

From: [SKERRITT, John](#)
To: s22
Cc: s22
Subject: RE: Urgent Media release on Norway deaths requested by Minister Hunt [SEC=OFFICIAL]
Date: Sunday, 17 January 2021 1:54:18 PM
Attachments: [image002.png](#)

Thanks for this

We have additional information on numbers which we are comfortable reporting on numbers.

The EMA is undertaking EU wide investigations – commencing last Friday – in a number of countries; this could lead to EU wide changes to vaccination recommendations, but we don't know yet. Am aware of the BMJ article as well as having direct contact with European counterparts.

Will clarify the wording in para 2, second sentence – thanks

John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
Deputy Secretary for Health Products Regulation
Department of Health
(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

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From: s22 <[REDACTED]@pfizer.com>
Sent: Sunday, 17 January 2021 1:44 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>
Cc: s22 <[REDACTED]@pfizer.com>
Subject: RE: Urgent Media release on Norway deaths requested by Minister Hunt [SEC=OFFICIAL]

Dear John,

Thank you very much for the opportunity to review the draft media release, and provide comment.

Please find here our comments for consideration:

- Regarding the number of deaths, NOMA's publicly released figure from the Norwegian Medicines Agency is 23 deaths currently as per their website. We are assuming that TGA has other specific verified, information to state 'about 30'? We will share any verified updates as we have them.
- Sharing additional information from NOMA for consideration:
 - A [direct quote](#) from the Norwegian regulator which states: "We are not alarmed or

worried about this, because these are very rare occurrences and they occurred in very frail patients with very serious disease”. The quote was from Steinar Madsen, Medical Director of NOMA, and published in *The BMJ’s 15 January 2021 article: [Covid-19: Norway investigates 23 deaths in frail elderly patients after vaccination | The BMJ \(openathens.net\)](#)*

- NOMA confirms the number of incidents so far is not alarming, and in line with expectations.
- All reported deaths will be thoroughly evaluated by NOMA to determine if these incidents are related to the vaccine.
- In paragraph 2, second sentence - the sentence: *“It is not expected that these common adverse reactions following immunisation will be of risk in the vast majority of individuals vaccinated with the Pfizer BioNTec vaccine.”* “will be of risk” may be open to various interpretation. (i.e. does this refer to risk of death?) We note that the BMJ article quotes Steinar Madsen, Medical Director of NOMA, who states that these common reactions would not be dangerous in fitter, younger patients.
- ‘BioNTec’ – correct spelling of company name is BioNTech.

Please also find a copy of Pfizer’s global media response for your information. This will be offered reactively to local media enquiries:

- *Pfizer and BioNTech are aware of reported deaths following administration of BNT162b2. Our immediate thoughts are with the bereaved families*
- *We are working with the Norwegian Medicines Agency (NOMA) to gather all the relevant information.*
- *Norwegian Authorities have prioritized the immunization of residents in Nursing Homes, most of whom are very elderly with underlying medical conditions and some which are terminally ill. NOMA confirms the number of incidents so far is not alarming, and in line with expectations.*
- *All reported deaths will be thoroughly evaluated by NOMA to determine if these incidents are related to the vaccine.*
- *The Norwegian Government will also consider adjusting their vaccination instructions to take the patients’ health into more consideration.*

Please feel free to call s22 or myself if you have any questions or need further information.

Kind regards, s22

s22
s22 Pfizer Australia and New Zealand
Internal Medicine Developed Asia

Pfizer Australia

s22

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From: SKERRITT, John

Sent: Sunday, 17 January 2021 12:02 PM

To: s22 [REDACTED]@pfizer.com' <s22 [REDACTED]@pfizer.com>; s22 [REDACTED]@pfizer.com' <s22 [REDACTED]@pfizer.com>

Subject: Urgent Media release on Norway deaths requested by Minister Hunt
[SEC=OFFICIAL]

Importance: High

s22 [REDACTED]

Will text you s22 [REDACTED] but Minister has asked for a MR along the lines of the attached to go up. Cant promise that we can include edits from all but if there is anything that doesn't seem right please phone me.

John Skerritt

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
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Department of Health

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