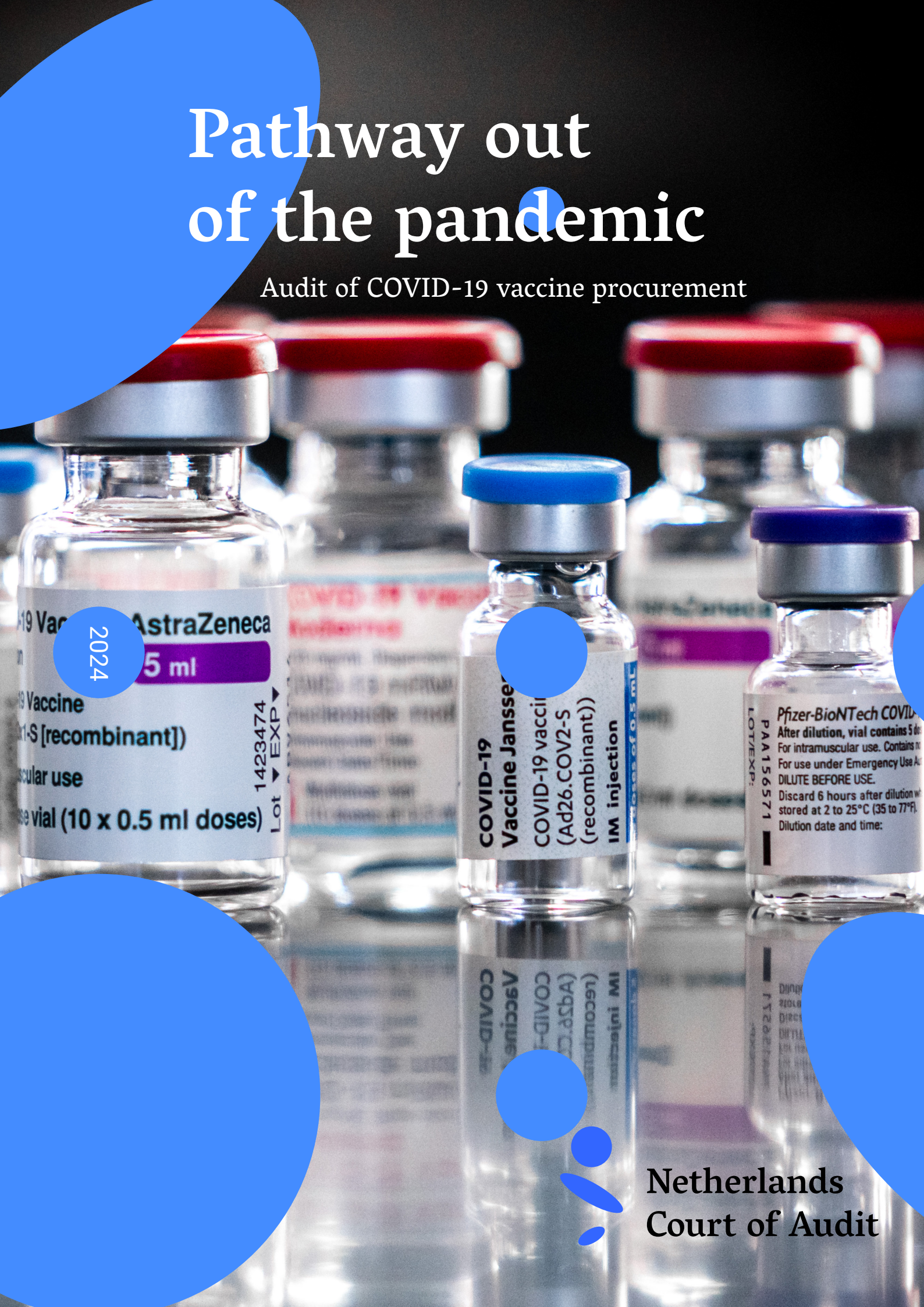
Pathway out of the pandemic

Audit of COVID-19 vaccine procurement



2024

Netherlands Court of Audit

Preface

The Netherlands Court of Audit has previously audited other aspects of the fight against the COVID-19 crisis. These investigations resulted in 3 studies and a monitor. The purpose of the monitor was to analyse the measures taken (Corona Account, Summer 2020 – December 2023). One of the 3 studies looked at the policy and capacity to test people for the coronavirus and at the public's access to tests (Corona testing – *What happened in the spring*, September 2020). A second study focused on the risks for public finances resulting from sureties and loans (*Corona crisis: the risks of sureties and loans to public finances*, November 2020). The third study examined the various measures provided to assist large businesses (*Support for large businesses*, June 2020).

Contents

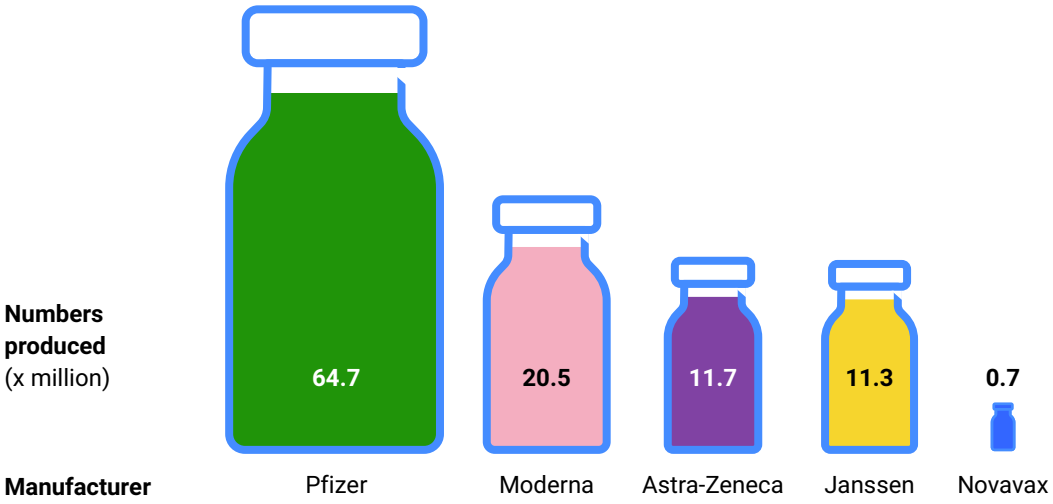
1. Summary

The objective of the Minister of Health, Welfare and Sport – acting for and on behalf of the Netherlands – was to obtain sufficient numbers of safe and effective vaccines against corona. We assess the approach adopted by the minister as reasonable to good. Although the minister was not prepared for the outbreak of a pandemic and the impact of COVID-19, he was nevertheless able to find a way to promote the development of vaccines and procure effective vaccines within a short space of time. These vaccines proved to represent the primary pathway out of the global pandemic.

In 2020 and 2021 the Netherlands purchased around 109 million vaccines, mainly from Pfizer, but also from Moderna, AstraZeneca, Janssen and Novavax. As not all these vaccines proved to be necessary, the number was reduced in 2023 to 102 million, for which just under €1.8 billion was paid (excluding funds spent by the European Union and the costs of administering vaccinations).

Highest numbers of vaccines bought by the Netherlands were from Pfizer

Breakdown by number and manufacturer



While the Ministry of Health, Welfare and Sport ('the ministry') called on external expertise for help in procuring vaccines, it retained responsibility for overall management, with the minister himself playing an important role in this respect. Although the decision-making process during the crisis differed from the normal procedures, we found no indications that this adversely impacted the decisions taken.

The Netherlands was receptive to opportunities to work with various other EU member states to accelerate the joint procurement of vaccines. It then went on to play a leading role in the European negotiations with pharmaceutical companies. The Netherlands made a strong case for the Janssen vaccine, both for epidemiological and economic reasons. Together with other countries, it also spoke out in favour of a diversified portfolio of vaccines so as to spread the risk of a vaccine proving to be ineffective and the risk of business failure. The Netherlands was an active member of the small group of countries conducting the procurement negotiations and acted as an intermediary to resolve EU member states' differences of opinion on strategy and budgets.

For reasons of solidarity and enlightened self-interest the Netherlands was one of the countries arguing in favour of providing support to vulnerable countries, while nevertheless continuing to prioritise protection of its own population. Rather than being provided through global organisations, this support was generally provided as an extension of the country's own procurement. The European Union proved unable to make appropriate provision for this support in the procurement contracts;

however, once surpluses started arising, the Netherlands donated 23 million vaccines that it no longer needed for its own population.

With regard to the ministry itself, its understanding of vaccine production and supply chains was and remained inadequate. Similarly, it was also insufficiently focused on the need to avoid conflicts of interest or the semblance of any such conflicts. A major disadvantage of the decision to make the manufacturers responsible for the entire vaccine supply chain (from development and manufacturing to supply) was that it left purchasing governments with very little control of the individual links in the chain. In practice, the problems in the vaccine supply chain proved difficult to resolve.

Ultimately, and with some assistance from the Netherlands, the European Commission was able to sign 11 vaccine contracts with 8 different companies. This audit analyses these individual contracts and specifically the extent to which they ensured that primary public interests were protected. Among other things, we concluded that the most effective provisions in place were those designed to ensure safety and to check that agreements were verifiable. We also saw improvements in later contracts as far as production and supply guarantees were concerned. At the same time, however, we noted that vaccine prices increased over time.

Recalling the primary objectives of the Netherlands and the EU (i.e. to obtain sufficient numbers of safe and effective vaccines as quickly as possible), our analysis found the contract with the vaccine manufacturer Novavax and the third contract with Pfizer to be the best in terms of meeting these objectives. However, the way in which the latter – extremely large – contract was established was insufficiently transparent.

Based on our audit, our recommendations to the Minister of Health, Welfare and Sport are as follows:

- Although the approach ultimately chosen in this case, and without any preparations, can be regarded as reasonable to good, it is important to devise a series of scenarios so as to ensure that, in future, the country is better prepared for the main types of major, cross-border health emergencies that could arise. This is because proper preparations will make the country less vulnerable to the specific circumstances of any particular moment. These circumstances are explicitly not limited to outbreaks of infectious diseases; they could also involve other emergencies with a potentially major impact on the healthcare system;

- Ensure greater in-house expertise so that the country is better prepared for a variety of types of crises with healthcare implications. This should at least include expertise on the pharmaceutical industry, and particularly the development, manufacturing and supply of medicines and vaccines;
- Carefully examine legal advice when entering into obligations under pressure and ensure that the expectations of all parties to agreements are realistic and clear. Lawyers (whether in-house or external) should be given reasonable time in which to form their opinions. On the other hand, lawyers also have to understand that the dynamics of a crisis may require them to work differently than in normal circumstances;
- Keep a closer eye on avoiding conflicts of interest or the semblance of any such conflicts, certainly in negotiations where major interests are at stake;
- Actively support international initiatives to facilitate worldwide access to vaccines, also outside times of crisis.

In a response the minister for Medical Care thanks the Netherlands Court of Audit for its thorough research, endorses its conclusions in general terms and expresses content with its overall positive assessment. The minister also writes it is important to follow the recommendations and mentions the following measures she has taken:

- The National Institute of Public Health and Environmental Protection is considering scenarios for dealing with possible outbreaks of infectious diseases in the future;
- Expertise will be concentrated within a new department of the ministry;
- When determining in-house activities, attention will be paid to legal advice when entering into major commitments under high time pressure;
- In negotiations when major interests are at stake a conflict check will be performed beforehand in order to avoid conflicts of interest or the semblance of any such conflicts;
- The Netherlands actively supports initiatives facilitating global access to vaccines.

In our afterword we reiterate the importance of also considering scenarios for other types of crisis that could put pressure on the healthcare system. In addition, we call on the minister to be transparent about the tension that exists between global access to vaccines and the procuring of vaccines to protect the country's own population.

Overview conclusions and recommendations

Conclusion	Recommendation	Commitment
Before the pandemic, the Netherlands was not sufficiently prepared for having to incentivise the development and procurement of effective vaccines. Under great pressure, however, it found a way of doing so.	Although the approach ultimately chosen in this case and without any preparations can be regarded as reasonable to good, it is important to devise a series of scenarios so as to ensure the country is better prepared in future for the main types of major, cross-border health emergencies that could arise. These circumstances are explicitly not limited to outbreaks of infectious diseases; they could also involve other emergencies with a potentially major impact on the healthcare system.	The National Institute of Public Health and Environmental Protection is considering scenarios for dealing with possible outbreaks of infectious diseases and pandemics in the future. Among other things, these scenarios will be incorporated into a National Crisis Plan for Infectious Diseases (LCP-I). The Ministry of Health, Welfare and Sport is also contributing to the national crisis plans being prepared by other ministries for dealing with emergencies that could potentially put considerable pressure on the healthcare system. These plans will be periodically tested in practice and assessed.
The ministry lacked in-depth knowledge of the exact workings of the process of developing and supplying vaccines, but was able to recruit expertise from elsewhere.	Take steps to ensure greater in-house expertise so that the country is better prepared for a variety of crises with healthcare implications in the future. This should at least include expertise on the pharmaceutical industry, and particularly the development, manufacturing and supply of medicines and vaccines.	This will take shape, for example, through the creation of a new department for Policy on Infectious Diseases in mid-2024. This department will be tasked with safeguarding the knowledge and experience gained during the COVID-19 pandemic and ensuring it remains available. Expertise on the pharmaceutical industry is additionally available through the day-to-day work of the National Institute of Public Health and Environmental Protection and the Pharmaceuticals and Medical Technology (GMT) department.

Conclusion	Recommendation	Commitment
The Netherlands quickly managed to obtain sufficient numbers of effective and safe vaccines to protect the population. However, decision-making in the contract negotiations was regularly less than optimally careful and contained inaccuracies, such as in the legal advice, where the in-house lawyers reported that they had too little time and scope to consider matters properly. However, this did not have any serious consequences.	Carefully scrutinise legal advice when entering into obligations under pressure, and make sure that all parties to agreements have clear and realistic expectations. Lawyers (in-house or external) should be given reasonable time in which to form their opinions. On the other hand, lawyers also need to understand that the dynamics of a crisis may require them to work differently than in normal circumstances.	When determining in-house activities, the minister is alert to the need for legal advice (and creating additional capacity for this) and for ensuring procurement regularity, including when entering into commitments under high time pressure. The minister thus envisages acting on the recommendation to clarify parties' expectations regarding legal advice.
The Ministry of Health, Welfare and Sport paid insufficient attention to avoiding conflicts of interest or the semblance of any such conflicts.	Keep a closer eye on the need to avoid conflicts of interest or the semblance of any such conflicts, certainly in negotiations where major interests are at stake.	Avoiding conflicts of interest or the semblance of any such conflicts is important, particularly in negotiations when major interests are at stake. In the future, therefore, a conflict check will be performed beforehand in order to ensure a clear mandate for any staff recruited to handle such crises.
The Netherlands was actively involved in Europe's collaborative efforts to develop and procure vaccines. Certain disadvantages arose from the EU's choice to make the pharmaceutical industry responsible for the entire chain.		

Conclusion	Recommendation	Commitment
The Netherlands was mindful of the need to help vulnerable countries, but had only limited success in this respect. The contracts signed by the European Commission did little if anything to remove the obstacles. Help was primarily provided by donations of vaccines that we did not need for ourselves.	Actively support international initiatives to facilitate worldwide access to vaccines, also outside crisis times.	The minister will support international initiatives facilitating worldwide access to vaccines, including outside times of crisis. One of the priorities of The Dutch government's Global Health Strategy 2023-2030 is to improve international pandemic preparedness; boosting access to medicines and vaccines, particularly in low and middle-income countries, is a part of this. That also goes for the WHO's global pandemic treaty to which the Netherlands contributes. In addition, the European Union has set up the Health Emergency Preparedness and Response Authority (HERA) to ensure (among other things) the availability of vaccines.

2. About this audit

The corona pandemic dominated headlines around the world for 2 years. Tens of thousands of people in the Netherlands lost their lives, while others became and sometimes still are seriously ill. Lockdowns, travel bans and other rules imposed by governments had an unprecedented impact on all our lives. As well as human suffering, the pandemic also caused major economic damage. Looking back we can conclude that safe and effective vaccines proved to be the most significant pathway out of the crisis. This audit examines how the Dutch and European governments contributed to developing, manufacturing and procuring those vaccines.

2.1 Why did we perform this audit?

This audit is not about whether vaccine procurement was efficient, given that the total costs of the pandemic, both worldwide and in the Netherlands, were so high that the costs of almost any effective investment would pale in comparison. The economic damage caused in the Netherlands alone is estimated at €65 billion (Franses, 2023). Nevertheless, the amounts spent on researching, manufacturing and procuring vaccines were not negligible, with the Dutch government spending close to €1.8 billion on vaccines in the years to 2023 and total government spending around the world estimated at €93 billion (Health Policy Watch, 2021). These amounts do not include investments made by pharmaceutical companies themselves. On top of that, European and other governments guaranteed their purchases, thus limiting the investment risks to which pharmaceutical companies were exposed.

What this audit investigates is how the Netherlands set about procuring vaccines, and specifically whether the central government did everything possible to ensure supplies of sufficient numbers of safe and effective vaccines to secure a pathway out of the pandemic, and whether sufficient account was taken of other public interests at stake. The audit examines the results achieved by European countries under direction of the European Commission and the actions of the Ministry of Health, Welfare and Sport operating on behalf of the Netherlands. The latter played an important role in negotiations with pharmaceutical companies on developing and procuring vaccines. Before this audit, we had little insight into this process and the Netherlands' role in it. The aim of this audit, therefore, was to improve this insight and to make recommendations for dealing with comparable crises in the future. The audit can also be used if the House of Representatives decides to conduct a wider-ranging parliamentary investigation of the corona policy.

2.2 What did we audit?

The audit focused on 3 main questions:

1. How did the Netherlands deal with the procurement of corona vaccines, and did its approach meet the requirements that can reasonably be set?
2. Are there any indications that the Netherlands exerted influence on the procurement of vaccines that were ultimately purchased through the European Commission?
3. To what extent did the procurement contracts signed take sufficient account of the public interests that could be expected to be protected?

2.3 How did we perform this audit?

To answer the first two questions we reconstructed the processes in the procurement of vaccines in 2020 and 2021 as closely as possible, based on many thousands of documents, e-mails and chat messages obtained from the Ministry of Health, Welfare and Sport (see the box on page 15). In addition we interviewed dozens of people involved in procuring vaccines for the Netherlands, as well as key individuals from the European Commission and other member states. Although we examined all vaccine procurement, our focus was on the contracts with 3 specific companies: AstraZeneca (because this was the first vaccine for which a contract was signed), Janssen (because this vaccine was partly a Dutch product) and Pfizer (because this was the vaccine the Netherlands ultimately bought the most of). Lastly we assessed this reconstruction against a set of norms agreed in advance with experts.

To assess the third question, about the procurement contracts agreed, we also used a set of norms drawn up in liaison with experts. These specified the public interests (e.g. supply certainty and intellectual property rights) we expect to be protected in contracts with pharmaceutical companies, and how this protection should be provided. We then analysed the contents of all 11 contracts and the extent to which each ensured protection of public interests.

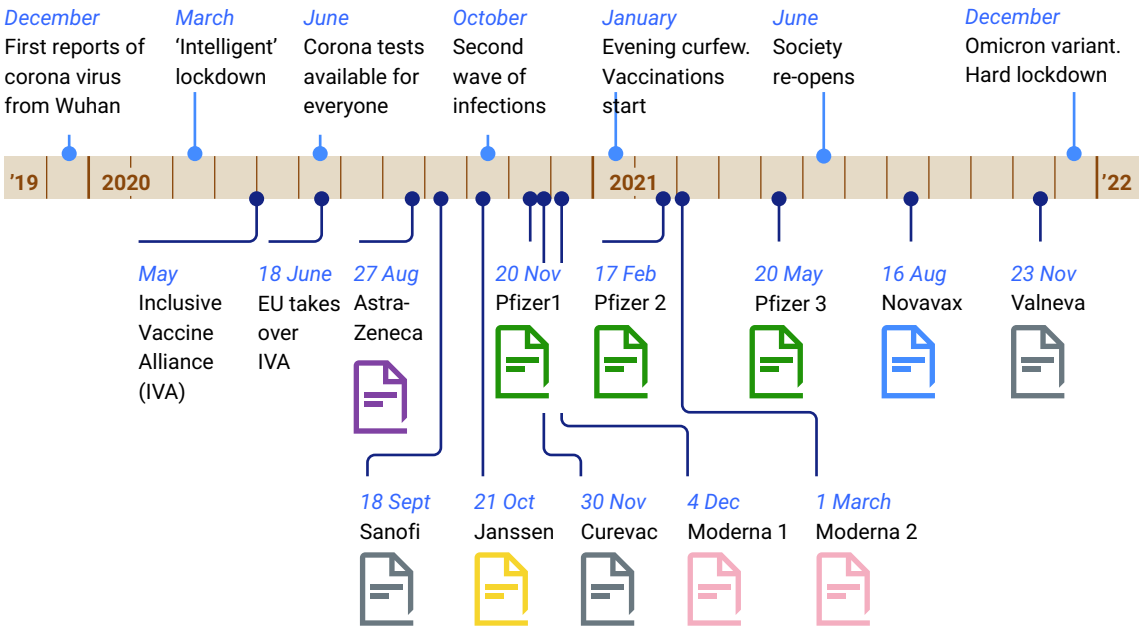
Our review took account of the crisis facing the Netherlands at the time, whereby we appreciate that decision-making in a crisis can be less structured than in normal circumstances and understand why not all relevant public interests were given equal attention. The primary objective of the Dutch government (and also the European Commission) was to secure sufficient numbers of safe and effective vaccines as quickly as possible in order to protect its own population. We also realise that, just like everyone else, civil servants and other officials involved in procuring vaccines were also personally affected by the consequences of corona and had to do their work under great pressure and in difficult circumstances.

We explain our approach to this audit in detail in Appendices 1 and 2.

2.4 Format of this report

The report is largely structured chronologically. We show how corona vaccines were procured in 6 phases during 2020 - 2021 (chapters 3-8) and explain how we assessed each phase. Each chapter starts with a timeline and ends by looking back at events and developments. Lastly, in chapter 9, we present our conclusions and recommendations.

Figure 1 *Chronology of the pandemic and the signing of vaccine contracts*[1]



Ministry of Health, Welfare and Sport's provision of information

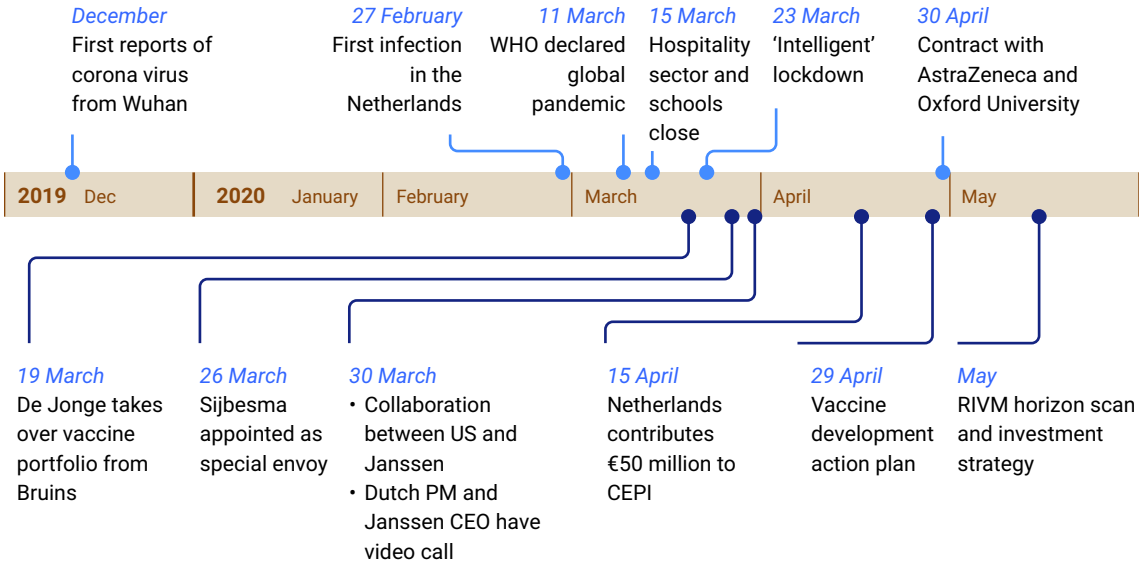
The audit was based largely on information available to the Ministry of Health, Welfare and Sport. For various reasons it was difficult for us to obtain the right documents. This was because the digital files of the managers responsible for the vaccine procurement programme proved to be far from complete. As a result, the ministry had to request the European Commission to provide copies of various contracts that had been signed. However, we also found very little information on the Netherlands' role in the negotiations and contracts. Our audit found meeting reports to be missing. These had to be requested separately, sometimes from the European Commission. It was not until late 2020 that the ministry started more systematically archiving decision-making, based on the main points at issue and in a file of 'decision memoranda' for the minister.

