

Australian Government

Department of Health Therapeutic Goods Administration

Post market review compliance dashboard

User guide for sponsors of medical devices



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The purpose of this guidance is to help sponsors and manufacturers understand the process in which the TGA expects sponsor and manufacturer to respond to notifications relating to post-market reviews of medical devices.

This is a guide only, and sponsors and manufacturers are encouraged to familiarise themselves with the legislative and regulatory requirements in Australia. If necessary, seek professional advice as it is the responsibility of each sponsor and/or manufacturer to understand and comply with these requirements.

This document will evolve over time and updates and clarifications will be included as required. Feedback on the guidance is always welcome.

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Introduction

This Post Market Review Compliance Dashboard User Guide provides step-by-step instructions on how to respond to a medical device post-market review notification from the Therapeutic Goods Administration (TGA) through the Post Market Review (PMR) compliance dashboard.

The dashboard is designed to allow sponsors to view any requests or notifications from the TGA, and to respond to them. Requests and notifications may include:

- requirement to provide information and documents;
- requirement to provide samples; and
- proposal to suspend or cancel entries from the Australian Register of Therapeutic Goods (ARTG).

Role types

In the PMR compliance environment, there are two role types:

- **Drafter:** The drafter can review, upload documents, and edit responses to a notification.
- **Submitter:** The submitter can review, upload documents, edit, and submit responses to a notification.

These roles have been designated by your TGA Business Services (TBS) administrator.

How to login to the PMR compliance dashboard

The PMR compliance dashboard is found within the <u>TGA Business Services (TBS) website</u>. Once you log-in with your sponsor user name and password, follow the instructions below:



How to view your notifications

You can sort and view your notifications by the following status:

- **Notification Active:** Select this option to view for notifications you need to review and submit a response to.
- Notification All Notifications older than 32 days: Select this option to view notifications older than 32 days.
- **Notification Submitted:** Select this option to view those notifications that a response has already been provided.
- **Notification View Action:** Select this option to view notifications which provide information on actions being taken by the TGA.
- **Notification View Migrated Notifications:** Select this option to view notifications which were sent from the TGA prior to the portal being deployed, but are currently in progress.

MR Compliance Das	shboard				
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Notification - Active Notifications - All Notifications either than 32 days					
Notification - Submitted	Sponsor Name	Notification Type	Status	Response Due Date	
Notification - View Action Notification - View Migrated Notifications	1TGA	Section 41JA	Sent/Awaiting Response	21/10/2020 5:00 PM	*

There are two ways you can view your notifications:

- 1. Preview your notification
- 2. Draft a response to your notification

Preview your notification

You can view your notification from the **Preview** screen. You cannot add a response from this view. Additionally, selecting **View Details** or the **reference number** will show a 'read-only' preview.

Click on the drop-do	wn arrow ar	nd click on l	Preview.		
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PMR Compliance Da	shboard				
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Draft a response to your notification

The second way you can view your notification is when you respond to a notification. This is the only view in which you can add a response.

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Home PMR	Compliance Dashboard					
PMR Co	mpliance Da	shboard				
	mpliance Da	shboard			Such	Q
PMR Col	mpliance Da	shboard Sponsor Name	Notification Type	Status	Search Response Due Date	α
PMR Col Transcessor Act Reference Number PMR-2020-01302	Review Description ARTG Devices	Sponsor Name 1TGA	Notification Type Section 413A	Status Sent/Awaiting Response	Search Response Due Date 21/10/2020 5:00 PM	α
PMR Col Interaction Acts Reference Number PMRI-2020-01302 PMRI-2020-01300	Review Description ARTG Devices Test Environment	Sponsor Name TTGA 1TGA	Notification Type Section 41JA Section 41JA	Status Sent/Awaiting Response Sent/Awaiting Response	Search Response Due Date ↓ 21/10/2020 5:00 PM 20/10/2020 5:00 PM	Q Dan O Vew datain Preverw

Instructions	
Home PMR Compliance Dashboard	
PMR Notification Draft	
Expand All Collapse All	
Notification Details	+
ARTGs and Model Details	+
Legislative Breaches and Responses	+
Other Required Responses	+
Extension Requests	+
Validate Back Refresh	

