Acknowledgement email

Email	s11C	
Email from	adr.reports@health.gov.au	
Email cc		
Subject	TGA Adverse Event (AE)	
	Report S11C [SEC=OFF	FICIAL]
Date and Time	27/07/2022 03:59:05 PM	
Attachments	s11C	

Dear This email is related to your submission to the TGA's Australian Adverse Event Management System (AEMS). Please refer to the attachments.



Australian Government

Department of Health

Therapeutic Goods Administration

Email Address:	
Dear Sir/Madam	
Re: TGA AE Reference:	
Drug: Covishield Vaxzevria (ChAdOx1-S, Oxford/AstraZ	<u>'enec</u>
Your Reference:	

Thank you for submi. ng your adverse event report, which was entered into the Therapeutic Goods Administration's (TGA)'s Adverse Event Management System (AEMS) on 27/7/2022. This report has been identified as a duplicate of AE Report Number which is the active number for this case. If you submit any further information, please quote the active TGA AE reference number allocated.

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If you wish to receive regular updates about Safety Information on medicines and devices you can subscribe to our notification system. Information about subscribing can be found at http://www.tga.gov.au/newsroom/subscribe-rss.htm.Thank you in anticipation of your ongoing assistance.

This is an automatically generated acknowledgment letter. There is no need to respond to this correspondence. Any enquiries about this report should be directed to adr.reports@health.gov.au.

Yours sincerely,

The Adverse Event & Medicine Defect Section on behalf of the Head Pharmacovigilance Branch 27/7/2022

PRIVACY STATEMENT

For general privacy information, go to www.tga.gov.au/about/website-privacy.htm.

Information provided in your report is collected to assist in the post market monitoring of the safety of therapeutic goods under the *Therapeutic Goods Act 1989* (the Act). All reports are entered into the Therapeutic Goods Administration's (TGA's) Australian Adverse Event Management System. Further information about how the TGA uses adverse event information that is reported to it is available at https://www.tga.gov.au/reporting-adverse-events.

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Email cc		
Subject	TGA Adverse Event (A	E)
	Report s11C	[SEC=OFFICIAL]
Date and Time	27/07/2022 04:01:22	PM
Attachments	s11C	

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From: ADR Reports
To: ADR Reports

Subject: Update for file upload: \$11C - [SEC=OFFICIAL] CRM:0004098

Date: Friday, 29 July 2022 2:30:48 AM
Attachments: file upload.xml

This is an automated email generated from a File Upload

Organisation:

Most Recent Information Date: Report type: Amendment

TGA Case Reference Number: 51

Sender Case Reference:

Reported Product Names: Covishield Vaxzevria (ChAdOx1-S, Oxford/AstraZenec

See attached data.

When processing this email, if action is taken in AEMS(i.e.to amend, withdraw or nullify the case), attach this email to the version. If no action is taken, add this email to vaccine file.

AU-TGA-0000746367

Case details:

Sender details:

Reporter details:

Original received date: \$47F

Creation date: 27/07/2022

NSW Health - Immunisation Unit Health Protection NSW

Date sent to WHO:

Involves an unapproved product?:

Unapproved product access:

Modified on:

Decision Reason: Duplicate

Serious ICSR: \$476

Sender type: Regional Pharmacovigilance Centre

Sender's ICSR indentifier: 117334076

Consumer or other non health professional

Patient details:

Patient initials:

Sex: Male

Weight:

Age: 30 (Year)

Date of birth: \$47F

State: \$475

Ethnicity: Phone:

Case narrative:

Reactions:

Preferred term	Onset date	End date	Outcome
Adverse event following immunisation	s47F	s47F	Fatal

Drug information:

Product na	me		Ro	le characterisa	tion /	Action taken
TN010190 C AstraZeneca		e AstraZeneca - CO	VID-19 Vaccine Su	spect		
Dosage/s						
Dosage/s	Interval	Dose form	Route of admin	Start date	End date	Batch

Tests and procedures: