Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Minutes

Meeting 23, held 30 July 2021

COMMITTEE IN CONFIDENCE

TRIM Reference no. D21-2922956

TGA Health Safety Regulation

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[redacted]

Item 3 Pharmacovigilance Issues

3.1 COVID-19 vaccine AstraZeneca and Guillain-Barre Syndrome

s22

[redacted]

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Document 1

ACV Advice

s22

[redacted]

2. **The Committee is requested to provide advice on whether the addition of GBS to the Australian Product Information (PI) for COVID-19 Vaccine AstraZeneca (ChAdOx1-S) would be an appropriate risk minimisation measure at this time based on currently available evidence?**

The ACV advised that a warning on GBS should be included in the Product Information. This would alert practitioners to the risk.

Wording aligned with the European summary of product characteristics would be suitable.

3. **If an update for the Australian Product Information (PI) for COVID-19 Vaccine AstraZeneca (ChAdOx1-S) is recommended, can the committee provide advice on suitable messages for the general public, particularly concerning the discrepancy between the number of reported cases and the number considered to be possibly related to vaccination?**

The ACV noted the usual process for warnings in the PI to be included in the CMI.

'Greater than expected' was suitable wording for consumers, with explanation that there is a background rate of GBS in the absence of vaccination. A simple tabulation of expected and observed cases could be useful.

Useful information for consumers includes: what are the risks? how serious? symptoms and time window of onset? what to do and where to go? what is the prognosis for recovery?

Given the expanding lists of adverse events, it was noted that consumers may appreciate a timeline setting out which adverse events may occur in what time windows following vaccination.

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Attachment 1

Minutes for the Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators Teleconference

Date: 14 September 2021

Chair: s22 [redacted]

s22 [redacted]

s22 [redacted]

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5. Update Summary

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VIC reported:

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s22 [redacted]

- Victoria is publishing a public facing weekly report about adverse event summaries on the website – data is from the last week. See https://mvec.mcri.edu.au/vaccinesafety/

s22 [redacted]

Document 3

The Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators (TGA AEFI JIC) Teleconference

Tuesday 6 July 2021

Chair s22 [redacted]

s22 [redacted]

Attachment 1: Minutes of TGA AEFI JIC teleconference, 29 June 2021

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[redacted]

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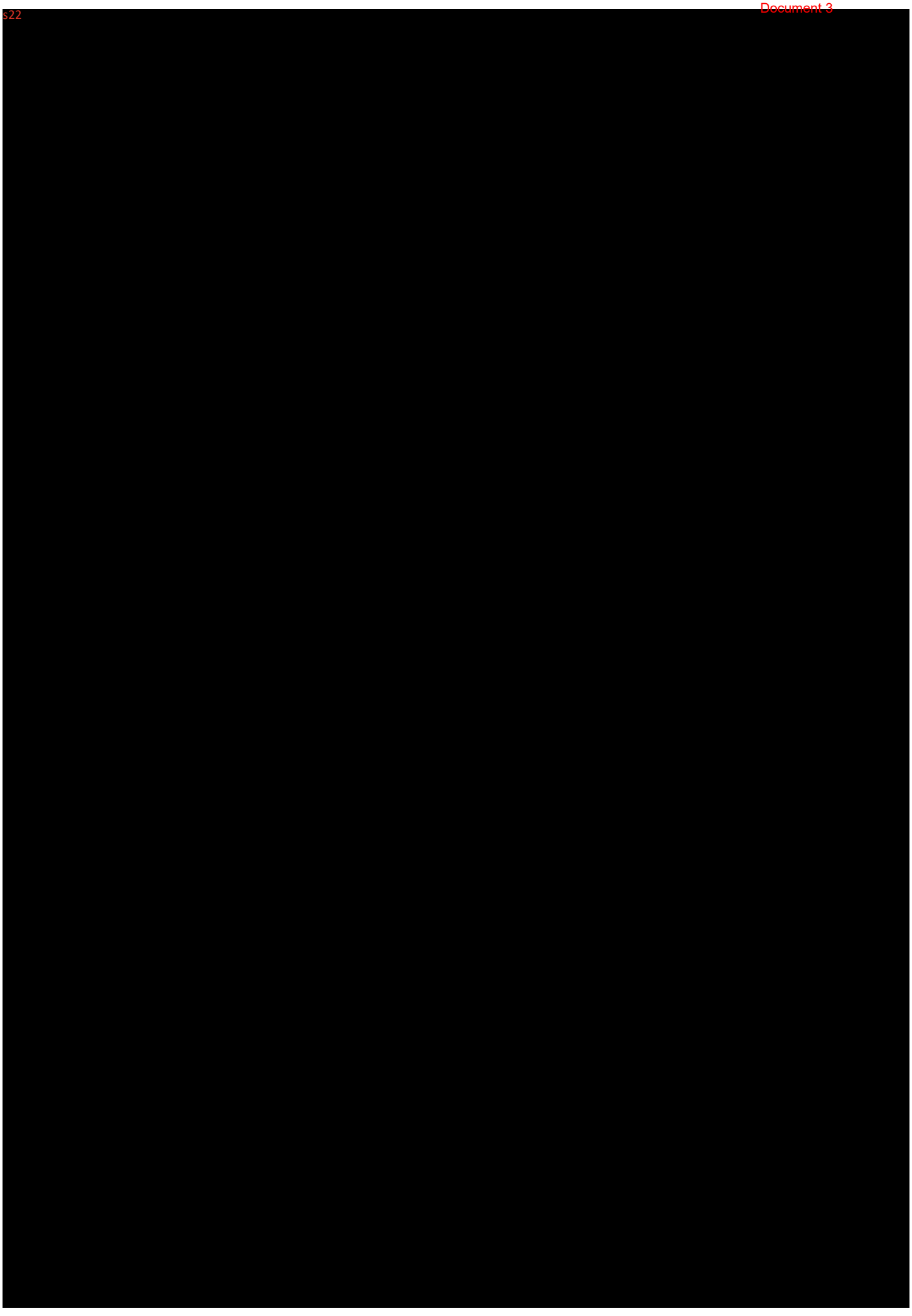
Document 3



7 Serious AEFI of interest for discussion

- TTS has been the main concern for the last several months. The TGA presented on TTS cases based on data current to 29 June 2021.

- NCIRS commented that there was value in providing the rates by age group data as part of the weekly safety update report. The public availability of rate and severity is important to support GPs in being able to advise on risk and benefit.

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Document 4

The Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators (TGA AEFI JIC) Teleconference

