From:

S22
To:

SKERRITT, John; COOK, Jane; KAY, Elspeth; S22
; S22

Subject:

Norway - Adverse Pfizer outcomes/Vaccine risks [SEC=OFFICIAL:Sensitive]

Monday, 18 January 2021 9:54:05 AM

Attachments:

Fwd Norway - Pfizer vaccination risks SECOFFICIAL (26.1 KB).msg

## **OFFICIAL:Sensitive**

Dear John, Jane, Elspeth, <sup>\$22</sup> and <sup>\$22</sup>

Please find additional information regarding the adverse Pfizer outcomes in Norway courtesy of DFAT's overseas network, as requested by Minister Hunt over the weekend (see <a href="https://www.canberratimes.com.au/story/7088701/health-minister-seeks-answers-over-norway-deaths-following-vaccine/?cs=17318">https://www.canberratimes.com.au/story/7088701/health-minister-seeks-answers-over-norway-deaths-following-vaccine/?cs=17318</a>).

## Media also refers:

- https://www.bloomberg.com/news/articles/2021-01-15/norway-warns-of-vaccinationrisks-for-sick-patients-over-80
- https://legemiddelverket.no/nyheter/covid-19-vaccination-associated-with-deaths-inelderly-people-who-are-frail
- https://www.bmj.com/content/372/bmj.n149

Steinar Madsen, Medical Director at the Norwegian Medicines Agency, has provided the following advice (attached email also refers):

Norway has vaccinated more than 30,000 people so far, with the following order of priority, starting with nursing home residents:

- Residents in nursing homes and selected healthcare personnel
- Age 85+ and selected healthcare personnel
- Age 75-84
- Age 65-74, and people between 18 and 64 with diseases/conditions at high risk of severe disease
- Age 55-64
- Age 45-54
- Age 18-44

See: <a href="https://www.fhi.no/en/id/vaccines/coronavirus-immunisation-programme/who-will-get-coronavirus-vaccine-first/">https://www.fhi.no/en/id/vaccines/coronavirus-immunisation-programme/who-will-get-coronavirus-vaccine-first/</a>

Madsen also advised DFAT Post that Norway's policy had been to vaccinate all people in nursing homes, even those with very short remaining life spans. He said the adverse reactions from the vaccine, such as nausea and diarrhea had caused a turn for the worse as the people were already so fragile. Madsen said they had since asked doctors to evaluate nursing home residents before vaccination using a clinical family scale on fragility for older people. He said the decision then whether to vaccinate was based on an individual assessment of the person's situation – some people were so close to the end of their life span that they may decide not to vaccinate. Madsen said the cases were very rare and Norway was not concerned. Only 1/1000 people vaccinated so far had

been affected. He said 23 people had died in connection with the vaccine but all, as mentioned above, were cases of elderly people with very severe underlying conditions. Norway was aware of this risk in advance of the vaccination program and had decided it was still worth vaccinating all nursing home residents.

Please do not hesitate to contact us should Health/TGA requires any further information. DFAT stands ready to set up a webex with Madsen to ask more technical questions, should it be required.



s22

**DFAT Liaison Officer** 

National Incident Room (COVID-19), Department of Health

Mobile: **\$22** 

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From: \$22 To: \$22 Cc: \$22

Subject: Fwd: Norway - Pfizer vaccination risks [SEC=OFFICIAL]

Date: Monday, 18 January 2021 8:46:59 AM

OFFICIAL

Additional info also for TGA Thanks

\$22

## **OFFICIAL**

Subject: Norway - Pfizer vaccination risks [SEC=OFFICIAL]

## OFFICIAL

Dear s22 and s22

Further to my last message, Steinar Madsen, Medical Director at the Norwegian Medicines Agency, has provided information in his message below with links to a notice on 15 January regarding 23 deaths associated with COVID-19 vaccination, the approval process for COVID-19 vaccines, Norway's weekly reports of suspected adverse reactions to COVID-19 vaccination which are assessed on a continuous basis, and an article which quotes Madsen and Pfizer.

Norway has vaccinated more than 30,000 people so far, with the following order of priority, starting with nursing home residents:

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- Age 65-74, and people between 18 and 64 with diseases/conditions at high risk of severe disease
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See: <a href="https://www.fhi.no/en/id/vaccines/coronavirus-immunisation-programme/who-will-get-coronavirus-vaccine-first/">https://www.fhi.no/en/id/vaccines/coronavirus-immunisation-programme/who-will-get-coronavirus-vaccine-first/</a>

Please let me know if you need anything else,





From: Steinar Madsen \$22 @legemiddelverket.no>

Sent: Sunday, 17 January 2021 12:13 PM

To: 622 @dfat.gov.au> Subject: SV: Pfizer vaccination risks [SEC=OFFICIAL]

Dear <mark>s22</mark> ,

Here are some links that explains the situation:

https://legemiddelverket.no/nyheter/covid-19-vaccination-associated-with-deaths-in-elderly-people-who-are-frail

https://www.bmj.com/content/372/bmj.n149

So as you can see, we are not alarmed by this. We are still vaccinating nursing home residents, but have adviced doctors to evaluate the oldest and most frail patients wether vaccination is warranted or not.

Regards

Steinar Madsen, MD, FACP(Hon)
Medical director
Norwegian Medicines Agency
@legemiddelverket.no

Mobile **\$22**