancy; however, data on the use of Vaxzevria during pregnancy are very limited. Although there are no studies on breastfeeding, no risk is expected during breastfeeding.

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

Can people with allergies be vaccinated with Vaxzevria?

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

Allergic reactions (hypersensitivity) have been observed in people receiving the vaccine. Cases of anaphylaxis (a severe allergic reaction) have also occurred. As with all vaccines, Vaxzevria should be administered under close medical supervision, with appropriate medical treatment available in the event of an allergic reaction. People who experience a severe allergic reaction after receiving the first dose of Vaxzevria should not receive the second dose.

How effective is Vaxzevria for people of different ethnicities and genders?

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

What are the risks associated with Vaxzevria?

The most common side effects of Vaxzevria are usually mild or moderate and improve within a few days of vaccination. Compared with the first dose, side effects reported after the second dose are milder and occur 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, a general feeling of being unwell, chills, fever, joint pain and nausea (feeling sick). These may affect more than 1 in 10 people.

Thrombocytopenia (low blood platelet levels), vomiting, diarrhoea, pain in the legs or arms, swelling and redness at the injection site, flu-like symptoms and asthenia (weakness) may affect up to 1 in 10 people.

Lymphadenopathy (enlarged lymph nodes), loss of appetite, dizziness, drowsiness, lethargy (lack of energy), hyperhidrosis (excessive sweating), abdominal (stomach) pain, muscle spasms, itching, rash and urticaria (itchy rash) may affect up to 1 in 100 people.

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

Thrombosis (the 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 characterised by inflammation of 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 with all vaccines, Vaxzevria should be administered under close supervision, with appropriate medical treatment available.

Vaxzevria must not be administered to people who have experienced thrombosis with thrombocytopenia syndrome (TTS) following vaccination. Vaxzevria must also not be administered to people who have previously experienced capillary leak syndrome.

Why is Vaxzevria authorised in the EU?

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 was around 60 per cent effective against the main strain of SARS-CoV-2 in circulation at the time. Most side effects are mild to moderate in severity and subside within a few days.

The European Medicines Agency has concluded that the benefits of Vaxzevria outweigh its risks and that it can be authorised for use in the EU.

Vaxzevria was originally granted 'conditional authorisation' because further evidence regarding the vaccine was still to be provided. The company has provided comprehensive information, including data on its safety and efficacy, confirming the findings from earlier studies previously submitted. In addition, the company has completed all the studies requested concerning the pharmaceutical quality of the vaccine. As a result, the conditional authorisation has been converted to a standard authorisation.

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 gather further information and how to minimise 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 with all medicines, data on the use of Vaxzevria are continuously monitored. Suspected side effects reported with Vaxzevria are carefully evaluated and any necessary action is taken to protect patients.

Further information about Vaxzevria

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

Further information on COVID-19 vaccines, such as the use of adapted vaccines and booster doses, 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 November 2022.

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

Jcovden¹ (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 over. COVID-19 is caused by the SARS-CoV-2 virus.

Jcovden is made from another virus (from the adenovirus family) that has been modified to contain the gene for producing 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 administered at least 2 months after the first dose of Jcovden in people aged 18 years and over. A booster dose may also be administered following 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 administered for such vaccines.

The vaccine should be used in accordance with official recommendations issued at national level by public health authorities. For further information on the use of 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 consists of another virus (an adenovirus) that has been modified to contain the gene for producing the SARS-CoV-2 spike protein. This is a protein on the surface of the SARS-CoV-2 virus that the virus needs to enter the body's cells.

¹ Previously known as COVID-19 Vaccine Janssen



The adenovirus delivers 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 recognise 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, their immune system will recognise 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 showed that Jcovden was effective at preventing COVID-19 in people aged 18 and over. This study involved over 44,000 people. Half received a single dose of the vaccine and half were given a placebo (a dummy injection). The participants did not know whether they had been given Jcovden or a placebo.

The trial found a 67 per cent reduction in the number of symptomatic COVID-19 cases after two weeks in people who received Jcovden (116 cases out of 19,630 people) compared with those given a placebo (348 out of 19,691 people). This means that the vaccine was 67 per cent effective.

Further data showed an increase in antibody levels when a booster dose was administered following completion of a primary course with Jcovden, an mRNA vaccine, or another adenoviral vector vaccine in people aged 18 and over.

Can children be vaccinated with Jcovden?

