





## 5.1.2e Statement

The expert committee PRAC has come to a conclusion regarding the blood clots and AstraZeneca. The vaccine is safe and effective against COVID 19.

The committee also concluded that the vaccine is not associated with a higher risk of thrombosis.

During the investigation and review we began to see a small amount of cases with rare conditions.

Based on the evidence and after in depth analyses of lab results autopsies and clinic reports, we cannot rule out a link definitively between cases and vaccination.

The vaccine is safe and effective to protect against Covid-19. There is at least a 60 percent effectivity and it might be higher.

We need to raise awareness and include it in the product information.

We will have to inform the public and the health care professionals

By informing the health care professionals and the public we can support the confidence in vaccinations.

We are also launching additional studies and will do targeted observations

We need to keep investigating all incoming reports of side effects

We are aware of countries pausing the vaccination and given the thousands of people that die every day, also 2500 last week, we made this review our highest priority.

We want to highlight that this situation is not unanticipated. This will always happen when you vaccinate a lot of people. We need to detect and monitor all the reports coming in. We can investigate very rapidly. We remain fully mobilized for further investigation.

## 5.1.2e Statement

PRAC has looked in great detail into the cases of blood cloth after AstraZeneca vaccination

As soon as the concerns arose we started doing review.

The vaccine is safe and effective for Covid and the benefits are fare greater than the risks.

No evidence of a quality or batch issue with the AstraZeneca vaccine

We have assessed pre-clinical data and detailed datasets

Critical to the review has been clinical assessments and clinical scrutiny

Number of thrombose events after vaccination is lower than normally, there is no increase in thrombo events after the vaccination started.

The vaccine is effective against Covid 19

The vaccine likely reduces thrombotic effects

The case reports describe very specific events of rare combinations regarding thrombo-linked effects.

The review has shown a predominance in some groups: women and younger women, but it is too premature to conclude on a specific group.

We don't know why it has occurred more in these groups, it could also be because of the vaccination strategies that more women have gotten AstraZeneca in different countries.

We will look into this in the coming studies

**Why do you see a difference in Thrombo-event reports when you compare the UK and the EU?**



majority were women. Because these events are rare, and COVID-19 itself often causes blood clotting disorders in patients, it is difficult to estimate a background rate for these events in people who have not had the vaccine. However, based on pre-COVID figures it was calculated that less than 1 reported case of DIC might have been expected by 16 March among people under 50 within 14 days of receiving the vaccine, whereas 5 cases had been reported. Similarly, on average 1.35 cases of CVST might have been expected among this age group whereas by the same cut-off date there had been 12. A similar imbalance was not visible in the older population given the vaccine.

The Committee was of the opinion that the vaccine's proven efficacy in preventing hospitalisation and death from COVID-19 outweighs the extremely small likelihood of developing DIC or CVST. However, in the light of its findings, patients should be aware of the remote possibility of such syndromes, and if symptoms suggestive of clotting problems occur patients should seek immediate medical attention and inform healthcare professionals of their recent vaccination. Steps are already being taken to update the product information for the vaccine to include more information on these risks.

The PRAC will undertake additional review of these risks, including looking at the risks with other types of COVID-19 vaccines (although no signal has been identified from monitoring so far). Close safety monitoring of reports of blood clotting disorders will continue, and further studies are being instituted to provide more laboratory data as well as real-world evidence. EMA will communicate further as appropriate.

### **Information for patients**

- COVID-19 Vaccine AstraZeneca is not associated with an increased overall risk of blood clotting disorders.
- There have been very rare cases of unusual blood clots accompanied by low levels of blood platelets (components that help blood to clot) after vaccination. The reported cases were almost all in women under 55.
- Because COVID-19 can be so serious and is so widespread, the benefits of the vaccine in preventing it outweigh the risks of side effects.
- However, if you get any of the following after receiving the COVID-19 Vaccine AstraZeneca:
  - breathlessness,
  - pain in the chest or stomach,
  - swelling or coldness in an arm or leg,
  - severe or worsening headache or blurred vision after vaccination,
  - persistent bleeding,
  - multiple small bruises, reddish or purplish spots, or blood blisters under the skin,

please seek prompt medical assistance and mention your recent vaccination.