Tuesday 30 March 2021
Chair: s22

Minutes of TGA AEFI JIC teleconference, 23 March 2021

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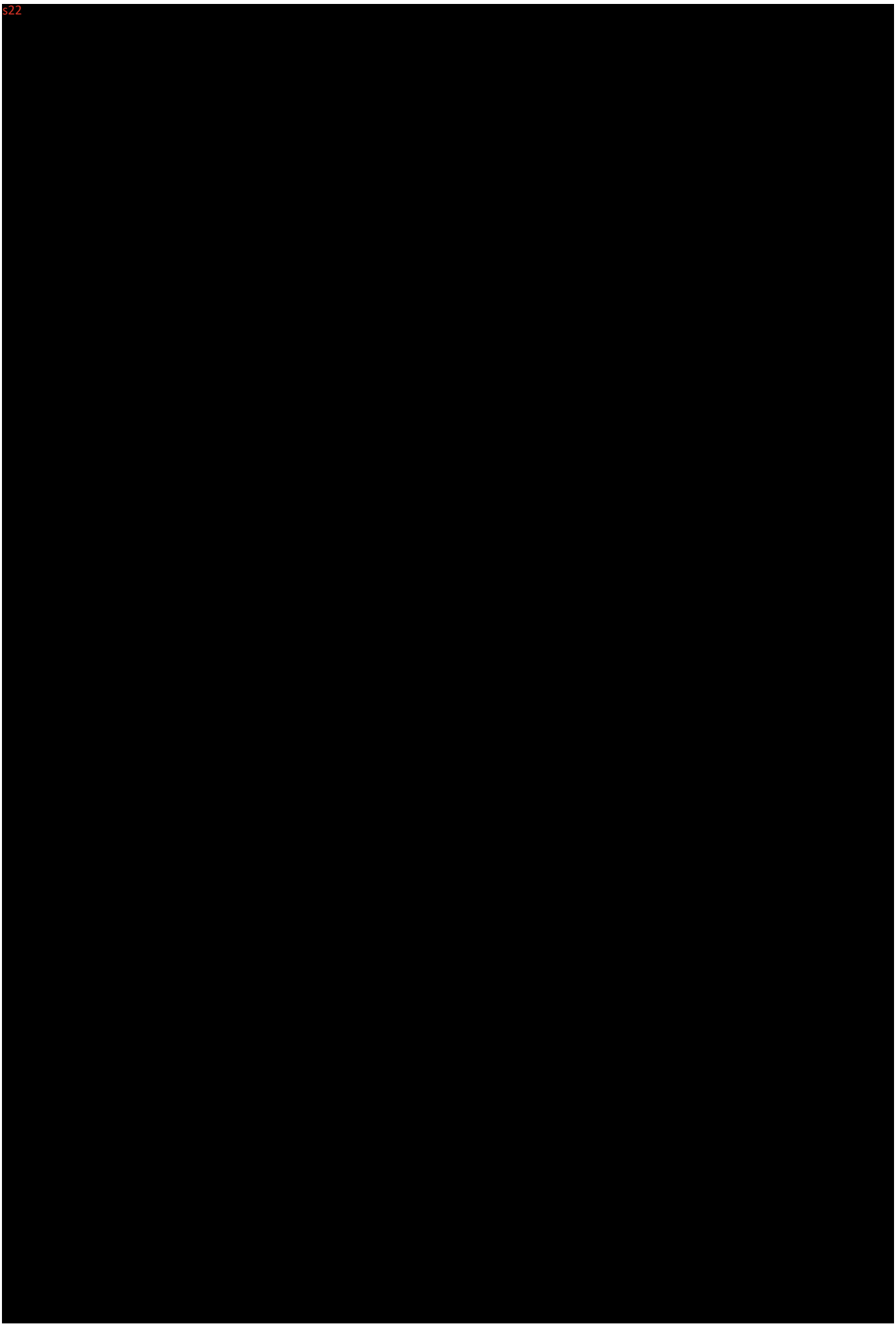

s22 [redacted]

5. Round Table

5.1 TGA COVID-19 vaccination surveillance update

The TGA presented the latest data (up to 21 March 2021) based on AEFI reports received by the TGA on Pfizer and AstraZeneca COVID-19 vaccines. There were a total of about 280,000 doses administered, 1508 AEFI reports received, and a reporting rate of 5.4 per 1000 doses across both vaccines. The reporting numbers were higher in VIC and NSW due to population. More detailed information is provided in the TGA COVID-19 vaccine weekly safety report (to be published on Wednesday 24 March 2021). s22 [redacted]

s22 [redacted]

s22 [redacted]

[redacted]

Vaccine Safety Investigation Group (VSIG) Recommendations

Wednesday 28 July 2021

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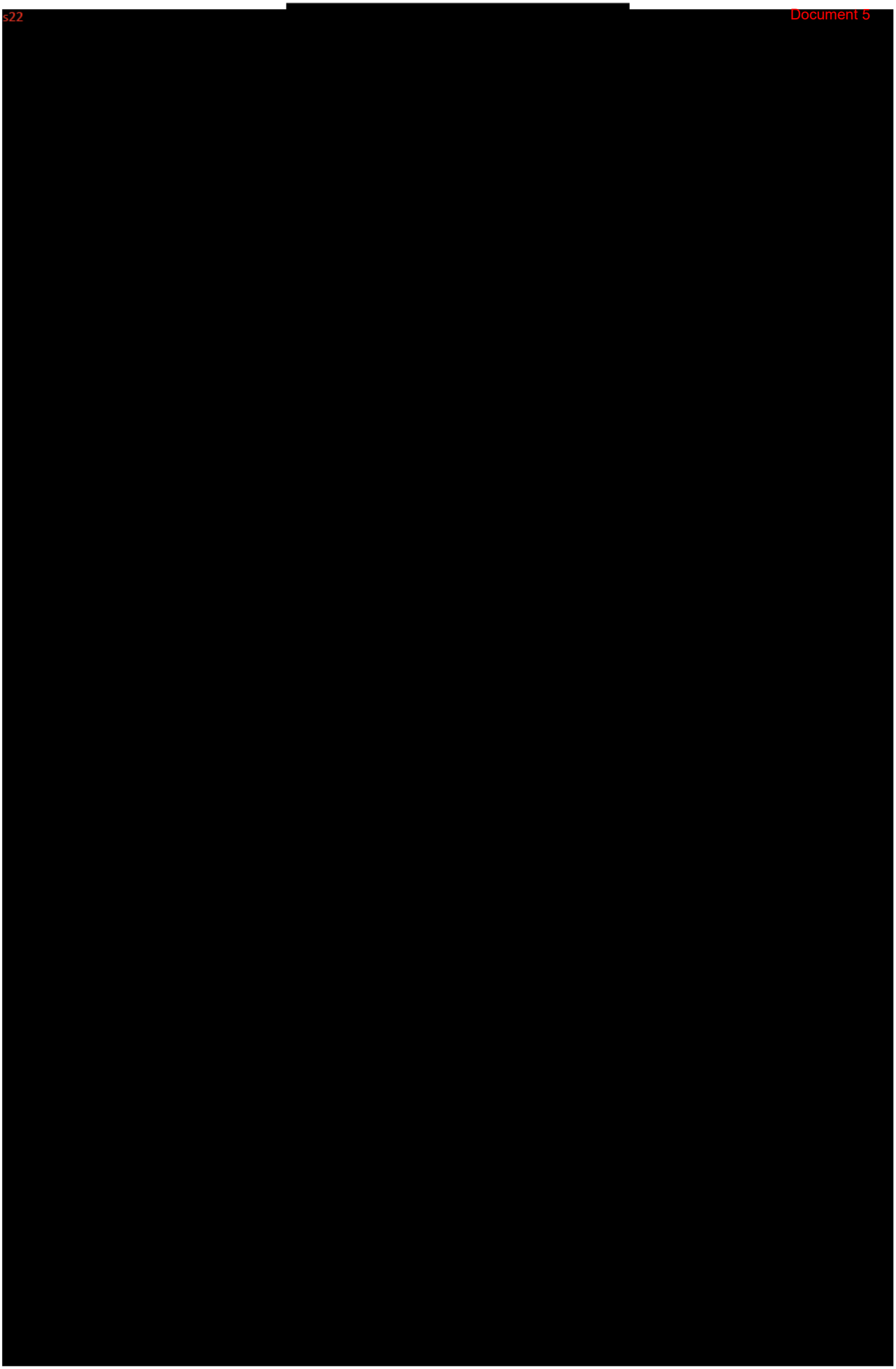

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[redacted]

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[redacted]. The VSIG considered that the outcomes of the meeting could be taken as an opportunity to provide a positive message to the public:

- The VSIG have not been able to confirm any cases of TTS following dose 2 of the COVID-19 vaccine AstraZeneca.

