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Subject: from the Red phone for tomorrows catch up [SEC=OFFICIAL]
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Based on information received from the Norway EMA PRAC member:

- 42.003 people received the first dose (as of 14-01-2021); first priority for vaccination in NO is nursing homes and long term care facilities and hence all/almost all people who received the first dose so far are >80 years old
- review of 13 cases triggered the Press Release (currently in NO there are over 30 reports of fatal cases; under review); uniform picture – nausea, vomiting, diarrhoea leading to acute kidney injury in frail patients; some additional details in the attached below; PR aimed to flag to HCP to carefully consider B/R of vaccination in frail patient; no updated communication expected at this stage
- an average of around 400 people die every week nursing homes and long term care facilities (we cross checked that with EUROSTAT data)
- in Norway, 3.7% of population in older than 80 years of age; Total population Norway: 5,367,580; Total population > 80: 203,431.

Incident Review Network and PRAC are informed. General LTT (covering deaths among the elderly) was sent yesterday to the network and communication colleagues will consider if an update is required.

Next steps: we are performing an analysis of fatal reports in EudraVigilance (aiming at preliminary results on Monday for all fatalities in EU); will obtain further details on NO reports not in EV, liaise with the PRAC rapporteur to consider if action is required based on review of the cases; ETF advice can be sought next week, as needed

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