Jcovden is not currently authorised 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 breastfeeding women be vaccinated with Jcovden?

Animal studies do not indicate any harmful effects of Jcovden during pregnancy. However, data on the use of Jcovden during pregnancy are very limited. There are no studies on the use of Jcovden whilst breastfeeding, but no risk to the baby via breast-feeding is expected.

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

Can people with allergies be vaccinated with Jcovden?

People who are allergic to any of the vaccine's components 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 (a severe allergic reaction). As with all vaccines, Jcovden should be administered under close medical supervision, with appropriate medical treatment available in the event of allergic reactions.

How effective is Jcovden for people of different ethnicities and genders?

The clinical trials included people of different ethnicities and genders. The vaccine was effective across all genders and ethnic groups.

What are the risks associated with Jcovden?

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

The most common side effects of Jcovden are usually mild or moderate and improve 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 the injection site may affect up to 1 in 10 people. Dizziness, shaking, coughing, pain in the mouth and throat, sneezing, diarrhoea, 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) include lymphadenopathy (enlarged lymph nodes), an itchy rash, hypersensitivity (allergy), paraesthesia (unusual sensations such as numbness, tingling or pins and needles), hypoesthesia (reduced sensation of 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 doses, the number and severity of reactions tend to be higher in people who have previously been vaccinated with a vaccine other than Jcovden, compared with those who have completed a primary course with Jcovden.

Thrombosis (formation of blood clots in the blood vessels) combined 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 (a severe allergic reaction), have occurred in people receiving the vaccine. As with all vaccines, Jcovden should be administered 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 attacks 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 characterised by inflammation of the spinal cord), myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the membrane surrounding the heart) have been reported with Jcovden.

Jcovden must not be administered to people who have previously had capillary leak syndrome; nor must it be administered to people who have experienced TTS following vaccination with any COVID-19 vaccine.

Why has Jcovden been authorised in the EU?

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

The European Medicines Agency therefore decided that the benefits of Jcovden outweigh its risks and that it can be authorised for use in the EU.

Jcovden was originally granted 'conditional authorisation' because further evidence regarding the vaccine was still to be provided. The company has provided comprehensive information, including data on its safety and efficacy, confirming the findings from earlier studies previously submitted. In addition, the company has completed all the studies requested concerning the pharmaceutical quality of the vaccine. As a result, the conditional authorisation has been converted to a standard authorisation.

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

Further information about Jcovden

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

Further 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 June 2023.

cOVID 19 vaccine: BioNTech/Pfizer

No. 2020/29, The Hague, 24 December 2020

SamSammary

GHealth Council



The BNT162b2 vaccine against COVID-19, developed by BioNTech and Pfizer (brand name *Comirnaty*), has been assessed by the European Medicines Agency (EMA) and approved by the European Commission. This means that it can be used in the Netherlands to combat

the COVID-19 pandemic. The Minister for Health, Welfare and Sport has asked the Health Council to advise on the use of this vaccine among various target groups eligible for

vaccination. The Committee on Medical Aspects of COVID-19 has assessed the vaccine on the basis of the standard criteria used by the Health Council of the Netherlands when advising on vaccinations.

The disease burden of COVID-19 is high

The first criterion for the use of a vaccine is that there must be a significant

disease burden. This is clearly the case with COVID-19. By mid-December, the GGD had 628,577 cases and 10,168 deaths from COVID-19. The risk of severe disease increases in people with chronic conditions and with advancing age. The average age of patients in general wards was 67 years and in intensive care units 64 years. The vast majority of deaths have been among older people, a large proportion of whom were living in care homes.

The vaccine works well in adults, older people and high-risk medical groups

A further criterion is that vaccination must be effective. The vaccine is administered in two doses, approximately three weeks apart. The efficacy of the BNT162b2 vaccine against COVID-19 was assessed in over 36,000 people, half of whom received the vaccine and half a placebo. The results

it emerged that the vaccine provides good protection for adults, older people and high-risk medical groups alike. In all groups, efficacy was well over 90 per cent.

It is not yet known how long the protection lasts or to what extent vaccination can also prevent the spread of the virus.