Instructions	
mou actions	

ection 41JA of the Therapeutic Goo	ods Act 1989	
e TGA is conducting a post market review of ARTG De	vices	
otification Name *	Review Reference Number	
/IR-2020-01302 - 1TGA - 01	PMR-2020-01302	
eview in scope		
e ARTG devices within this review are in scope becaus	e they have been identified as requiring further assessment.	
eview out of scope		
e ARTG devices not within this review are not in scope	because they have not been identified as requiring further assessment.	
otification Documents		
 pply details, complaints and adverse events data can b lowing steps to generate and upload the file: Click on 'Generate template', then refresh Three files will be generated in the list. It may take u Open the file and enter supply, complaints and adve and the UnitValues files contain the lists of adverse i Save the file and rename it 'ModelDetails.csv'. Pleas Click on 'Add Files' and upload the ModelDetails.csv Click on 'Process Bulk Upload'. 	the entered in a single file, provided that the models have been identified and scoped first. Use the provided that the models have been identified and scoped first. Use the provided that for each model for the last three financial years. The AdverseEventsCategory\ event and unit values. These can be used as references or to copy and paste values into the files ensure that the file is renamed as 'ModelDetails.csv'. y file. Table Section after few minutes, after the Refresh. If the upload contains any errors, you will be Generate Template	he /alues le.
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Ins	tructions		
f.	Click on the notification to appear as a download at the	download and open a copy of the letter ne bottom left of the screen.	The notification will
		Notification Documents Supply details, complete its and activerup events data can be entered in a single file, provided that the m Mouving might is prevents and uplicat the file. • Other or Generate and uplication file file. • There file with be generated in the last, they take up to two initiates for the files to appear. Dow • Open the file and event apply, comparish and actives event data for each model for the cast • or there (initiates) and uplicated in the last, they take up to two initiates for the files to appear. Dow • Open the file and event apply, comparish and actives event and unit reason. There are an and unit in takes. • Since the lite and reasons it Model/Decisit and "These reasons that the 4th a removed as Model • Occount Add Files and uplicate the Model/Decisit zer file. • Occount Presente data' (lasted). • Decision Presente data' (lasted). The uplicated Model Catalo will appears under Model/Decisit bodies after two minutes after the Balan extended by email.	nobels have seen startfield and account first Clar the migad the Mode/Ledule Temptote car- tits was formout years. The Advance/InvestCasepopyistices watchemore in the copy and passes values also the file Details.com/ ent. If the Latood contains any entries, you will be Controls Temptote
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How to respond to a notification

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1.	Click on the drop dow	vn arrow an	d click on D	raft.			
- OF	Australian Government Department of Health Complete	ance Portal]
	Home PMR Compliance Dashboard						
F	MR Compliance Das	hboard					
	E Notification - Active+				Search	Q	1
R	teference Rumber Review Description	Sponsor Name	Notification Type	Status	Response Due Date		
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P	MR 2020-01300 Test Environment	1TGA	Section 41JA	Sent/Awaiting Response	20110/2020 5:00 PM	Draft Orant Orant Prevew	
P	MR-2020-01300 Test Environment	1TGA	Section 41JA	Sent/Awaiting Response	20/10/2020 5:00 PM		
P	MR Notification Dra	ıft					
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E	Extension Requests					+	
	Validate Back Refresh	1					

How to edit and add ARTGs and Model Details

In the **ARTGs and Model Details** section, you can view the Australian Register of Therapeutic Goods (ARTG) entries that have been included in the notification.

If this notification is an intial request for information (section 41JA or section 31 notification) you may add model details and additional ARTG entries that may be in scope of the post-market review.

Adding ARTG entries, model details, and supply information is only available when responding to initial requests for information. For all other notifications you can skip this section and go to the '**How to provide evidence of compliance with requirements**' section.

Instructions							
1. Click on the + butt	on in th	e ARTGs a	and Mode	l Details s	ection.		
PMR Notification	Draft						
Expand All Collapse All							
Notification Details							+
ARTGs and Model Details	5						[3]
ARTGs and Model Details The following ARTG entries have be If your organisation sponsors ARTG en list below The name of all models must be enter scope of the review. Click on the arrow to the right of the A If an ARTG entry or model was added	een selected ntries that are ed for each A RTG entry to in error, sele	for a post-mark e not listed below IRTG entry. If an select 'Add mode ct 'Edit', then sele	et medical devic ; but are in the sc ARTG entry inclu el', then select 'Ec ect 'Out of scope'	e review ope of the review, des multiple mode lit model' to enter t and enter the reas	click on the 'Add AR' Is, they must all be e he model name and on: 'This model was	TG' button to ntered, ever other inform added in err	n include them in the if they are not in the lation.
Models							Add ARTG
ARTG ID ↑ ARTG Entry Name	ARTG Status	GMDNS Code	Manufacturer Name	Model	Model in Scope?	Cloned?	Created On ↓
1517156 1TGA - TGAUAT PRODUCT-Adhesive, sof tissue approximation	Active	TG15171563			Yes	No	14/09/2020 🔽 4:08 PM

Instructions	
3. Click on the search icon.	
Add ARTG	×
ARTG*	
Save	
4. A list of the ARTG entries associated with your sponsor log in (both active and revoked entries) will be available for you to select.	1
a. Select the ARTG that is related to this post-market review.	
b. Click Select .	
Add ARTG	×
ARTG *	
Lookup records × Q	
Search Q	
Save	
✓ 1518446 !TGA - TGAUAT PRODUCT-Adaptor, specify Active	
1518321 1TGA - TGAUAT PRODUCT-Adaptor, specify Active	
1517156 1TGA - TGAUAT PRODUCT-Adhesive, soft Active tissue approximation	
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i	
Select Cancel Remove value	
The list will only contain ARTG entries associated with your login.	

