Vaccin strategy The Netherlands

A properly functioning vaccine is the most important asset to halt the worldwide spread of the corona virus. Ultimately, we are not protected until there are effective vaccines. That is why researchers worldwide are working on more than 200 vaccines against the coronavirus. The developments are encouraging; dozens of vaccine candidates are currently in the final stages of clinical research. The Netherlands has, through the European Commission, made agreements with six different vaccine developers. Obviously, we will only have a vaccine if all test phases have been successfully completed and the European Medicines Agency (EMA) has indicated that the vaccine is effective and safe - because that is an absolute precondition.

This is the first step of The Netherlands towards a vaccination strategy and the associated prioritization. I would like to emphasize that the process surrounding the COVID-19 vaccination still contains unknowns. We do not yet know which vaccines will eventually be marketed, when, and in what quantities. Nor do we know for which groups these vaccines will be suitable. The government is therefore preparing - together with various parties - for several scenarios, and will revise the strategy when the available information so requires. Based on the most recent information, I expect that the first vaccinations can be started in early 2021.

In order to speed up the implementation of the vaccination, in parallel with the Health Council's advisory process, the Dutch government has asked the RIVM to prepare for the vaccination campaign and to conduct an exploration among possible implementing parties. Along with various international reports these two recommendations form the starting point for the Dutch vaccination strategy. To this end, we have worked out various elements with the RIVM and other parties, such as the logistical preparations and safety aspects, the selection of target groups, implementation, planning and communication. The Netherlands, furthermore would like to confirm once again that the COVID-19 vaccination will not be compulsory, we believe that people have a responsibility towards themselves, their loved ones and other, more vulnerable people, we will therefore continue to emphasize the importance of vaccination. The collaboration of the Joint Negotiation Team (JNT) led by the European, does everything within its power to increase the chance of eventual availability of a vaccine. Negotiations with vaccine developers are now in an advanced phase. Agreements have been made with six producers about the purchase of vaccines for the European countries, and the underlying contracts have now been signed with five producers. If the vaccines of all these producers prove to be successful and market authorization is granted, this could lead to the availability of approximately 50 million vaccines for the Netherlands. It should be noted that most vaccine candidates require more than one dose for effective protection.

Despite the fact that no vaccine has yet been marketed, there is good hope that the first vaccines from these manufacturers will become available in the first months of 2021. The European Commission expects that there may be several weeks between market authorization and delivery, which producers need to become fully operational. The Netherlands is doing everything it can to keep that period as short as possible. The overview below shows when different producers expect to submit their application for authorization. Table 1. Expected deadlines for application for market authorization and delivery Producer State of the art of clinical tests Expected application for EMA admission Expected start of delivery AstraZeneca Phase III Over 4 e quarter 2020 Q1 2021 BioNTech / Pfizer Phase III Over 4 e quarter 2020 Q1 2021 Moderna Phase III During one e quarter 2021 Q1 / 2 2021 Janssen Pharmaceuticals Phase III During one e quarter 2021 Q2 2021 Curevac Phase II Over 2 e quarter 2021 Q2 / 3 2021 Sanofi / GSK Phase I / II Over 2 e quarter 2021 Q3 2021 availabilty It is not yet known which vaccines are allowed to be marketed. Availability is very likely to be limited in the first months of 2021, also because deliveries will take place in different installments. This means that there will not be vaccines for everyone yet. The agreements with a producer always consist of the delivery of different parts of the total agreed number of vaccines over a period of two or more quarters (see table 2). Ultimately, it comes down to the exact delivery schedules from which vaccines become available on the basis of actual production. If there are two parties that can deliver vaccines in the first quarter of 2021, it means that about 3.5 million people could be vaccinated with the first deliveries (not all of which may be available at the same time), according to the latest reports from the producers. For most vaccines in the portfolio, two vaccines are required per person to be vaccinated, which should probably be

