**ATTACHMENT A**

**SCHEDULE OF DOCUMENTS – FOI 3094**

| Doc No. | Date | Pages | Description | Decision on access[1] | Exemption |
|---|---|---|---|---|---|
| 1 | 1 October 2021 | 77 | Covid-19 Vaccines and Treatments State of Play | RI | section 22 (Part) |

[1] RIE = Release with Irrelevant Information Removed

**COVID-19 Vaccines and Treatments: State of Play – w/e 1 October 2021**

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Headline updates

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- There are **315** vaccine candidates in pre-clinical and clinical trials, including **121** undergoing clinical trials in humans (WHO COVID-19 vaccine candidate landscape). **3505** randomised controlled trials relating to COVID-19 have been registered with the WHO International Clinical Trials Registry Platform.
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Vaccine efficacy against SARS-CoV-2 variants

| | | Variant (country first reported) (WHO label) | | | | |
|---|---|---|---|---|---|---|
| | | Original strain | B.1.1.7 (UK) (Alpha) | B.1.351 (South Africa) (Beta) | P.1 (Brazil) (Gamma) | B.1.617 (India) (Delta) |
| Vaccine | Pfizer/BioNTech | 95% efficacy | 95.3% efficacy (published) | 75% efficacy (correspondence) | No significant difference (correspondence) | 88% efficacy (published)<br>5.8 fold decrease in antibody titres (correspondence) |

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| Laboratory studies | Neutralising antibodies in sera of vaccinated people. Neutralising titres are described relative to the original SARS-CoV-2 strain. |
| In clinical trials | Prevention of symptomatic COVID-19 in vaccinated people was assessed in Phase 3 clinical trials. |
| Real-world Data | Prevention of symptomatic COVID-19 in vaccinated people was assessed in a large-scale, national level study. |

## Vaccines

## Clinical trials

| | | Clinical Trial Phase | | | Regulatory status | | | |
|---|---|---|---|---|---|---|---|---|
| Vaccine candidate | Technical platform | 1 | 2 | 3 | Australia (TGA) | Overseas regulators | CEPI | COVAX |
| Pfizer/BioNTech | mRNA | P | P | P | Provisional approval | Approved in 90 countries WHO Emergency Use Listing | | X |

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*Table key*

| | | | | |
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| Final results | | | | **Shaded cell** denotes results announced or preprint |
| Preliminary results | | | | **P** denotes results published in a peer-reviewed journal |
| Phase commenced and ongoing | | | | |

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## mRNA:

- The **Pfizer/BioNTech** mRNA vaccine (COMIRNATY, BNT162b2) from the US/Germany
  - Phase 3 results showing 95% efficacy were released in the New England Journal of Medicine in December 2020.
  - On 31 March 2021, Pfizer announced results of a study in adolescents aged 12 – 15 years old, with 100% efficacy in the 1131 participants, which exceeded the results in the 16 – 25 years group. The vaccine was generally well-tolerated.
  - On 18 May 2021, preliminary results of a trial of "mixing and matching" the AstraZeneca and Pfizer vaccines in 600 people in Spain were announced in an online presentation. The Pfizer vaccine substantially boosted antibody responses in people previously vaccinated with the AstraZeneca vaccine.
  - On 22 May 2021, results of a German study on the safety of "mixing and matching" the AstraZeneca and Pfizer vaccines in 326 healthcare workers were made available in preprint. The study showed a comparable safety profile for Pfizer-Pfizer and AstraZeneca-Pfizer schedules at an interval of 12 weeks.