	ctions								
Cl	ick Save .								
م Add	ARTG								
	ARTG *								
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Тс	o enter the mod	el detai	ls and oth	er inform	ation for ye	our ARTG er	try:		
а	Click Edit Mo	odel							
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A. RTGs e follow our org below o name ope of th ck on th ock on th	Click Edit Mc	odel.	I for a post mark e not listed below VRTG entry. If an select 'Add mod	ket medical devic v, but are in the so ARTG ontry inclu let', then select Ec lect 201 of scool	ce review cope of the review, dos multiplo mode tit model" to enter t	click on the 'Add ARI Is, they must all be ei the model name and o	"G" button to stored, ever other inform	o include them n if they are no nation.	- in the t in the
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a. RTGs e follow rour arg t below t b	Click Edit Mc	odel.	I for a post-mari e not listed below VRTG entry. If an select 'Add mod ct 'Edit', then sel ct 'Edit', then sel GMDNS Code TG15183215	ket medical devia v, but are in the so ARTG entry inclu lef, then select 'Ed lect 'Out of scope' Manufacturer Name	ce review ope of the review, dee multiple mode tit model' to enter t and enter the reas	click on the 'Add ARI le, they must all be en the model name and ion' 'This model was a Model in Scope? Yes	"G" button to attorned, even other inform added in en clioned? No	o include them n if they are no labon. ror' Created On ↓ 21/09/2020 2:02 PM	in the in the it in the diant the diant the diant the diant the

Instru	ctions		
C.	Select No or Yes if to the notification you need to provid the scope of the po	the model is in-scope of the post-market review. You for details of the scope of the post-market review. If de a reason why you consider the ARTG entry/model ost-market review.	u should refer you select No , l is not within
Edit Mo	odel	×	
	ARTG	A	
	ARTG ID	ARTG Entry Name	
	1518321	1TGA - TGAUAT PRODUCT-Adaptor, specify	
	Model * CS6633 Is this model in the scope of the revi No O Yes Provide the reason why it is not in so	ew? cope *	
	Attach the English version of the Instru It is advised that you include the ARTG support upto 50MB. 'Upload Large files removed under any circumstance.	tions for Use provided with of on the device. and model when entering a file name for easy identification. 'Add Files' 's support upto 5GB. Large File Folder created in SharePoint should not be ▲ Add files Upload Large files	
7. If th m	there are multiple Me e ARTG entry and car odel number field if a	odels under the one ARTG entry, select Add model. T nnot be deleted, but can be marked out of scope with added in error.	his will clone N/A in the

a. Click Add Model

The name of all models must be entered for each ARTG entry. If an ARTG entry includes multiple models, they must all be entered, even if they are not in the scope of the review.

Instru	ctions								
ARTGS	and Model Details	s ()							-
The follow	ing ARTG entries have b	een selected	for a post-mark	ket medical devi	ce review				
Il your orga	anisabon sponsors ARTG e	ntries that are	not listed below	, but are in the sc	ope of the review.	click on the 'Add ART	G' button to	o include them	i in the
list below The name	of all models must be enter	red for each A	RTG entry. If an	ARTG entry inclu	des multiple mod	els, they must all be er	ntered, eve	n if they are no	ot in the
scope of th Click on th If an ARTG	ie raview e arrow to the right of the A S entry or model was addeo	RTG entry to I in error, sele	select 'Add mod ct 'Edil', then sel	el", then select 'Ed	tit model" to enter and enter the rea	the model name and i son: 'This model was i	other inform added in en	iabon. ror"	
Models									
									ad Juking
1000			CHENIC			Model			
	ARTG Entry Name	Status	Code	Name	Model	In Scope?	Cloned?	On 🕹	
1518321	1TGA - TGAUAT PRODUCT-Adaptor, specify	Active	TG15183215			Yes	No	21/09/2020 2:02 PM	Add Model
1517156	1TGA - TGALIAT	Active	TG15171563			Vec	No	14/09/2020	Edit woder
b.	Click Procee	d.							
Add	d Model								×
Do y	ou want to add	d a Moo	lel?						
							,		_
						Proce	eed	Cance	
							_		

instructions								
А сору	v of the ARTG er	ntry for	the selec	ted mode	l is created.			
Repea	t step 6 and edi	t the m	odel deta	ils.				
ARTG	s and Model Details	•						14
The follow	ving ARTG entries have b	een selected	for a post-mark	et medical devi	ce review			
It your drg list below The name scope of ti Click on th If an ARTO	emolecan spansars ARTG e of all models must be enter he review he arrow to the right of the A 3 entry or model was added	nenes mar are red for each A RTG entry to Lin error, sele	RTG entry. If an select 'Add mod ct 'Edit', then sel	ARTG entry inclu ARTG entry inclu ef, then select E ect 'Out of scope	ope of the review, click of ides multiple models, the dit model' to enter the mo and enter the reason. Th	n me Add AR y must all be o del name and his model was	ndered, ever other inform added in en	a nouse them in the if they are not in the ation. or ²
ARTG	ARTG Fotor Name	ARTG	GMDNS	Manufacturer	Model	Model in Scopp?	Cloned?	And ARTG
ARTG ID + 1518321	ARTG Entry Name 1TGA - TGAUAT PRODUCT-Adaptor specify	ARTG Status Active	GMDNS Code TG15183215	Manufacturer Name	Model	Model in Scope? Yes	Cloned? Yes	Add ARTG Created On 4 21/09/2020 2.17 PM