given within a few weeks. Table 2. Expected delivery numbers Company EU basic delivery 3.89% to NL = How much NL'ers Phase AstraZeneca 300 mln 11.7 mln 5.8 mln Contract closed BioNtech Pfizer 200 mln 7.8 mln 3.9 mln Contract closed Moderna 80 mln 3.1 mln 1.6 mln Sell talk around Janssen 200 mln 7.8 mln 7.8 mln Contract closed Curevac 225 mln 8.8 mln 4.4 mln Contract closed Sanofi 300 mln 11.7 mln 5.8 mln Contract closed 4. Advising target groups and prioritizing The ultimate aim is for everyone in the Netherlands to have a COVID-19 vaccination available. In this context, I asked the Health Council to advise before the summer on the various options for vaccination and the prioritization of different target groups. This advice, "strategies for COVID-19 vaccination", was published on 19 November and forms the basis for the government to arrive at a vaccination strategy. In its advisory report, the standing committee on Vaccinations of the Health Council has examined which strategies exist to prioritize vaccines in the event of limited availability of COVID-19 vaccines. Various considerations are involved here, because in addition to medical-scientific aspects, ethical and social considerations also play an important role. Based on ethical considerations, the Health Council has identified possible priorities for prioritization. This results in four possible vaccination strategies that can be used in the event of limited availability of COVID-19 vaccines (see Table 3). Table 3. Health Council strategies for prioritizing target groups Strategy Explanation Target audiences Reduce (serious) illness and mortality as a result of COVID-19 This strategy is aimed at saving as many lives as possible. This involves prioritizing the groups at increased risk of serious illness or death after infection. In addition, it concerns people who run a high risk of infecting this vulnerable group or who themselves run a high risk of infection because of their profession or living environment. Vulnerable health groups: people over 60 and medical risk groups (broadly comparable with groups of pandemic flu)[6] 2009). Groups at increased risk of infecting people from medical risk groups (for example, caregivers in long-term care facilities or caregivers of people who belong to a medical risk group). Groups with a higher risk of infection due to occupation or living environment The first group here are the care workers (including home care workers, elderly care, long-term care). According to the Health Council, this group could be further divided into employees who run a greater or lesser risk of infection. Finally, it concerns other professions in which there is direct contact with patients or clients and employees in the agricultural and food industry. Working, living and living conditions also play a role, because, for example, there are no possibilities to keep a physical distance. Reducing spread coronavirus The aim of this strategy is to achieve a reproduction rate that is lower than 1. It is more about indirect protection of vulnerable groups, by focusing when vaccinating on the groups that make the greatest contribution to the spread of the coronavirus (risk-forming agents). This depends on the epidemiological situation and the extent to which the available vaccine can prevent the spread of the virus. These are the largest distributors. Based on the epidemiological situation in the autumn of 2020, these are young people in the age group 20-30 years. Prevent social disruption In this strategy, the Health Council not only looked at health considerations, but also at social arguments. In this strategy, the Health Council's attention is focused on people who play an important role in keeping society running. Groups that are important for maintaining the care and preservation of vital infrastructure: care workers, education, public order, public administration. First of all, attention is paid to the healthcare sector, based on a different objective than strategy 1. Combination strategy Two or three of the above objectives are combined, for example the prevention of serious illness and death and the maintenance of vital sectors, such as healthcare. Requires further prioritization based on the various objectives. On the basis of the current (epidemiological) situation, in which the pressure on care remains high and vulnerable people are still severely affected by (the consequences of) COVID-19, the Health Council advises to start vaccinating older people over 60 years and medical risk groups (strategy 1). If there are people within these groups who cannot be vaccinated themselves for medical reasons, the Health Council recommends vaccinating healthcare workers who pose a risk to them. In the event of limited availability of vaccines, the Health Council, within this strategy, has set the following priorities: Elderly people from 60 years of age who belong to medical risk groups, starting with the oldest age group, because that is where the risk of serious illness and death is greatest. A medical indication also includes people with intellectual disabilities who live in an institution, and nursing home residents; Other people aged 60 and over, starting with the oldest age groups. Because re-infections are possible, elderly people who have already experienced an infection are also eligible. People under the age of 60 who belong to medical risk groups; The Health Council indicates that there are also vulnerable people who cannot be vaccinated for medical reasons. In that case, it is also important to vaccinate the informal caregivers and healthcare workers who pose a risk to them. In addition to the above groups, the Health Council also mentions healthcare workers with

direct patient contact. The Health Council estimates that at least 5 million vaccines are needed to vaccinate all elderly (over-60s) and medical risk groups (and 10 million for two vaccinations). In addition to this, it concerns approximately 1.5 million care workers in nursing homes, home care, long-term care, and informal carers who have contact with medical risk groups. The Health Council emphasizes that this is a preliminary advice. According to the committee, the strategy to be chosen strongly depends on the epidemiological situation and the effect of vaccines. According to the Health Council, this makes it difficult to make statements about the situation in three or six months. As soon as new information becomes available, the Health Council will issue further advice on the use of vaccines. 5. Cabinet response to advice I greatly appreciate the careful advice drawn up by the Health Council. By vaccinating the elderly and people from medical risk groups first, we can prevent serious illness and death as a result of the coronavirus as much as possible. This is in line with the goals that the cabinet has formulated to combat the virus: protecting the vulnerable and preventing healthcare from becoming further overburdened. The cabinet is therefore adopting the Health Council's advice. Not only because this strategy is the most obvious from an epidemiological perspective, but social and economic considerations also play a role in this. The sooner we are able to protect vulnerable people from the virus, the sooner we can move beyond the most restrictive measures.