- On 24 May 2021, Pfizer initiated a study exploring the co-administration of its 20-valent pneumococcal conjugate vaccine candidate with a third dose of the COVID-19 vaccine in adults 65 years and older.
- On 28 May 2021, Pfizer announced that the Conditional Marketing Authorization for Pfizer in the EU had been expanded to include individuals 12 to 15 years of age. This extended the use of Pfizer in all 27 EU member states.
- On 1 June 2021, Israel reported a possible link between the Pfizer vaccine and myocarditis (inflammation of the heart muscle), particularly seen in young men. One in 3000 to 6000 young men aged 16 to 24 who received the vaccine developed the condition, but most cases were mild and resolved within a few weeks.
- On 14 June 2021, Public Health England released data suggesting that the Pfizer vaccine is 96% effective against hospitalisation from the Delta variant, in those who have had two doses of the vaccine.
- On 29 June 2021, preliminary results from 463 participants in the Com-COV trial, investigating a mix and match approach to COVID-19 vaccines, were released.
- On 21 July 2021, a study in the New England Journal of Medicine showed that the effectiveness after one dose of vaccine was notably lower (30.7%) among persons with the delta variant, than among those with the alpha variant. For the Pfizer vaccine, the effectiveness of two doses was 93.7% among persons with the alpha variant, and 88% among persons with the delta variant.
- On 23 July 2021, the TGA granted provisional approval of the Pfizer-BioNTech COVID-19 vaccine to include 12 – 15 years.
- On 12 August 2021, the FDA authorised third doses of Pfizer and Moderna's coronavirus vaccines for people with weakened immune systems.
- On 16 August 2021, Pfizer announced submission of initial data to US FDA to support booster dose of COVID-19 vaccine.
- On 23 August 2021, the FDA granted full approval to the Pfizer/BioNTech COVID-19 vaccine for people age 16 and older. The vaccine is the first COVID-19 vaccine to be granted approval by the FDA
- On 27 August 2021, ATAGI recommended vaccination against COVID-19 for all individuals from 12 years of age, extending the current recommendation for those aged 16 years and older.
- On 31 August 2021, a pre-print study was released in MedRxiv that demonstrated that waning vaccine-induced protection against SARS-CoV-2 infection may be countered in the short term by a third dose of Pfizer.
- On 6 September 2021, the EMA announced they have started evaluating:
    - an application for the use of a booster dose of Comirnaty to be given 6 months after the second dose in people aged 16 years and older.
    - data from the literature on the use of an additional, third dose of an mRNA vaccine (Comirnaty or SpikeVax) in severely immunocompromised people.
- On 17 September 2021, the FDA's Vaccine and Related Biological Products Advisory Committee voted to recommend the FDA grant EUA for a booster dose of Comirnaty in individuals 65 years of age and older and individuals at high risk of severe COVID-19. The committee recommended that the additional dose be administered at least six months after the two-dose series. The panel also agreed that healthcare workers and others at high risk for occupational exposure should be included in this EUA. At this time, VRBPAC did not vote in favour of approval of a booster dose for the full population for which Pfizer and BioNTech submitted their supplemental Biologics License Application, which was individuals 16 and older.

- On 20 September 2021, Pfizer and BioNTech announced positive topline results from their trial of COVID-19 vaccines in children under 12 years of age. Children aged 5 – 11 years had a two dose regimen of 10 micrograms, and demonstrated that the vaccine was safe, well tolerated and showed robust neutralising antibody responses.
    - Data will be submitted to the FDA, EMA and ither regulatory agencies as soon as possible.
- On 22 September 2021, Emergency Use Authorisation was granted for individuals 65 years of age and older, and individuals aged 18 through 64 within certain risk groups (high risk of severe COVID-19 and frequent occupational to SARS-CoV-2), for a COVID-19 vaccine booster of the Pfizer vaccine.
    - A booster dose given at least six months after completion of the primary series may help preserve a high level of protection against COVID-19.
- On 28 September 2021, Pfizer announced they had submitted data to the US FDA from the Phase 2/3 trial of their COVID vaccine in children 5 – 11 years.
- On 1 October 2021, the Australian Government Health Minister, the Hon Greg Hunt MP announced that all Australians aged 12 and over would be eligible to receive an mRNA COVID-19 vaccine (Moderna or Pfizer) from their GP or pharmacist.

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