For each model of device (both those that you consider to be in-scope and out-of-scope of the post-market review) you will need to upload a copy of the Instructions For Use (IFU). There are two options dependent upon the size of the document:

- "Add files" button to upload documents less than 50MB size.
- "Upload Large files" button to upload documents more than 50MB size.
- Please note, folders are created in the background during this process to store the information so it may take 1 to 2 minutes for the "Add files" and "Upload Large files" buttons to appear.

3. To add fil	es less than 50M	1B size:				
a. Click	on Add files .					
Edit Model						
ARTG						
ARTGID	ARTG E	ttry Name				
1518321	ITGA -	IGALIAT PRODUCT-Adaptor, specify				
Model						
Model						
C56633						
Is this model in the sco	pe of the review?					
ABach the English versio it is advised that you incl support onto 50MB. Usiv removed under any circu	n of the Instructions for Use provided with ude the ARTG and model when entering a sed Large files' support upto 508. Large F materice	ar on the device. Sie name for easy identification. Widd Pis Ie Poter created in SharePoint should in	ra' or be			
		O Add Nes Upland Larg	e files			
Add files	ine, the on Au	a mes button.	×			
Choose files	Choose Files D20-86296	3) (1).docx				
	• Overtime existing nes					
		Add files	Cancel			
The file you u	ploaded will be o	lisplayed.				
Model *						
C56633						
Is this model in the scope	of the review?					
LEAD DIE FONER VERMON	of the Sector Box Star Stee recorded with	or on the desire	- 1 a			
It is achieved that you includ support upto \$0MB. Uploa	e the ARTG and model when entering a d Large Ries' support upto 508. Large f	file name for easy identification. 'Add lie Folder created in StierePoint should	Files' I not be			
record and any cream		O Add then Upland L	argo films			
Name &		Monthead				
CODA-MORE OFWERE T	EMP 1.1 & s4124 Requirements for intr	mat25/95/2020 3.39 PM	0			
c. Selec	t the check-box	to acknowledge	that at leas	st one file	e has bee	n uploaded and
CHCK	Save.					
		O ASI Sins	and Large files			
		Contracticity (1)				
Marrie +	Modified	u	1270			
Channel (1 ett.	01/10/2020 10:40 A	M	•			
Please provide your at	knowledgement that at least one file	has been uploaded				
·						

- 9. To add files more than 50MB size: Click on Upload Large file. a. Edit Model ARTG ARTG 10 ARTG Entry Name 1518321 11GA - 1GAUAT PRODUCT-Adaptor, specify Model Model* C56633 Is this model in the scope of the review? Attach the English version of the Instructions for Use provided with or on the device it is advised that you include the ARTG and model when entering a file name for easy identification. Was support unt Stelling Used and app file's support upto SG8 Large File Folder created in SharePoint shou removed under any inclusion. Skot Files • There are no folders or files to steplay Sam
 - b. A new window will open directing you to the SharePoint site. Click Next.



c. Click **Upload** and then **Files**.

DP D365-C	CF-Test-Site	
Home	+ Now 🗸 🕆 Upload 🖂 🗄	Edit in grid view
Conversations	Files	
Documents	Review > PM Folder	son Johns
Shared with us	C Nume	

	ctions									
d.	Upload your	file and	close the	window	once you h	ave uplo	ade	d the l	arge file	e(s).
0	PMR Notification	n Draft - Cu	ustom X	5 D3	65-CCF-Test	t-Site - La	rge F	iles 🗴	4	
÷	→ C û	h h	ealthgov	dev.share	point.com/	/sites/D3	865-1	PMR-T	est-Site	/tga_
	SharePoin	t								
e.	Select the ch click Save .	eck-box	to ackno	wledge th	at at least	one file l	has l	oeen u	ploaded	l and
Na	me 🛧		Modifi	ed		Add files		Upload L	arge files	
Pitest.txt (1 KB)										
	est.txt (1 KB) Please provide your a	cknowledger	01/10/2	2020 10:40 Af	M nas been uploa	ded			0	
D ^t C P Si Sels	est.txt (1 KB) Please provide your a ave	cknowledger s updated	01/10/	east one file t	Mas been uploa	ded			0	dd ARTG
Dt F S S S S S S S S S S S S S S S S S S	est.txt (1 KB) Please provide your a ave	cknowledger s updated	01/10/ ment that at I d against	east one file to the ARTC	Model	ded Ma in Sc	odel	Cloned?	Created On +	dd ARTG
Ch F S S S S S S S S S S S S S S S S S S	ARTG Entry Name	cknowledger s updated ARTG Status Active	01/10/ ment that at I d against d against	east one file to the ARTC	Model CS6633	ded Ma in Sc Ye	ope?	Cloned? Yes	Created On ↓ 21/09/2020 2:17 PM	dd ARTG

For each of the models of devices you will be required to provide supply, complaint, and adverse event details. Please check the notification letter for details on how many financial years you are required to provide data for.