A considerable amount of relevant information was obtained from e-mails and WhatsApp messages between ministry civil servants rather than from official memos. Some of our findings are also based on handwritten notes by the chief negotiator. Together, these various sources combined to provide a good overview of communications between civil servants and the minister, between civil servants themselves and between other relevant parties both in the Netherlands and abroad. The ministry has retrospectively ensured that this

information has been safely archived with effect from early 2020. By using a search machine and relevant search terms we were able to obtain some tens of thousands of messages, which we then analysed using our own search machine.

Of concern to us is that the ministry invoked the General Data Protection Regulation and the Dutch Open Government Act [WOO] as justification for redacting various passages in reports, claiming that the redacted information was of a personal or confidential nature or redacted for party political reasons. However, the Government Accounts Act [Comptabiliteitswet] 2016, governing the powers of the Netherlands Court of Audit, is clear on the scope of these powers: the Court of Audit should be allowed access to all information it considers necessary for its audit. This unconditional access to all the information that is available to ministries is of fundamental importance if we are to perform our statutory tasks properly. We therefore formally objected to passages being redacted and were ultimately allowed to view them in unredacted form. Some of these passages proved indeed to contain information of relevance to our audit. The differing views on providing the Court of Audit with access to information considerably delayed completion of the audit.

3. Outbreak and how the Netherlands responded



The Netherlands did not have any plans in place for large-scale procurement of vaccines in the event of an outbreak of a rapidly spreading and potentially fatal infectious illness such as COVID-19. It was not until April 2020 that the Ministry of Health, Welfare and Sport started thinking more structurally about how to obtain safe and effective vaccines for the country. From then on, however, it acted rapidly and effectively. This included preparing an action plan and setting up a vaccine team of experts from within and outside the ministry. Although some support was provided for global initiatives, the Netherlands focused primarily on establishing an active role for itself in the market for developing and manufacturing vaccines.

3.1 How it all started

Following the first reports of an outbreak of a new corona virus in China in December 2019, the Netherland started appreciating the seriousness of the situation in late January 2020. This was when the World Health Organization (WHO) declared its highest form of alert and the first meeting of the Outbreak Management Team (OMT) was held in The Hague. At that time, little was yet known about the chances of being able to develop an effective vaccine against the new disease. However, the Ministry of Health, Welfare and Sport was familiar with various WHO-related initiatives, such as the Coalition on Epidemic Preparedness Innovations (CEPI). The CEPI had been set up after the Ebola outbreak in 2007 and started working on developing corona vaccines for the entire global population in early 2020. The Norwegian prime minister, Erna Stolberg, asked her Dutch counterpart and other government leaders for financial support for this initiative in a letter of 27 February 2020, the day on which the first corona patient in the Netherlands was diagnosed. It was only after long hesitation, however, that the government agreed in early April to make €10 million available for the CEPI and then, a week later, increased this to €50 million.

Worldwide access to vaccines was also discussed by the Dutch House of Representatives in spring 2020: the House was concerned that the pharmaceutical industry's power would cause poor and vulnerable countries to miss out on vaccines. A motion submitted in early April by Corinne Ellemeet, a Member of Parliament for GroenLinks, called on the government to show 'leadership' at the then forthcoming WHO annual meeting by arguing for a 'patent pool' for freely sharing knowledge, intellectual property and data on developing a vaccine. It was decided that the Netherlands should invest only in vaccines developed under 'acceptable conditions' (House of Representatives, 2020).

3.2 Ambitious action plan

Around this time, other developments were forcing the ministry to take action. The prime minister had had a video call with Paul Stoffels, CEO of vaccine manufacturer Janssen, on 30 March 2020 after they had met each other at an international conference in Munich in February that year. Stoffels was very optimistic about developing a vaccine and wanted to expand production capacity in the Netherlands. The prime minister, too, was enthusiastic and made it clear that nothing would be allowed to 'stand in the way' of these plans.

The Minister of Health, Welfare and Sport responded positively when he heard about this online meeting on 2 April 2020 (Hugo de Jonge had taken over the corona portfolio 2 weeks earlier from Bruno Bruins, the Minister for Medical Care and Sport, who had become ill). In response to a request by De Jonge for an update on vaccine developments, his ministry started preparing an inventory. The minister felt that matters were not progressing sufficiently quickly and, 4 days later, instructed his civil servants to accelerate their efforts because the Netherlands could otherwise miss the boat. The various specific questions he asked included 'Why are we not doing more?', 'Why are we not playing a more active role at CEPI?' and 'What is our strategy for "getting to the front of the vaccines queue"?'

We conclude that the Ministry of Health, Welfare and Sport did not have any plan ready for obtaining sufficient numbers of effective vaccines to deal with a potentially fatal pandemic. Admittedly the ministry had gained some experience of this when procuring vaccines for the 2009 outbreak of Mexican flu. However, and although we did not find any documents detailing any explicit decision-making confirming this, the seriousness of the corona crisis meant the lessons learned in 2009 seemed to be of little practical use this time around. Although the National Institute for Public Health and the Environment (RIVM) is normally responsible for procuring vaccines against infectious diseases, the Ministry of Health, Welfare and Sport itself took on responsibility in the case of COVID-19. We can conclude from internal e-mails exchanged that the ministry's Public Health Department was the 'lead player' for procuring vaccines under the overall responsibility of the Director-General (DG) for Public Health. In practice, it turned out that while the DG signed the contracts for procuring vaccines, the National Institute of Public Health and Environmental Protection took on responsibility for implementing the contracts and distributing the vaccines. Lastly, the Municipal Health Service (GGD) centres were responsible for injecting the vaccines.

While the minister continued to emphasise the need for speed, his civil servants gathered information. This resulted in an action plan being approved by the minister in late April 2020. This plan assigned 'top priority to developing and obtaining a safe and effective vaccine against COVID-19 as quickly as possible,' as the minister also reported to the House of Representatives (Ministry of Health, Welfare and Sport, 2020).

This ambition, combined with the aim to procure sufficient numbers of vaccines, remained the primary objective throughout the period covered by our audit, even though changing circumstances resulted, over time, in the minister also having to

focus on other aspects. These are discussed in more detail later on in this report. By this point, the Minister of Health, Welfare and Sport had committed €50 million to CEPI for vaccine development purposes. While he viewed this as sufficient at the time of the action plan being drawn up, he also wanted to encourage 'substantial investments' in vaccine-manufacturing capacity in or with a link to the Netherlands. The wishes communicated to the prime minister by the pharmaceutical company Janssen were referred to in an appendix to the action plan.

3.3 Tensions with global initiatives

The action plan did not focus any attention on an issue that had been recognised during the ministry's preparations: specifically, the potential tensions between the ministry's own ambitions to invest in vaccines, on the one hand, and providing support to initiatives designed to ensure access to vaccines for the world population, on the other hand. The director of the ministry's International Affairs Department (who was later the chief negotiator on behalf of the Netherlands) made it clear to the DG Public Health (who was responsible for vaccines) that while he did not have any objections in principle to allocating more funds to CEPI, this did not mean the Netherlands would be 'at the front of the queue', in contrast to what the minister had stated he wanted. As the director wrote, 'If we are really serious about ensuring access to vaccines, we need to make sure, for example, that we sign contracts with pharmaceutical companies working on promising vaccines.'

The ministry recognised that this could result in a conflict of interests. A policy officer described this dilemma as a choice between 'internationalisation' or 'NL first'. In other words, 'We either go all out for the patent pool or we facilitate Janssen as much as possible.' As well as in the Ellemeet motion referred to above, the Netherlands had by then also been requested by Costa Rica's president to participate in the worldwide 'Call for Action' patent pool. This request had been made to the Dutch prime minister and others, both by letter and telephone.

Our investigations found that, from spring 2020, the focus increasingly started shifting towards the Netherlands' role in procuring vaccines for itself and away from the patent pool. In-house documents, for example, contained references by senior civil servants to a smaller role for the Netherlands in the patent pool, while statements made on the subject were also less clearly in support of such a pool. On top of that, the government also made it clear in parliament that the patent pool would not be made compulsory for pharmaceutical companies (House of Representatives, 2020a). By that time, the Netherlands was also seeking to

collaborate with pharmaceutical companies, and a director called on the Minister for Medical Care to adopt an even lower profile in the 'Call for Action'. This was because the patent pool was focused on achieving 'as wide-ranging access as possible for everyone', while this ambition was 'conceivably not wholly aligned with' agreements with pharmaceutical companies. Other sources make it clear why the decision ultimately went against the patent pool: the chances of achieving international agreement on distributing vaccines were not seen as particularly high, while 'competitors' such as the United States and the United Kingdom were already active in the market to secure future vaccines for their own populations. On top of that, the ministry believed that the world would ultimately also benefit from Dutch investments in vaccines.

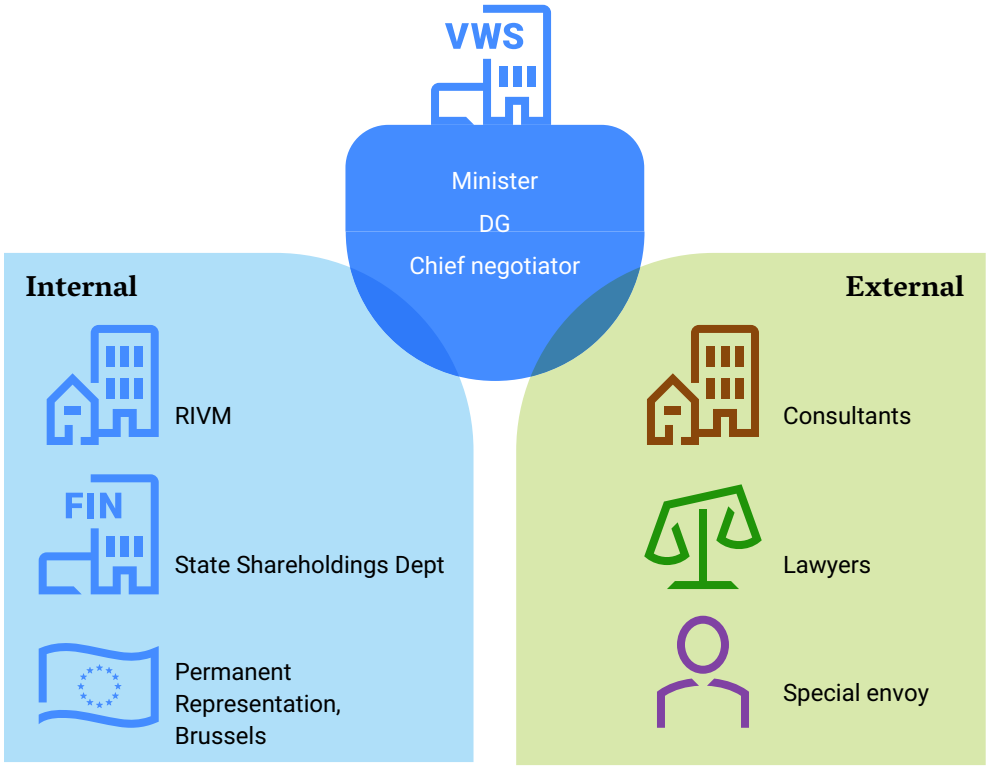
In the months that followed the Netherlands continued to draw attention, through the Ministry of Health, Welfare and Sport, to the question of helping vulnerable countries, often referred to as 'Low and Middle-Income Countries' (LMICs). However, the fact that priority was being given to the Dutch population became increasingly evident, including in communications by the minister in international contacts. As a senior civil servant put it in September 2020, 'It is true that we are also setting money aside for vaccines for developing countries, but we should be careful about suggesting that we are working to ensure equal access for everyone around the world, because that is simply not the case. We (the Netherlands) are our priority.'

3.4 Setting up a vaccine team

As well as preparing an action plan, the Ministry of Health, Welfare and Sport was also quick to set up an interdisciplinary vaccine team in April 2020. This team was tasked with promoting the development of and, where possible, procuring vaccines. Within a relatively short period of time the ministry managed to set up a core team of experts, combining the most relevant knowledge and expertise, and surrounded by various 'flexible layers'. A coordinator recruited staff from the ministry's Public Health and Pharmaceuticals and Medical Technology departments to join the team. As the Ministry of Health, Welfare and Sport did not have much experience of vaccine contracts, the team was expanded to include a representative from the Ministry of Finance's State Shareholdings Department.

Figure 2 *Overview of the parties involved in vaccine procurement*

Vaccine team recruited expertise from within and outside government



The Ministry of Health, Welfare and Sport was primarily reliant on the National Institute of Public Health and Environmental Protection (RIVM) for in-depth knowledge of vaccine development. Although the latter warned that the past few years had seen some of its expertise being phased out, 2 RIVM epidemiologists joined the vaccine team's meetings in spring 2020. Based on recent scientific publications and contacts with pharmaceutical companies, they prepared a 'horizon scan' of the most promising efforts to develop a successful vaccine. The ministry then used this scan to select the most important partners for its vaccine development discussions. The ministry later set up a scientific panel to advise it on vaccines. This panel included experts from outside the National Institute of Public Health and Environmental Protection.

For legal and business advice the ministry engaged a law firm and a firm of consultants, both of which already worked for the Ministry of Finance's State Shareholdings Department. In the subsequent months, these advisers were consistently quick to comment on the progress of negotiations, primarily with AstraZeneca and Janssen.

The DG of Public Health was responsible for managing the vaccine team in spring 2020, but when the negotiations with the pharmaceutical companies became increasingly specific in the summer of that year, the minister appointed a 'chief negotiator'. Although we did not find any documents providing a clear overview of decision-making at this early stage of the crisis, the minister clearly continued to have close personal involvement in the vaccine team's activities. A WhatsApp group at the ministry was active throughout the audited period, with the minister discussing recent developments with the vaccine team and other advisers, outlining policy and making decisions, sometimes on a daily basis. The need to work in this way was obviously driven by the crisis in which the Netherlands found itself at the time. Although the ministry's reporting was somewhat chaotic, working in this way nevertheless often enabled the ministry to respond flexibly to obstacles encountered along the way.

3.5 Role of the special envoy

The former DSM CEO Feike Sijbesma played a special role in vaccine procurement after the government appointed him on 26 March 2020 as its special envoy in the fight against corona. In a draft press release, the ministry originally referred to Sijbesma's role as focusing only on 'corona testing'. The latter, however, refused to accept this role and e-mailed to say that he would then rather 'do nothing'. Following discussions with the minister the department chose to phrase the envoy's responsibilities in broader terms, stating that he would focus on 'various aspects of the corona crisis', thus creating scope for him to become involved in procuring vaccines.

Our audit found that the envoy played an important role in the Dutch negotiations with pharmaceutical companies in spring and summer 2020 as he had something that the ministry's vaccine team did not have or had too little of: high-level contacts in the relevant vaccine developers' and manufacturers' market, as well as an understanding of the processes for manufacturing and supplying vaccines. This latter aspect remained a weak point in the vaccine team. The envoy started contacting the most promising parties in May 2020 to exchange information. In conjunction with a firm of consultants he also prepared a market analysis as the basis for the vaccine team's investment strategy.

Our audit found there to have been continuing confusion as to the exact mandate of the envoy. In effect he acted as a go-between between the government and the companies that the government was doing business with, but Sijbesma had to be

reminded by the ministry that it was the only party entitled to take decisions. We also noted that when preparing for the vaccine negotiations, the ministry paid too little attention to avoiding conflicts of interest or the semblance of any such conflicts, also in the case of the envoy. For example, a brother of the envoy held a senior position at AstraZeneca, a vaccine manufacturer with which Germany was already holding discussions in spring 2020. The ministry had not discussed potential conflicts of interest with Sijbesma before appointing him as the envoy.

That resulted in an embarrassing incident in late May 2020 when the envoy took part in a video call discussing international cooperation with various EU member states. Afterwards, the German DG asked the Ministry of Health, Welfare and Sport's representative whether the envoy was related to AstraZeneca's managing director with the same surname. It was only after this that the ministry and Sijbesma discussed the subject; the latter stated that he had had no contact with his brother on the subject of vaccines. They agreed that the envoy would avoid any involvement with AstraZeneca and would write a letter clarifying his role as envoy. For the sake of good order we emphasise that we found no indication that the envoy had favoured AstraZeneca in any way whatsoever. On the contrary, the considerations expressed by Sijbesma when selecting candidate vaccines were particularly critical of Germany's initial focus on AstraZeneca.

3.6 Frontrunners named in the investment strategy

In May 2020, the vaccine team translated the ambitions expressed in the action plan into a draft investment strategy. The 2 RIVM representatives refined their horizon scan and named the 7 vaccine 'frontrunners'. In view of its 'expected efficacy and availability', the National Institute of Public Health and Environmental Protection regarded the vaccine being developed by Oxford University (the manufacturer, AstraZeneca, was not yet prominently mentioned) as being 'the most promising vaccine' at that time. This was followed by the vaccines being developed by Janssen and the Chinese CanSino, both of which were based on the same tried and tested technology. Although new mRNA vaccines (Pfizer and Moderna) were reported as being able to be developed quickly, the RIVM representatives described the registration process for vaccines based on this technology as 'uncertain'.

Vaccine technologies

Based on a WHO overview, the RIVM stated that 110 vaccines against COVID-19 were being developed. It discussed those considered to be the most promising. These could essentially be divided into 3 categories, based on the underlying technology:

- Viral vector vaccines: a harmless virus is adapted to target COVID-19 (e.g. AstraZeneca, Janssen)
- Protein: a protein-based vaccine (e.g. Sanofi, Novavax)
- mRNA: a vaccine containing genetic code instructing cells to make the virus protein (e.g. Pfizer, Moderna)

The plan was for the special envoy to quickly initiate discussions with the suppliers of the most promising vaccines. The ministry expected vaccines to cost around €700 million annually, assuming contracts could be signed with around 5 manufacturers. Discussions with the Ministry of Finance made it clear that this amount was exceeded by the costs of the lockdown for society. After receiving personal approval from his counterpart at the Ministry of Finance, the minister presented an incidental supplementary budget to the House of Representatives in June. The arguments substantiating the amount requested in the budget were shared with the House of Representatives, along with other information, on a confidential basis.

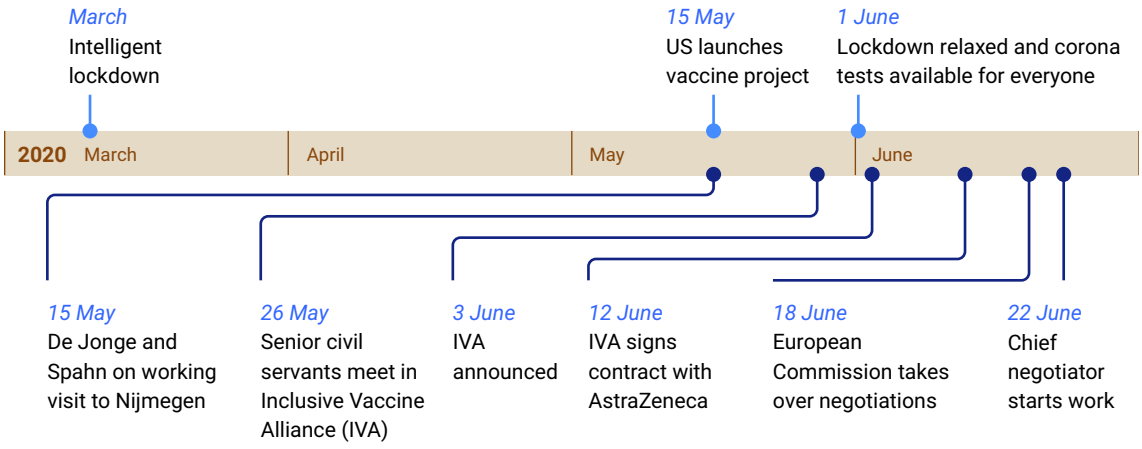
It is striking that the focus in both the action plan and the investment strategy being prepared was on how production of the vaccines was to be funded. To drive the development of vaccines, the Netherlands contributed to CEPI and looked more to similar initiatives. This focus was overtaken by reality in subsequent months. As a result, the contracts ultimately signed by the Netherlands in conjunction with other European countries were all package deals covering the whole chain from development to supply.

3.7 Looking back

The Netherlands had not been prepared for the need to procure vaccines on a large scale in response to the outbreak of a pandemic such as COVID-19. From April 2020 onwards, however, the Ministry of Health, Welfare and Sport was quick to prepare an action plan and set up a team, with the primary objective being to ensure the availability of sufficient numbers of safe and effective vaccines as quickly as possible.

While bringing in expertise and skills from outside its organisation to ensure proper oversight of the vaccine procurement process, the ministry itself remained in overall charge. The special envoy played an important role in this process as an expert in the field and also as the contact for the business sector. We found that too little attention was paid to avoiding conflicts of interest or the semblance of any such conflicts when the ministry was preparing for negotiations. We also found the vaccine team to have too little knowledge of the process of manufacturing and supplying vaccines. Lastly it should be noted that the early contacts with and wishes expressed by the 'Dutch' pharmaceutical company Janssen influenced both the action plan and the investment strategy.

4. Start of European cooperation



The Netherlands was one of the initiators of negotiations with various vaccine manufacturers considered promising. This was alongside Germany, France and Italy. These 4 countries accelerated the process in which the European Commission ultimately oversaw the procurement of vaccines for the entire European Union. By assuring itself of a prominent position in these negotiations, the Netherlands also enabled the Ministry of Health, Welfare and Sport to achieve the objectives that it had set for itself.

4.1 Germany pushes for acceleration

Under the Commission's leadership, the European Union sought to find a way in spring 2020 to obtain vaccines to protect the member states' populations. This was no easy task: nothing like this had ever been done before and the Commission had no authorisation for joint procurement of medical products. In April 2020, the EU set up an emergency fund so that money could quickly be made available for

investments in vaccines. However, the 27 member states were slow to take decisions on structuring their vaccine procurement at a time when the United States and the United Kingdom in particular were both already active in the market.

The decision-making went too slowly for Germany. When the Dutch minister, Hugo de Jonge, met his German counterpart, Jens Spahn, on Friday, 15 May 2020 during a joint working visit to the Radboud University in Nijmegen, he was urged by Spahn to join Germany, France and Italy in signing contracts with vaccine developers. These 4 countries all had vaccine-manufacturing facilities of their own.