The recommendations made by the Health Council also tie in well with the recommendations of the Strategic Advisory Group of Experts on Immunization (SAGE) of the WHO and the ECDC, and the recently presented vaccination strategy of the European Union. This connection is important, because fighting the pandemic is a joint task.

Main route

The Netherlands wants to start vaccinating the elderly (over-60s), medical risk groups and healthcare workers who come into contact with these groups. This is a large group of people for whom rapid availability of a COVID-19 vaccine is important. Because there will very likely be limited quantities of vaccines in the first months, we will also have to make further priorities within these groups. We do this by starting with those groups where the risk of serious illness and death is highest. The cabinet has opted to make the first vaccines available to residents of nursing homes. This concerns approximately 130,000 people who are inpatient, and between 20,000 and 25,000 people in various forms of housing, which are sometimes indistinguishable from a nursing home. In addition, it also concerns all people with an intellectual disability living in an institution, as advised by the Health Council. For people who cannot be vaccinated because of underlying suffering, the Health Council recommends investing in 'ring protection': protecting people in the vicinity of a vulnerable person, in order to reduce the risk of infection and disease. Because this distinction is difficult to make in nursing homes and institutions for people with an intellectual disability, we also vaccinate all employees. In the case of nursing homes, this involves at least 265,000 employees. I will also hold further consultations with the institutions about the way in which carers can be included with the vaccinations. After this first group, other groups follow, such as: people over 60 with a medical indication (starting with the oldest age groups), people over 60 without a medical indication (where also the oldest age categories come into consideration first), people under 60 years with a medical indication, the healthcare staff of these groups, and the healthcare staff who are in direct contact with patients with COVID-19. As more vaccines are delivered, groups can be added: other health care workers and finally also the group of people under 60 years without a medical indication. Within this group can also be further prioritized. In doing so, we look on the one hand at reducing the spread of the virus (the epidemiological situation), and on the other hand at maintaining vital sectors. Ultimately, the intention is that everyone in the Netherlands can be vaccinated against the corona virus. When the vaccines are approved we can be sure that the vaccines are suitable for a specific target group. Our approach and strategy must therefore be flexible. In this context, I work out several scenarios together with implementing parties, including a further definition and interpretation of the groups mentioned above. I will keep you informed of the progress via the progress letter. We expect to be able to start with this main strategy in January, but we also expect first availability in December.

Considerations

The COVID-19 vaccination is a complex process with many dependencies, not all of which are known at this time. This has an impact on how the strategy looks in daily practice. The final

choices we make are related to the suitability of a vaccine for a specific group, and information about the extent to which a vaccine can reduce spread. This will be evident from the final test results and in the assessment for authorization of a candidate vaccine. The following variables may result in the government having to opt for an adjustment of the main route:

i. The suitability of vaccines for specific target groups Not all vaccines will be suitable for every group. Only when vaccines have been approved by the EMA and the MEB will we know for which groups a vaccine can be used. The WHO Strategic Advisory Group of Experts on Immunization (SAGE) advises on the suitability of vaccine candidates for specific groups as soon as the vaccines become available (expected within two weeks of marketing authorization). The Health Council may also be asked for additional advice.

ii. The numbers that are always available The extent to which one or more priority groups can be vaccinated at the same time depends on the amount of vaccines available. Receiving smaller tranches means that we have to come to an even more specific breakdown. Of course, more space will be created as the number of candidate vaccines that becomes available increases and the production also functions on time and properly.

iii. How the vaccines are delivered The properties of the different types of vaccine candidates influence the logistical preparations. For example, the BioNTech / Pfizer must be stored at -70 ° C, and that places demands on the organization of the administration. The number of vaccines packaged per unit also makes some vaccines more or less suitable for, for example, small-scale administration. In summary, it is about using the right vaccine, for the right application, at the right stage. As soon as more data - such as definitive results from the final phase of the clinical investigation - is available, the main route must be able to be adjusted based on the latest insights. We do this together with RIVM and other involved parties. RIVM will chart the situation weekly for this purpose.