The supply, complaint, and adverse event data can be completed in the Model Details section. You can update the model details for each individual financial year or you can enter the supply details, complaints and adverse events data for all models in a single file using the bulk upload functionality.



00	kup red	cords					×	
					Search		۹	
-	ARTG ID	ARTG Entry Name	ARTG Status	Model		Created On	^	
~	1517156	1TGA - TGAUAT PRODUCT- Adhesive, soft tissue approximation	Active			14/09/2020 4:08 PM		
	1518321	1TGA - TGAUAT PRODUCT- Adaptor, specify	Active			21/09/2020 2:02 PM		
	1518321	1TGA - TGALIAT	Active	C\$6633		21/09/2020 2-17 PM	•	
				s	elect Cano	el Remove va	lue	

d. Select the financial year and click **Select**.

R-202 Lookup records			×		
15183	Search		۹	a	
ancial Fill autwauto	2.0	aveuev 3 PM	*		
FIN 2015/2016	111 2.3	3/2020 3 PM		Q	
FIN 2016/2017	110 2.3	3/2020 3 PM			
PIN 2017/2018	11/ 23	13/2020 3 PM			
 FIN 2018/2019 	11/ 2.3	93/2020 2 PM	1		
PIN 2019/2020	111	33/2020 3 PM	-		
< 1 2 3 ×			×		

Instructions
e. Click Save .
Add Model Financial Year *
RFI
PMR-2020-01302 - 1TGA - 01
Nodel *
1518321 × Q
Financial Year "
FIN 2018/2019
Save
The financial year details are updated.
If you select the incorrect financial year, you can remove the financial year by clicking on Remove .
Model Details
Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year, then click on the name to add the model details for each year. You can also enter the supply details, complexits and edverse events deta for all models into a single file instead of adding them separately for each model by following the instructions in the Notification Documents section.
Name Model Financial Year Number Supplied in Australia Number Supplied Overseas Received Compliants Received Reports Created Ov+ Fin 2018/2019 C58633 Fin 2018/2019 Fin 2018/2019 Fin 2018/2019 Fin 2018/2019 Fin 2018/2019 Fin 2018/2019
 11. The following instructions outline how to add the supply details, complaints and adverse events data. Please check the notification for details on how many financial years you are required to provide data for. a. Click Edit
Model Details Model Details Model details must be added for the last three financial years. Click 'Add Model Financial Year' to add each financial year; then click on the name to add the model details for each year 'too can also enter the supply details, complicits and edverse events data for all models into a single file instruct of adding them separately for each model by following the instructions in the Notification Documents section. Add Model Financial Year
Name Model Pinancial Year Number Supplied in Australia Number Supplied Overseas Received Complaints Received Adverse Event Complaints Received Chated Complaints FIN 2018/2019 - TEGA-TGAUAT PRODUCT: Adapor, specify FIN 2018/2019 2018/2019 21:00/2020 21:00/2020 21:00/2020
This is the overarching screen that will appear.Image: Screen will turn green as you complete each section.

Instructions	
FIN 2018/2019 - 1TGA - TGAUAT PRODUCT-Adaptor, specify	
Expand All Collapse All	
Financial Year 🔗 +	
Supply Details () +	
Complaints () +	
Adverse Events () +	
Save	
12. In the Supply Details section:	
 Enter the Number Supplied in Australia. To select the unit measurement Number Supplied Australia – Unit Measurement field for that financia on the magnifying glass and select one of the options: 	ent in the al year, click
• Box	
• Each	
• Pack	
• Other	
Supply Details ()	Ť
Number Supplied in Australia	7
I 10 I Number Supplied Australia - Unit of Measurement *	
Box	×Q
Lookup records	
Search	Q
✓ Short Description ★	
Box Each	
Other	
Pack	
Select Cancel Remov	re value

Instructions	
b. Enter the number of devices supplied overs	eas in that financial year.
Supply Details 🕗	
Number Supplied in Australia *	
10	
Number Supplied Australia - Unit of Measurement *	
Box	×Q
Number Supplied Overseas "	
5	
Number Supplied Overseas - Unit of Measurement	

13. In the **Complaints** section:

You have the option to select **Yes** or **No** if any complaints were received in the selected financial year.

Complaints ()	-
Have you received complaints about this model during the financial year?	

- a. If you select **No**, complete the Adverse Events section in step 14.
- b. If you select **Yes**, complete the following steps:
 - Enter the **Total number of complaints that came from Australia in the financial year**.
 - Enter the **Total number of complaints that came from overseas in the financial year**.
 - Enter at least one **Type of complaint received** and **Number received**.