The Dutch minister welcomed Spahn's request and soon afterwards, on Monday, 18 May 2020, he and his most senior civil servants decided to 'explore' opportunities for cooperation and to include this in the investment strategy that the ministry was working on. Although the Netherlands believed that a vaccine-manufacturing country such as Sweden should also be invited to join the group, the other countries were not in favour of this. Top civil servants from the 4 countries held a video conference on 26 May 2020. In the invitation to attend the conference the German director-general referred to AstraZeneca as the 'prime candidate' because, at that point, Germany was already in discussions with the company on supplying 300 million vaccine doses to the EU.

At that time, Dutch experts, too, viewed the AstraZeneca vaccine (developed by Oxford University) as the most promising. However, the Ministry of Health, Welfare and Sport wanted a more diversified portfolio of candidate vaccines, as also argued for by the envoy. This strategy was seen as increasing the chances of obtaining a successful vaccine, as well as spreading the risks. In an internal e-mail the minister summarised what he wanted to 'end up with': several deals, a focus on manufacturing, an opportunity for the European Union to become involved and a 'fair share' for Africa. The extent to which these objectives were agreed with the rest of the government is unclear to us, although the final two points aligned with the Ministry of Foreign Affairs' views. Only a few weeks earlier and partly in response to an urgent request for advice from the Advisory Council on International Affairs, the Minister of Health, Welfare and Sport had given an undertaking to Sigrid Kaag, Minister for Foreign Trade and Development Cooperation, to provide help to vulnerable countries in Africa. This decision was also prompted by the above-mentioned Ellemeet motion.

4.2 Setting up the Inclusive Vaccine Alliance

The subsequent discussions between Germany, France, Italy and the Netherlands focused on setting up the Inclusive Vaccine Alliance (IVA). Our audit was unable to establish the exact influence that the Netherlands had on events as we do not know what would have happened if the country had not been involved. The documents we saw indicate, however, that the Netherlands played a highly active role in this alliance and that quite some of the country's wishes were met. These included the 4 countries' decision to aim to agree several deals. While the Netherlands was in favour of Janssen, France was for Sanofi and Germany proposed a deal with both Moderna and AstraZeneca. It was agreed that the IVA countries themselves would take the lead in negotiations on their 'preferred' vaccine. The efforts undertaken by the Netherlands are likely, therefore, to have had an impact on the results.

The Netherlands was keen to keep some control over the process without losing momentum. In the ministry's view, it was very important for the pharmaceutical companies' clinical data to be assessed before any contracts were signed. The Netherlands was also the author of the first draft of a Memorandum of Understanding (MoU) between the 4 countries. Comments on this were added by France, which was very much in favour of inviting the European Union to join the initiative. So, too, was the Netherlands. The Netherlands, in turn, was keen to include a passage on help for vulnerable countries, particularly in Africa. When words to this effect turned out to have been deleted from a later version of the MoU, the minister intervened personally and messaged his German counterpart that what was needed was 'a small but important reference to me, also because of an ongoing debate with my parliament.' This intervention proved successful, with the minister informing his ministry that 'We're a small country and paying 25% of the costs. And we're doing it specifically so that we don't lose out in these sorts of discussions.'

On 3 June 2020 the Netherlands, France, Germany and Italy announced to the world that they had set up the IVA. This triggered quite some reactions, including both praise and criticism from elsewhere in Europe. Some member states were indignant about these 4 countries taking action outside the EU's normal consultative structures, while others asked whether they could join the IVA. Outside Europe, too, parties actively in the market for vaccines expressed interest. These included the United States embassy, which immediately contacted the ministry for more information.

Netherlands' approach to negotiations

The Netherlands' negotiating objectives were not set in stone. In other words, there was no core document to which the Ministry of Health, Welfare and Sport consistently referred back to over the 2-year period. Our audit was able, however, to reconstruct what the Netherlands was generally seeking to achieve. This was despite some shifts in focus over time in response to changing circumstances. The Netherlands sought to achieve:

- sufficient numbers of effective and safe vaccines as quickly as possible;
- deals for several types of vaccines because it was not yet known which vaccines would work;
- monitoring by vaccinologists and epidemiologists;
- use of manufacturing facilities in the Netherlands, wherever possible;
- prioritisation of protection of the country's own population;
- access to vaccines for vulnerable countries, particularly in Africa.

We note in this respect that, in practice, seeking to obtain 'sufficient numbers of vaccines' generally meant seeking to obtain 'as many as possible'. However, there was no reliable estimate of the numbers actually needed. The size of the population to be protected was known, but not the number of doses that would be needed for this purpose.

4.3 Negotiations in the IVA

Once the IVA had been set up, the Netherlands was primarily involved in negotiating with AstraZeneca and Janssen. The Ministry of Health, Welfare and Sport took the lead in discussions with the latter, building on the contacts that it already had with the company. We conclude from the documentation that most of the negotiations with Janssen were via the envoy, Feike Sijbesma, even though he wrote that the company also phoned the minister and the prime minister directly during this period. While the latter possibility cannot be ruled out, our audit did not find any concrete information to this effect.

On 1 June 2020, the envoy sent a proposal by Janssen to the minister and his department. This was then forwarded to the IVA partners. According to the envoy, the European Commission was also sent a copy of the proposal. The most salient points in the proposal were that Janssen primarily wanted to fund the development of the vaccine itself and would be assisted in this respect by a deal previously reached with the United States. However, Janssen was keen for the IVA or EU to build

various production facilities ('bio fermentors'), where vaccines could start being manufactured from early 2021 onwards. According to the envoy, Janssen would then be able to supply reasonably priced vaccines to protect 600 million people: 'Let's say' 400 million for EU citizens and 200 million for Africa. The deal with the United States did mean, however, that the very first vaccines would go there, even if they had been manufactured in Leiden. In responding, the ministry's advisers also warned that Janssen was requesting some unusual changes in the rules on liability (see § 5.4).

At the time of the IVA being set up, Germany had already received a proposal from AstraZeneca to supply 300 million vaccines. The other IVA countries all commented on this proposal, but, once again, the German minister thought things were still going too slowly. On 5 June he messaged his Dutch counterpart that the manufacturer was not willing to concede on issues such as pricing and intellectual property because these were reported to be in line with AstraZeneca's agreements with CEPI. Spahn said that he understood that and proceeded to increase the pressure on the IVA countries: 'So we need to decide very soon if we do it together or not. If you hesitate – frankly spoken – I'll do it alone.'

It is not easy to establish the extent to which the substantive negotiations were influenced by this threat on the part of Germany. What is clear, however, is that the substantive discussions with AstraZeneca, which were led by France, continued over the next few days, with a range of topics being discussed. During this period, the 4 ministers spoke to each other, but also had individual discussions with the manufacturer. The Netherlands' discussion points related to issues such as the liability clause proposed by the company and which the Netherlands viewed as 'very undesirable', given that the IVA countries would be liable for loss or damage if the vaccines were to be used elsewhere in the EU. There were also obstacles to be overcome with regard to intellectual property and the management of clinical data. By the time of the 4 ministers' next video call on 10 June 2020, it was clear to the Netherlands that compromises would be needed if vulnerable countries were to be helped. Although provision for the 'fair share' principle could not be made in this individual contract, it would have to be made visible 'over various deals'. In other words, the need to help vulnerable countries in Africa, for example, would have to be covered somewhere in the IVA's overall arrangements. Two days later, on 12 June 2020, the IVA countries signed an agreement with AstraZeneca for 300 million vaccine doses.

4.4 Under the European Commission's direction

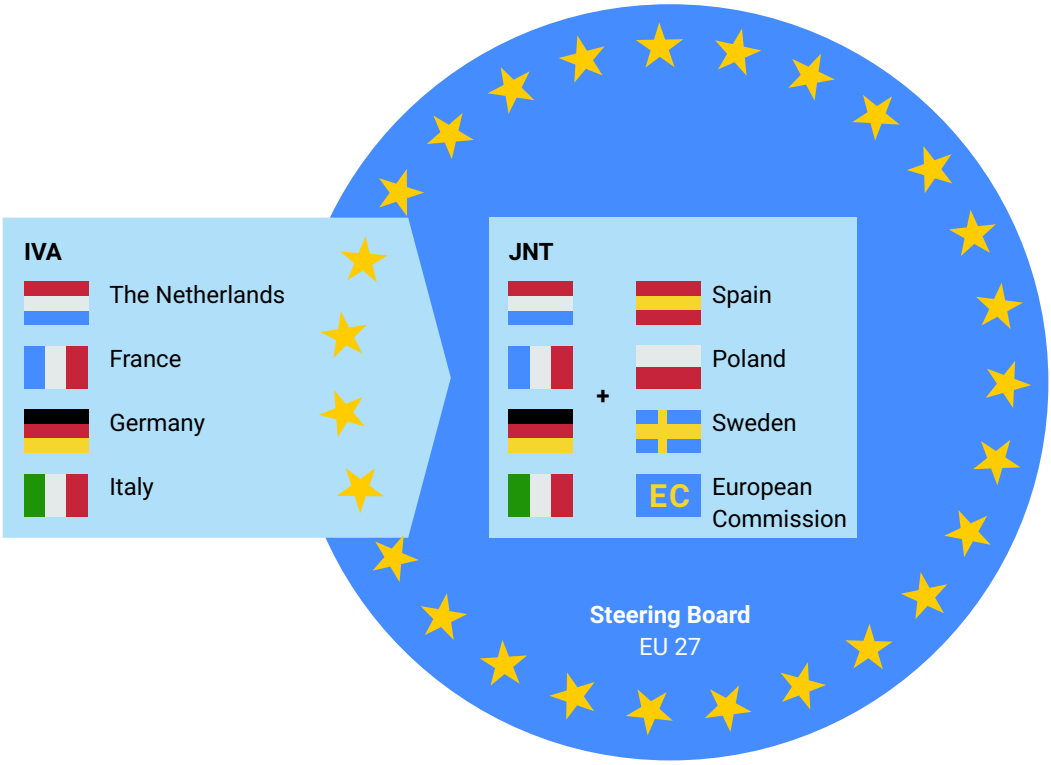
Right up until the morning on which the agreement with AstraZeneca was signed, the 4 IVA countries continued to hope that the European Commission would join them. That, however, did not happen because the Commission stated that it could not simply sign 'on the dotted line'. As well as the Commission not having been involved in the negotiations, there were also constitutional obstacles preventing it from signing. As soon as it was set up, the IVA had started discussing the possibility of cooperating with the Commission, while the Commission had referred to the possibility of using the €2 billion emergency fund to pre-finance future deals with pharmaceutical companies. As this was an attractive prospect for the IVA countries, they discussed among themselves how best to involve the Commission. The Dutch minister made it clear to the alliance that he wanted to offer the Commission a fifth seat in the IVA, but also wanted to agree a deal with Janssen so as to remain in the 'driving seat'. While he was ultimately willing to allow the Commission to take charge, he believed the IVA needed to maintain speed for the time being and in this way exert pressure on the Commission. The minister was also keen to create a strong position for the Netherlands in the 'front row of the negotiations'.

Meanwhile the Commission was working on a regulation to enable joint investments in vaccines. Under that regulation, all 27 member states would have a seat on a Steering Board (SB), but certain countries would take the lead, along with the Commission, as members of a Joint Negotiation Team (JNT).

The Commission wanted to leave decisions on the JNT's composition up to the SB, but this was not acceptable to the IVA countries. The Dutch minister phoned the responsible European Commissioner at least twice to secure a role for the Netherlands in the JNT. At an official level, too, the ministry warned about a 'political problem'. Ultimately it was decided that all 4 IVA countries should be members of the JNT, along with Sweden, Spain and Poland. The wording used by the minister in his letter to the House of Representatives, to the effect that the Netherlands had been 'asked' to join the JNT, was at the very least somewhat less than transparent (Ministry of Health, Welfare and Sport, 2020a). Indeed, the Netherlands' appointment as a JNT member was preceeded by a great deal of 'power play'.

Figure 3 *Member states participating in IVA and JNT*

IVA countries absorbed into JNT negotiating on behalf of the 27 member states



The Netherlands did not get its way on all the disputed issues. It was ultimately agreed that the JNT would 'not have the final word' in the negotiations, but 'at best influence'. However, members of the JNT, as the evaluation committee, would be responsible for overseeing the procedure for signing future contracts. The Commission would be in charge and would set out the procedures for joint procurement and how this was to be governed in an agreement with all the member states individually on 18 June 2020. This agreement allowed the Commission to sign Advanced Purchase Agreements (APAs) with pharmaceutical companies on behalf of the member states, but left it up to the member states to decide whether they ultimately wanted to procure vaccines under these APAs. In turn, the member states undertook not to conduct any individual negotiations on vaccines (European Commission, 2020a).

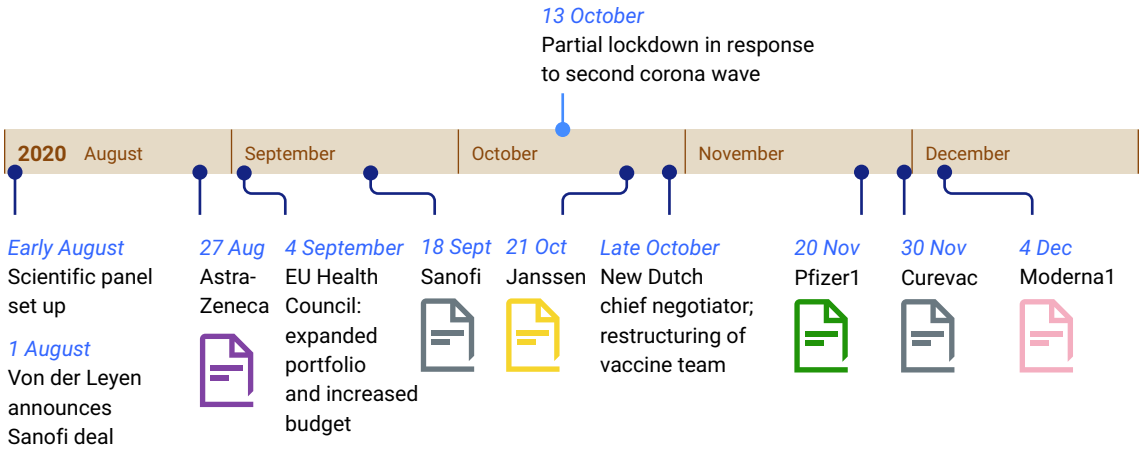
4.5 Looking back

Looking back, and based on what happened, we conclude that it is very plausible that the IVA – whatever the different views on it may be – acted as a catalyst for accelerating the establishing of a joint European procurement programme. This was also confirmed in our interviews with relevant individuals from non-IVA countries and

the European Commission. In other words, the Netherlands' international interventions were effective in helping to accelerate vaccine procurement, while also taking account of vulnerable countries' interests.

By collaborating through the IVA the Netherlands was able to find allies within Europe for achieving its own objectives. As well as working together to accelerate the process, these member states sought to procure a diversified range of vaccines so as to increase the chances of success and reduce the risks of failure. By 'fighting' to secure membership of the JNT the Netherlands ensured it was well placed to influence the subsequent European negotiations.

5. First vaccine contracts



The negotiations initiated by the European Commission and JNT countries (including the Netherlands) with the manufacturers developing promising vaccines started in summer 2020 and resulted in agreements with companies such as AstraZeneca, Janssen and Pfizer. The Netherlands was involved in these negotiations in various ways, including focusing on a diversified package of vaccines, promoting Janssen and acting as a mediator to resolve conflicts.

5.1 Approach in the European negotiations

The transition from the IVA to joint procurement under the direction of the European Commission did not result in any change in the most important objectives. In the new constellation, too, all efforts focused on seeking to make a safe and effective vaccine quickly available to the member states' populations (European Commission, 2020). We mentioned in chapter 4 that the Netherlands was on the Steering Board

and also a member of the JNT from late June 2020 onwards. In the subsequent months, the Steering Board held weekly and the JNT almost daily online meetings.

For each candidate vaccine, 2 countries and the Commission initially took the lead. In the case of Janssen, the leading roles were assigned to the Netherlands and Spain. The Netherlands was also involved in discussions with Valneva and MSD Merck (on a vaccine that never came to market). Although 2 countries always took the lead, all the JNT countries could keep a close eye on the negotiations. However, this division into pairs became more diluted during 2020.

Procedure during negotiations

European procurement of vaccines was intended to be based on preliminary negotiations with manufacturers and for these to result in 'term sheets' setting out the main agreements on vaccine prices and numbers, as well as on production and liability. Details of these oral agreements would then be worked out in an official tender procedure, ultimately resulting in an Advanced Purchase Agreement (APA) being signed by the Commission and the vaccine manufacturer. The APA would be an 'advanced' agreement because the Commission would make an advance payment from the ESI emergency fund to purchase a vaccine that had not yet been approved. In this way, Europe would facilitate the further development and production of that vaccine, while prices and quantities would also be assured upon approval of the vaccine. The government authorities took a risk in this respect because if the vaccine failed to come to market, they would lose their money. Ultimately the member states themselves would pay for the vaccines they purchased, less the amounts advanced from the European emergency fund.

The impression from the documents we examined is that the JNT was primarily involved in the preliminary negotiations of the term sheets and played a less prominent role in drawing up the contracts; it was then that the Commission's lawyers took over. Those involved both in the Netherlands and elsewhere paint a more nuanced picture, emphasising that the JNT countries continued to monitor the interim results of the negotiations. We cannot verify this, however, as no reports were prepared.

5.2 How the Netherlands decided to proceed

Until the start of the JNT, most of the discussions on behalf of the Netherlands were conducted by the ministry's DG Public Health. However, once the European JNT

cooperation began, the minister appointed a new chief negotiator at director level to focus solely on vaccine procurement. This chief negotiator – a competition lawyer who was very familiar with relationships in Europe because of having previously worked at the Permanent Representation in Brussels – was the link between the minister and the negotiating partners. He also led the vaccine team, which provided him with substantive support. The external advisers could be called on to comment on aspects in the term sheets that the Netherlands was negotiating with the pharmaceutical companies. Throughout this period the Minister of Health, Welfare and Sport continued to be closely personally involved on the operational side.

From August 2020, a scientific panel of 6 members (including the 2 people from the National Institute of Public Health and Environmental Protection who were already involved) played an important role in advising on epidemiological issues and vaccines. The agreement with the EU also made provision for this at a European level. Although the ministry pushed for an international panel to assess candidate vaccines, no such panel was ever set up. However, the Dutch experts regularly liaised with their European colleagues.

We note that it was sometimes difficult for member states in the JNT and SB to reach agreement on the way forward. For financial reasons, the poorer Central European countries were not always willing to join in with procurement plans. Meanwhile Germany and France frequently clashed in the JNT, with the Netherlands regularly being called on to mediate.

5.3 AstraZeneca contract

The first task for the new European partnership was to convert the IVA's agreement with AstraZeneca into a contract with the Commission, acting on behalf of all the member states, as the contract partner. In terms of contents, this was no great problem as the conditions could more or less be taken over from the earlier agreement. From a legal perspective, however, it was a different matter. The Commission had to spend considerable time making changes because it stated that it was acting in a different 'legal framework' from that of the member states. Within the JNT the Netherlands regularly expressed impatience about the slow speed of progress, partly because the IVA countries had entered into payment obligations in their own agreement. Meanwhile, the minister tried to reassure AstraZeneca's CEO by text, stating 'Thank you for your leadership and for your patience.'

A preliminary agreement was signed at the end of July. Two weeks later, on 14 August 2020, this was converted into an initial contract for 300 million vaccine doses via the tender procedure. It should be noted that the AstraZeneca vaccine was relatively cheap compared with the vaccines in later contracts (see Appendix 2, Table 1) and that the manufacturer offered it to EU countries at cost. From a perspective of public interests, this contract was also slightly better in terms of ensuring vulnerable countries' access to vaccines. When negotiating the contracts, the pharmaceutical companies made few concessions to European countries' wish to make vaccines more accessible to vulnerable countries outside Europe, and this later made it more difficult to donate vaccines that had been purchased. The manufacturers were determined, for example, to retain intellectual property rights to their vaccines. The only party to display any degree of flexibility in this respect was AstraZeneca, probably because of the conditions that the developer, Oxford University, had imposed on the manufacturer.

However, the contract with AstraZeneca cannot be regarded as entirely positive, given that it scored less well in terms of guaranteed production and supplies of vaccines. As discussed in the next chapter, it was precisely in the areas of production and supply that AstraZeneca subsequently experienced major problems. Whether these problems were caused by provisions in the contract, however, is open to question as it is certainly not inconceivable that AstraZeneca would also have encountered problems in the event of a 'better' contract. We found no indications that those advising the ministry or other countries warned about any contractual provisions on production and supply, although the chief Dutch negotiator did describe the atmosphere between the parties as 'extremely bad'. This was mainly because, in the period leading up to the final contract, AstraZeneca sought to extend its protection against the financial consequences of liability beyond what had been agreed in the preliminary agreement.

This difference was noted by the Dutch lawyer, who concluded that the agreements had 'perhaps' become slightly less favourable because the Netherlands was now liable in the event of vaccine donations to other countries. However, this analysis was intended more for future negotiations and could no longer be taken into account in the Netherlands' decision on whether to proceed with AstraZeneca. By then the minister had already given approval, based on a decision memorandum drawn up by the chief negotiator and advising that all the vaccine doses available from the manufacturer should be purchased.

Opportunity not to proceed with a contract

The European Commission signed the contracts with vaccine manufacturers on behalf of the member states. In principle, the vaccines were then distributed pro rata, depending on the member states' population. However, each member state had the opportunity to opt out in the 5 days immediately after the contract was signed (**'opt-out phase'**). Vaccines for countries using this opt-out could then be redistributed among the other member states. The Swedish negotiator in the JNT devised a 'vaccine bazaar' with the help of the Netherlands. Member states could then sign up for left-over vaccines via this bazaar.

During the opt-out phase the minister had to decide, on each occasion, whether to proceed with the envisaged procurement. The Dutch strategy was initially always to take part unless the scientific panel advised the minister to the contrary or the legal risks were considered to be too high. On no occasion was any negative advice received.

5.4 Janssen contract

The Netherlands was most closely involved in the Janssen vaccine and had been talking to the company about this since spring 2020. It therefore continued these discussions, but now on behalf of the EU. The envoy, too, remained very involved, while lawyers exchanged texts, the National Institute of Public Health and Environmental Protection discussed the clinical data and the vaccine continued to be regarded as promising because of being based on proven technology. The ministry clearly also viewed the possibility of mass production in the Netherlands as an attractive prospect, despite fears that the initial supplies would be sent to the United States. We note that the ministry promoted the Janssen vaccine within the European partnership, just like other countries in the JNT promoted 'their' vaccines.

Two potential stumbling blocks were encountered in summer 2020: the numbers of vaccine doses to be ordered and the question of product liability. Both these potential obstacles demonstrate how the ministry had to juggle many different issues at the same time during the dynamic negotiations in 2020: in the case of product liability, discussions were with the manufacturer, while its counterparties for discussions on the numbers of vaccine doses were the other member states and the Commission.

Just like in the IVA, the Netherlands put Janssen's offer to supply 400 million doses on the European partnership's agenda, as well as the offer to donate a further 200 million doses to vulnerable countries in Africa. No reference to this surplus was made at the second SB meeting, probably because the Commission thought that the ESI fund for pre-financing these deals could only be used for EU member states. In other words, the Netherlands and Europe would have to find other ways of helping vulnerable countries (see also chapter 8).

