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Sent: Thur 3/11/2021 11:26:56 AM
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Met vriendelijke groet,

[redacted]

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Verzonden: donderdag 11 maart 2021 12:26

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Onderwerp: FYI - vertaling van statement Deense autoriteiten aangaande AE cases

Beste allen,

In de media is vanochtend bekend geworden dat de Denen vooralsnog vaccinatie met het AZ vaccin on hold hebben gezet op basis van bijwerkingen (blood clots). AstraZeneca is deze casus momenteel aan het onderzoeken en komt naar verwachting vanmiddag met een statement.

Voor nu heb ik het statement van de Deense Autoriteiten vertaald in het Engels, voor jullie ter info. Het lijkt dus idd een nieuwe casus in Denemarken (zie gele highlight).

Vaccination with the COVID-19 vaccine from AstraZeneca is put on pause until further notice

It occurs after reports of severe cases of blood clots in people who have been vaccinated with the COVID-19 vaccine from AstraZeneca. On that basis, the European pharmaceutical authorities have launched an investigation into the AstraZeneca vaccine. One report relates to a death in Denmark. It cannot be concluded at this time whether there is a link between the vaccine and the blood clots.

MAR 11, 2021

Based on the concern raised by the drug authorities, the Health Executive has chosen, on a precautionary principle, to pause vaccination with the COVID-19 vaccine from AstraZeneca. The break will last for 14 days until further notice and the Board of Health, along with the Medicines Agency, will make a new assessment in Week 12.

"We are in the midst of the largest and most important vaccination rollout in Denmark history. And right now we need all the vaccines we can get. Therefore, it is not an easy decision to pause one of the vaccines. But precisely because we vaccinate so many, we also need to respond with timely care when there is knowledge of possible serious side effects. We need to clarify that before we can continue to use the vaccine from AstraZeneca," stated Søren Brostrøm, Director at the Health Board. The Danish and European drug authorities are keeping a sharp eye on the rollout of vaccines against COVID-19, both in terms of the more common mild side

effects and the rare, but serious, possible side effects. As a starting point, health authorities assess that it is unacceptable to have very serious side effects associated with a preventive treatment, such as vaccination. That's why we respond early if there is the slightest sign of a possible risk from the vaccine.

'It is important to stress that we have not opted out of the AstraZeneca vaccine but that we pause it. There is good evidence that the vaccine is both safe and effective. But both we and the Medicines Agency need to respond to reports of possible serious side effects, both from Denmark and other European countries. It shows that the surveillance system is working.'

'At the same time, it is important for us that citizens are comfortable with the offer we make them and trust that we can vouch for the quality of the vaccines we have in our programme. That's why we react promptly until we have been examined whether there is a link between the vaccine and the possible side effects'. The health board is now awaiting drug authorities in the EU to conduct a closer examination of a possible link between the COVID-19 vaccine from AstraZeneca and the severe cases of blood clots reported. Pause means changes to vaccine plan

The pausing means no more people who have a time for first vaccination are being vaccinated with the AstraZeneca vaccine so far. It also means that those who have already got 1st connector and are waiting for the 2nd connector, tentatively have to wait with this.

'We've got a very long way in vaccinating the front staff in Group 4, but we're not in goal. I am very sorry that we will now have to say to the staff who have already received the first plug or already booked or invited to the first plug that they will unfortunately have to wait until later in spring or early summer before they can be pre-vaccinated'.

'But we still have to offer vaccine to just under 1 million older people aged between 65 and 84, and we need to prioritise leg hard so they get the other two vaccines we have now. We must protect the very weakest if we have a big flare-up of the epidemic again. We also need to make sure that health care and elderly care don't crack, but our assessment is that we have already vaccinated so much front staff that we can cope with it,' said Søren Brostrøm. All booked times and invitations for vaccination with the vaccine from AstraZeneca are cancelled. Later new times will be able to be booked via vacciner.dk. Booked times for vaccination with one of the other vaccines from Pfizer and Moderna respectively will not change. Front staff aged 65 or older will continue to receive offers of vaccination with one of the other two vaccines. A new version of the vaccination plan has been made, with AstraZeneca taken out entirely, to illustrate a worst-case scenario. It shows that anyone in Denmark aged 16 or older may not have been offered vaccination until week 28 (the second week of July) and that all may be pre-vaccinated about 4 weeks thereafter. But it is important to stress that the vaccination plan will look better if we resume using AstraZeneca at the reassessment in week 12.

Met vriendelijke groet,

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