Complaints 🧭	
Have you received complaints about this model during	the financial year?
Total number of complaints that came from Australia i	the financial year "
2	
Total number of complaints that came from overseas i	the financial year "
1	
Describe the ten most common types of complaints made complaint.	n Australia about the model during the financial year and enter the number of each type of
1. Type of complaint received *	Number received *
Faulty device	1
2. Type of complaint received	Number received

Instructions	
 You have the option to upload supporting d Upload Large files function. Refer to step 8 10 for large files (more than 50MB size) for upload files. 	ocuments using the Add files and for small files (less than 50MB size) or step by step instructions on how to
It you wish to attach supporting documents relating to this complaint type, the English ve It is advised that you include the ARTG and model when entering a file name for easy ide upto 5GB. Large File Folder created in SharePoint should not be removed under any circ	sions can be attached here intification. 'Add files' support upto 50MB. 'Upload Large files' support umstance O Add files Upload Large files
Name 🕈	Modified
D20-86296 DPMRRS TEMP 1.1 b s41JA Requirements for inform.	21/09/2020.3.39.PM
Any files that have already been uploaded relati the list of files.	ng to this ARTG entry will be displayed in
14. In the Adverse Events section:	
You have the option to select Yes or No if any adverse model in the selected financial year.	e event reports were received about this
Adverse Events ()	e e e e e e e e e e e e e e e e e e e
Have you received any adverse event reports about this model during the financial Yes ONO	year?
a. If you select No, click Save and refer to step	15.
Adverse Events 🧭	ा ल .
Have you received any adverse event reports about this model during the financial O'Yes No	rear?
If you wish to attach supporting documents relating to this complaint type, the English vers It is advised that you include the ARTG and model when entering a file name for easy ider upto 5GB. Large File Folder created in SharePoint should not be removed under any circu	ions can be attached here titilication. 'Add files' support upto 50MB. 'Upload Large files' support mstance.
	Add thes Upload Large files
Name 🛧	Modified
D20-85206 DPMRRS TEMP 1:1 b s41JA Requirements for inform	21/09/2020 3,39 PM
Save	
b. If you select Yes , complete the following ste	eps:
• Enter the Total number of adverse evo financial year .	ents that came from Australia in the
• Enter the Total number of adverse events financial year.	ents that came from overseas in the
 Provide a breakdown of the adverse even from the International Medical Device R http://www.imdrf.org/documents/do	nts by type of adverse event (derived egulators Forum Adverse Event Codes <u>uments.asp</u>). Select at least one common

Instructions				
Category for that p adverse e	of adverse eve articular model, went types can b	ent and Numbe during that fin be provided.	r reported fo ancial year. T	or that adverse event type, The ten most prevalent
 If there w related to in Austral The regio 	vere adverse eve the Australian a lia, the adverse o n is identified in	nts reported in adverse events event types are 1 the heading.	Australia, th If there were related to th	e adverse event types are e no adverse events reported e worldwide adverse events.
Adverse Events 🧭				<i></i>
Have you received any adverse even Yes O No Total number of adverse events that	nt reports about this model	during the financial year?		
2 Iotal number of adverse events that	came from overseas in the	financial year		
1				l
Select the ten most common categoria	s of adverse events reported	in Australia about the mod	during the financial yes	a:
Biological Problem Ide 🗙 Q	Cytotoxicity Problem I	* Q	٩	1
2. Category of adverse event	Level 2	Level 3		Number reported
instructions If you wish to attach supporting documents in It is advised that you include the ARTG and appo 508. Large File Folder created in Stars	on how to uploa elating to this compliant type, the i encodel others endering a file name is ePowel should not be removed used	Id files. English versions can be attach to easy identification. <i>Xidd files:</i> ler any croomstance	d Trans. auggoort rynty SCAMI - Cyblow O Add Res	d Largo lika' support Upkod Large Res
Any files that hav the list of files.	ve already been u	uploaded relati	ng to this AR'	TG entry will be displayed in
15. Click Save and th to the previous pa	e following mes age.	sage will appea	r and click or	n the Back button to go back
"Model Details ha the previous page	s been successful "	lly saved. Please	click on the '	'Back' button to go back to
FIN 2018/2019 - 1TGA - TGAUAT PRODU Control of the control of the	ICT-Adaptor, specify		•	
Supply Details 🥑 Complaints 🧭		3	•	
Adverse Events 🧭			-	