However, the 400 million vaccine doses for Europe, too, met with opposition from within the JNT, with fears that purchasing these numbers of doses would quickly exhaust the budget. In addition, Germany argued for a balanced spread of technologies in the overall vaccine package. This would mean sourcing no more than 200 to 300 million doses from Janssen, which used the same technology as AstraZeneca. The Dutch envoy was indignant for two reasons: Janssen needed to be sure of sufficient sales if it was to invest in new factories in Europe, and the EU was allowing itself to miss out on this opportunity to show leadership in helping Africa.

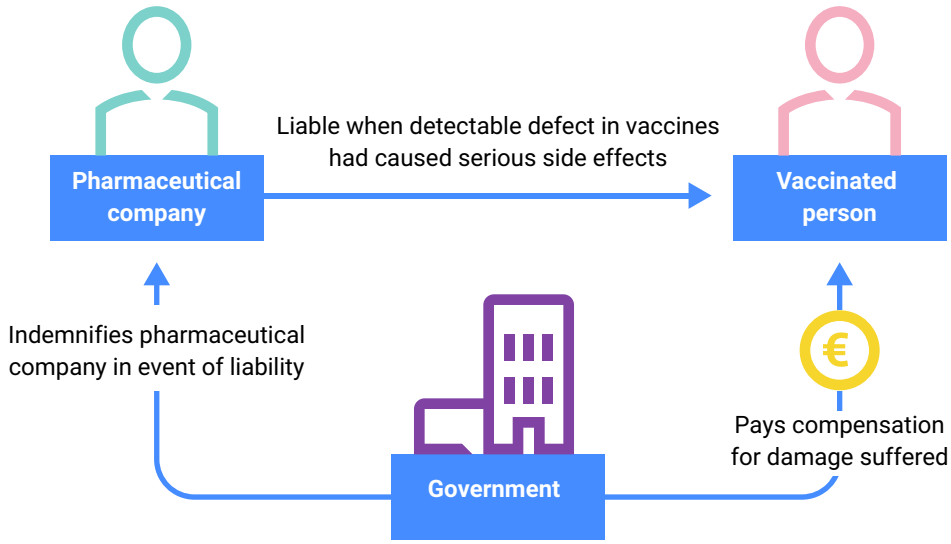
Janssen's later offer to split this into a basic package of 200 million doses and an optional package of a further 200 million did nothing to reduce the opposition, given that the manufacturer demanded a fee for this option. The Netherlands was willing to pay part of this fee and asked its former IVA allies to agree to contribute. It also promised to pay a fee, if necessary, for options on other vaccines. The Minister of Health, Welfare and Sport had a role in these diplomatic activities, too, because he personally contacted other ministers on the subject. Germany ultimately agreed to contribute to the fee. The minister viewed these options as a way for Europe to buy time for itself and be able to determine at a later date how many vaccines it actually needed.

Later that summer, negotiations with Janssen focused on who would be liable for loss or damage if the vaccine were found to have serious side effects. Janssen – which has a US shareholder, Johnson & Johnson – wanted the EU to amend its Product Liability Directive, such that Janssen would be almost entirely immune from liability. This would have been in line with the undertaking that it had been given by the United States. But while the Netherlands and other JNT members were prepared to consider potential compromises, the European Commission rejected the possibility of any form of compromise. Similarly it ruled out a possible compromise in the form of a European fund to deal with claims for damages. For a while, therefore, the negotiations were deadlocked. After consulting his Dutch counterpart, the German minister called Janssen's US CEO to discuss a way forward. Finally, on

the very day that the Commission signed a term sheet with AstraZeneca, Janssen agreed to drop its requirements regarding liability. Two weeks later, on 13 August 2020, Janssen, too, signed a preliminary agreement with the Commission. In this agreement, the company agreed to remain liable, while the government authorities agreed to indemnify it against financial consequences, unless the manufacturer had intentionally made errors or breached the rules on good manufacturing practices or the European Medicines Agency (EMA) rules.

Figure 4 *Indemnifying against the financial consequences of liability*

Subject to certain conditions, governments will bear the financial consequences of serious side effects if the manufacturer is held liable



Although there are no reports detailing his exact activities, the Dutch chief negotiator was closely involved in the subsequent formal negotiations between Janssen and the European lawyers. This included in any event helping with drafts and discussing them in the JNT. On several occasions, the chief negotiator also asked the Dutch lawyer to take a look at documentation, without evidence of this being recorded in any reports. We did, however, see a written request of 5 October 2020 asking the lawyer to assess a document that was 'almost final' so as to see whether there were any 'reasonable grounds' for not signing the contract. Two days later, the lawyer confirmed that no 'red flags' had been seen, although she commented that the contract was primarily a 'series of undertakings [by Janssen] to perform to the best of its ability' rather than commitments to achieve a specific result. Similarly, the corporate adviser had no major objections.

We would point out that these written opinions issued by the lawyer and corporate adviser could no longer play any formal role in the decision memorandum that the negotiator sent to the minister on 6 October 2020. In this memorandum he advised the minister to proceed with the Janssen contract, primarily because the National Institute of Public Health and Environmental Protection had issued a positive opinion on the effectiveness, safety and opportunities for manufacturing the Janssen vaccine. The minister notified the House of Representatives on 8 October 2020 that he would purchase the Janssen vaccine (Ministry of Health, Welfare and Sport, 2020b). Shortly afterwards it was rumoured that Italy, a former IVA ally, was not planning to procure this vaccine. The minister responded by messaging his Italian counterpart and asking for clarification, given that the Netherlands was very keen for all the major countries to participate in this procurement. 'We are in' was the reassuring message received from the Italian minister. Three days after the contract was signed, the special envoy reported that his work was complete.

In terms of the extent to which the contracts protected public interests, we regard the contract with Janssen as a mid-ranker (see Appendix 2, Table 1). It is striking that this contract scored low on indicators relating to the provision of help to vulnerable countries, despite the efforts that had been undertaken in this respect by the Netherlands. However, this was also the case in most of the other contracts.

5.5 Pfizer contract

Most of the JNT members also viewed the vaccine being developed by Pfizer as an attractive prospect. Like the Netherlands, these countries, too, were aiming for a diversified portfolio of vaccines. While its innovative mRNA technology meant the Pfizer vaccine would fit this description, doubts existed as to whether it would obtain regulatory approval. The ministry's interest in this vaccine was such that it was also considering 'the conditions for an exclusive deal between Pfizer and the Netherlands' in parallel to the European discussions. While the ministry regarded these discussions 'without commitment' as a way of keeping all options open, they were nevertheless at odds with the agreement that the EU member states had signed just over a week earlier with the Commission and in which they undertook not to conduct any separate negotiations. When Pfizer asked for a non-disclosure statement to be signed, the ministry no longer regarded the discussions as being without commitment and referred Pfizer to the negotiations being conducted by the Commission and Germany on behalf of the JNT. The manufacturer regarded this response as confusing.

Towards the end of July 2020, the negotiations with Pfizer had led to tensions in the JNT, primarily between Germany and France and because of French scientists issuing a negative opinion on the Pfizer vaccine. There was consequently a risk that if France was unwilling to help procure the Pfizer vaccine, Germany would block attempts to sign up for the vaccine being developed by Sanofi, the manufacturer with whom France was in talks. The Dutch chief negotiator mentioned this 'white noise' when talking to Europe's chief negotiator, Sandra Gallina, and tried to mediate between Germany and France. He was unpleasantly surprised, therefore, by what he regarded as the Commission president's interference in this sensitive process in the form of the deal with Sanofi that she announced on 1 August 2020 without first consulting the member states. The negotiator feared this could cause the German minister, Jens Spahn, to feel he had 'been abandoned'.

One of the problems with the Pfizer vaccine was that its price seemed considerably higher than average. The JNT negotiators managed to reduce this difference, partly in response to calls for this by the Netherlands. However, the EU's announcement in August 2020 that it had also signed preliminary agreements with CureVac and Moderna meant that the bottom of the €2 billion emergency fund was now in sight, and there was a shortfall of around €300-350 million for a deal with Pfizer. Germany could not accept this and demanded renegotiation of the earlier deals to reduce the numbers of doses committed to be purchased.

The other member states obviously did not view this as an attractive prospect. The alternative was to try to increase the budget. While this could have been agreed by the EU Health Council (the council of the member states' health ministers) at the meeting on 4 September 2020, the question was how this would be funded. The Netherlands was the only member state to notify the SB that it was willing to contribute to pre-financing the amount. This was because, as well as a contract with Pfizer, the minister wanted to secure a more diversified portfolio, possibly including vaccines from manufacturers such as Valneva and MSD Merck, with whom discussions were also ongoing. The minister viewed the risk of missing out on an effective vaccine as greater than the disadvantage of incurring higher costs because of purchasing too many vaccines. This was another issue that the minister himself discussed with his German counterpart and others. The EU Health Council ultimately decided that the EU would aim for more deals and that 10 countries, including the countries that had been members of the IVA, would confirm their willingness to provide extra budget to pre-finance these deals. In the case of the Netherlands, this meant an amount of €43 million. Sandra Gallina later informally thanked the Dutch

chief negotiator for his contribution to this result. As she said in her message, 'You planted this!!! THANK YOU!!!'

Five days after the Health Council's announcement, the European Commission agreed a term sheet with Pfizer for 300 million vaccine doses and an option for an additional 100 million, although a decision on financing the agreement was still awaited. The EU lawyers once again set to work, but it was another 2 months before the Commission and Pfizer signed the contract. Like certain other countries, the Netherlands hoped that the bazaar would enable it to obtain more vaccines than its population size entitled it to. That hope indeed materialised, with the Netherlands ultimately being able to order 8.4 million Pfizer doses; in other words, 600,000 more than its pro rata share in the basic contract.

Our comparative analysis of the extent to which public interests were protected showed the contract with Pfizer to score just below that of Janssen (see Appendix 2, Table 1), largely because of its price structure not being optimally transparent. With regard to public health in the Netherlands, the most important issue was that Pfizer proved to be the first manufacturer actually able to supply vaccines, as described in more detail in the next chapter.

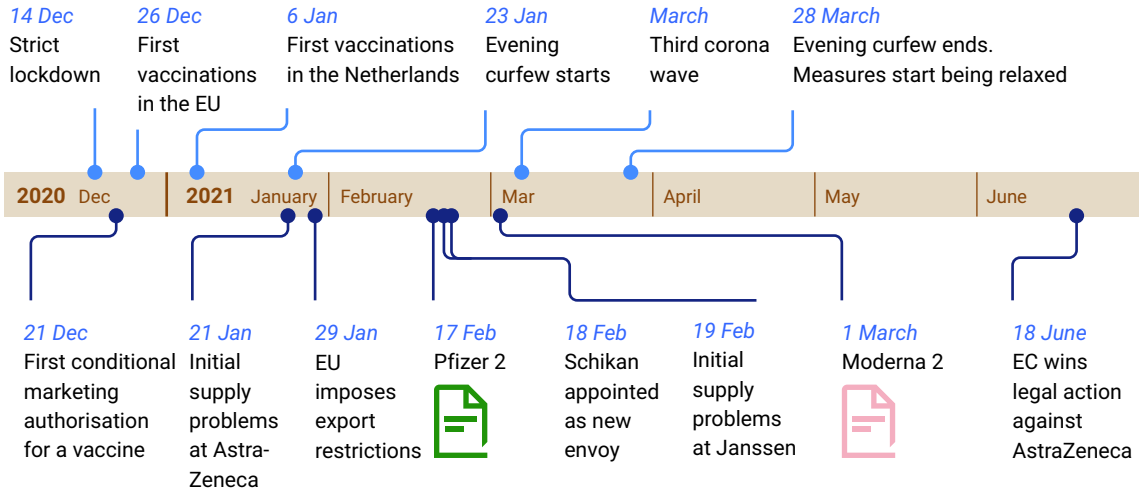
5.6 Looking back

Against the background of interplaying interests in Europe, the Netherlands targeted a diversified package of vaccines. This was because, in 2020, the question of which vaccines would prove effective against corona was still very uncertain. The economic interests at stake were one of the reasons for the Janssen vaccine being slightly ahead in the preference stakes. The Ministry of Health, Welfare and Sport played a leading role in the JNT, even though the voices of the larger countries often carried decisive weight. The ministry acted as an intermediary in conflicts between member states and was also willing to step in and smooth 'ruffled feathers', such as when problems arose during the negotiations of the Pfizer contract.

Looking back at the initial contracts and how they came about, we found the Ministry of Health, Welfare and Sport's decision-making to have been lacking in structure. Legal advice was sometimes received too late to be included in decision memoranda for the minister. That is hardly surprising in itself, given the substantial pressure from society and the unfamiliarity with the processes involved. We also regard it as unlikely that a more streamlined process would have resulted in fundamentally different outcomes. It should be noted, however, that some of the problems arising

later with regard to vaccine donations were partly attributable to the lack of clear agreements on this aspect in the initial contracts.

6. Regulatory approval and supply chain problems



After the first vaccine contracts had been signed in autumn 2020, the next step was to wait for regulatory approval and for vaccines to be supplied. As Pfizer was the quickest in this respect, this manufacturer's vaccines were the first to be injected, whereas both AstraZeneca and Janssen experienced various delivery delays. In the meantime, the Netherlands and the JNT continued negotiating new contracts, with the top priority still being to satisfy the need to procure sufficient numbers of effective and safe vaccines as quickly as possible.

6.1 New phase

In October 2020, the Dutch chief negotiator in the JNT resigned after getting a new job. The appointment of his successor – the director of the ministry's International Affairs Department – marked the start of a new phase. By then, the first major vaccine contracts had been signed and the focus shifted to supplying and

administering doses of the vaccines. The new chief negotiator decided to restructure the vaccine team from staffing designed to deal with an emergency to more structural staffing. Whereas his predecessor had largely had people on call for consultations whenever necessary, the new chief negotiator's approach was based on more regularly scheduled consultations. However, the ministry's expectations of a calmer period ahead did not materialise. As well as various vaccines encountering problems, new vaccine doses continued to have to be procured in 2021 because the basic vaccinations proved not to provide sufficient protection. As a result, orders had to be placed for booster vaccines.

6.2 First vaccinations

While the Netherlands faced a second wave of infections in autumn 2020 and another lockdown, regulatory approval for the first vaccines was taking longer to obtain than forecast. Granting this approval was a task for the EMA. This prompted discussions among EU member states in the SB about the possibility of starting vaccinating before vaccines had been approved. Both the United States and United Kingdom were considering this, and there was scope for this under European legislation. However, as messages between the ministry and the European Commission showed, the Netherlands and Germany were not in favour of this: 'Our minister contacted [German minister] Spahn, stating we attach importance to a full and transparent process by EMA. Trust in quality and safety over speed.'

The first conditional marketing authorisation for a vaccine – the Pfizer vaccine – was given on 21 December 2020. Authorisation by the EMA was followed by the European Commission paving the way for the vaccine launch, including arranging for a small initial batch of vaccine doses. To boost morale, it was considered important to administer the first dose before the end of 2020, ideally on the same day across Europe. With this in mind, the Commission consistently called on the member states to act as a community and not to turn vaccination into a 'competition'. Despite generally agreeing with this approach, the Netherlands was also somewhat ambivalent. As the minister put it in an in-house message, 'I'm not against competition... as long as we win.' The first vaccination in the Netherlands was ultimately administered on 6 January 2021. The fact that this was later than in other member states had nothing to do with the procurement. Instead, the Municipal Health Service (GGD) was simply not equipped to start before then (Dutch Safety Board, 2022). With authorisation for the Moderna, AstraZeneca and Janssen vaccines being received in the first quarter of 2021, the path was now clear for rolling out a diversified package of vaccines to protect the population.

6.3 Run op Pfizer

Demand for as many vaccine doses as possible remained high in many EU countries for a long time. Germany in particular was almost always looking for extra doses. Indeed, the minister often compared the Dutch situation with that in Germany. The two ministers were also in frequent contact, although their relationship was not always one of equals. In late 2020, for example, the minister contacted his German counterpart following a rumour that Germany had circumvented the EU agreements by ordering extra doses of the Pfizer vaccines. When Spahn more or less confirmed this rumour, the minister asked whether the Netherlands could 'hitch a ride on these extra arrangements,' but was told by his German counterpart that this would not be possible. Those involved now doubt whether these doses were ever actually purchased, given that they never showed up in the German vaccination figures.

Incidentally, initial interest in the Pfizer vaccine was somewhat lower than had been anticipated: some member states did not immediately trust the new technology, while the vaccine was also relatively expensive. Germany, by contrast, placed large orders. The Netherlands, too, was interested and ordered 7.5 million doses. As soon, however, as this vaccine proved to be highly effective, other member states wanted to order more doses. That meant changing the allocations that had been agreed in the bazaar arrangements. This happened often, and included cases of countries not having been sufficiently alert when first agreeing allocations and then subsequently seeking to claim extra vaccines. The Netherlands and Germany were generally reluctant to agree to such requests because they would then have to give up some of their own allocations. They also felt that the procedure for signing up for the bazaar arrangements had been fair and transparent. However, the Netherlands was willing to make exceptions to this rule, such as when Poland and Belgium wanted additional options on Pfizer. While the ministry was not keen to relinquish vaccine supplies, a civil service e-mail commented that 'It is Belgium that is asking' in advice given to the minister, who had been phoned about this by his Belgian counterpart. As a result, both Poland and Belgium got the extra vaccines they requested.

In its efforts to rapidly secure high numbers of vaccine doses Germany regularly threatened to 'go it alone' if other member states were not willing to proceed with subsequent steps. In this way it put pressure on the options for extra doses of the Pfizer vaccine and also on the supplementary contracts with both Pfizer and Moderna, the manufacturer of the second mRNA vaccine. These subsequently resulted in Purchase Agreements ('PAs'), referred to in this audit as 'Pfizer 2' and 'Moderna 2', respectively. Unlike their predecessors, these contracts were not APAs

because, by then, the vaccines had received regulatory approval. These contracts were therefore more a case of straightforward orders for existing products..

6.4 Legal concerns

In the meantime the ministry's Legislation and Legal Affairs Department had concerns about the vaccine procurement process. While the previous chief negotiator had kept the ministry's lawyers advised of developments in the contracts and sent them copies of these documents (sometimes in draft form), he obtained his legal advice on the contracts directly from the external lawyers. This all changed in autumn 2020, when the vaccine team made more efforts to involve the Legislation and Legal Affairs Department's in-house lawyers in decision-making.

These in-house lawyers expressed their concerns in November 2020, claiming they were not in a position to assess the vaccine contracts properly. As they reported, neither they nor the external lawyer had sufficient knowledge of Belgian law, which was the law governing the APAs as European agreements. They consequently set out to find a firm of lawyers in Belgium with this expertise. Given the difficulty, however, of finding lawyers in Brussels not already working for parties actively involved in procuring vaccines, it was not until March 2021 that they were able to engage a firm of Belgian lawyers.

On top of that, the ministry's in-house lawyers felt they were being given too little time to prepare a properly substantiated assessment of the contracts, both during the negotiations and in the opt-out phase (i.e. when a member state could still choose not to proceed with procurement). Our audit found examples of advice given during this phase of the negotiations being rather chaotic or issued too late, including when the ministry had to rush into a decision on a possible opt-out in the contract with CureVac. In the case of the contract with Pfizer, meanwhile, the opt-out period turned out to have expired by the time the lawyer was able to examine the final version of the contract. It should be noted, however, that this lawyer did not subsequently see any 'red flags' in this Pfizer contract.

The ministry's chief negotiator was aware of the lawyers' concerns. He, too, found it difficult to maintain an overview of all the different legal aspects in the various contracts and so tried to focus on the broad outlines and main indicators, such as during JNT meetings, when participants went through all the contracts, clause by clause. He also relied in part on the expertise of the European Commission's lawyers,

who were responsible for working out the details of the contracts in liaison with the pharmaceutical companies' lawyers.

Looking back, many of those involved, both in the Netherlands and abroad, confirm they were satisfied with the European lawyers' expertise. The Dutch chief negotiator reported a difference between the speed of the process and the speed at which the Ministry of Health, Welfare and Sport's lawyers were operating. He claimed that it had been decided by officials at the highest level – including the minister – to maintain the momentum. However, we did not find any explicit statement by the minister on handling legal advice. The exact way in which legal risks were assessed during the opt-out period remains unclear to us.

Looking back, the ministry's in-house lawyers said that the clauses on supply, indemnification, donations and information-sharing could have been improved. While they are probably correct in this respect, a major public interest was at stake: the Netherlands and the EU had to procure sufficient numbers of safe and effective vaccines as quickly as possible in order to fight the pandemic. Being aware of the competition with the United States and the United Kingdom, the Commission was certainly operating at a fast pace. From the outset, however, the Dutch policy was known to enjoy wide-ranging support, both within the ministry and in the House of Representatives. We conclude, in this respect, that the legal imperfections in the contracts that the ministry's in-house lawyers retrospectively drew to our attention were outweighed by the importance of rapidly securing vaccines as a pathway out of the pandemic. The contracts made no concessions regarding the most important requirements: vaccine safety and efficacy. This was also confirmed in, for example, the agreement to follow the EMA procedures, which were admittedly accelerated. Similarly, we found no indications that the alleged lack of knowledge of Belgian law harmed the Netherlands to any material extent.

6.5 Manufacturing and supply problems

Fairly soon after the first vaccines were authorised for use, problems began to arise with supplies of various important vaccines. On 20 January 2021, AstraZeneca reported that its deliveries were a month behind schedule because of problems at a supplier. The Commission immediately claimed a breach of contract. However, this may have been when the next problem became evident: the fact that the contract did not state that production destined for Europe was a priority. Admittedly the EU had invested a substantial amount in advance. In the event of a supply shortage, however, the manufacturer seemed to have a preference for supplying the United

Kingdom because the latter had invested earlier. Although the EU held talks with AstraZeneca at a ministerial level, the supply problems just continued to increase.

These problems prompted the European Commission to take far-reaching steps in the form of export restrictions. From late January 2021, therefore, exports of vaccines (or vaccine components) for which a contract had been signed required a licence. The ministry was hesitant to proceed down this route, given that protectionist measures of this nature could prove disadvantageous for the EU. A month later, however, the Commission moved towards implementation by seeking to ban exports of AstraZeneca vaccine components manufactured by a company in Leiden. Although the indignant UK prime minister contacted his Dutch counterpart, the latter backed the position adopted by the EU. Boris Johnson ended the conversation with the words 'Thank God we left the EU.'

Meanwhile, AstraZeneca continued to experience delivery delays. In April 2021, the Minister of Health, Welfare and Sport consequently gave consent for the European Commission to take legal action against the manufacturer on the Netherlands' behalf, with the aim of forcing the company to supply the agreed number of doses. According to the Commission, AstraZeneca had not complied with its duty to perform to the best of its ability as it had not deployed all its available capacity for supplying the EU. This included not using its factories in the United Kingdom for this purpose. In June 2021, the Court of First Instance in Brussels found in favour of the Commission and imposed a penalty on the company if it failed to deliver the agreed doses. Ironically, this ruling was ultimately of little importance in practice because, by then, demand for the AstraZeneca vaccine had bottomed out in response to reports of side effects in a very small number of people who had received this vaccine. As a result, Denmark and Norway stopped using the AstraZeneca vaccines in May 2021 and the Netherlands was then able to take over some of those countries' stocks.