[redacted]

The group advised that for potential second dose cases specific communication should be provided by the TGA:

- Australian TTS rates should be made public once these available.
- In the absence of a sufficiently large Australian dataset the second dose rates available from the UK should be provided to the Australian public.
- s22 [redacted]

The TGA advised it planned on communicating these cases in the weekly report on 29 July 2021, providing some of the clinical detail of the cases.

Document 6

Australian Government

Department of Health

Therapeutic Goods Administration

electronic Vaccine Safety Investigation Group (eVSIG) assessment report

Tuesday 24 August 2021

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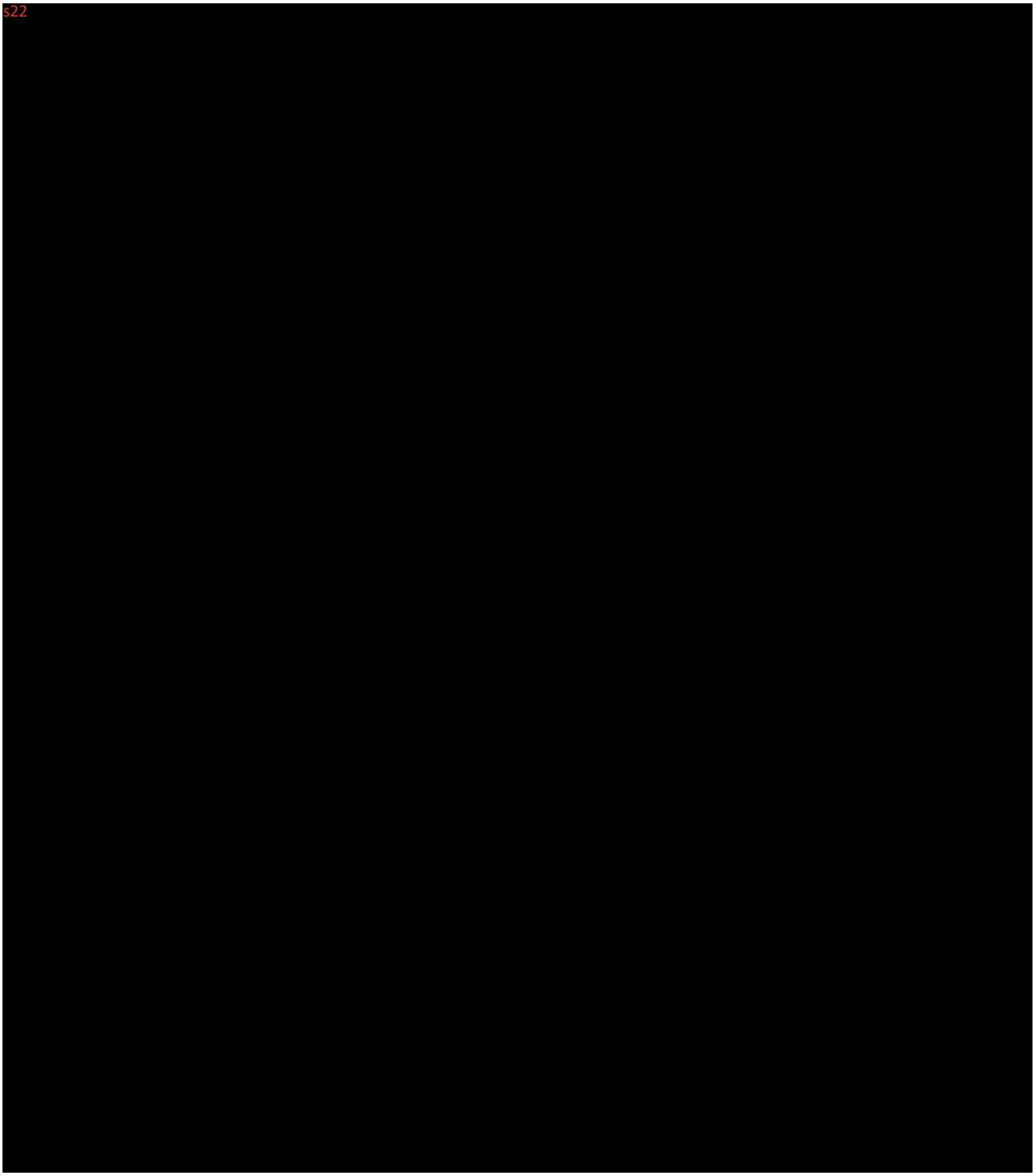

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TGA Health Safety Regulation

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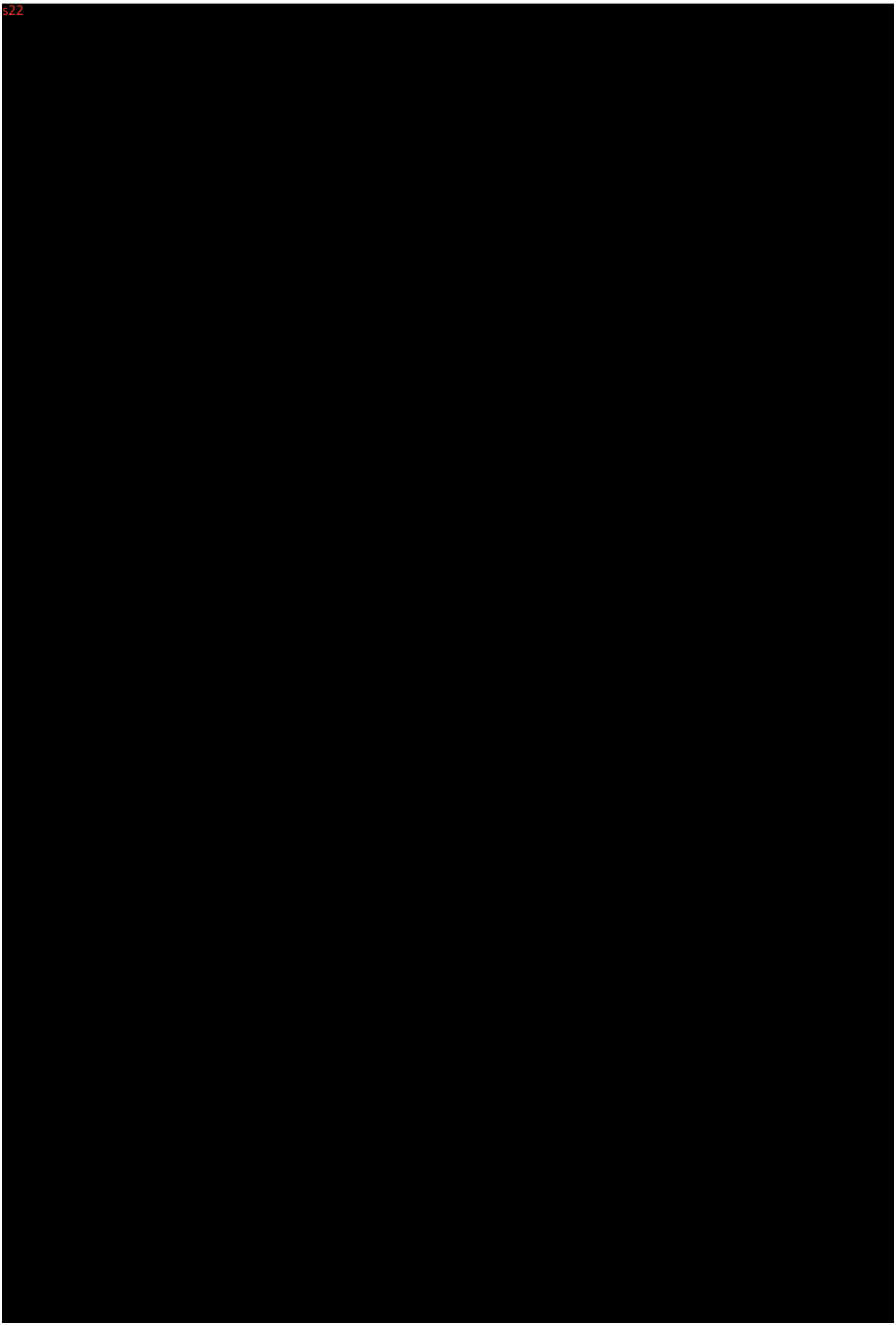