The vaccine is sufficiently safe: side effects are generally mild

The safety of vaccination is also an important criterion. The BNT162b2 vaccine is sufficiently safe and is well tolerated. Like all medicines, vaccines also have side effects. The purpose of vacci-

is to trigger a response from the immune system, and this is often accompanied by temporary symptoms. Vaccination with the BNT162b2 vaccine causes side effects in most people after both the first and second doses. The most common were



mild to moderate pain at the injection site, as well as tiredness, headache and muscle pain. These reactions were more common in younger people and more frequently occurred after the second dose.

Most side effects had disappeared within a few days.

Vaccination is acceptable: the benefits outweigh the disadvantages

The committee considers that the benefits of vaccination (health gains through protection against COVID-19) outweigh the disadvantages (side effects that are generally mild and short-lived). This also means that the criterion of acceptability has been met. The cost-effectiveness of vaccination cannot yet be assessed as no data are currently available on this.

Recommendation: roll out the vaccine, primarily to older people

aged 60 and over

Vaccination with the BNT162b2 vaccine is effective, sufficiently safe and acceptable for adults, older people and those at medical risk

groups. The committee therefore recommends in places where acute health damage may occur due to the absence of healthcare workers, the BNT162b2 vaccine should be used in public due to the absence of healthcare workers. vaccination programmes targeting COVID-19. According to the committee, the AstraZeneca vaccine could offer a solution because the vaccine has shown unexpectedly high AstraZeneca vaccine could offer a solution, given its higher-than-expected efficacy in older people and the fact that the disease burden vaccination of all healthcare workers, as the burden of disease resulting from COVID-19 is greatest in this group, the committee recommends that the BNT162b2 2021 in a large quantity of 4.5 million doses primarily for older people aged doses could be supplied.

60 years of age, starting with the oldest. This is in line with vaccination strategy 1, as set out in the recent advice from the Health Council of the Netherlands on vaccination strategies. This strategy yields the greatest health benefits and also helps to prevent the influx of COVID-19 patients into hospitals, which will . According to the committee, the BNT162b2 vaccine should be used on a limited basis to vaccinate staff in long-term care, specifically for as long as the medical risk groups they care for cannot be vaccinated themselves. The vaccine could also be used very selectively in acute care to maintain the provision of care



The Health Council, established in 1902, is an advisory body tasked with 'informing the government and parliament about the state of scientific knowledge regarding issues in the field of public health and health (care) research' (Article 22 of the Health Act).

The Health Council receives most of its requests for advice from the ministers for Health, Welfare and Sport; Infrastructure and Water Management; Social Affairs and Employment; and Agriculture, Nature and Food Quality. The Council may also issue advice on its own initiative, and identify developments or trends that are relevant to government policy.

The Health Council's advice is public and is generally drawn up by multidisciplinary committees comprising Dutch and, on occasion, foreign experts appointed in a personal capacity.

You can download this document from www.gezondheidsraad.nl.

This publication may be cited as follows: Health Council of the Netherlands. COVID-19 vaccination: BioNTech/Pfizer. The Hague: Health Council of the Netherlands, 2020; publication no. 2020/29.

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COVID-19 a Maternal vaccination: the vaccine and the vaccination strategy

No. 2021/01, The Hague, 11 January 2021

Summary
a Summary

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The mRNA-1273 vaccine against COVID-19, developed by Moderna (brand name *COVID-19 Vaccine Moderna*), has recently been positively assessed by the European Medicines Agency (EMA) and authorised by the European Commission. This means that it can be used in the Netherlands to combat the COVID-19 pandemic.

The Minister for Health, Welfare and Sport has asked the Health Council of the Netherlands to advise on the use of this vaccine among various target groups eligible for vaccination. The Committee on Medical Aspects of COVID-19 has assessed the vaccine on the basis of the standard criteria used by the Health Council of the Netherlands when advising on vaccinations.

The disease burden of COVID-19 is high

The first criterion for the use of a vaccine is that there must be a significant

disease burden. This is clearly the case with COVID-19. By early January, the GGD had 834,064 cases of the disease and 11,826 deaths from COVID-19. The risk of a severe course of the disease increases with age and in people with a chronic condition.

The average age of patients in general wards was 67 years and in intensive care units 64 years. The vast majority of deaths have been among older people, a large proportion of whom were living in care homes.

The vaccine works well in adults, older people and high-risk medical groups

A further criterion is that vaccination must be effective. The vaccine is administered in two doses, 28 days apart. The efficacy of the mRNA-1273 vaccine against COVID-19 was assessed in over 28,000 people, half of whom received the vaccine and half a placebo. This showed

that the vaccine provides good protection for adults, older people and medical risk groups alike, over a follow-up period of approximately two months. In all groups, efficacy was well over 80 per cent.