During 2021, Janssen, too, started experiencing problems with its deliveries. During a presentation to the SB on 19 February, the company was still unable to confirm whether it would be in a position to supply vaccines the next month. This was because of vaccine components being manufactured at 8 different locations, 3 of which were in the EU. The EU member states discovered to their dismay that Janssen was sending supplies to the United States and that the agreements with this latter country, too, may have been stronger from a legal perspective than those signed with Europe. Although the ministers of the Netherlands, Germany and

Belgium all subsequently phoned Janssen's CEO, we were unable to establish what, if any, effect these calls had.
From April 2021, Janssen once again started experiencing major problems in its supply chain. First it was forced for safety reasons to impose a temporary stop on deliveries, while problems then arose in one of its US factories. Communications between the parties reveal that the Dutch negotiating team was not entirely clear on how the vaccine production chain was structured at that time. It had assumed, for example, that the drug substance was manufactured entirely in Leiden and that 'filling and finishing' was done in South Africa. When the chief negotiator asked a staff member in Brussels, 'They're not sending anything from the US to the EU, are they?' the response was 'Well, apparently they are!!!' When the supply problems continued, the EU member states argued that this was because Janssen had disregarded the Commission's advice to manufacture in Leiden instead of in the United States. Although the company promised in July that, from then on, it would manufacture exclusively within the EU, it failed to live up to this promise. As a result, the Netherlands continued to face disruptions in the supplies of the Janssen vaccine, mainly because the country wanted to be able to use these doses for donations (see chapter 8).

6.6 Return of the old envoy and appointment of a new one

In response to the vaccine supply problems that had arisen, the government contacted Feike Sijbesma in February 2021 to ask whether he would be willing to return to his role as envoy. This time, his task would be to find ways of resolving the problems caused by stagnating supplies of contracted vaccines. The former CEO of DSM was willing to take on this role, but only if he could operate 'beneath the radar'. However, as the government had undertaken to the House of Representatives to appoint a special vaccines envoy, the ministry publicly announced on 18 February 2021 that Hans Schikan, another businessman with extensive experience in the biopharmaceutical industry, had taken on this role.

That same day, Feike Sijbesma completed his investigations behind the scenes. His letter to the prime minister and the Minister of Health, Welfare and Sport included 3 recommendations:

- Sign deals with vaccine manufacturers that have not developed a vaccine themselves;
- Opt for a less accusatory approach to the pharmaceutical industry;
- Analyse the bottlenecks.

Sijbesma also criticised the approach that had been adopted by the Netherlands and the EU. As he put it in his recommendations, Europe had chosen not to involve itself in the vaccine supply chain. That contrasted with the approach adopted by the United States, which had chosen not only to sign deals with vaccine developers, but also to reserve production capacity at third parties. As Sijbesma wrote, 'This has made the whole supply chain more of a "black box" for the EU than for the United States.'

Although the minister could not do much with these recommendations at the time, the envoy's point was very salient. The Netherlands had originally planned to invest in production capacity, but ultimately opted to follow the European Commission in signing 'all-inclusive' contracts with pharmaceutical companies. Under these contracts, the companies were responsible for the entire development, production and supply chain. While this approach clearly had certain advantages in that the risks were with the pharmaceutical companies, the question arising was how this would help Europe's population if the pharmaceutical company proved unable to deliver. This was hard for the government party in the contract to resolve, given that it had little control of the individual elements in the chain. When Hans Schikan suggested that it should try to persuade Janssen to have the bulk vaccine doses that it produced in Leiden also 'filled and finished' in the Netherlands, another adviser made it clear to him in no uncertain terms that it was Janssen's responsibility to ensure its production was as efficient as possible. The message was that this was what had been agreed in the contract and the adviser did not see this as a responsibility of the ministry.

6.7 Options circumventing the EU

Given the huge demand for vaccines, the supply problems being encountered prompted the minister also to look at possible options outside the joint European procurement process. Once again, this idea was at odds with the agreements that had been reached within the EU. In the meantime, the ministry had received various suggestions for obtaining extra vaccine doses, either in response to requests or otherwise, and sometimes from people in very senior positions. While some of these suggestions were immediately rejected, others were given serious consideration.

These included the suggestion in March 2021 of possibly having AstraZeneca vaccines manufactured in India. When the Commission proved to have little interest in pursuing this option, the ministry wondered whether 'in theory, going it alone with a national procedure' would be possible. Although the ministry then invited an Indian company's CEO to visit the Netherlands, a major outbreak of corona in India itself

and the country's subsequent banning of exports prevented any further exploration of this option.

A month later, the minister heard from a fellow minister about a possible shipment of tens of millions of Janssen vaccines. This offer came via a 'highly respected lawyer' and the prime minister was also said to be aware of it. Although the minister realised that many of these stories proved not to be true, he nevertheless gave instructions to explore this option.

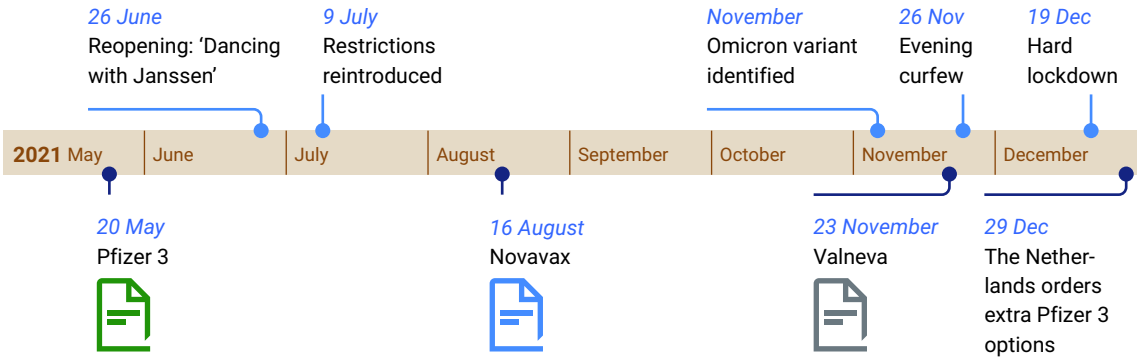
Some of the proposals for 'vaccine deals' that reached the ministry may seem reminiscent of the issues regarding medical appliances, such as face masks, that were widely reported in the press in the early days of the crisis. While our audit did not examine any of these aspects, there are certain similarities in the case of proposals communicated to the ministry through people in senior positions. As far as we were able to establish, however, and in contrast to the case of medical appliances, none of these proposals for vaccine deals resulted in purchase orders being placed. In any event we did not find any evidence of such orders.

There are various possible explanations for this: the procedures for admitting vaccines to the market via the EMA and the Dutch Medicines Evaluation Board (CBG) are likely to be considerably stricter than those applying to medical appliances, and the amounts involved are also larger. The agreement to purchase vaccines at a European level, via the European Commission, and the Netherlands' major involvement in this process are likely to have acted as a brake on efforts to explore possible options arising outside this framework.

6.8 Looking back

Signing the initial contracts did not mean a green light for mass-scale vaccinations. The vaccines first had to be approved and the manufacturers then had to deliver. The latter issue was where the weak link in the European chain became all too evident, and this weak link was one that was simultaneously difficult to remedy: the fact that the European Commission had signed 'all-inclusive' contracts with pharmaceutical companies meant it had little control of the individual elements in the development, production and supply chain. While the ministry's lawyers expressed concerns about the limited opportunities to influence the process, their concerns were to little avail. The top priority in the crisis was to act fast. Bearing in mind the overriding objective, we found no indications that any imperfections from a legal perspective caused any significant harm to Dutch public interests.

7. Later and more expensive contracts



Mass vaccination of the European population got underway during 2021, by which time the European Commission and the Netherlands, as a member of the JNT, were focused on procuring new rounds of vaccines for use in the near future. The plan was for the new contracts to contain more tightly worded provisions on supplies and on adapting to new variants of the virus. However, prices were going to be higher. While the focus was on the successful Pfizer vaccine, the need for alternative vaccine technologies continued.

7.1 Same strategy, but a shift in focus

The Netherlands followed largely the same approach to procuring vaccines in 2021 as it had done in 2020. Just like at the outset, the primary objective was to procure sufficient numbers of safe and effective vaccines as quickly as possible, with price being of lesser importance. As the minister said in the House of Representatives in May 2021, 'I would emphasise that in this pandemic we haven't got any choice. We need all these vaccines, every single one of them. (…) The fact that some parties are

earning on this is not the biggest problem I'm facing right now. Because if you look at how much another week of lockdown costs, and another week of paying out for all the support packages, it's currently costing us 700-800 million euros a week. So the business case is never going to be negative.' (House of Representatives, 2021).

These efforts to achieve the primary objective do not detract from the fact that the focus shifted over time. In private, the chief negotiator sometimes suggested that he was willing to hold back and wait before procuring every batch of vaccines on offer. After the agreement was signed with CureVac, for example, he advised the minister in January 2021 not to purchase more than the Netherlands' pro rata share. However, the minister wanted to get hold of all the vaccines that were available. The chief negotiator's preference around this time was also not to purchase extra doses of Moderna because they were relatively expensive and would not be delivered until late 2021. Ultimately, however, the Netherlands agreed to an improved proposal.

In early April 2021, the Commission president, Ursula von der Leyen, launched a new joint procurement strategy. She called the Dutch prime minister and other government leaders to discuss how the EU should secure sufficient numbers of vaccines for the coming years. According to a decision memorandum sent to the minister, large volumes of vaccines would be needed in both 2022 and 2023 to continue the fight against COVID-19. Although the successful mRNA vaccine of Pfizer (and also Moderna) was intended to be the cornerstone of the strategy, the plan was also to procure vaccines based on other technologies. As well as the AstraZeneca and Janssen vector vaccines, this meant the protein-based vaccines of Sanofi (for which a contract had already been signed) and Novavax, which was not yet on the market. In other words, the minister wanted to join in with procurement of the mRNA vaccines, but also to continue betting 'on other horses'.

The European Union also imposed strict requirements on certain aspects of what the JNT negotiators referred to as the 'second-generation contracts'. Based on their previous experience, the negotiators set high requirements for these contracts:

- they had to include clear delivery schedules;
- better provisions had to be in place to enforce contractual agreements;
- they had to include agreements on prioritising supplies for the EU and production within the EU;
- they had to allow member states as much scope as possible to procure vaccines adapted to new variants of the virus.

In the meantime, the European Commission was also working on a new organisation that would be tasked with preventing and rapidly responding to cross-border health emergencies in the EU. This organisation, the Health Emergency Preparedness and Response Authority (HERA), was established in September 2021.

7.2 Third Pfizer contract

The move to a new strategy was clearly related to the third Pfizer contract, which the European Commission signed on 19 May 2021. The background to the signing of this mega-contract – for up to 900 million vaccine doses, and an option for the same number again – was different from that of its predecessors. This time it was Commission president herself who conducted the preliminary negotiations on the main contractual conditions with Pfizer's CEO, without the involvement of the JNT. The European Commission did not provide the European Court of Auditors with any information about these negotiations during the latter's audit, and the European Ombudsman's requests for copies of the text messages exchanged by the Commission president and the Pfizer CEO have so far also been in vain (European Court of Auditors, 2022). Our audit also found no information on this subject. Similarly, and as far as we could see, the ministry did not receive any such information either.

While the ministry's in-house lawyers made it known around this time that they and their new Belgian lawyer wanted to become more involved in drawing up new contracts, we found that, in fact, the opposite happened. This was because apart from the preliminary negotiations taking place without any role for the Netherlands, there was also very little time for the formal tendering procedure with Pfizer. Although the Dutch chief negotiator complained about this, pressure from the Commission to move matters forward was intense. The negotiating team attributed this pressure to the opportunity that had arisen to sign a very substantial contract, with a priority position for Europe. The faster the Commission was able to commit, the more certain it would be of receiving large numbers of vaccines. As well as supply certainty, the main obstacle to be overcome under pressure was that the member states wanted the contract to allow a considerable degree of flexibility to adapt vaccines to new variants of the virus. Unfortunately, the opinion issued by the ministry's new Belgian lawyer, who was focusing on aspects such as penalty clauses, came at a time when it was no longer possible to make many changes in the contract.

The basic contract with Pfizer was approved on 20 May 2021. In September, the Netherlands ordered 35 million vaccine doses under this contract, while by December the minister was considering whether to exercise the option to order more. On this occasion, too, there was pressure for quick decision-making. According to the Dutch delegation, it was Pfizer that was exerting this pressure. However, Germany, too, was keen to schedule booster vaccines without delay. The Commission president also contributed to this pressure by messaging the Dutch prime minister and emphasising that she was expecting a decision from the member states within a week.

The Netherlands would have preferred to wait a bit longer because it was afraid it would end up with more vaccines not adapted to the Omicron variant of the virus. It still had stocks of Pfizer vaccines for 2022, but the Omicron variant was soon expected to become dominant. The thinking was that the later the new vaccine doses were ordered, the higher the chances that Pfizer would have adapted them to the new variant, as contractually required. The ministry therefore prepared a response for the prime minister to the Commission president, asking her to use her influence to persuade Pfizer to adapt the vaccine as quickly as possible. Ultimately, in late 2021, the Netherlands agreed to order 5.9 million extra doses of the Pfizer vaccine, hoping that they would be delivered as late as possible.

7.3 Assessing the third Pfizer contract

We found the third Pfizer contract negotiated also to lack transparency as far as the Netherlands was concerned. Nevertheless, comparison with the other contracts puts it in second place (alongside Novavax) – and just behind the contract with AstraZeneca (see § 5.3 and Appendix 2) – if equal weight is assigned to the protecting of all the relevant public interests. If, however, we were to assign greater weight to the priorities set by the Netherlands and the European Commission, the Novavax contract and this final contract with Pfizer would be in joint first place. This is because these 2 contracts contained the best provisions for guaranteeing production and supply (see also figures 6 and 7), and the Netherlands and the Commission both attached greater importance to vaccines actually being available than to their relatively high prices.

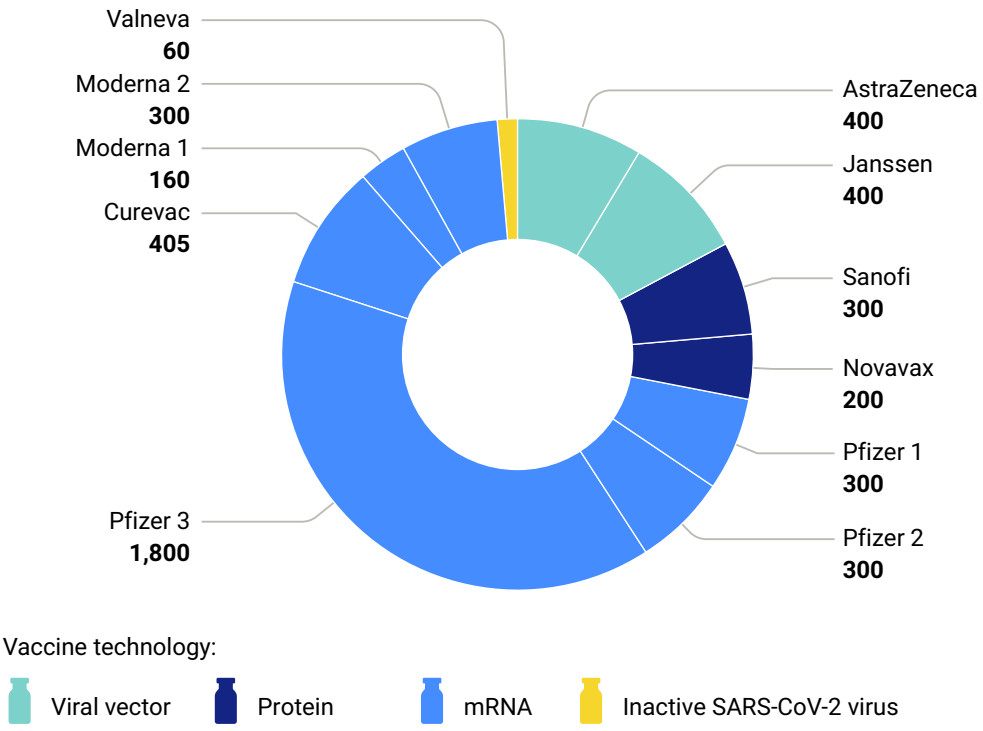
However, signing the third Pfizer contract resulted in the balance in the overall package skewing even further towards mRNA vaccines. Indeed, by then, these vaccines represented almost three quarters of the total, as previously noted by the European Court of Auditors (European Court of Auditors, 2022) and as clearly shown

in figure 5:

Figure 5 *Breakdown of vaccines purchased by EU, including options*

Almost three quarters of European vaccines based on mRNA

Numbers in millions of doses



In the case of the Netherlands, the breakdown was even more skewed towards mRNA vaccines, with 7/8 of the vaccines purchased being mRNA-based.

In itself, this is hardly surprising, given that these vaccines had been shown by then to be the best in terms of performance and supply. Nevertheless we also saw that member states were hesitant about so explicitly betting everything on 'just one horse'. The Dutch National Institute of Public Health and Environmental Protection, too, had doubts, given the various reasons for preferring a more diversified range of vaccines. According to those involved, it was ultimately a 'conscious choice' by the Minister of Health, Welfare and Sport, who was fully aware that this contract would skew the balance in the overall vaccine package and that considerable numbers of vaccines were likely to end up not being used. Indeed, this later proved to be the case. The Ministry of Finance had to be called on to arrange for an increased budget to cater for these more expensive vaccines. But, as a civil servant involved in the process stated, making any other choice during the corona crisis would have been politically 'totally unrealistic'.

7.4 Total vaccine package

The third Pfizer contract was followed by the Commission's signing of contracts with both Novavax and Valneva. In the case of Novavax – which added the only effective protein-based vaccine to the package – the Netherlands ordered 840,000 doses, which was slightly above its pro rata share. These were intended for people who could not or did not want to have an mRNA vaccine. In the case of Valneva, the ministry purchased only 10,000 doses. This was more of a symbolic step, with the Netherlands seeking to ensure it was a party to the contract just in case this vaccine proved to be necessary in the future.

The Novavax and Valneva purchases brought the total number of contracts in 2020 - 2021 to 11, with 8 different pharmaceutical companies and amounting to a total of over 2.3 billion doses. On average, that meant each EU citizen could potentially be vaccinated 6 times, which was more than enough to substantially reduce infection rates and protect most people against becoming seriously ill from COVID-19.

However, this was an average for the EU as a whole; some EU member states placed fewer orders than others, possibly for financial reasons. Similarly, vaccines supplied were not evenly spread over the subsequent months, given that whether a vaccine could be supplied depended very much on when it received regulatory approval and on the available manufacturing capacity. We saw that the first contracts signed by the Commission, from summer 2020 onwards, were with the companies that were expected at the time to be able to start delivering supplies quickly. Not all those companies, however, proved able to live up to expectations. AstraZeneca and Janssen, for example, encountered major production problems, while Sanofi ultimately had to abandon its efforts to develop a vaccine. As a result, vaccination programmes in the EU only really got going when doses of the Pfizer vaccine became available.

7.5 More reliable supplies at higher prices

If we examine the contents of the contracts chronologically in terms of their protecting of public interests, we can conclude that the contracts signed by the EU did not generally improve over time; for each contract, the average scores for the public interests we defined remained fairly constant. What we did see, however, were shifts over time in the individual underlying interests. The most striking aspect in this regard was the increased attention that later contracts paid to safeguarding production and supply, following the problems associated with supplies of the first

vaccines for which contracts were signed (see figures 6 and 7). The European Court of Auditors also noted that the later contracts had 'stronger provisions on key issues such as delivery schedules and production location' (European Court of Auditors, 2022, p. 40).

Figure 6 *Successive vaccine contracts' scores for supply certainty*

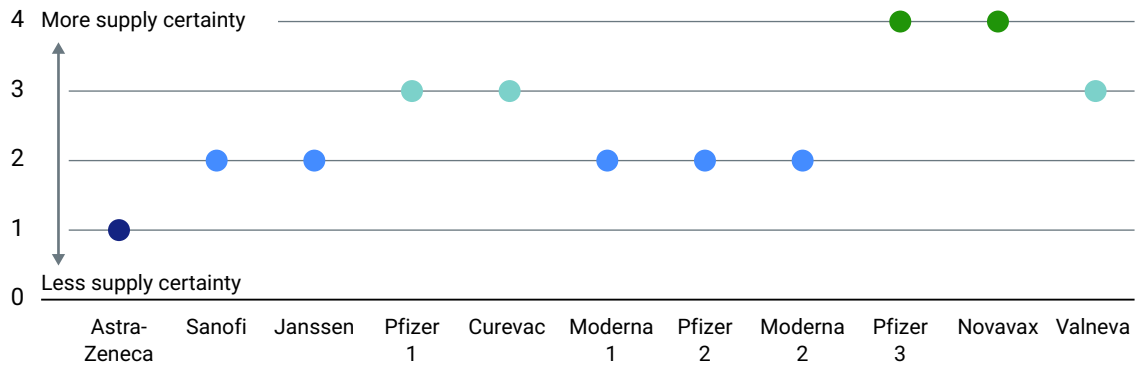
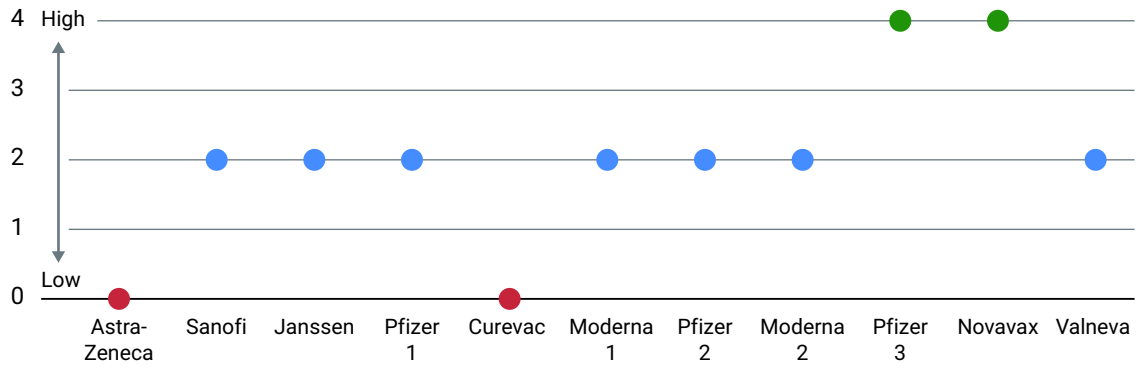
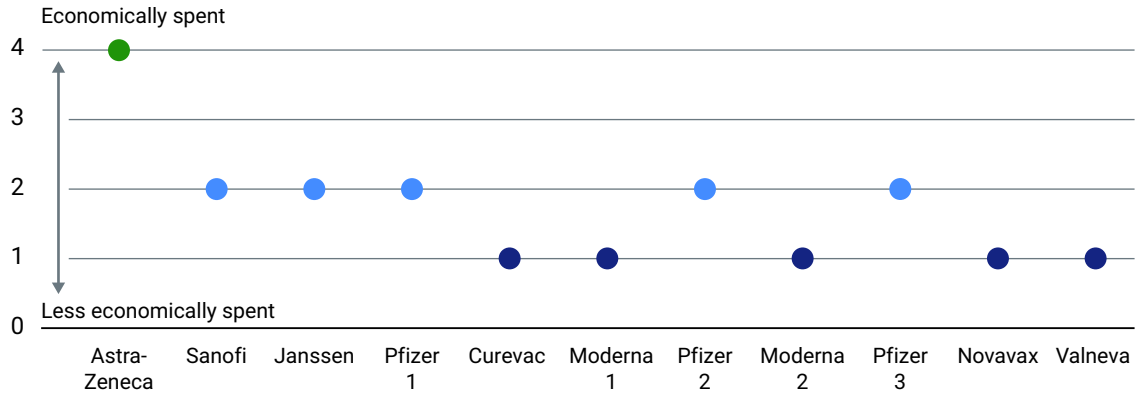


Figure 7 *Successive vaccine contracts' scores for production certainty*



On the other hand, the prices agreed for the vaccines during this period increased, as is also evident from the developments in our norm for assessing whether public funds were being spent economically (figure 8). We emphasise that this criterion relates not only to the price of vaccines, but also, for example, to provisions on reimbursement in the event of a vaccine not being successful (see also Appendix 2). Although this is not mentioned so explicitly in the negotiations process, these figures clearly indicate that the EU proved willing to pay higher prices in order to avoid the production and supply problems it had previously encountered.

