

**DILEMMA: APPLY INTERVALS OF 3 WEEKS OR 6 WEEKS BETWEEN 1<sup>ST</sup> AND 2<sup>ND</sup> PFIZER VACCINATION**

RIVM states that the current guideline for the Pfizer vaccine indicates that the second dose is given 6 weeks after the first. Motivation is to increase the volume of persons that can be vaccinated in the first round and thereby increasing the speed of the roll out of the vaccine in the Netherlands. The demand for a vaccine in the Netherlands is higher than the supply, therefore delaying the second dose will create double the supply in the first round.

The Medicines Evaluation Board of the Netherlands advises that it is safe to push back the second dose from 3 weeks to 6 weeks. This is contrary to the instruction of the European Medicine Agency (EMA) who has stated that:

- There is insufficient evidence to show that extending the gap between 2 injections is harmless
- The vaccine recipient may not be completely protected if the 2<sup>nd</sup> dose is administered more than 3 weeks after the first.

The pushback also conflicts with the message of Pfizer itself, which states that the second dose must be given 19 – 23 days after the first one. This is what was tested in the clinical trials.

**Scientific support:**

No research has as yet been conducted on delaying the second Pfizer dose. There is no data available to show the impact on the level of protection against covid-19 disease.

**Legal framework:**

Who determines the vaccination schedule on 5.1.2a? Is that RIVM? Is that Minister of VSA?

This legal question was posed to 5.1.2e legal of Inspectorate. She indicated this question must be posed by the Minister (or on his behalf) and with all relevant information.

	Pro's (+)	Cons (-)
<b>3 weeks interval</b>	<p>This interval was researched in the clinical trials and has shown a protection of 94-95% a week after the second dose at day 21. Research data supports this interval.</p> <p>EMA has strongly advised to follow the interval regimen as instructed by Pfizer.</p> <p>WHO also advises an interval of 21 – 28 days. But allows a pragmatic approach of extending it to 6 weeks, depending on "exceptional epidemiological circumstances".</p> <p>Commitment for second dose is expected to be higher with shorter interval.</p> <p>We may gain trust of the population if we stick to the proven and advised interval.</p> <p>This interval matches the info already shared in leaflets, community leader sessions etc.</p> <p>With 2 guaranteed shipments at weeks 7 and 10, the 2<sup>nd</sup> dose for the first group is guaranteed and will be of the same brand.</p> <p>In the event shipments 3 and 4 will be a different vaccine, this will be no issue as a whole new group will be vaccinated then.</p> <p>Bigger chance of show up.</p> <p>More lee-way if person does not show up on day or time of appointment (related to discipline and local cultural practices).</p>	<p>Less persons (7,605 in total) can be vaccinated in the first 3 weeks of the vaccine program</p>

	Pro's (+)	Cons (-)
<b>6 weeks interval</b>	More persons (15.210 in total) can be vaccinated in the first 6 weeks of the vaccine campaign.	<p>No data to support that this is safe and that it will not affect the effectiveness of the vaccine. Pfizer's instruction is to administer the second dose 19 – 23 days after the first one.</p> <p>Changing to 6 weeks interval is against clear EMA advice.</p> <p>Higher risk of no-shows for the second dose, the delay is too long, you will lose commitment.</p> <p>High risk of lack of trust by the population in the program. They will not believe the delay is safe. How can we proof that it is?? It will increase their mistrust in the program.</p> <p>Adjusted schedule conflicts with all vaccine information shared to many groups and platforms.</p> <p>Risk of shipment 3 and 4 not arriving on time. Delivery dates unknown, what if it arrives (much) later than 6 weeks?</p> <p>Risk of no Pfizer stock available in the Netherlands to complete the 2<sup>nd</sup> dose. How is this guaranteed?</p> <p>The highest risk group is less protected for a longer period of time, leaving them at risk for infection and complications.</p> <p>No lee-way in case of no show on date and time of appointment after six weeks.</p>