It is not yet known how long the protection lasts or to what extent vaccination can also prevent the spread of the virus.

The vaccine is sufficiently safe: side

effects are generally mild The safety of the vaccine is also an important criterion. The mRNA-1273 vaccine is sufficiently safe and is well tolerated.

Like all medicines, vaccines also have side effects. The aim of vaccination is to trigger a response from the immune system, and this is often accompanied by temporary symptoms. Vaccination with the mRNA-1273 vaccine causes side effects in most people after both the first and the



second dose. The most common were mild to moderate pain at the injection site, as well as tiredness, headache and muscle pain. These reactions were more common in younger people and more frequently occurred after the second dose.

Most side effects had resolved within a few days.

Vaccination is acceptable: the benefits outweigh the risks

The committee considers that the benefits of vaccination (health gains through protection against COVID-19) outweigh the disadvantages (side effects that are generally mild and short-lived). This also means that the criterion of acceptability is also met. The cost-effectiveness of vaccination cannot yet be assessed as no data are currently available on this.

Advice: deploy the vaccine, primarily among older people

The committee concludes that vaccination with the mRNA-1273 vaccine is effective, sufficiently safe and acceptable for adults, older people and medical risk groups. The committee therefore recommends that this vaccine be used in public vaccination programmes targeting COVID-19. As the vaccine demonstrates very high efficacy in older people, the disease burden resulting from COVID-19 is greatest in this group, and the vaccine is available in relatively small quantities, the committee recommends that the mRNA-1273 vaccine be used primarily for older people aged 60 and over, starting with the oldest, regardless of whether they belong to a medical risk group or not.

Vaccinating older people – both those living independently and those in long-term care homes – will reduce the burden of disease in

this group, which will in turn ease the pressure on the healthcare system. It is therefore important to use the vaccines currently available to vaccinate older people and to organise the vaccination programme in such a way that the chosen vaccination strategy can continue to be followed.



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This publication may be cited as follows:
Health Council of the Netherlands. COVID-19 vaccination: the Moderna vaccine and the vaccination strategy. The Hague: Health Council of the Netherlands, 2021; publication no. 2021/01.

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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 Oxford University and pharmaceutical company AstraZeneca (brand name: AstraZeneca COVID-19 vaccine) have been given a positive assessment by the European Medicines Agency (EMA) and authorised by the European Commission. This means that it can be used in the Netherlands to combat the COVID-19 pandemic. The Minister for Health, Welfare and Sport has asked the Health Council to advise on the use of this vaccine among various target groups eligible for vaccination. The Committee on Medical Aspects of COVID-19 has assessed the vaccine on the basis of the standard criteria used by the Health Council when advising on vaccinations.

The disease burden of COVID-19 is high

The first criterion for the use of a vaccine is that there must be a significant disease burden. This is clearly the case with COVID-19. By the end of January, the GGD had confirmed 956,867 cases of the disease and 13,665 deaths due to COVID-19. The risk of severe disease increases with age and is higher in people with a chronic condition.

The vaccine works well

A further criterion is that the vaccine must be effective. The vaccine is administered in two doses, with an interval of 4 to 12 weeks between them. The efficacy of the ChAdOx1-S nCoV-19 vaccine against COVID-19 was assessed in over 10,000 people, half of whom received the vaccine and half a placebo.

During a follow-up period of approximately two months, the efficacy of the

vaccine was found to be approximately 60 per cent in adults and medical risk groups. For people aged 56 and over, there is still too little data available to calculate the vaccine's efficacy. However, as the vaccine does elicit an immune response in this group that is comparable to that of 18–55-year-olds, the committee assumes that the vaccine will be effective. It is not yet known how long the protection lasts or to what extent vaccination can also prevent the spread of the virus.

The 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 is well tolerated.

Like all medicines, vaccines also have side effects. The aim of vaccination is to trigger 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 and occur less frequently after the second dose. The most common were tenderness and pain at the injection site, tiredness and headache. The reactions were predominantly mild to moderate in severity and usually resolved within a few days.