Long-term vaccination

We also want to be able to protect society against the virus in the longer term. How this can best be achieved depends on, among other things, the duration of the immunity, the circulation of the virus and participation in the vaccination program. Little is known about the duration of protection of vaccines. We therefore take into account the possibility that the COVID-19 vaccination will have to become an annual vaccination campaign, just as with the flu shot. Start date and coherence of measures Depending on when a registered vaccine becomes available, a start date will be determined. The expectation is early 2021 at the earliest, due to the ongoing investigations, the assessment procedure and the preparation of the deliveries. We are also preparing for a scenario where vaccines are delivered as early as December. The step to vaccination is also a step towards better control of the virus and a reopening of society. As well as the expansion of the number of tests. It is important to see what vaccination means for the restrictive measures we have taken at the moment. In that context, the cabinet will ask the OMT to give its views on the relationship between vaccination and current measures, partly on the basis of the epidemiological situation.

Calling up target groups and registration of COVID-19 vaccination

The RIVM is working on a national registration system especially for COVID-19 vaccination. The central register is a necessary part of the vaccination strategy, and important in the context of safety surveillance and monitoring of side effects, swift action in the event of calamities, and the fight against the pandemic. It is very important that the data in the central register is as complete as possible so that security surveillance and monitoring can be done carefully. I consider privacy to be of paramount importance and I consider it important that the register complies with privacy laws and regulations. It is significant that the record will consist of no more than the minimum necessary information such as who, when, what has received vaccine and to privacy by design principles as a starting point. Nevertheless, it may be the case that someone objects to the processing of his / her data by the RIVM, in which case it will be possible for the vaccinated person to have his / her data removed by the RIVM. It will be minimal data such as who received which vaccine, when. I would like to emphasize that it is desirable not only for everyone's own safety, but also for the safety of others to have this minimal set of data registered with RIVM. Registration is essential for the individual interest of the vaccinated, but also for the public social interest that RIVM can optimally fulfill its role with regard to vaccination in the fight against the pandemic. A lot

of work is being done on the technical implementation of the central register. This will be in line with the system and infrastructure of the National Immunization Program and efforts will be made to limit the administrative burden for the operators as much as possible. We use the system and infrastructure of an existing system, so that a central register is ready as soon as possible. This system can be used to monitor vaccination coverage, safety and effectiveness.

Implementation of COVID-19 vaccination

The Ministry of Health has commissioned the RIVM for preparation and implementation of the COVID-19 - vaccination. This also includes directing the implementation of the vaccination by implementing parties, such as GPs and the GGD. In anticipation of the Health Council's advice, RIVM - on behalf of the Ministry of Health, Welfare and Sport - carried out a scenario study into the possible parties that could play a role in the implementation of the COVID-19 vaccination. Normally, RIVM does not map out the implementation aspects, such as possible implementing parties and the associated costs, only after advice from the Health Council. Due to the high urgency, RIVM has already carried out an exploratory study describing how implementation can be carried out in an efficient and accessible manner. There are several implementing parties in the picture: GPs for the medical risk groups and the elderly (extramural); Institutional doctors for medical risk groups and the elderly (inpatient); Employers and occupational health services / company doctors for healthcare personnel; and, GGDs for the rest of the population and possibly as a safety net for the above target groups. The RIVM has recommended that the vaccination be carried out by the aforementioned parties, because it links up as much as possible with the existing structures of, for example, influenza vaccination, so that work can be done quickly and as efficiently as possible. In order not to lose valuable time and to be as well prepared as possible - even in this phase in which much is still unknown - RIVM has also been working hard on the practical implementation since the summer. Each of the parties involved can contribute to a successful vaccination campaign based on their own knowledge and skills. The unknowns surrounding the availability and suitability of vaccines for specific target groups also influence the preparations that implementing parties make. That is why we work out various scenarios together with the implementing parties. Among other things, attention is paid to setting up supporting IT systems and agreements about the distribution of vaccines and the setting up of vaccination locations. The parties involved are also working on drawing up guidelines and e-learning for the advancement of expertise of the professionals. During the implementation, I want to make as much use as possible of the existing structures and locations that are familiar to the target groups concerned. This is as closely as possible with the structure of the flu vaccination, which is a well-known route for the relevant target group. Employers can offer this vaccination themselves or in collaboration with the health and safety services. GGD ' and can use large-scale injection sites such as they do with the HPV vaccination and the meningococcal vaccination or smaller locations where necessary. It is possible that the GGD will also be able to use their (large) test locations for this in due course. We are preparing for the scenario that vaccinations will start nationally in January. The preparations have also taken into account the possibility that the first vaccines will be available in December. It is clear that the implementation is (also) a major and complex challenge. For all parties involved. That is why we desperately need everyone's commitment and expertise. It is nice to know that there is a lot of positive energy to shape this challenging job together. This is also evident from the help that is offered, such as that of the Red Cross.

