From: SKERRITT, John
To: COOK, Jane; s22 [redacted]
Subject: RE: Further PI changes requested to Pfizer covid 19 vaccine [SEC=OFFICIAL]
Date: Monday, 18 January 2021 4:05:16 PM
Attachments: image001.png
image002.png
image003.png

Yes

We should push back and copy the note to the managing director of Pfizer Australia. I can then put the ball firmly in their court.

Can you draft something this afternoon; respond to this reg affairs person and cc me and then I will escalate to their CEO

We could consider saying VERY frail elderly as clearly it would only be a minority of aged care people who may be excluded – your thoughts ?

John

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)

PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6289 4200 Fax: (02) 6203 1265
Email: john.skerritt@health.gov.au

From: COOK, Jane <Jane.Cook@health.gov.au>
Sent: Monday, 18 January 2021 3:59 PM
To: SKERRITT, John <John.Skerritt@health.gov.au>; s22 [redacted]@health.gov.au>
Subject: FW: Further PI changes requested to Pfizer covid 19 vaccine [SEC=OFFICIAL]

John,
I would like to push back and have such a statement included. I don't think they have provided any rationale for why it shouldn't be and in fact I believe the information in the email actually supports such a statement.
It may delay approval though – any thoughts?
Jane

From: s22 [redacted]@pfizer.com>
Sent: Monday, 18 January 2021 3:37 PM
To s22 [redacted]@health.gov.au>
Cc: s22 [redacted]@health.gov.au>; COOK, Jane <Jane.Cook@health.gov.au>; s22 [redacted]@pfizer.com>; s22 [redacted]@pfizer.com>; s22 [redacted]@pfizer.com>; s22 [redacted]@pfizer.com>
Subject: RE: Further PI changes requested to Pfizer covid 19 vaccine

Dear s22

I forgot to mention that as Mon 18 is a public holiday in the US, any further negotiation regarding this matter, which will require global agreement, would be unlikely to be resolved before Wednesday (Syd/Can time).

Kind regards,

s22 Senior Regulatory Affairs Associate, Global Regulatory Affairs - International
Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s22

Pfizer Breakthroughs that change patients' lives®

From: s22 @pfizer.com>
Sent: Monday, 18 January 2021 3:25 PM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; COOK, Jane <Jane.Cook@health.gov.au>; s22 @pfizer.com>; s22 @pfizer.com>; s22 @pfizer.com>; s22 @pfizer.com>
Subject: RE: Further PI changes requested to Pfizer covid 19 vaccine

Dear s22 ,

In relation to your email below suggesting amendments to the Comirnaty PI, Pfizer would like to provide the following updated information:

On 15 Jan 2021, the Norwegian Medicines Agency and the National Institute of Public Health announced that 23 deaths associated with the COVID-19 vaccine had been reported and 13 were assessed. They stated that adverse reactions experienced by the elderly frail following vaccination (e.g. fever, nausea) may have contributed to the fatal outcomes. They further stated that adverse reaction statistics for the different COVID-19 vaccines are not directly comparable because they have not been used in the vaccination program for the same length of time and because they are administered to different numbers of people and to different age groups.

Also, on 15 Jan 2021, the Norwegian Institute of Public Health updated their COVID-19 vaccination guide with more detailed advice on vaccinating the frail elderly stating:

For most elderly who live with frailty the reduced risk of becoming seriously ill from COVID-19 will greatly outweigh the possibility to experience adverse reactions after taking the vaccine. However, for those who have serious frailty, relatively mild adverse reactions to the vaccine can

have serious consequences. For those who have a very short lifespan left, the gains of taking the vaccine can be marginal or irrelevant. For severely frail patients (for example equivalent to Clinical Frailty Scale 8 or higher) and terminally ill patients, it is therefore recommended to do a careful assessment of the benefit versus risk of the vaccination.
Pfizer has received and assessed 15 spontaneous fatal reports for Pfizer/BNT COVID-19 vaccine from Norway as of 17 Jan 2021. Thirteen of the cases provided some clinical detail on the patients' conditions before or after vaccination. All the elderly patients were frail and appeared to be nursing home residents. They had multiple co-morbidities including dementia, cardiovascular, cerebrovascular, renal, pulmonary and metabolic disease and were on concomitant medications. Some of the patients were described as terminal and/or bedridden and some were being treated for concomitant infections. Five of the patients were described as having had reactogenicity events such as malaise, nausea, diarrhea, fever or vaccination site swelling and redness. It appears that none of the patients underwent autopsy so definitive causes of death are not available. Pfizer will continue to review all reports of death coincident with vaccination with the Pfizer/BNT COVID-19 vaccine and will update safety information for healthcare professionals and vaccine recipients as warranted.

Based on the above information, Pfizer does not feel that the addition of the proposed statement in the PI is warranted at this time.

Of course Pfizer will, however, continue to keep the TGA informed of any developments regarding this matter.

Kind regards,

s22 Senior Regulatory Affairs Associate, Global Regulatory Affairs - International
Level 15-18, 151 Clarence Street, Sydney, NSW, 2000 / s22

From: s22 @health.gov.au>
Sent: Monday, 18 January 2021 10:49 AM
To: s22 @pfizer.com>
Cc: s22 @health.gov.au>; COOK, Jane <Jane.Cook@health.gov.au>
Subject: [EXTERNAL] Further PI changes requested to Pfizer covid 19 vaccine [SEC=UNOFFICIAL]

Hi, s22,

With the emerging safety issues in the frail elderly, I would like to request the following statements to be included to the PI Section 4.4 "Special warnings and precautions for use" "Use in the elderly" subsection :

The data for use in frail elderly is limited in the clinical trial. The potential impact of systemic adverse events in the frail elderly should be carefully considered before vaccinating individuals in this group.

Please inform TGA if you have any update regarding the regulatory action taken by FDA, EMA, and other regulatory agecies on this issue.

Kind regards,

s22

s22
s22 – Clinical Evaluation Section A

Medicines Regulation Division | Health Products Regulation Group
Prescription Medicines Authorisation Branch
Australian Government Department of Health

T: s22 | E: s22 @health.gov.au
Location: TGA Symonston, 136 Narrabundah Lane, Symonston ACT 2609
PO Box 100, Woden ACT 2606, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.