Figure 8 *Successive vaccine contracts' scores for spending of public money economically*

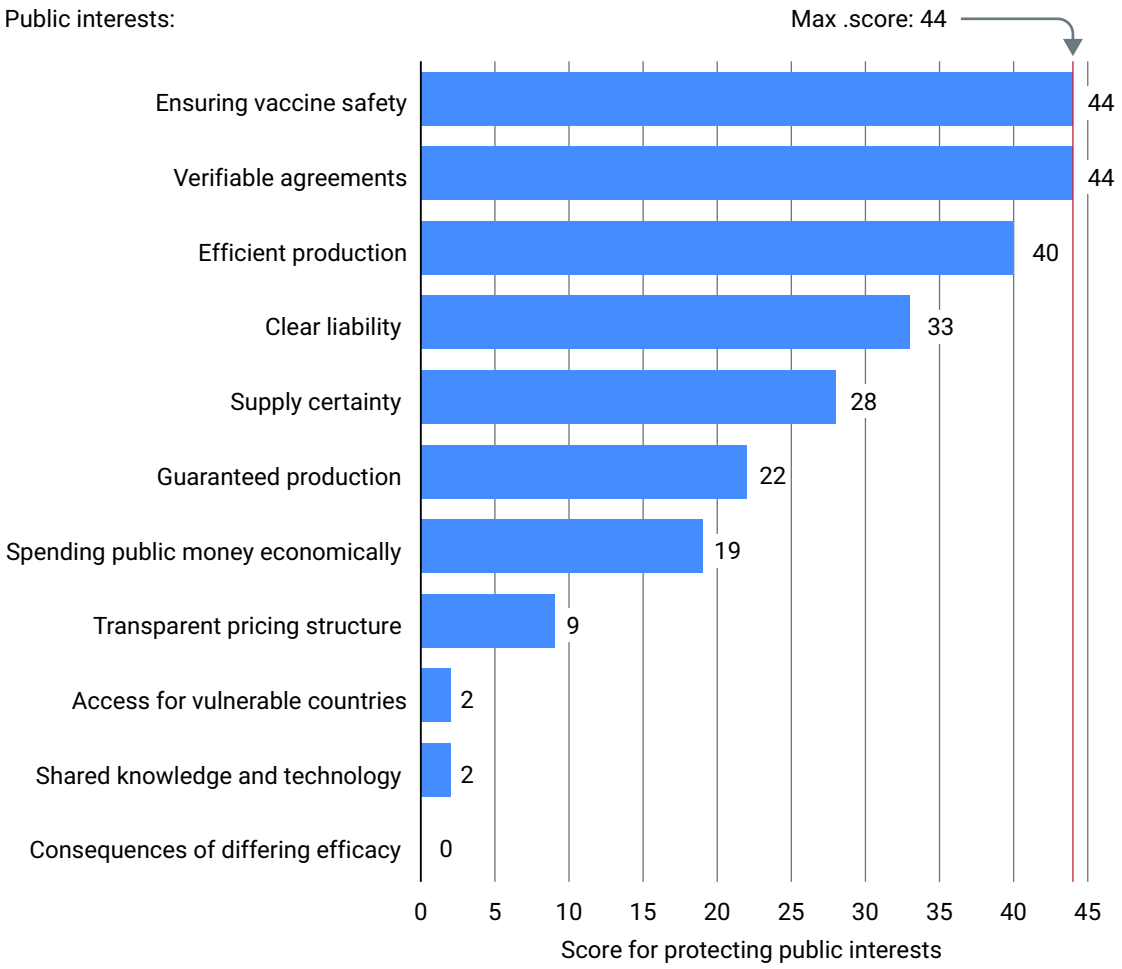


7.6 Protecting public interests in the contracts

If we look at the totality of the contracts signed in 2020 and 2021 rather than examining them chronologically, we can see that the best provisions were those relating to the verifiability of agreements and the measures in place to ensure safety. Note that this is not the same as concluding that the vaccines themselves are safe. That is not where our expertise lies. It is also not within the scope of this audit. Both the European regulatory authority (EMA) and the Dutch Medicines Evaluation Board (CBG) assessed all the purchased vaccines as being safe.

Figure 9 *Scores for protecting public interests in the totality of contracts*

Better provision for safety and verifiability than for sharing knowledge and technology



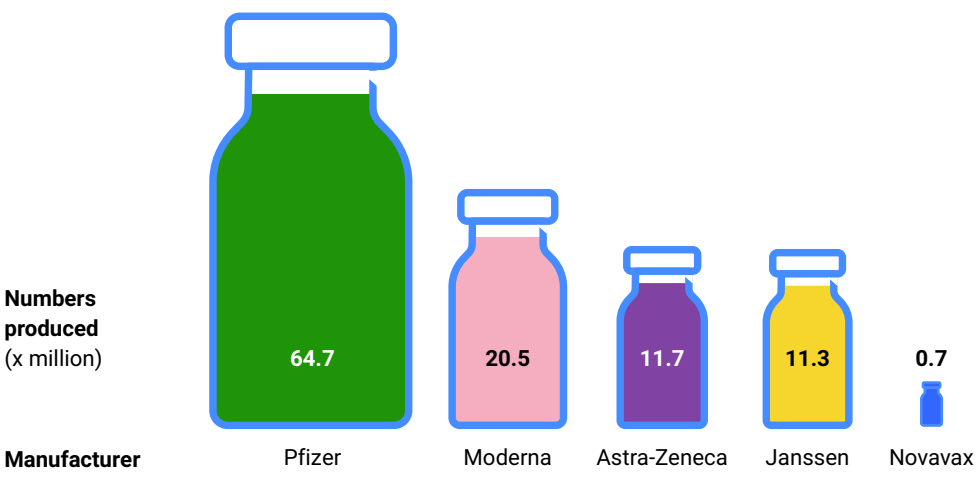
While the contracts scored less well in respect of pricing structure transparency, the European Commission was even less successful in agreeing contractual provisions on sharing knowledge and technology and on removing obstacles preventing vulnerable countries from accessing vaccines, even though the Netherlands had initially explicitly wanted to include such provisions. During the negotiations, however, it soon turned out that sharing knowledge and technology was a no-go area for almost all the pharmaceutical companies, given that their earnings models were largely based on patent protection. The European Commission and the Netherlands agreed to drop this requirement because it seemed it would otherwise be impossible to reach agreement. The only company to display slightly more flexibility in this respect was AstraZeneca, probably because its partner – vaccine developer Oxford University – had insisted on this. The efforts nevertheless undertaken by the Netherlands and the Commission to try to help vulnerable countries secure access to vaccines are discussed in the next chapter.

Although the Netherlands was actively involved in the contract negotiations through its membership of the JNT, we were unable to establish the Ministry of Health, Welfare and Sport's exact influence on individual provisions. We also note the ministry's decreasing involvement in the contents of contracts over time because the Commission itself then started playing the leading role.

Vaccines purchased by the Netherlands

The Netherlands purchased around 109 million vaccines in 2020 - 2021. These purchases were under the basic contracts and the options for the AstraZeneca, Janssen, Pfizer, Moderna and Novavax vaccines. The Netherlands did not buy any Sanofi or CureVac vaccines and bought only a very few doses from Valneva.

Figure 10 *Breakdown of vaccines bought by the Netherlands*



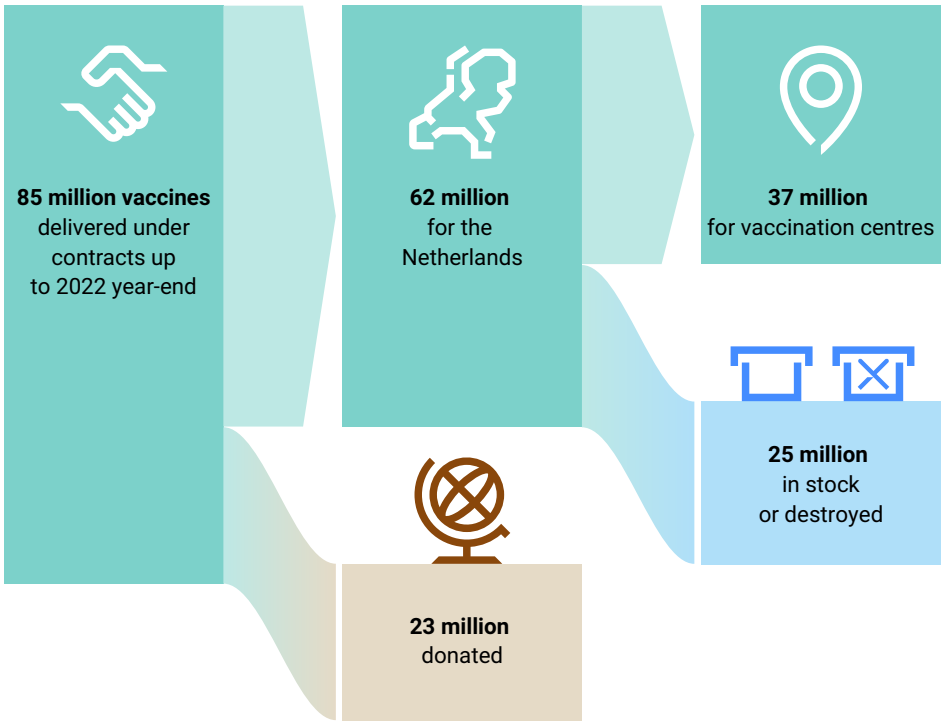
Some of the vaccines purchased were for delivery in later years. The European Commission responded to the sharp drop in the need for vaccines in 2022 by initiating discussions with Pfizer on reducing the numbers of doses to be supplied, for which a fee was charged. Some orders placed with Moderna were also cancelled. Ultimately, therefore, the Netherlands purchased a total of almost 102 million doses. This meant total spending on vaccines (and financial obligations) of just under €1.8 billion. In other words, an average of €17.27 per vaccine dose.

Vaccines supplied to the Netherlands

By 1 January 2023, 85 million doses of contracted vaccines had been supplied to the Netherlands, while the rest still had to be delivered. Figure 11 outlines how vaccines supplied to the Netherlands were used.

Figure 11 *Use of vaccines supplied to the Netherlands*

Over 60% of vaccines supplied to the Netherlands went to vaccination centres

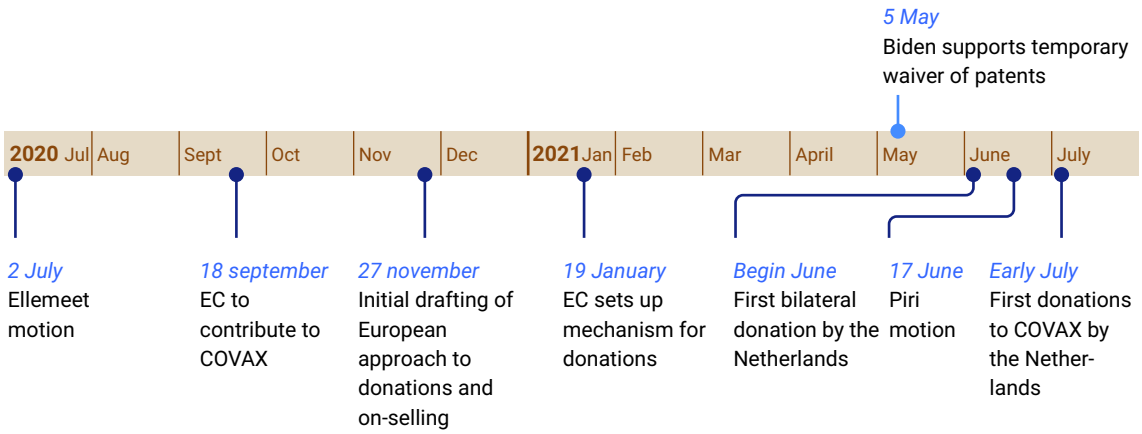


The 23 million vaccines that were donated to other parties are discussed in the next chapter. Figures from the National Institute of Public Health and Environmental Protection show that just over half of the 25 million vaccine doses not ending up at vaccination centres as at 1 January 2023 were still held in stock and were intended to be used in future vaccination rounds. The rest had been destroyed, sometimes because of having passed their expiry date. While we did not audit the destruction of vaccines, we mentioned earlier that the Netherlands had procured as many vaccines as possible and simply accepted that some would be surplus to requirements. There were no reliable estimations of how many vaccine doses would be needed to exit the pandemic: that depended on too many different factors. In this respect, therefore, the fact that vaccines were destroyed was a result of the strategy that had been chosen.

7.7 Looking back

Once vaccines started arriving in 2021, the European Union's focus was on procuring vaccines for use in the near future. The strategy, both of the EU and the Netherlands, was to procure sufficient numbers of safe and effective vaccines, although the specific focus evolved over time. The president of the European Commission was personally and explicitly involved in negotiating the large third contract with Pfizer. As well as this process lacking transparency, the very size of the contract distorted the balance in the overall vaccine package. However, the Pfizer vaccine was highly successful, and we regard that third contract and the contract with Novavax as the best of the 11 contracts signed from a perspective of the main public interests at stake. If, however, all the public interests are assigned an equal weighting, we found the AstraZeneca contract to be the best. On average, the vaccine contracts did not improve over time in the sense of providing greater protection of public interests, although production and supply certainty improved over time. At the same time, however, the costs of vaccines rose. Based on the overall package of vaccine contracts, the best provisions were found to be those on protecting safety and ensuring the verifiability of agreements. The aspect given least consideration in the contracts was vulnerable countries' access to vaccines. Ultimately the Netherlands purchased close to 102 million vaccine doses for a total of just under €1.8 billion.

8. Worldwide access to vaccines



It was only after the contracts with the EU had been signed and vaccines were being supplied to Europe that vulnerable countries started receiving help. This issue was of genuine public interest, given the worldwide impact of the pandemic. This help was ultimately provided by surplus vaccines being donated through COVAX and bilaterally.

8.1 How it started

Although its priority was to protect its own population, the Netherlands was not blind to the problems facing vulnerable countries. To some extent, this awareness could be explained by enlightened self-interest, given that a pandemic would not stop at Europe's borders. Earlier in this report we mentioned the Ellemeet motion and the minister's efforts to include the provision of help to Africa in the IVA's objectives. While the Netherlands held back from joining various worldwide initiatives to agree on a fair distribution of vaccines, it nevertheless hoped to be able to live up to its

promise by actively involving itself in the vaccine market with the other EU member states and offering help through this channel (see § 3.3). For Europe as a whole, too, the priority was its own population. At the same time, however, the Commission also wanted to lead the 'global solidarity effort' (European Commission, 2020).

In the first SB meeting in June 2020, the Netherlands confirmed 'its commitment to purchase vaccines for the rest of the world and its openness to top up ESI budget to [sic] that purpose.' As mentioned earlier, it even brought up a proposal that Janssen had made to the IVA to provide a further 200 million vaccines for Africa. Power relationships within Europe meant, however, that this was not a feasible way forward. According to the Commission, the emergency fund was to be used only for member states themselves. On top of that, it became clear during the contract negotiations that sharing intellectual property and eliminating other obstacles to providing help to vulnerable countries represented a bridge too far for almost all the pharmaceutical companies (see § 7.6). While the EU obviously could have chosen to maintain its stance, that could have put it at risk of failing to achieve its objective of obtaining sufficient numbers of vaccines for its own population as quickly as possible. As a result, the only way for the Netherlands and the EU to help vulnerable countries was by donating their own surpluses.

8.2 Relationship with COVAX

COVAX – a coalition of various globally active organisations such as the WHO, UNICEF, CEPI and the vaccine alliance GAVI (a public–private global health partnership) – was set up in April 2020 and was an important vehicle for ensuring a fair distribution of vaccines across the world. The idea was that COVAX would sign contracts with pharmaceutical companies and then distribute the vaccines fairly around the world. Countries such as Sweden, but also the Netherlands, drew attention to this in the JNT. However, the European Commission initially regarded COVAX primarily as a competitor in the vaccines market and explicitly requested the member states not to contribute their own vaccines to COVAX because that would have a 'disruptive' effect. These discussions revealed a difference in opinion between the Minister for Foreign Trade and Development Cooperation, who was more accommodating towards COVAX, and the Minister of Health, Welfare and Sport, whose views were more in line with those of the European Commission. This sometimes led to misunderstandings and irritations in the Dutch camp.

Although the Commission saw some scope for donating money or vaccines to vulnerable countries via COVAX, its relationship with the latter remained tense. The

Commission wanted to keep control of donations and repeatedly emphasised that the EU had already signed contracts with the pharmaceutical companies, whereas COVAX had not yet signed any at all. In September 2020, however, COVAX and the EU decided to join forces, with the Commission undertaking to contribute €400 million and the member states partnering each other in 'Team Europe'. In line with the Commission's intentions, the Netherlands did not obtain any vaccines for its own use from COVAX, but instead used the latter purely for donations.

8.3 Donation strategy

While discussions about helping vulnerable countries continued, vaccines did not start being donated in practice until the EU member states themselves had built up surpluses. That was not yet the case in late 2020/early 2021. In response to the supply chain disruptions and increasing political pressure, the Netherlands switched in early 2021 to focusing on limiting damage to its own vaccination campaign. However, the Minister of Health, Welfare and Sport often regarded the opportunity to donate vaccines as a good reason to justify not being too reticent about placing orders under existing contracts. The decision memorandum sent to the minister on the first Pfizer option stated, for example, that: 'There is a worldwide shortage of vaccines: so there will be a big market for the Netherlands to donate or on-sell vaccines later this year.'

Early on, therefore, the Ministry of Health, Welfare and Sport took account of the possibility to donate at a later stage. For a long time, however, it was unclear how these donations would be made. The ministry and the Commission initially thought that some of the money for COVAX should ideally flow back to member states that had contributed surplus vaccines. Ultimately, however, that did not happen and the Netherlands donated without receiving any money in return. The Minister of Health, Welfare and Sport also wanted to keep open the opportunity for bilateral donations of vaccines to countries of a member state's choice, whereas the Minister for Foreign Trade and Development Cooperation was more focused on donating via COVAX.

When other countries, such as France, started donating vaccines in spring 2021, the Dutch government decided on a strategy: each donation would have to be approved by the government, and the Ministry of Health, Welfare and Sport would only donate surplus vaccines not needed for booster programmes in the Netherlands. On top of that, and if the Netherlands were to be in a position to donate, other EU member states would be the first candidates for possible donations. Only after that would

donations to COVAX be considered, while 'targeted bilateral donations' by the Netherlands would be possible in 'exceptional circumstances'.

The Dutch chief negotiator remained in close contact with the National Institute of Public Health and Environmental Protection on the extent of the vaccine surplus. The latter kept detailed records of how many vaccines had been procured and were still expected to be supplied, and how many the Dutch Municipal Health Service itself would be using. This information had to be kept up-to-date so that the Ministry of Health, Welfare and Sport could notify the manufacturers as to whether the vaccines were to be sent directly to other countries or to COVAX. This was because vaccines have a limited shelf-life and so sending them via the Netherlands would only waste time.

In the meantime, the JNT tried to improve the provisions on donations and on-selling in the new vaccine contracts. Our assessment of the contracts found these attempts to have been largely unsuccessful. At the same time, renewed discussions arose around the world about whether the intellectual property rights on vaccines that had been developed should be waived (temporarily or otherwise) in the fight against the pandemic. In May 2021, the US president, Joe Biden, surprised many people by suddenly announcing that he would be supporting an initiative by India and South Africa in this respect. This then increased the pressure on the Minister of Health, Welfare and Sport, certainly when the Minister for Foreign Trade and Development Cooperation responded enthusiastically and the House of Representatives voted in favour of a motion 'to put a stop to European objections to temporarily waiving patents' (House of Representatives, 2020b). However, the Minister of Health, Welfare and Sport continued to oppose patent waivers, claiming that it was not patent protection that was causing the bottlenecks, but rather shortages of raw materials and production capacity. He also referred to the purpose of the patent system being to keep the investment climate attractive for pharmaceutical companies.

8.4 Bilateral donations

Although the strategy foresaw direct donations of vaccines to vulnerable countries as an exception, in practice they happened regularly. The Dutch government's main focus was on ensuring that the numbers of bilateral donations did not exceed the numbers of donations via COVAX.

The first direct request for vaccines came in spring 2021 from Suriname, which had previously asked the Netherlands for help in the fight against COVID-19 in summer

2020. At the time, the Ministry of Health, Welfare and Sport had looked into opportunities for providing vaccines to Suriname because it was afraid that the country would not be considered sufficiently poor to be eligible for free vaccines from COVAX, but would also be unable to pay for them itself. The then chief negotiator suggested ordering extra AstraZeneca vaccines for Suriname, as allowed under the terms of the contract. The Ministry of Foreign Affairs would then be expected to pay the transport costs. To the frustration, however, of the Minister of Health, Welfare and Sport, who was keen to help Suriname, the Netherlands did not pursue this opportunity. According to a civil servant at the Ministry of Health, Welfare and Sport, this was because the Minister for Foreign Trade and Development Cooperation wanted to adhere to the WHO's distribution plans and the agreement that 'distribution should be based on need and not on political preference'.

In late May 2021, the government decided to grant a new request it had received from Suriname, although the Minister for Foreign Trade and Development Cooperation criticised the decision to charge the transport costs to her department. The Netherlands planned to donate around 600,000 vaccines, mainly from AstraZeneca and for delivery in batches from the summer onwards. Following consultations, the Minister of Health, Welfare and Sport signed a donation agreement with Suriname in June. In this agreement, which was drawn up by the ministry's in-house lawyers in liaison with the State Advocate, all the relevant responsibilities of the Netherlands to the manufacturer were assigned to the receiving country. The Ministry of Health, Welfare and Sport did not ask AstraZeneca for permission because the Dutch lawyers did not consider this to be necessary under the terms of the contract, which referred to a need for 'notification', but not to a need for approval.

Suriname also requested a small number of doses of the Moderna vaccine for vaccinating pregnant women. In this case, by contrast, the Ministry of Health, Welfare and Sport was contractually required to request the manufacturer's permission. When Moderna initially failed to respond to the request, the ministry decided to push ahead, given that its lawyers viewed the risks as limited. The manufacturer later gave permission retrospectively. Other than these vaccines, the Netherlands ultimately donated a total of 228,000 doses of the AstraZeneca vaccine to Suriname. We were unable to establish why this total was so much lower than originally planned.

From summer 2021 onwards, more requests for donations were received, including requests from Indonesia, the Cape Verde islands and Namibia, and the Minister of

Health, Welfare and Sport was keen to oblige. Donations to these countries each required a separate agreement, thus creating considerable work for lawyers in the ministry's Legislation and Legal Affairs Department and the external lawyers. We also found regular mention of discussions with the Ministry of Foreign Affairs about charging the transport costs to that ministry.
The initial donations to Indonesia consisted mainly of Janssen vaccines as these were considered an attractive option in the circumstances: the fact that only one injection was needed meant that the vaccines could be used to protect twice as many people. However, quite some obstacles had to be overcome before this vaccine could be used, including the requirement for the Indonesian authorities to grant specific market authorisation. It was not until September 2021, therefore, that the first Janssen vaccine doses, together with some Moderna doses, could be sent to Indonesia. Although the Netherlands had originally undertaken to donate 3 million doses of the Pfizer vaccine, the shipment was postponed because the Netherlands needed these doses for its own booster campaign. This was also the reason why vaccine doses intended for Pakistan were held back by the Netherlands.