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[redacted]

Communication recommendations (to the TGA)

The VSIG advised that communications on second dose cases should reflect the following points:

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[redacted]

- inclusion of separate rates of TTS following first and second doses in publications, such as 'X million second doses administered and nil confirmed case'

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[redacted]

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The TGA advised it planned to publish this summary, as a media release or part of the weekly report on 26 August 2021.

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Document 7

The Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators (TGA AEFI JIC) Teleconference

Tuesday 15 June 2021

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[redacted]

Attachment 1: Minutes of TGA AEFI JIC teleconference, 8 June 2021

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[redacted]

s22 Document 7

[redacted]

7 Serious AEFI of interest for discussion

- The TGA presented reporting rates for TTS cases. Well over 3 million doses have been administered. Based on the number of doses administered as well as the new cases to inform the weekly safety update report. s22 [redacted]

[redacted]

The Therapeutic Goods Administration Adverse Event Following Immunisation Jurisdictional Immunisation Coordinators (TGA AEFI JIC) Teleconference

Date: Tuesday 27 July 2021

Chair s22 [redacted]

s22 [redacted]

ATTACHMENT 1: Minutes of the TGA AEFI JIC teleconference 20 July 2021

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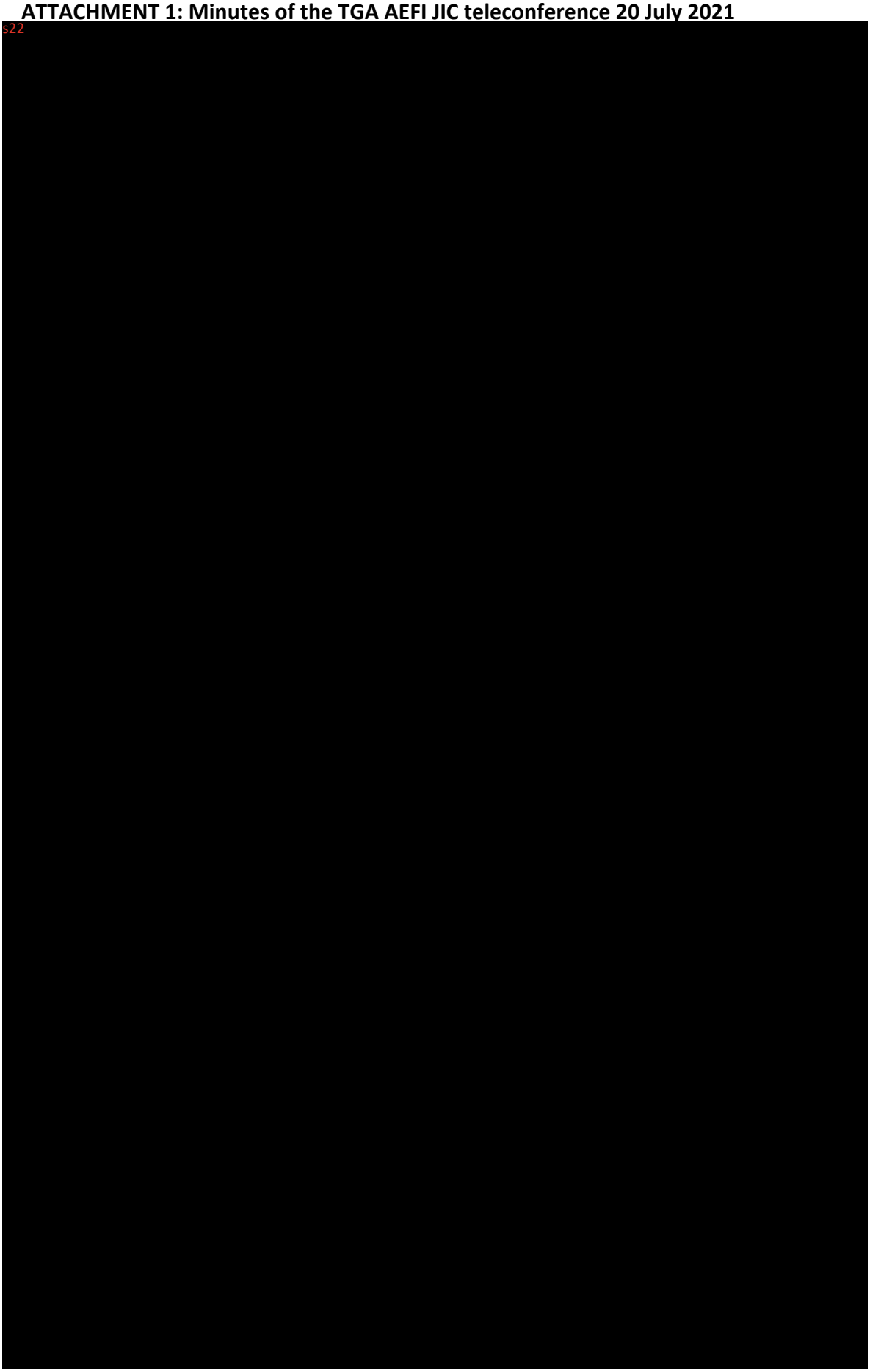