Instructio	ns							
The model	details	for the se	elected financi	al year are upo	lated.			
Model Details	i,							
								-
model details for ea	st be added to each year. You ch model by fo	r the last three I can also ente Mouring the ins	the supply details, com tractions in the Notificati	ou moder Financiar Year plaints and adverse even	to add each linano its data for all mode	ar year, then cack on Its into a single file in:	the name to a tead of adding	g them
separately for ea	an model by it	would one ma	naceons in the reolinger	лгаласанияна эксноп.				
							Add Model Finar	ncial Year
		Cinanelal	Number Supplied In	Number Sumplied	Decaluard	Received	Created	
Name	Model	Year	Australia	Overseas	Complaints	Reports	On 🕹	
FIN 2018/2019 1TGA - TGAUA	CS6633	FIN 2018/2019	10	5	Yes	Yes	21/09/2020 7:37 PM	
Adaptor, specify								
16. To up	date the	supply d	letails, compla	ints and adver	se events d	ata for all m	odels, fo	r
multip	ole finan	cial year	s, in a single fi	le, you can use	the bulk u	pload functi	ionality:	
a. Y	ou need	to gener	ate the bulk u	pload template	e from the N	otification	Details	
S	ection.	0		· -				
b. C	lick on G	enerate	Template.					
Notification	n Details (
Section 41	JA of the	Therapeu	utic Goods Act	1989				
The TGA is cond	ucting a post r	narket review (of ARTG Devices.					
Notification Nar	ne *			Review Refer	rence Number			
PMR-2020-01302	2 - 1TGA - 01			PMR-2020-01	302			
Review in scope)							
The ARTG devic	es within this r	eview are in so	ope because they have	been identified as requir	ing further assessm	ient.		
Review out of s	cope							
The ARTG devic	es not within tł	nis review are r	not in scope because the	ey have not been identifie	ed as requiring furth	er assessment.		
Notification D	ocuments							
Supply details, c	omplaints and	adverse event	s data can be entered in	a single file, provided th	at the models have	been identified and s	coped first. U	se the
following steps to) generate and	l upload the file	1					
 Click on 'G Three files Open the fi 	enerate templa will be generat le and enter su	ate', then refres ted in the list. I upply, complair	h t may take up to two min its and adverse events o	utes for the files to appe lata for each model for th	ar. Download the M le last three financia	lodelDetailsTemplate. al years. The Adverse	csv file EventsCatego	oryValues
 and the Un Save the fil Click on 'Ac 	t values files c e and rename Id Files' and u	ontain the lists it 'ModelDetail pload the Mode	or adverse event and u s.csv'. Please ensure th elDetails.csv file.	nit values. These can be at the file is renamed as	usea as reterences 'ModelDetails.csv'	or to copy and paste	values into th	ie 111e.
 Click on 'Pl 	осеза виж Ор	iload .						
The uploaded Me contacted by em	odel Details wi ail.	ll appear unde	r 'Model Details' section	after few minutes, after ti	he Refresh. If the u	pload contains any ei	rrors, you will l	be

Process Bulk Uplo

Add files

Generate Template



Instructions
UnitValues file:
A 1 Box 2 Each 3 Other 4 Pack 5 f. Enter the supply, complaints and adverse events data for each model for the last
three financial years
a a b C D F D H T F C T M N O F Model ElgArtTG CCMAded NamModel Financial Viannebes SUein DRive Vak Nambes SUein Other Vak Hanne Set Statist Other Vak Hanne Set Statist Drive V
Please note:
• You must complete all rows or delete the rows you don't need to enter data.
The following columns are mandatory to complete:
– Column E: Financial Year
– Column F: Number Supplied in Australia
– Column G: Unit
– Column I: Number Supplied Overseas
– Column J: Unit
 Column L: Have you received complaints about this model during the financial year? (Yes/No)
– Column M: Total number of complaints that came from Australia in the financial year

- Column N: Total number of complaints that came from overseas in the financial year
- Column O: type of Complaint Received
- Column P: Number Received
- Column AI: Have you received any adverse event reports about this model during the financial year? (Yes/No)
- Column AJ: Total number of adverse events that came from Australia in the financial year
- Column AK: Total number of adverse events that came from overseas in the financial year

Instructions			
– Column A	L: Category of Adverse Event L	evel 1	
– Column A	Ο: Category of Advser Event Νι	umber Reported	
Once you have com need to save the fil "ModelDetails.csv"	pleted the required information e as "ModelDetails.csv". Note: if for the system to identify the d	on in the ModelDe t is important to s locument.	tails ave
Save As			×
← → - ↑ 🕹 - KUN	tBIR > Downloads ~ ひ Se	arch Downloads	P
Organize • New folder		10 ·	0
💄 Digital Transform ^	Name	Date modified	Ty
 Post Market Revi Presentations Training Microsoft Excel 	AdverseEventsCategoryValues (1).csv AdverseEventsCategoryValues.csv ModelDetailsTemplate (1).csv ModelDetailsTemplate.csv UnitValues.csv	21/09/2020 9:46 PM 14/09/2020 2:55 PM 21/09/2020 9:36 PM 14/09/2020 2:56 PM 21/09/2020 9:47 PM	Mi Mi Mi
This PC Network	¢		>
The same Maria			
g. To upload the docum	l the file, click on Add files and nents section.	the new file you u	uplo
Notification Details 🌗			
Section 41JA of the Therap	peutic Goods Act 1989		
The TGA is conducting a post market revi	ew of ARTIG Devices		
Notification Name *	Review Reference Number		
PMR-2020-01802 - 115A - 01 Review in scope	PMR-2020-01302		
The ARTG devices within this review are i	n scope because they have been identified as requiring further assessi	ment.	
Review out of scope			
The ARTG devices not within this review a	we not in scope because they have not been identified as requiring furt	Der assessmert	
Notification Documents			
Supply details, complaints and adverse et following steps to generate and upload the Click on Generate template', then re Three files will be generated in the II Open the file and enter supply, comp and the Unit/Neurs files contain the Save the file and rename it 'Micde/D Click on 'Add Files' and upload the Click on 'And Files' and upload the Click on 'Ancess Bulk Upload'	ents data can be entered in a single file, provided that the models have rifle: thesh at, it may take up to two minutes for the files to appear. Download the A listic and achierse events data for each model for the last three finance lists of achierse events data for each model for the last three finance lists of achierse event and unit values. These can be used as references tals, car'. Rease ensure that the file is renamed as ModelDetails .cav AccelDetails.csv file	s been identified and scoped first. Use th NodelDetails Template cay file all years. The AdverseDvents/DategoryV a or to copy and paste values into the file r	e sbes
The uploaded Model Details will appear u contacted by email	nder Model Detaile' section after few minutes, after the Refresh. If the u	upiced contains any errors, you will be notes O Add lies Process Buik U	abad]