8.5 Donations via COVAX

The government had agreed that more vaccines should be donated via COVAX than bilaterally. This is also what happened in practice. The Netherlands donated over 6 million vaccine doses directly, whereas COVAX received over 16 million 'Dutch' vaccine doses for countries in need.

However, the donations made via COVAX often encountered problems along the way. At a certain point, the Dutch negotiating team described the practical and legal aspects involved in these donations as 'a real nightmare' and as causing problems both with pharmaceutical companies and with COVAX. Basically, a facilitating country was designated for each vaccine (the Netherlands was not one of these countries). Member states gave the facilitating member states a 'donation commitment'; in other words, an undertaking to donate a stated number of vaccine doses. The scheme was administered by the facilitating countries (Sweden, France and Belgium), which also signed the tripartite agreement with the manufacturer and the receiving country. Every Friday, member states were sent a vaccine schedule and asked whether they wanted to receive the specific vaccines, redistribute them within the EU or donate them. They could also keep track of donations on a 'dashboard'.

Just like when the basic contracts with the pharmaceutical companies were being drawn up, the Ministry of Health, Welfare and Sport's in-house lawyers were highly

critical of the tripartite agreements, which they considered to have been carelessly drafted. Although the Netherlands was not party to these agreements, the lawyers were concerned that this meant that the country would not be covered by the contractual safeguards applying to donations via COVAX. Would the Netherlands, for example, be able to be held liable in the event of side effects? The lawyers consequently believed the contracts should be amended, but the vaccine team was not willing to go down that route. On the contrary, its aim was to prioritise speed and pragmatism over a 'legally totally air-tight' contract. Apart from the fact that eliminating all the risks from a legal perspective would have consumed a lot of valuable time, it also did not really seem to be possible; according to the chief negotiator, none of the other member states were concerned about this, and it simply was not feasible to amend the agreements specifically to suit the Netherlands.

This difference of opinion caused a sharp rise in tensions at the Ministry of Health, Welfare and Sport in October 2021, when the donation agreements with AstraZeneca and Pfizer were waiting to be signed. The in-house lawyers gave a negative opinion on these agreements. Like his senior civil servants, however, the minister regarded getting an agreement in place for these donations to be more important than eliminating every possible risk in 'legal belts and braces'. A comparable in-house meeting was held a month later to discuss donating Janssen and Moderna vaccines, with precisely the same result. Our audit found no indications that the risks that the in-house lawyers had warned about actually materialised, at least not in the period we investigated.

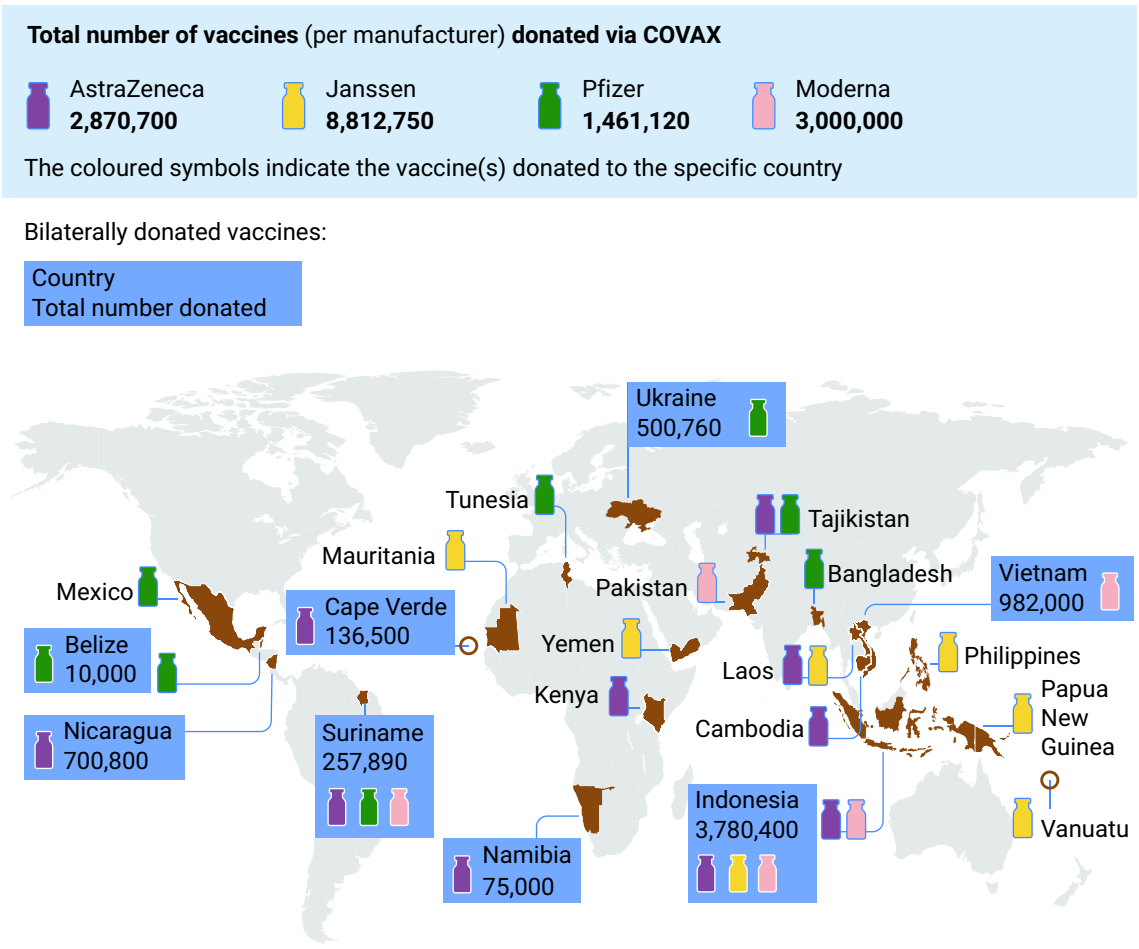
By late 2021, other obstacles had arisen in addition to the lawyers' discussions about donations. These included COVAX's refusal to accept millions of vaccines donated by the EU, claiming that the receiving countries had too few resources available to administer the vaccinations. By 26 November 2021 it turned out that only 45 million of the 70 million doses promised by the EU had been distributed. One explanation given was that vulnerable countries were hesitant to accept certain vaccines, particularly AstraZeneca. Although the limited shelf-life was sometimes given as a reason, much of this hesitancy was suspected to relate to the reputation that the AstraZeneca vaccine had acquired. Indeed, by then, Europe was hardly using this vaccine at all and it looked like considerable numbers of AstraZeneca doses donated to COVAX would end up being destroyed.

Despite these practical difficulties, the government continued to regard donating vaccines as an important objective, such that at the end of the year the Minister of

Health, Welfare and Sport was using 'Get one, give one' as a rule of thumb; in other words, each dose in the Netherlands should be matched by a dose for a vulnerable country (Ministry of Health, Welfare and Sport, 2021). This rule of thumb seemed to be working out well in late 2021 in terms of the numbers of vaccine doses promised to be provided. As mentioned above, however, millions of donations to Indonesia and Pakistan had been postponed because the Netherlands itself needed them for its own booster campaign. If we look at the total numbers of vaccines actually supplied as at 1 January 2023 (see figure 11 on page 65), we can also see that the Netherlands used more vaccines for itself than it donated.

Figure 12 *Overview of vaccine donations by the Netherlands*

The Netherlands donated 16,1 million vaccines via COVAX and 6,4 million bilaterally



Ultimately, Dutch donations of vaccines, whether via COVAX or bilaterally, ended up in 21 countries, ranging from Tajikistan to Mexico. As mentioned earlier, the Netherlands had drawn specific attention to the needs of the African continent at an early stage of the pandemic. In practice, we can see that the net result was that Netherlands donated vaccines to 5 African countries: bilaterally to the Cape Verde islands and Namibia, and via COVAX to Kenya, Mauritania and Tunisia (see figure 12).

8.6 Looking back

Although its own population was the priority, the Netherlands continued to view help to vulnerable countries as an important objective, both for reasons of solidarity and enlightened self-interest. To achieve that objective, the contracts should in principle have allowed more scope for sharing intellectual property rights on vaccines. However, the negotiations with most of the vaccine manufacturers soon showed that this subject was simply not open to discussion. On top of that, a Dutch attempt to immediately procure extra doses of the Janssen vaccine for Africa failed to take off. After extensive discussions in the Netherlands and the EU, the help ultimately provided to vulnerable countries by the Netherlands largely comprised the 23 million surplus vaccine doses donated bilaterally, but also and primarily through COVAX, an organisation with which the European Union had a somewhat difficult relationship. When procuring vaccines, the Netherlands took some account of the wish to donate to vulnerable countries, but in the end only donated the vaccines that we did not need ourselves.

9. Conclusions and recommendations

The Minister of Health, Welfare and Sport's approach to procuring corona vaccines can be viewed as reasonable to good and made a significant contribution, within the European collaboration arrangements, to securing a diversified package of safe and effective vaccines as quickly as possible. In doing so, the Netherlands was mindful of the needs of vulnerable countries, but its efforts in this respect had only limited success.

Reasonably good approach, but lack of knowledge of pharmaceutical industry
The Netherlands had not been sufficiently prepared to incentivise the development and procure stocks of effective vaccines in a pandemic. Under great pressure, however, it found a way of doing this. Its primary objective was to ensure the availability of sufficient numbers of safe and effective vaccines as quickly as possible. That remained its most important objective, despite some changes in focus over time. Against the background of the crisis, we believe that the Ministry of Health, Welfare and Sport's performance can be viewed as reasonable to good. The ministry brought in the necessary expertise from outside, while itself remaining in overall charge. We note, however, that the ministry lacked in-depth knowledge of the vaccine chain, and specifically the process from development to supply. Similarly, it paid insufficient attention to the need to avoid conflicts of interest or the semblance of any such conflicts.

Important role for the Netherlands; no significant loss or damage attributable to carelessness
The Netherlands was mindful of the opportunities for entering into alliances with like-minded EU member states. Indeed, it played a leading role in the joint European

negotiations, even though the voices of the larger countries often carried decisive weight. We regularly found sloppiness and a lack of accuracy in the Ministry of Health, Welfare and Sport's work on contracts with pharmaceutical companies, including in the legal advice for which the in-house lawyers reported having too little time and scope to deal with properly. However, we found no indications that these problems damaged Dutch public interests to any fundamental degree, although we believe that some of the problems arising later with regard to vaccine donations were partly attributable to the lack of clear agreements on this aspect in the initial contracts. These initial contracts were in the form of 'all-inclusive' agreements, with the pharmaceutical company being responsible for the entire chain, from production to supply. The disadvantage of this was that the Netherlands and the EU had little control of the various elements within the chain.

Active in European negotiations and arguing for a diversified package of vaccines

By being actively involved in the IVA the Netherlands helped to accelerate negotiations at a European level. The Netherlands made a strong case for the Janssen vaccine, both for epidemiological and economic reasons, and also spoke out strongly – along with other countries – in favour of procuring a diversified portfolio of vaccines so as to spread various risks. The Netherlands fought to ensure a place for itself in the small group of member states conducting the negotiations on behalf of the EU and was an active member of this group. It also acted as an intermediary to resolve differences of opinion on strategy and budgets among member states. Although protecting its own population remained its top priority, the Netherlands made a case for providing help to vulnerable countries at various moments in the early stages. Over time, this help took the form of donations of surplus vaccine doses.

While contracts did not help vulnerable countries, they provided guarantees of safety and verifiability

Our analysis of the 11 contracts found that they did not eliminate obstacles to providing help to vulnerable countries, even though worldwide infections meant that this was also in the European public interest. In the negotiations, the vaccine manufacturers successfully managed to oppose any requirement to share intellectual property rights. On the other hand, the contracts included good provisions on ensuring vaccine safety and opportunities to verify agreements. Generally, the contracts did not improve over time and neither was there any increase in the totality of safeguards protecting public interests. While we found the arrangements on production and supply certainty to have improved over time, we also saw that the vaccines became more and more expensive.

If equal weight is assigned to all the public interests analysed, we view the contract with AstraZeneca as the best. If, however, we take account of the priority of getting sufficient numbers of safe and effective vaccines as quickly as possible, the best contracts were the contract with Novavax and the large third contract with Pfizer, even though the manner in which the latter contract was established was found to be lacking in transparency. Ultimately the Netherlands purchased close to 102 million vaccine doses for a total of just under €1.8 billion. Of these doses, 23 million were subsequently donated to vulnerable countries.

Although vaccine procurement can be regarded as having been reasonable to good, we reiterate the concerns expressed in our earlier audit (see, for example, Netherlands Court of Audit, 2023) regarding the speed of sorting out the Ministry of Health, Welfare and Sport's overall financial management (including the procurement function). Being better prepared for procurement in a crisis (including, for example, making provision for legal advice to be given under great time pressure) will strengthen the procurement function. It will also reduce the chances of major procurement-related errors in a new crisis, even though such errors were admittedly not made in the vaccine procurement process during this pandemic.

Based on our audit, our recommendations for the Minister of Health, Welfare and Sport are as follows:

- Although the approach ultimately chosen in this case, without any preparations, can be regarded as reasonable to good, it is important to consider a series of scenarios so as to ensure that, next time, the country is better prepared for the main types of major, cross-border health emergencies that could arise. These emergencies are explicitly not limited to outbreaks of infectious diseases; they could also involve other emergencies with a potentially major impact on the healthcare system;
- Take steps to ensure greater in-house expertise so that the country is better prepared for a variety of crises with healthcare implications. This should at least include expertise on the pharmaceutical industry, and particularly the development, manufacturing and supply of medicines and vaccines;
- Examine legal advice critically when entering into obligations under pressure and ensure that the expectations of all parties to agreements are both clear and realistic. Lawyers (whether in-house or external) should be given reasonable time in which to form their opinions. On the other hand, lawyers also need to understand that the dynamics of a crisis may require them to work differently than in normal circumstances;

- Keep a closer eye on the need to avoid conflicts of interest or the semblance of any such conflicts, certainly in negotiations where major interests are at stake;
- Actively support international initiatives to facilitate worldwide access to vaccines, also outside times of crisis.

10. Minister's response and Netherlands Court of Audit's afterword

Minister’s response and Netherlands Court of Audit’s afterword
The Minister for Medical Care responded to our draft report on 1 March 2024. Her response is summarised below and can be found in full at www.rekenkamer.nl. This chapter ends with an afterword.

10.1 Minister for Medical Care's administrative response

The minister noted the report with interest and thanks the Court of Audit for its thorough audit. The minister appreciates being provided with a clear and conscientiously prepared reconstruction of the events leading up to the Ministry of Health, Welfare and Sport’s procurement of corona vaccines, along with the negotiations and the results achieved. Based on this reconstruction, the minister endorses the report’s main conclusions. In view of the unprecedented situation we faced at the outbreak of the pandemic, the minister is pleased to note the predominantly positive assessment of how the ministry handled vaccine procurement. Indeed, the conclusions reflect the unwavering commitment and dedication demonstrated, under great pressure, by all the civil servants working to ensure that safe and effective vaccines became rapidly available. The minister recognises the importance of acting on the audit’s recommendations to ensure that the Netherlands is in future better prepared to deal with cross-border health emergencies.

The recommendation to devise a series of scenarios so as to ensure that, next time, the country is better prepared for the main types of major cross-border health

emergencies aligns with the earlier recommendations by the Dutch Safety Board. These recommendations are one reason why the National Institute of Public Health and Environmental Protection has been instructed to consider scenarios for dealing with possible outbreaks of infectious diseases and pandemics in the future. Among other things, these scenarios will be incorporated into a National Crisis Plan for Infectious Diseases (LCP-I). The Ministry of Health, Welfare and Sport is also contributing to the national crisis plans being prepared by other ministries for dealing with emergencies that could potentially put considerable pressure on the healthcare system. These plans will be periodically tested in practice and assessed.

The minister is alert to the need for the ministry's internal organisation to be equipped to respond to emergencies of this nature. One of the ways in which the minister will act on the recommendation to ensure greater in-house expertise so that the country is better prepared for various types of crises with healthcare implications is by creating a new department for Policy on Infectious Diseases in mid-2024. This department will be tasked with safeguarding the knowledge and experience gained during the COVID-19 pandemic and ensuring it remains available. Expertise on the pharmaceutical industry is additionally available through the day-to-day work of the National Institute of Public Health and Environmental Protection and the Pharmaceuticals and Medical Technology (GMT) department.

When determining in-house activities, the minister is alert to the need for legal advice (and creating additional capacity for this) and for ensuring procurement regularity, including when entering into commitments under high time pressure. The minister thus envisages acting on the recommendation to clarify parties' expectations regarding legal advice. In line with the fourth recommendation, the minister appreciates the importance of avoiding conflicts of interest or the semblance of any such conflicts in times of crisis, particularly in negotiations when major interests are at stake. In future, therefore, a conflict check will be performed beforehand in order to ensure a clear mandate for any staff recruited to handle such crises.

Lastly, the minister takes very much to heart the recommendation to actively support international initiatives facilitating worldwide access to vaccines, including outside times of crisis. The Dutch government's Global Health Strategy 2023-2030 aims to contribute at various levels to improving public health around the world. One of the priorities of this strategy is to improve international pandemic preparedness and minimise cross-border health threats. The government is therefore working to boost access to medicines and vaccines, particularly in low and middle-income countries.

Meanwhile, the Netherlands and its European partners are playing a prominent role in the global pandemic treaty being negotiated through the World Health Organization. In addition, the European Union has set up the Health Emergency Preparedness and Response Authority (HERA) to reinforce Europe's pandemic preparedness and with a specific focus on ensuring the availability of and access to medical countermeasures, such as vaccines, in Europe.

10.2 Court of Audit's afterword

We welcome the minister's endorsement of our audit conclusions and the undertaking to act on all our recommendations. Our comments on the minister's specific undertakings regarding the recommendations are set out below.

It is good that the minister is taking steps to improve the country's future ability to deal with infectious diseases and pandemics and their potential consequences for the healthcare system. We look forward to being informed of the scenarios devised by the National Institute of Public Health and Environmental Protection. In view of the experience gained during the corona pandemic we understand the emphasis being placed on infectious diseases, and consequently the National Crisis Plan for Infectious Diseases. However, we would call on the minister to adopt a broad-ranging view, given that other types of emergencies could potentially put equal or even greater pressure on the healthcare system. Here, too, detailing scenarios under the minister's responsibility, as well as contributing to the crisis plans being prepared by other ministries, could prove useful.

The minister takes very much to heart the recommendation to actively support international initiatives facilitating worldwide access to vaccines. However, such initiatives can conflict with the procuring of vaccines to protect the country's own population, as we outline in our report. Continuing to highlight tensions of this nature and the choices made would result in more transparent policy.

In her response the minister makes no reference to the passage in the report discussing the obstacles faced by the Court of Audit in seeking access to information from the Ministry of Health, Welfare and Sport for this audit. We reiterate that it is vital to ensure compliance with the provisions of the Government Accounts Act 2016 regarding access to information considered relevant if the Court of Audit is to perform its statutory task. After all, independent audits are an essential part of any well-functioning democracy governed by the rule of law.

Appendices

Appendix 1 Accounting for our methods

The Netherlands Court of Audit performed an audit of the Netherlands' procurement of corona vaccines in 2020-2021. This appendix outlines how we conducted this audit.

Developing sets of norms

In order to form an opinion on the answers to the audit questions (see § 2.2) we drew up various sets of norms for the vaccine procurement process and the results that the procurement contracts sought to achieve. These comprised a set of primary norms, broken down into various sub-norms (see Appendix 2).

The primary norms were compiled in 5 stages:

1. Studies of scientific literature and policy documents. These provided an initial impression of norms that could be of relevance.
2. Interviews and expert meetings. This information was used to supplement the results in 1. from various angles and perspectives.
3. We then used this information to prepare a set of norms for the process and the results.
4. These norms were then discussed at a second expert meeting.
5. The adjusted sets of norms were then sent to the Ministry of Health, Welfare and Sport for comment. The ministry accepted these norms, although pointed out that some policy objectives – some of which had been translated into norms – were more important than others when procuring vaccines. We took this into account in both our audit and our assessment.

Auditing the process

We analysed the process leading up to the procurement of vaccines by conducting a historical audit (referred to as 'process tracing' in the field of social sciences). That meant setting out a detailed timeline, based on thousands of documents. Using the source texts, we could then establish which events of relevance to our audit happened on which day and who was responsible for what.

The timelines were viewed at 3 different levels (the Netherlands, the European Union and the world), both alongside each other and as a whole. When gathering information to audit the process, our focus was on 3 companies:

1. AstraZeneca (because this was the first contract, and the Netherlands was involved in the negotiations as a member of the IVA);
2. Janssen (because of the Netherlands' special interest in this company);
3. Pfizer (because the Netherlands bought its highest volumes of vaccines from Pfizer, but seemed to have been less involved in the negotiations).

Our audits of the negotiations with other pharmaceutical companies concentrated more on the general outlines.

Based on the timelines we were able to compile a detailed reconstruction of events in chronological order. This served as the basis for examining which causal links should be considered most plausible, taking due account of all our sources. This question also played an important role in our many interviews with people involved in procuring vaccines, both in the Netherlands and abroad. We put our preliminary findings to the people being interviewed and asked whether they could explain them. Where necessary, we explicitly discussed causality in more depth.

This was also how we set out to determine the extent of the Netherlands' influence on the results ultimately achieved. We used information gained from our interviews with foreign officials closely involved in the negotiations to verify and, where necessary, supplement our preliminary findings on the Netherlands' influence.

We used these analyses as the basis for establishing the extent to which the norms we had set for the process were met (see Appendix 2).

Auditing the results

Arriving at our results involved analysing the entire texts of the 11 vaccine procurement contracts that the European Commission signed with the pharmaceutical companies on behalf of the member states. This was done using the Atlas.ti program that enables researchers to systematically analyse texts. We first translated all the sub-norms into 'codes' in Atlas.ti and then used Atlas to determine

whether specific contractual provisions met the sub-norm. We also used an extra code to indicate noteworthy aspects not directly relating to the norms. The codebook consisted of a total of 54 codes. These codes are available upon request.

Every contract was then codified in Atlas.ti in several rounds, each time by several team members. All issues that were still open and any cases on which doubts had arisen were then discussed by the team members until a consensus was reached. Team meetings were also held to identify similarities and differences between contracts, including over time. In these meetings we then determined whether the total of the sub-norms for the primary norm resulted in the aspect being qualified as meeting the norm, largely meeting the norm, partly meeting the norm, largely not meeting the norm or not meeting the norm.

These resulted in scores (assessments) for each contract (see Appendix 2). We then analysed the outcomes, with an analysis for each contract separately, for all the contracts together and for each individual norm. We used the process reconstruction (see above) to account for any outcomes or developments that stood out for any reason. We also notified the outcomes to those involved so as to refine our analysis.

Appendix 2 Norm testing

This appendix lists the norms used in the audit and how we weighed each norm, as well as providing a brief explanation. This explanation had to be kept limited because the contracts are confidential and were established on a confidential basis.