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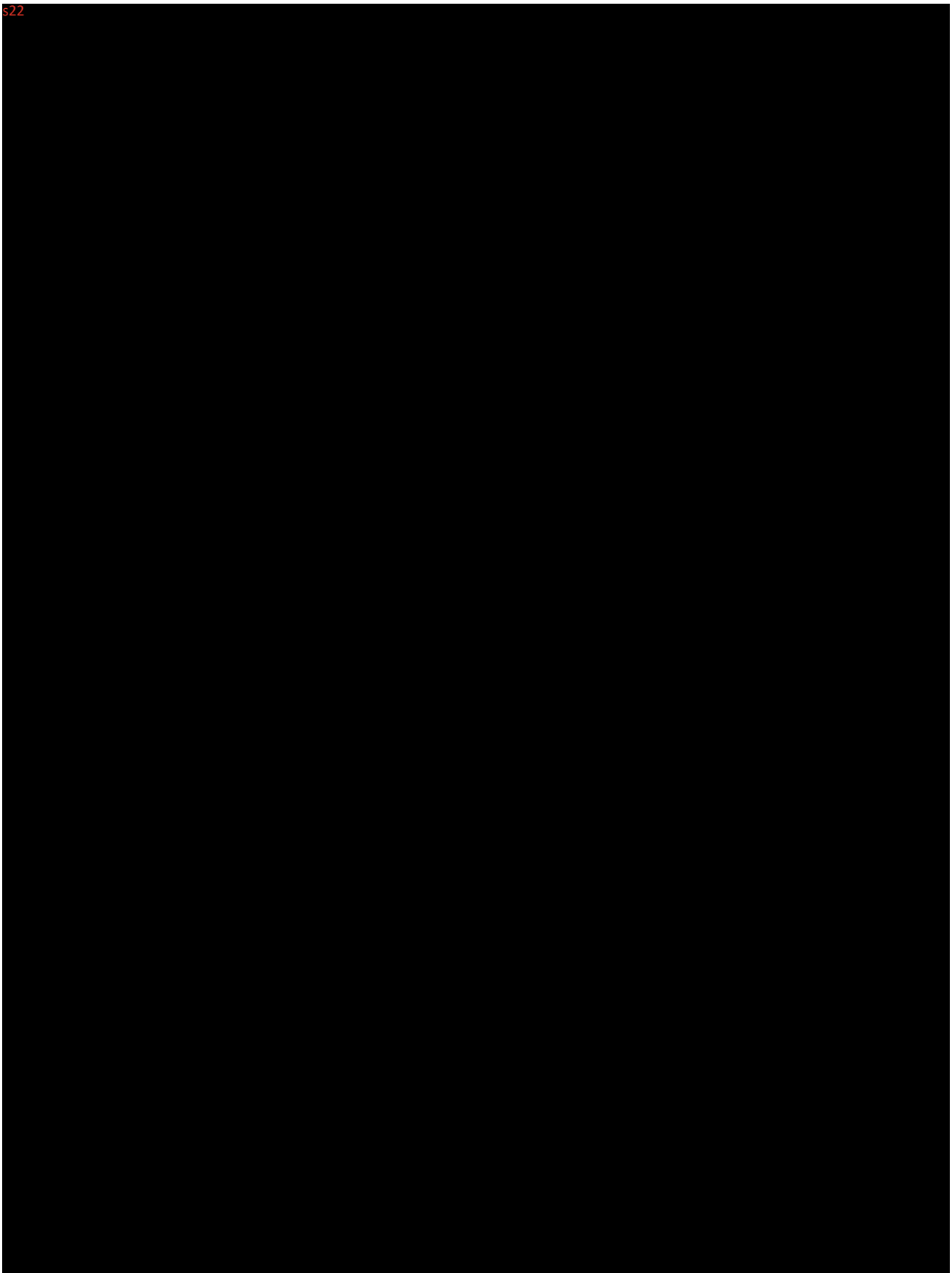

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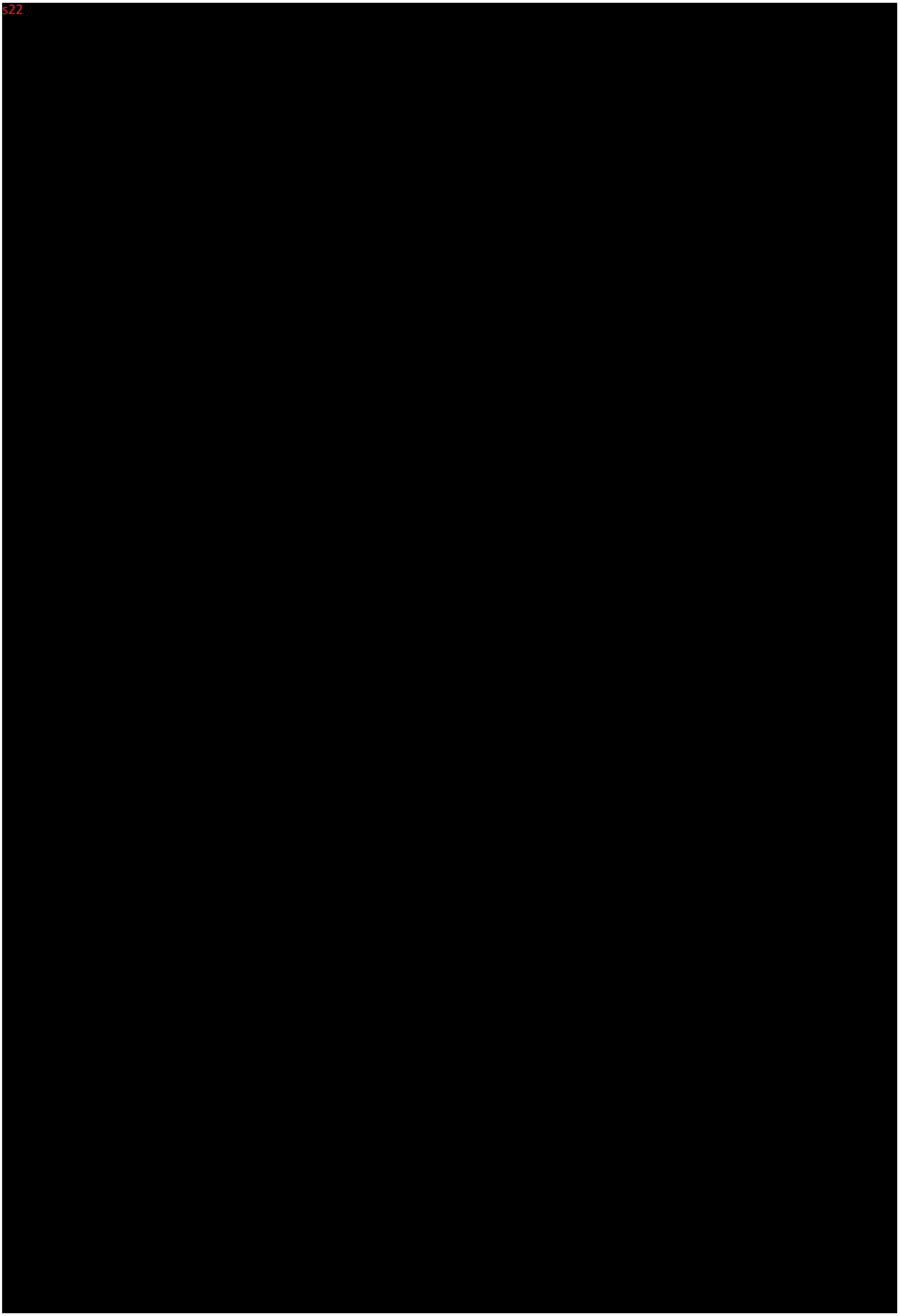