Vaccination is acceptable: the benefits outweigh the risks

The committee considers that the benefits of vaccination (health gains through protection against COVID-19) outweigh the disadvantages (side effects that are generally mild and short-lived). This also means that the criterion of acceptability has been met. The cost-effectiveness of vaccination cannot yet be assessed, as no data are currently available on this.

Recommendation: deploy the vaccine, prioritising those aged 60–64

The committee recommends that the ChAdOx1-S nCoV-19 vaccine be used in public vaccination programmes targeting COVID-19, as the vaccine is effective, sufficiently safe and acceptable. For people aged 56 and over, it is not yet possible to calculate the efficacy due to the small number of older participants in the phase 3 trial. However, it has been demonstrated that the ChAdOx1-S nCoV-19 vaccine elicits an immune response in older people. The committee therefore assumes that the vaccine is also sufficiently effective in this group.

As the immune system functions less effectively with increasing age (immunosenescence), it is uncertain whether the vaccine is sufficiently effective in older people aged 65 years of age, it is uncertain whether the vaccine is sufficiently effective. The committee therefore considers the vaccine suitable for use in adults up to the age of 65. To prevent serious illness and death as much as possible, the committee recommends that the first available doses of the ChAdOx1-S nCoV-19 vaccine be administered to older people aged

aged 60 to 64 inclusive, starting with the oldest. Modelling shows that this will result in a lower disease burden than if this group were vaccinated later – namely after all those aged 65 and over – with an mRNA vaccine, in line with the current vaccination schedule. The committee also recommends vaccinating specific medical risk groups at particularly high risk. Some of these patients can be vaccinated with the ChAdOx1-S nCoV-19 vaccine. Patients with severely compromised immune systems should preferably receive an mRNA vaccine. Once all older people have been vaccinated, the committee that vaccination with the ChAdOx1-S nCoV-19 vaccine should then proceed for two groups that face a similarly elevated risk of severe COVID-19: medical risk groups up to the age of 60 and people in the 50 to 60 age group, starting with the oldest members of both groups.



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This publication may be cited as follows: Health Council of the Netherlands. COVID-19 vaccination: AstraZeneca vaccine. The Hague: Health Council of the Netherlands, 2021; publication no. 2021/04

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COVID-19-vaccinatie: Janssen-vaccin

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

Samenvatting

Gezondheidsraad



The Ad26.COV2.S vaccine against COVID-19, developed by Janssen Pharmaceutica (brand name: Janssen COVID-19 vaccine), has recently been positively assessed by the European Medicines Agency (EMA) and authorised 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 of the Netherlands to advise on the use of this vaccine. The Committee on Medical Aspects of COVID-19 has assessed the vaccine on the basis of the standard criteria used by the Health Council of the Netherlands when advising on vaccinations.

The disease burden of COVID-19 is high
The first criterion for the use of a vaccine is that there must be a significant

disease burden. This is clearly the case with COVID-19. By early March 2021, the GGD had 1,128,202 cases and 15,917 deaths from COVID-19 had been confirmed by the GGD. The risk of severe disease increases with age and is higher in people with a chronic condition.

The vaccine works well

A further criterion is that the vaccine must be effective. The vaccine consists of a single dose. The efficacy of the Ad26.COV2.S vaccine against COVID-19 has been determined in over 39,000 people, half of whom received the vaccine and half a placebo. From 28 days after vaccination, the vaccine's efficacy was found to be 66 per cent against disease (a positive PCR test combined with symptoms) and 85% against severe disease. It is not yet known how long the protection lasts or to what extent vaccination

can also prevent the spread of the virus. Research is also ongoing into the added benefit of a second dose of the vaccine.

The vaccine is sufficiently safe

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



Vaccination is acceptable:

the benefits outweigh the risks

The committee considers that the benefits of vaccination (health gains through protection against COVID-19) outweigh the disadvantages (side effects that are generally short-lived).

This also means that the criterion of acceptability has been met. The cost-effectiveness of vaccination cannot yet be assessed, as no data on this are currently available.

Advice: use of the vaccine

The committee recommends using the Ad26.COV2.S vaccine in public vaccination programmes targeting COVID-19, as the vaccine is effective, sufficiently safe and acceptable for adults, older people and medical risk groups. The committee also recommends provisionally using the Ad26.COV2.S vaccine for older people aged 60 and over and vaccinating from oldest to youngest, until everyone in this group has had the opportunity to be vaccinated. By vaccinating this group first, serious illness and death caused by COVID-19 will be prevented as much as possible.



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