Logistics and security aspects

We are making full preparations for the logistics process. We use the experience we have gained with vaccination against pandemic flu. However, this is a unique logistics operation, partly because of the great diversity in purchased vaccines. In addition to the properties of the different types of vaccines that affect storage, packaging and transport, delivery times also play a role. The most promising vaccine candidates and the expected delivery times that are expected are now leading in the timeline of our preparations. For example, RIVM is working on having sufficient cooling and freezing capacity available on time. The latter in particular is a complicated operation because vaccines are also being developed that require a very low storage temperature. The facilities for frozen vaccines (-70 degrees) will be ready at the end of December. The RIVM has also currently purchased 25 million extra safety needles and syringes for the administration of the COVID-19

vaccines. In addition, the Netherlands is participating in the Joint Procurement of the European Commission for the purchase of safety needles. Given the national importance of the vaccines, safety aspects of the entire logistics process are also considered. A government-wide working group, led by the Ministry of Health and the RIVM, works all underlying agreements further out so that vaccines can be safely transported within the Netherlands, stored, and can be administered. Naturally, there is also contact with local parties, suppliers, logistics parties, etc. This not only concerns security, but also safety.

Communication

Important pillars in this vaccination strategy are public communication and dialogue with society. In this way we inform the general public about the vaccine and the vaccination approach. Naturally, we also pay attention to special target groups that have specific needs in terms of form, language, channel or sender status (for example, government, through umbrella organizations or through their own care provider, etc.) This concerns, for example, young people, people with a low socioeconomic status, low literate non-native speakers. Because the COVID-19 vaccines also raise questions, doubts and emotions, we put extra effort into answering those questions and addressing doubts, contradicting disinformation and referring again and again to the factually correct information. Where possible, we engage in dialogue to hear about any doubts and ideas that exist, and to be able to inform or refer, and reassure where possible. We will also start as soon as possible with means to reach large groups, including television and radio. Now that more and more information is becoming available about the COVID-19 vaccination, it is important to keep society well informed. This will concern a concrete action perspective, but also the relationship between measures and the various instruments that we use to get the corona virus under control. We will simultaneously motivate people for the vaccination and activate them to actually make use of a possible offer. That it is important to fully commit to this is also apparent from various recent studies by, for example, Ipsos and the behavioral unit of the RIVM. They outline that the willingness to vaccinate varies from 50- 71%. Research by Delft University of Technology shows that the majority of Dutch people do not want to be vaccinated immediately and that care staff have doubts about the vaccination. This is worrying, because a successful vaccine is an important tool in tackling the virus: in addition to individual protection, vaccines ensure that you also protect the group, if enough people are vaccinated. Addressing all people as well as possible, explaining the importance of vaccination and communicating this clearly and honestly. Communication with these groups to be vaccinated is undertaken by RIVM, as is communication with healthcare professionals who carry out the vaccinations.

This approach should ensure that people know where to find reliable information and where they can be helped, and that there is sufficient support for the important choices that must be made here. Naturally, communication is continuously adjusted based on the developments of the vaccines and the choices that still have to be made.

Finally

Developing a national vaccination strategy poses many challenges, especially as much is still unknown about the new vaccines. We have an overview of the most important steps: vaccines must go through a thorough authorization procedure before they can be used, there must be a carefully substantiated prioritization of target groups, and the implementation of the vaccination must be linked to this. Where possible, we make use of existing structures. At the same time, this operation has unique characteristics that require a great deal of adaptability from all parties involved. These parties are working very hard to be able to start the actual vaccination of society as soon as possible after the first deliveries of COVID-19 vaccines. Although health systems differ from country to country, we see that Member States have the same questions about logistics, implementation, registration, monitoring and security surveillance. We hope we con work on these questions together by working transparent and share knowledge and ideas.