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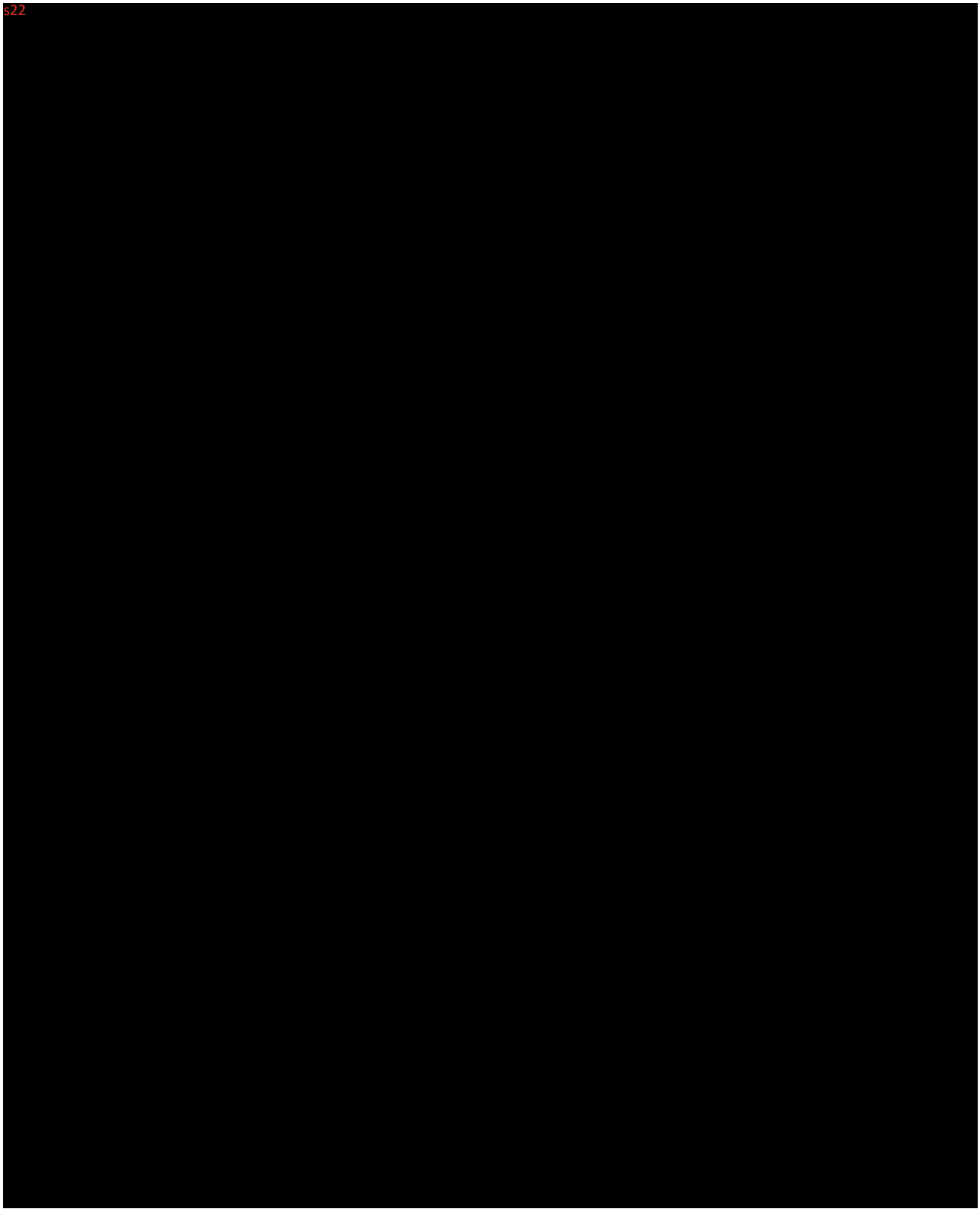

7. Serious AEFI of interest discussion

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- TGA presented on TTS cases based on current data:

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s22 [redacted]

- 40-49 years cohort remains stable and is the highest cohort in terms of rate. There is a gradual and slight creeping up of the 70-79 year old cohort.
- Overall the TTS rate is 1.9 per 100,000 doses – slightly increased.

s22 [redacted]

- NSW query whether the TGA will publish these rates. TGA noted that it has not been publishing rates within the weekly report however the information is presented to ATAGI who have been publishing their rates. SAEFVIC added that rates are published in the weekly ATAGI report and in the document: https://www.health.gov.au/sites/default/files/documents/2021/06/covid-19-vaccination-weighing-up-the-potential-benefits-against-risk-of-harm-from-covid-19-vaccine-astrazeneca_2.pdf. NCIRS explained that the rate in 40-49 is higher but also the denominator is smaller and CIs wide. It is severity in younger that stands out.

s22 [redacted]

Australian Government
Department of Health
Therapeutic Goods Administration

Advisory Committee on Vaccines

Minutes

Meeting 24, held 26 August 2021

COMMITTEE IN CONFIDENCE

TRIM Reference no. D21-3339317

TGA Health Safety Regulation

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s22 Document 9

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Item 2 Premarket Issues

2.1 Spikevax – Moderna Australia – new vaccine

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[redacted]

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ACV advice to the Delegate

The ACV advised the following in response to the Delegate's specific request for advice:

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3. Advice on any other issues relevant to the decision on whether or not to approve this application

The ACV advised that the Product Information should a precaution regarding higher risk of myocarditis / pericarditis in males under 30 years of age after the second dose. The Product

Information should describe the rate and severity of this AEFI, which currently appears to be relatively mild in most people.