A. Results

Table 1 *Findings for primary norms, in order of the contract signing date (meeting norm = 4, largely meeting norm = 3, partly meeting norm = 2, largely not meeting norm = 1 and not meeting norm = 0)*

	NORM APA	Ensuring vaccine safety	Verifiable agreements	Efficient production	Supply certainty	Clear liability	Guaranteed production	Spending public money economically	Transparent pricing structure	Shared knowledge and technology	Access for vulnerable countries	Consequences of differing efficacy	TOTAL
1	AZ	4	4	4	1	3	0	4	3	2	1	0	26
2	Sanofi	4	4	4	2	3	2	2	0	0	1	0	22
3	Janssen	4	4	4	2	3	2	2	2	0	0	0	23
4	Pfizer 1	4	4	4	3	3	2	2	0	0	0	0	22
5	Curevac	4	4	2	3	3	0	1	1	0	0	0	18
6	Moderna 1	4	4	4	2	3	2	1	1	0	0	0	21
7	Pfizer 2	4	4	4	2	3	2	2	0	0	0	0	21
8	Moderna 2	4	4	2	2	3	2	1	0	0	0	0	18
9	Pfizer 3	4	4	4	4	3	4	2	0	0	0	0	25
10	Novavax	4	4	4	4	3	4	1	1	0	0	0	25
11	Valneva	4	4	4	3	3	2	1	1	0	0	0	22

The above table shows our findings for the primary norms on the x-axis. The y-axis shows the contracts in order of the signing-date (from the first contract with AstraZeneca to the final contract with Valneva). In the case of Pfizer 2, Moderna 2 and Pfizer 3 the contracts were supplementary contracts for new orders of vaccines. The higher the score, the more the contract was considered to meet our primary norm. The various primary norms are shown on the x-axis in order of scores, with the highest-scoring norm on the left and the lowest on the right.

This analysis treats all the public interests as being of equal importance. We made this choice in order to make it easier to obtain an overview and to ensure that we arrived at our findings solely by testing the facts against the norms. In this weighting, therefore, provisions designed to guarantee vaccine safety were regarded as equally important as spending public money economically. As the report shows, however, not every public interest was equally important in the context of the pandemic. From the outset, both the Netherlands and the EU clearly prioritised certain public interests over others when procuring vaccines. These priorities also changed during the procurement process, as mentioned on various occasions in the report.

Safeguards for ensuring vaccine safety

The primary question regarding guarantees of safety is whether the EMA procedures (in their accelerated form or otherwise) were applied as a condition determining whether the vaccines would be admitted to the European market. This specifically does not mean that we assessed whether the vaccines were safe, but rather whether the contracts included provisions on guaranteeing safety. Member states wanted to procure sufficient numbers of vaccines as quickly as possible, but safety was nevertheless viewed as an essential pre-condition. By the time the later contracts were signed, EMA had already approved the vaccines. For comparative purposes, these vaccines, too, were scored as 'meeting the norm'.

Verifiable agreements

Agreements are regarded as verifiable if the contractual agreements show that the European Commission or EU member states ('the buyers') are allowed and able to verify and audit the sellers' production processes and quality controls in order, for example, to verify compliance with agreements. Another aspect is whether the pricing structures in the contract are verifiable. We found all the contracts to contain legal obligations and provisions of this nature.

Efficient production

Our expectation was that, during a pandemic, vaccines would be produced as efficiently as possible. We used 2 sub-norms to assess this:

- use of as many of the available facilities and as much of the available capacity as possible;
- production within the EU wherever possible.

Our analysis found that most of the contracts complied with both these sub-norms.

Supply certainty

We took supply certainty to mean guarantees not only that vaccines would be produced, but also that they would be delivered. This norm comprised 4 sub-norms:

- enforceable delivery schedules in the contract;
- specified periods during which the seller has to report any such problems;
- clear financial consequences in the event of failure to comply with delivery schedules;
- priority for supplies to the EU.

Only the later Pfizer 3 and Novavax contracts fully met this norm.

Clear liability

We expected the contracts to make clear provision for liability in the event of any side effects and for the member states to indemnify the sellers as little as possible. This norm, too, comprised a series of sub-norms:

- The contracts clearly specify the circumstances in which government authorities would indemnify the seller for the financial consequences of any liability;
- The contracts state the maximum amount for which government authorities would indemnify the seller for the financial consequences of liability;
- The contracts comply with existing EU legislation and regulations on product liability.

The contracts were largely uniform with regard to liability. All the contracts adhered to EU regulations, despite certain aspects being subject to discussion. None of the contracts state the maximum amount for which government authorities would indemnify the seller for the financial consequences of any liability.

Guaranteed production

Our expectation was that, during a pandemic, vaccine production would be guaranteed as much as possible. We assessed this in 2 ways:

- clear agreements on what would happen in the event of production delays or other production problems;
- clear financial consequences of such problems.
- The later contracts (Novavax and Pfizer 3) met these norms, whereas 2 earlier contracts (AstraZeneca and CureVac) did not.

Spending public money economically

The lower the price, the better the public interest is served. On this occasion, however, we also considered other aspects of ‘spending public money economically’

- Public money made available for vaccine research, technology and/or production is partly repaid in the form of a discount on the price per dose;
- The price reflects the cost price and also provides a 'reasonable' profit margin for the seller in the form of a maximum profit percentage (bandwidth: 4 – 7.5%);
- The ultimate price is based on a realistic cost price, with the maximum nominal profit in line with what was agreed at the time of procurement;
- If the vaccine does not receive EMA authorisation, the manufacturer will repay any public money not yet spent.

Only the first contract, with AstraZeneca, fully met this norm.

Transparent pricing structure

Contracts or underlying documents should show how the price per dose is calculated. Our analysis found that none of the contracts fully met this norm, despite differences in the extent to which contracts made this information available.

Knowledge and technology must be able to be shared

During a pandemic, knowledge and technology partly developed with the use of public money must be able to be shared. This norm comprised 2 sub-norms:

- in principle, knowledge accrued with public money must remain available for the public (or EU public);
- intellectual property funded by public money should be transferred, at least partially, to EU member states or the European Commission if the seller decides to stop developing the vaccine.

Almost none of the contracts lived up to this expectation. As we discuss in the report, only AstraZeneca did so, and then only partly.

Access for vulnerable countries

Given that the pandemic affected the whole world, our expectation was that vulnerable countries' access to vaccines should face as few obstacles as possible and should be promoted, wherever necessary. We defined 3 sub-norms for this:

- Agreements on intellectual property in the contracts should not obstruct the spread of technology (or production based on this technology) outside the EU;
- Sharing of vaccine technology and other intellectual property with the WHO;
- EU member states can donate vaccines they procure (whether surplus or otherwise) to vulnerable countries without having to comply with additional requirements.

The contracts with AstraZeneca and Sanofi met one of these sub-norms, whereas none of the others met them at all.

Consequences of differing efficacy

Our expectation beforehand was that the contracts would include a mechanism for dealing with the consequences of a vaccine's efficacy or the duration of the efficacy turning out to be different from what had been promised. This could mean a fine or a reward if the vaccine worked worse or better, respectively, than promised. We did not find any of the contracts to contain such a provision. Ultimately all the authorised vaccines proved to have relatively high efficacy in comparison, for example, with the annual flu jab. However, we note that the vaccines with the highest efficacy became more expensive in later contacts. At the level of the overall vaccine package, therefore, having greater efficacy than expected would seem to have had consequences.

Portfolio norms

As well as assessing norms at a contract level, we assessed 3 norms at a portfolio level: all of these norms are public interests that should be served by the package as a whole.

1. *The agreed numbers of vaccines doses for 2020 and 2021 are enough for sufficient protection of the EU population against serious illness.* The aspects that we considered in this respect were obviously the numbers of doses procured and considered sufficient to combat the virus. The numbers – close to 2.4 billion doses (and options for a further 2.2 billion or more) – were more than sufficient to combat infections in Europe. However, the spread of doses across manufacturers and technologies also had to be considered as this made it easier to spread the risks of efficacy and supply. At a portfolio level, the contracts reflected this spread, although in 2021 the balance ultimately skewed towards Pfizer and its mRNA technology. That, however, was a direct result of the strategy: this vaccine proved to be highly effective and able to be supplied in large numbers, with the result that extra orders for it were placed.
2. *The procured vaccines can be used to vaccinate the population within and outside the EU as quickly as possible.* At a portfolio level we indeed saw that the initial contracts were signed with the manufacturers expected at that time to be able to deliver the fastest. However, these expectations did not always prove justified. The contract with Sanofi, for example, was signed in September 2020, but this vaccine later became seriously delayed. Other vaccines, too, experienced delivery problems.
3. *Account is taken of changing risks and uncertainties.* The most obvious development that we observed in the portfolio over time was the increase in production and supply certainty. At the same time, however, vaccine prices also increased. Later contracts also made provision for adapting vaccines to new variants.

Reassessment

If all the public interests are assigned an equal weight (as in Table 1), the contract with AstraZeneca was found to provide most protection of public interests. However, the assessment is different if account is taken of the policy objective to ensure the availability of sufficient numbers of safe and effective vaccines as quickly as possible. That would mean assigning greater weight to the norms for guaranteeing safety, production and supply certainty, and for contributing to our 'portfolio norm' for numbers of vaccine doses. In that case, the contract with Novavax and the third contract with Pfizer score the best. The table below shows the effect that prioritising norms in this way has on the various contracts. The weighting for the portfolio norm relating to numbers of doses, which is also relevant in this respect, is not included in the table. The most important aspect for this priority is the norm relating to numbers. In terms of volumes, the Pfizer 3 contract is the most important, but Novavax also scores well because of adding to the desired range of different technologies.

Table 2 *Findings for prioritised norms, in order of contract signing date*

NORM APA		1. Ensuring vaccine safety	8. Supply certainty	6. Guaranteed production	TOTAL
1	AZ	4	1	0	5
2	Sanofi	4	2	2	8
3	Janssen	4	2	2	8
4	Pfizer 1	4	3	2	9
5	Curevac	4	3	0	7
6	Moderna 1	4	2	2	8
7	Pfizer 2	4	2	2	8
8	Moderna 2	4	2	2	8
9	Pfizer 3	4	4	4	12
10	Novavax	4	4	4	12
11	Valneva	4	3	2	9

B. Process

Based on our reconstruction of corona vaccine procurement, we assessed the extent to which the Minister of Health, Welfare and Sport met the norms that had been set beforehand. Although the norms reflect an ideal situation, they also take into account that the world was facing an acute crisis. Here, too, we set 5 scores for each sub-norm: not met, met to some extent, partly met, largely met and met. Table 3 shows the primary norms divided into sub-norms and their weightings, with a brief explanation.

Given the circumstances and taking the process as a whole, our overall conclusion is that the minister's handling of vaccine procurement was reasonable to good.

Table 3 *Assessment of the Minister of Health, Welfare and Sport's performance in corona vaccine procurement*

Process norms	Sub-norms	Weighting	Explanation of finding
The Ministry of Health, Welfare and Sport was prepared before starting the corona vaccine procurement negotiations.	Before the outbreak, the ministry had an up-to-date plan for dealing with a crisis (a pandemic), including details of procedures for procuring medical equipment and/or vaccines, and details of the relevant parties. The ministry used this plan.	Not met	When COVID-19 broke out, the ministry did not have a plan in place for dealing with the crisis and stating how the Netherlands would obtain sufficient numbers of vaccines to protect the population in the event of a pandemic.
	Both before and during the negotiations, the ministry obtained the technical, substantive and financial knowledge and experience of developing and manufacturing COVID-19 vaccines needed for a sufficient understanding of the details of the negotiations.	Largely met	We saw that, from April 2020 onwards, the Ministry of Health, Welfare and Sport obtained information from wide-ranging sources so that it could prepare to invest in developing, producing and procuring vaccines. Some of these sources continued to be consulted during the negotiations, while others were replaced. The negotiators themselves had knowledge and experience of international negotiations. The existence of specific knowledge of the pharmaceutical industry's production and supply chains is less evident.
	Both before and during the negotiations, the Ministry of Health, Welfare and Sport invested in building up a network of political and societal contacts in the Netherlands (including with other ministries, NGOs and the pharmaceutical sector) and abroad (such as other EU member states and institutions).	Largely met	The vaccine team contacted other ministries, such as Foreign Affairs, Foreign Trade and Development Cooperation, and Finance, as well as pharmaceutical companies and other EU member states. We found no evidence of in-depth contacts with NGOs in this area.

Process norms	Sub-norms	Weighting	Explanation of finding
	The Netherlands was aware of parties with similar interests and ambitions and was able to enter into alliances both before and during negotiations.	Met	The Ministry of Health, Welfare and Sport was almost permanently looking for allies, firstly in the IVA and later as a member of the JNT. The most obvious alliances during the negotiations were informal, with countries such as Germany, France, Sweden and Spain, but also with the European Commission.
The Ministry of Health, Welfare and Sport had set a negotiating strategy before negotiations for procuring corona vaccines started.	The strategy included political objectives and priorities for protecting Dutch public interests and set out an approach (policy instructions, for example) for achieving these objectives.	Largely met	The Ministry of Health, Welfare and Sport set objectives and priorities. The primary focus was on obtaining sufficient numbers of effective and safe vaccines as quickly as possible; This was a dynamic process; not surprisingly, other objectives changed in response to circumstances. Details of the opportunities for trade-offs and how to deal with options other than through the European Commission were less clearly recorded.
	The strategy is up-to-date; the ministry applies the strategy in line with changing circumstances, vaccine candidates and lessons learned from previous negotiations.	Met	See above: objectives and priorities were adapted to suit the circumstances. Initially, for example, the Netherlands consciously bought everything it could. Later, however, it became more selective.
	When determining its strategy, the ministry consulted various political, societal and private parties with expertise in vaccines (and at least expertise in legal, medical, technical, epidemiological and economic matters).	Largely met	The ministry's action plan and investment strategy were built on legal, medical, epidemiological and economic knowledge and expertise. The existence of knowledge about the technical side of production and supply processes in the pharmaceutical industry was less evident.
	Voor het formuleren van de strategie heeft het ministerie in kaart gebracht wat Nederland in de onderhandeling wel en niet 'te bieden' heeft (om de onder-handelingen in Brussel te kunnen voeren).	Met	The Netherlands was aware of its position as a country with pharmaceutical knowledge and production facilities, not least because of its contacts with Janssen. From a perspective of efficiency and value for money, it was also aware that money played little if any role because the costs of the vaccines were outweighed by the costs of the lockdown.

Process norms	Sub-norms	Weighting	Explanation of finding
	When determining its strategy, the ministry ascertained the common interests of the EU, the Netherlands and the pharmaceutical companies in the negotiations.	Met	When setting its investment strategy, the Ministry of Health, Welfare and Sport explored progress at the vaccine developers, on the one hand, and opportunities for cooperating with other EU member states, on the other hand.
	When determining its strategy, the ministry identified the existing uncertainties, risks and missing information at the time and put measures in place to deal with these aspects, wherever possible.	Largely met	Because it was unclear for a long time which vaccines would work and be reliable, the Netherlands consciously aimed for a diversified package of vaccines, primarily as a means of spreading the risks. At first, the Netherlands bought every vaccine that became available. It later also took account of the need for boosters. The Netherlands and the European Commission covered risks by signing 'all-inclusive' contracts with pharmaceutical companies. The advantage of these contracts was that they transferred the risks to the contracted companies. The disadvantage, however, was that government parties had little control of the individual elements in the process if companies did not keep their promises. In these situations, the potential control measures did not always prove effective.
	The ministry sought support for its negotiating strategy at least within its own ministry and from other ministries.	Largely met	The Ministry of Health, Welfare and Sport's DG Public Health was in charge of the vaccine procurement project. The DG Public Health was also in charge of putting together the vaccine team and seeking support for the strategy from other parts of the ministry. Our audit found complaints about a lack of commitment. Outside the ministry, the main contacts with other ministries were with Finance, Foreign Affairs and Foreign Trade and Development Cooperation. In practice we saw signs of friction between the Ministry of Health, Welfare and Sport's strategy and the strategy of the other two ministries.

Process norms	Sub-norms	Weighting	Explanation of finding
	When communicating the strategy in Brussels, the ministry ensured 'unanimity' on the part of the Netherlands (i.e. the strategy was agreed with other ministries and the government).	Partly met	The documents provided by the ministry contained only limited information on contacts between the various Dutch ministers. We saw, for example, that the Minister of Health, Welfare and Sport occasionally sought agreement with colleagues at the Ministry of Finance or Ministry for Foreign Trade and Development Cooperation. We also found evidence of friction between the Minister of Health, Welfare and Sport and the Minister for Foreign Trade and Development Cooperation regarding providing help to vulnerable countries. The Ministry of Health, Welfare and Sport tried to relieve these tensions. Sometimes these efforts were successful, but sometimes they were not.
The Ministry of Health, Welfare and Sport met the conditions for being able to influence the European negotiations on procuring corona vaccines in a manner enabling it to achieve its objectives.	The ministry identified the aspects in the negotiations that it could influence, as well as when and how. These were translated into operational agreements and mandates specifying who would take action and when. The ministry then implemented these agreements.	Partly met	The static situation in the norm (i.e. with mandates and operational agreements to be implemented) did not align with what proved to be the reality. That was simply not possible in the crisis and probably also not desirable. The many uncertainties associated for so long with the pandemic primarily demanded flexibility and perseverance. The ministry kept its most important contacts advised in a WhatsApp group; this was the approach most suited to the crisis. We noted, however, that the ministry did not focus much attention on recording details of agreements.
	The ministry focused as soon and as proactively as possible on achieving its negotiating strategy.	Met	From April 2020 onwards, the ministry was focused on obtaining effective vaccines without delay. This approach can be regarded as proactive because, unlike many other member states, the Netherlands chose not to wait for the European Commission to take the initiative. Instead it consciously took action to enable vaccine procurement.

Process norms	Sub-norms	Weighting	Explanation of finding
	Both the ministry and the Dutch representatives in Brussels continually gathered information on their negotiating partners' positions, responsibilities and interests, as well as on the status of the negotiations and the action to be taken. The ministry and representatives incorporated this information into their strategy and amended the strategy accordingly.	Met	As the negotiations were dynamic, few parties could be completely up-to-date with negotiating partners' positions, responsibilities and interests, the status of the process and action to be taken. Compared with various other member states, however, the Netherlands was well up-to-date with the negotiations (partly thanks to being a member of the JNT). The information gathered played a role in all the action the Netherlands took in seeking to achieve its objectives.
	During the negotiations, the ministry actively sought to find like-minded member states to increase the chances of achieving its own objectives.	Met	The Netherlands looked for allies both before and during the negotiations, including, for example, when the IVA was being set up. We also saw how the Netherlands sought to build relationships within the JNT, particularly with Germany, France. Sweden, Spain and the European Commission. Non-Dutch parties regarded the Netherlands as part of a 'coalition of the willing'.
The team leading the negotiations on corona vaccine procurement on behalf of the Netherlands had sufficient capacity, experience, expertise and knowledge.	The ministry had people with the necessary knowledge, experience and skills – or was able to find and deploy such people – to conduct the negotiations with the pharmaceutical companies. Sufficient FTE and budgets were available.	Partly met	The Netherlands gathered together the knowledge, experience and skills needed to conduct the negotiations. However, we also identified certain problems, specifically a lack of specialised knowledge on the pharmaceutical industry and the fact that obtaining legal advice did not always proceed smoothly. One of the negotiators commented that the support provided in the crucial summer months of 2020 was limited.

Process norms	Sub-norms	Weighting	Explanation of finding
	Those involved in the negotiations (i.e. the negotiating team itself and the support staff provided to this team) had at least knowledge and experience of European procurement and negotiations and the pharmaceutical industry.	Partly met	This was the first time that the European Commission had been involved in procuring vaccines on behalf of and for the member states. It consequently could not have had experience of this. In the Netherlands, vaccine procurement is normally the responsibility of the National Institute of Public Health and Environmental Protection, which was well represented in the vaccine team. Most of the ministry's knowledge of the pharmaceutical industry was concentrated in the Pharmaceuticals and Medical Technology (GMT) department, a vaccine team member that played only a limited role in these negotiations.
	People involved in the negotiations were familiar with relationships at a European level.	Met	The chief negotiators were well aware of relationships at a European level. The first chief negotiator had worked for the Permanent Representation in Brussels for 4 years, while the second chief negotiator was familiar with these relationships because of being director of the ministry's International Affairs Department.
	Those involved in the negotiations used advice obtained from a range of different experts during the negotiations.	Largely met	During the negotiations, the vaccine team obtained advice on various aspects. Legal advice was obtained from various lawyers, while scientific advice was obtained from a broader panel of experts than just the National Institute of Public Health and Environmental Protection. The provision of legal advice regularly failed to proceed smoothly.

Process norms	Sub-norms	Weighting	Explanation of finding
	The division of roles and responsibilities within the negotiating team were clear.	Partly met	The picture here was mixed. The responsibilities of the Minister of Health, Welfare and Sport and the negotiators were clear. This contrasted with those, for example, of the special envoy and the ministry's Legislation and Legal Affairs Department, which were less clear. The minister's personal commitment demonstrated that he was clearly in charge. The negotiators acted in his name. However, the exact role of the special envoy was less clear. We also found tensions in the role of the ministry's Legislation and Legal Affairs Department in decision-making.
	Action was taken to ensure that people involved in the negotiations did not have any conflicts of interest.	Met to some extent	There was an awareness of the need to avoid conflicts of interest, as evidenced by the difficulties the Legislation and Legal Affairs Department experienced when trying to find a lawyer specialising in Belgian law and not having any interests in the pharmaceutical industry. No account was taken of this in the important deployment of the special envoy: however, the potential conflict of interests was remedied. The possible semblance of a conflict of interests was not discussed with the vaccine team as civil servants at a central government level. This was despite the major interests at stake meaning there was every reason to raise this issue.
The Ministry of Health, Welfare and Sport was able to adapt its involvement in the procurement negotiations to changing circumstances.	There was ongoing coordination and communications between those involved in the negotiations (both in the Netherlands and abroad).	Met	Evidence was found of ongoing communications at all levels of the negotiations. The minister and the most senior members of the vaccine team agreed matters in a group chat, but also had other contacts with each other. The Dutch chief negotiators spoke to the other JNT negotiators in almost daily video calls. The negotiators also had multiple contacts with the European chief negotiator to agree matters.

Process norms	Sub-norms	Weighting	Explanation of finding
	Both the ministry and the Dutch representatives in Brussels continually gathered information on new scientific and other insights, data and other matters.	Met	The ministry's vaccine team obtained information on relevant developments on an ongoing basis or in response to requests. One of the important contacts in this respect was that between the scientific panel and the National Institute of Public Health and Environmental Protection. The vaccine team immediately sought contact in the event of any unexpected developments on the production or supply side. We note, however, that government authorities were partly reliant on information provided by the industry with which they were negotiating. There was no testing of vaccines, for example, under the ministry's direction.
	The strategy was subject to interim assessments or the process included moments for reflecting on strategy in response to changing circumstances (such as new variants of the virus, medical insights, and healthcare or economic developments) and opportunities to learn lessons from earlier negotiations.	Partly met	The Ministry of Health, Welfare and Sport subjected the strategy to more or less continual scrutiny in response to new variants of the virus, medical insights, and healthcare or economic developments. What we did not see over the 2-year period were clear moments being scheduled for an interim assessments or for reflection.
	See above: efforts were adapted to cater for the above points.	Met	The Ministry of Health, Welfare and Sport adapted its strategy and the resultant action in response to changing circumstances and insights. We regard this as a dynamic and relatively fluid process.

Appendix 3 Literature

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Appendix 4 Endnote

1. Some adjustments have been made to the timelines in this report compared to the draft report. The dating of the contracts now everywhere concerns the version signed by the responsible Commissioner of the European Union, which we have been able to check ourselves. This dating occasionally deviates from that in the current text because the parties often reached agreement earlier.

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