### **Information for healthcare professionals**

- Cases of thrombosis and thrombocytopenia, some presenting as mesenteric vein or cerebral vein/cerebral venous sinus thrombosis, have been reported in persons who had recently received COVID-19 Vaccine AstraZeneca, mostly occurring within 14 days after vaccination. The majority of reports involved women under 55, although some of this may reflect greater exposure of such individuals due to targeting of particular populations for vaccine campaigns in different Member States.
- The number of reported events exceeds those expected, and causality although not confirmed, cannot therefore be excluded. However, given the rarity of the events, and the difficulty of establishing baseline incidence since COVID-19 itself is resulting in hospitalisations with thromboembolic complications, the strength of any association is uncertain.





- Bij go op herstart kost het circa een week om weer op te starten (week later dus weer eerste vaccinaties met AZ)

Hoe verder (alle tijden onder voorbehoud):

- 16.00 Persco EMA
- Daarna persco CBG met duiding
- Vanavond persgesprek (digitaal met minister, 5.1.2e CBG en 5.1.2e 5.1.2e RIVM), streeftijd 20.00/20.30
- Tijdens / net na gesprek nieuwsbericht en publieksinformatie online (aanpassing teksten site, evt. nieuwe Q&A toevoegen)

**Van:** 5.1.2e 5.1.2e e 5.1.2e)

**Verzonden:** donderdag 18 maart 2021 12:52

**Aan:** 5.1.2e, 5.1.2e <5.1.2e @minvws.nl>; 5.1.2e, 5.1.2e, 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e, 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e, 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>  
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**Onderwerp:** RE: EMA/AZ donderdag

[Update: persconferentie EMA is pas om 16.00u.](#)

**Van:** 5.1.2e 5.1.2e e 5.1.2e)

**Verzonden:** woensdag 17 maart 2021 22:15

**Aan:** 5.1.2e, 5.1.2e <5.1.2e @minvws.nl>; 5.1.2e, 5.1.2e, 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e, 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e, 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>; 5.1.2e, 5.1.2e (5.1.2e) <5.1.2e @minvws.nl>  
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**Onderwerp:** EMA/AZ donderdag

Dag allen,

De mail die ik klaar had staan kan de koelkast in. Op basis van het overleg van vanavond met alle betrokken partijen is het DE VERWACHTING dat er morgen nog geen concreet/duidelijk advies of besluit volgt van de PRAC/EMA. En dat er dus ook nog niets gaat veranderen in de huidige situatie. De PRAC/EMA gaat door met onderzoek. Wellicht gaan wij nog advies vragen aan GR en/of OMT. Wel is er morgen nog overleg met andere landen die op de pauzeknop hebben gedrukt. Dat kan de situatie en hetgeen we gaan doen ook nog veranderen.

Afijn, al met al is de situatie nu erg onduidelijk, omdat we niet 100% zeker weten of PRAC/EMA met het bovenstaande naar buiten gaat. Het is werkverschaffing om nu met al die Q&A's aan de slag te gaan. Vervolg is nu als volgt (alle tijden onder voorbehoud):

10.00u Korte update intern (al ingepland)  
 13.00u Meer info over besluit PRAC/EMA  
 13.15u Overleg ministers van VWS verschillende landen  
 14.00u Overleg met alle partijen in NL (zoals zondag en vanavond)  
 15.00u Persco EMA  
 16.00u (Pers)info (vorm ntb) CBG  
 17.00u (Pers)info (vorm ntb) VWS

Of een Kamerbrief in deze variant nog nodig is betwijfel ik.

Tot slot lijkt het me wel goed om al een antwoord op te stellen op de volgende drie vragen 5.1.2e kunnen jullie dat met 5.1.2e oppakken?

1. Waarom blijft de situatie zoals die is/ houden we de pauzeknop nog ingedrukt?
2. Wat gebeurt er nu/welke stappen zetten we nu om tot een oplossing c.q. besluit te komen?
3. Wanneer verwachten we meer duidelijkheid?

Met vriendelijke groet,



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