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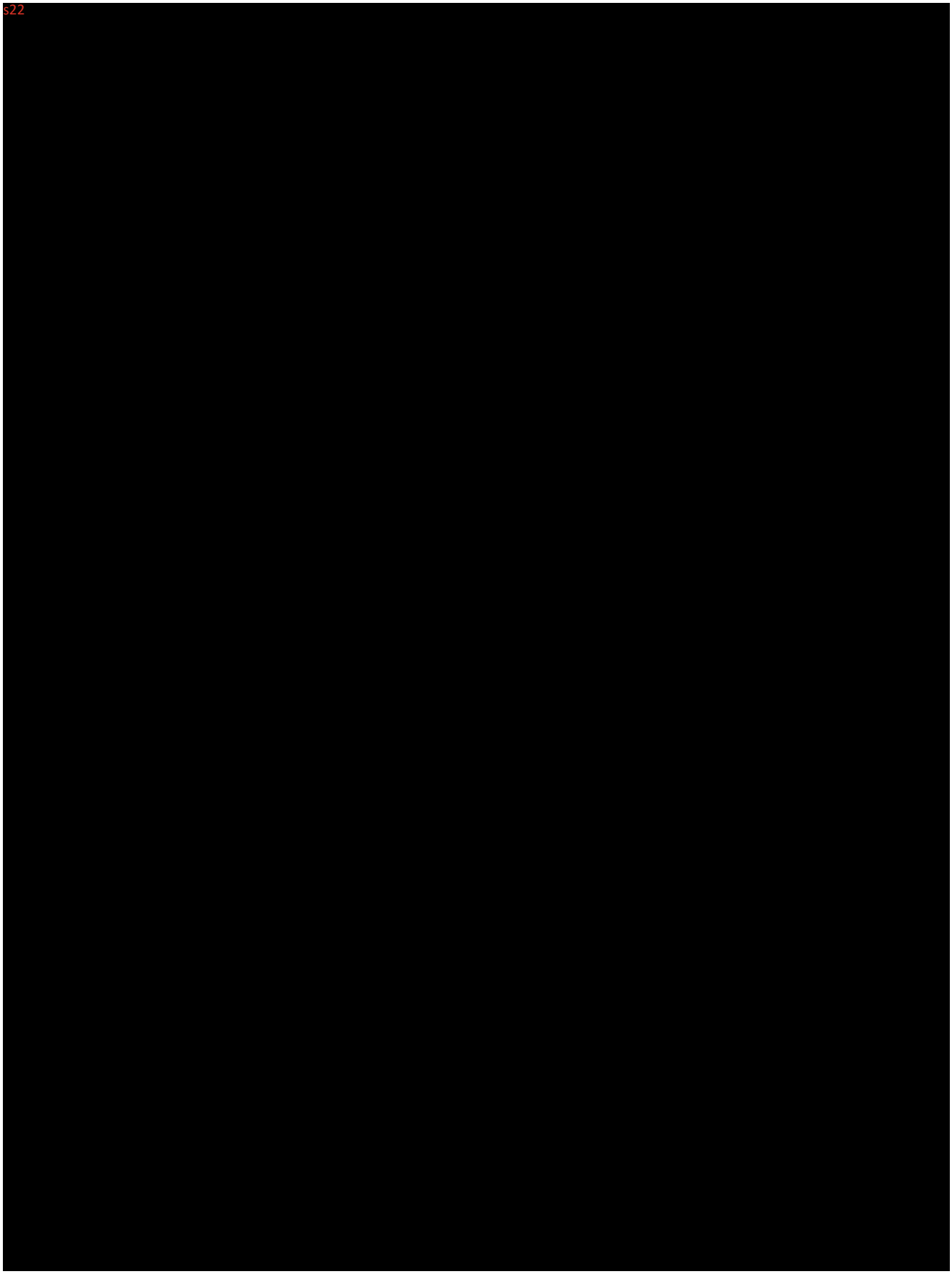
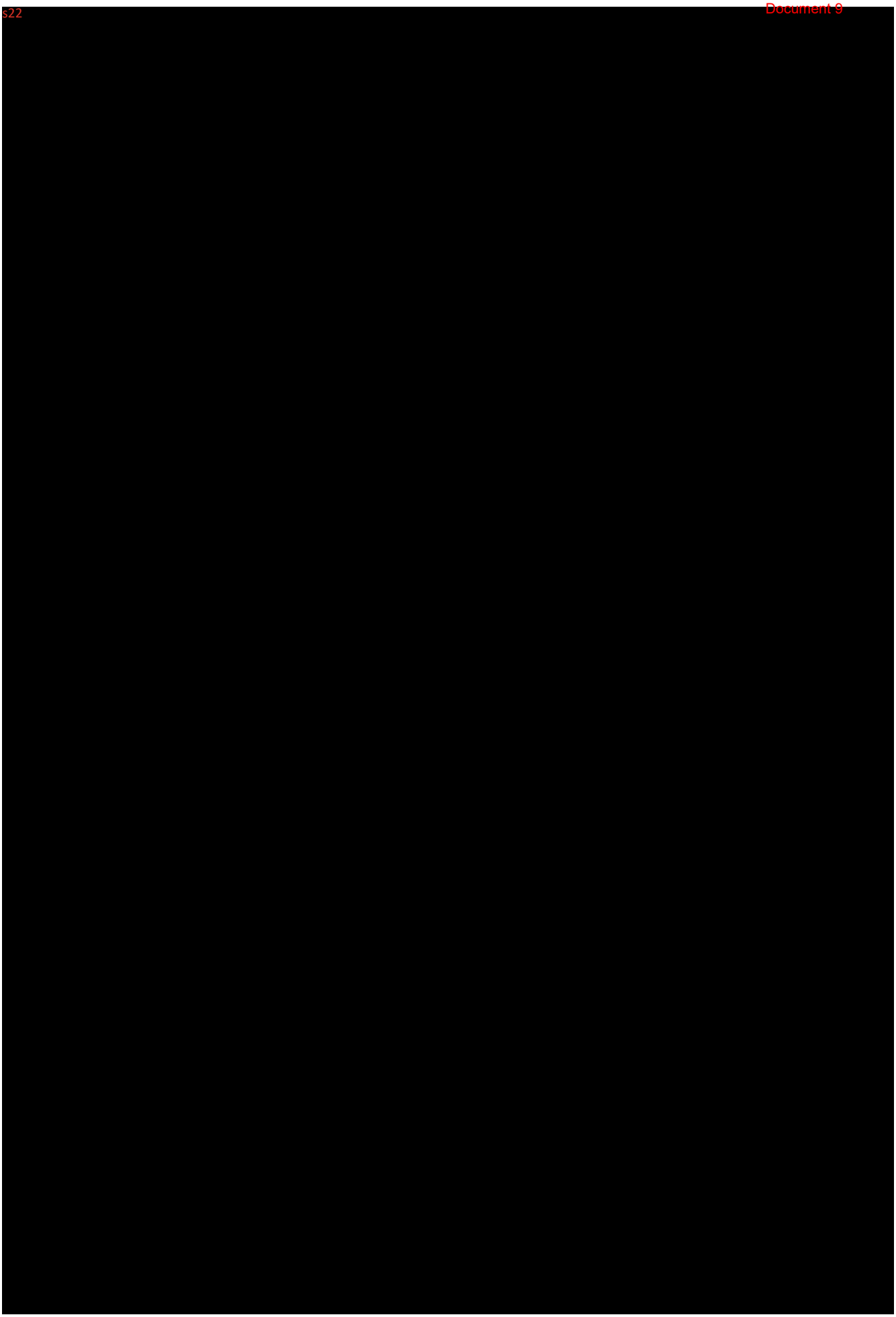


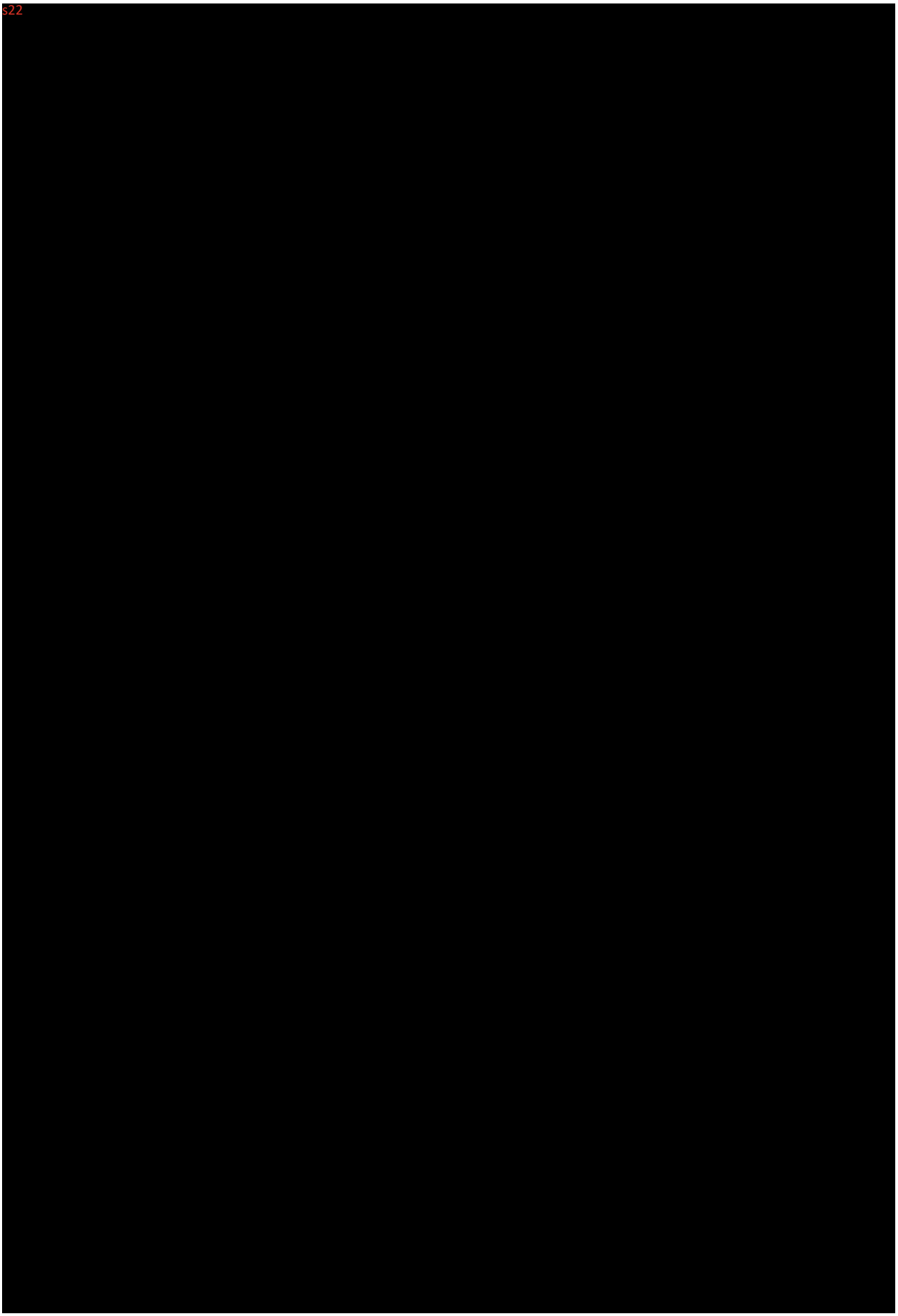


ICMRA COVID-19 Vaccines Pharmacovigilance Network

Date: 16 November 2021 Chair: s22 [redacted]

Meeting #27 –Draft minutes

s22 [redacted]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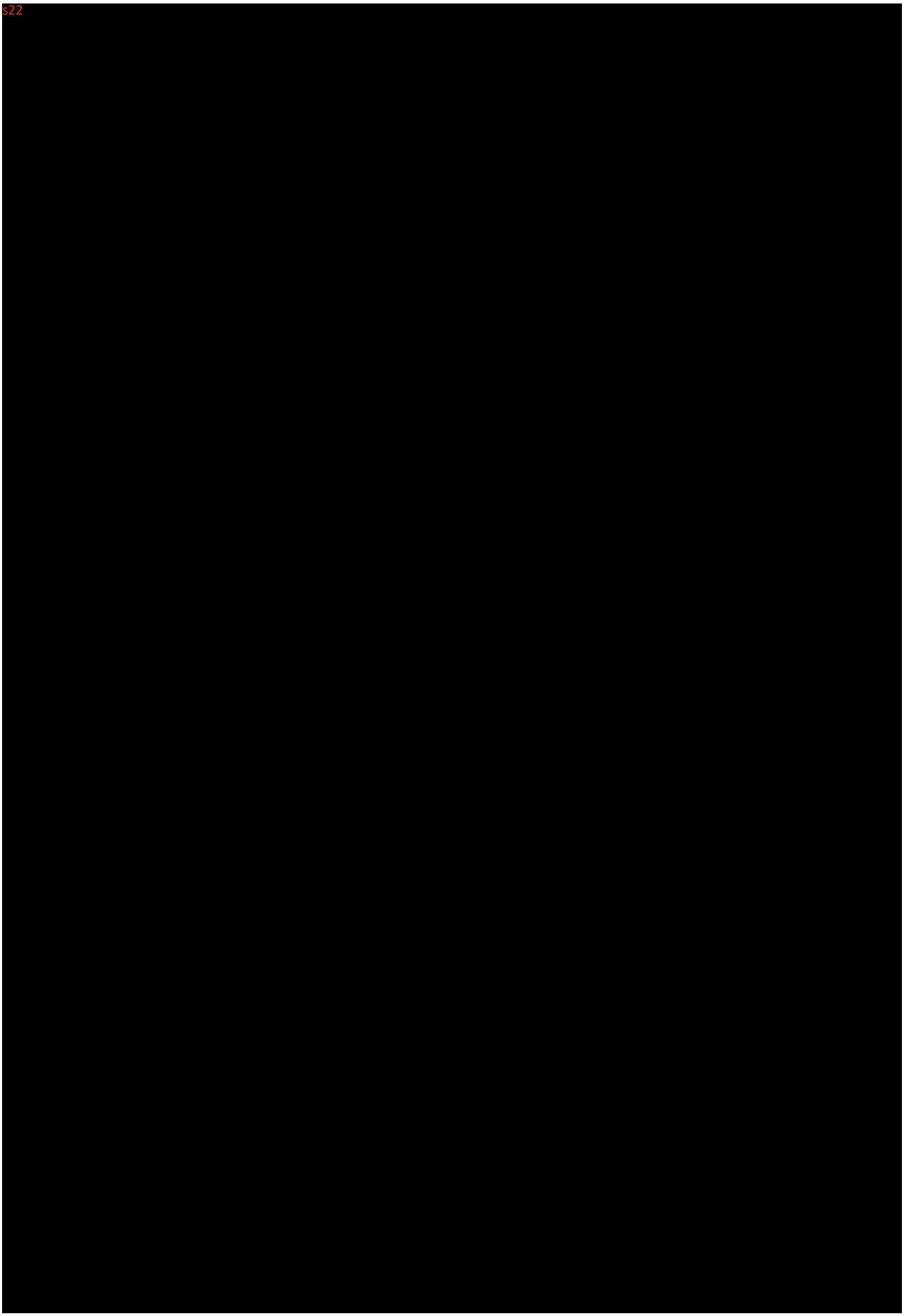
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TGA:

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-Myocarditis: s22 Rate 1.3/100,000 doses of Pfizer (1st and 2nd doses). Rate increases for 2nd dose. In weekly report.

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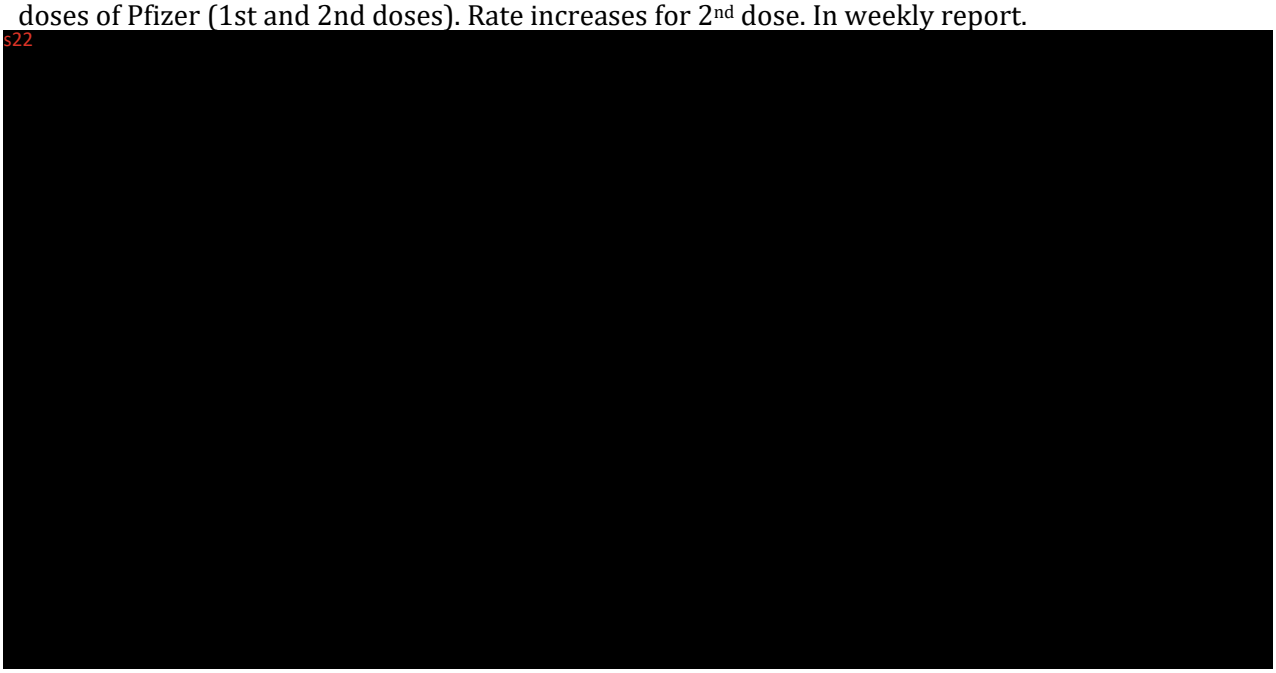

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