Instructions					
Name 🛧	Modified				
CAdverseEventsCategoryValues.csv (5 KB)	21/09/2020 9:26 PM				
ModelDetails.csv (\$ KE)	Jess than a minule ago				
CModelDetailsTemplate csv (5 K8)	21/09/2020 9:26 PM				
C/UnitValues.cav (1 KB)	21/09/2020 9:26 PM				

h. Click on **Process Bulk Upload** to upload your files.

The uploaded Model Details will appear under 'Model Details' section all contracted by email	er few minutes, after the Refresh If the upload contains any errors, you will be Generate Template O Add Thes Process Bulk Uplow
Name 🛧	Modified
[]AdverseEventsCategoryValues.cav (# KII)	21/09/2020 9/26 PM
(]ModelDetails.csv (5 K9)	about a minute ago
(]ModelDetailsTemplate.csv (616)	23/09/2020 8:29 PM
[]/UnifValues.csv (1 KB)	21/09/2020 9:26 PM
< 1 2 ×	

The model details will be uploaded in the ARTGs and Model Details section. If the model details are not uploaded in this section then there was an error when updating the bulk upload file in step 17f. Please make sure you enter all mandatory fields and the right information is entered. If you still have issues, please contact the Post Market Devices Team (postmarketdevices@health.gov.au).

NOVER D'ELBOS							
Jodel details must nodel details for é leparately for each	be added fo ach year You i model by fo	r the last three I can also ente Nowing the ins	financial years. Click 'Ad r the supply details, comp tructions in the Notificatio	id Model Financial Year slants and adverse ever in Documents section	to add each financ its data for all mode	ial year, then click on Its into a single file in	the name to add the Itead of adding them
							Add Model Feasocial Yes
Name	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On Φ

- Please note the following relating to the bulk upload functionality:
- If you have any documents associated to the model details you entered in the large file bulk upload, you can upload it at a candidate level by following steps 8 and 9.

Models									
ARTG	ARTG Entry Name	ARTG Status	GMDNS Code	Manufacturer Name	Model	Model in Scope?	Cloned?	Ad Created On 4	M ARTG
1518321	1TGA - TGAUAT PRODUCT-Adaptor, specify	Active	TG15183215		CS6633	Yes	Yes	21/09/2020 2.17 PM	Add Mode
1518321	1TGA - TGAUAT	Active	TG15183215			Yes	No	21/09/2020	- Eof Mode



Nodel Details							
ifodel details must nadel details for e reparately for eact	be added fo ach year You model by fo	r the last three I can also ente Illowing the ins	financial years. Click 'Ao r the supply defails, comp tructions in the Notificatic	ld Model Financial Year' alaints and adverse ever in Documents section	to add each financi Is data for all mode	al year, then click on i Is into a single file ins	the name to add the load of odding them Idd Model Financial Year
Name	Model	Financial Year	Number Supplied in Australia	Number Supplied Overseas	Received Complaints	Received Adverse Event Reports	Created On 🕹
FIN 2018/2019 - 1TGA - TGAUAT PRODUCT- Adaptor, specify	CS6633	FIN 2018/2019	10	5	Yes	Yes	21/09/2020

How to provide evidence of compliance with requirements

The following instructions outline how to upload the information and documents to demonstrate compliance with the specific areas of the legislation that have been identified in the notification letter.

Instructions				
1. Click Add Response in the investigation'.	e drop down c	option against t	the specified 'Breaches under	
Legislative Breaches and Responses ()			1 m	
The following Legislative Breaches have been found for a post-main	rket medical device review			
Evidence in relation to breaches under investigation of the legislation be review:	iow must be attached or a summ	nary provided for each model that	t is in the scope of the	
Click on the arrow to the right of the Breaches under investigation to sel	ect 'Add Response'			
Itreaches under investigation EP.1 - Use of medical devices not to compromise health and safety	Status	Row No.	and a second sec	
Safety and performance of the medical device	Draft	47	Add Heliponia	
2. Click Proceed .				
Add Response			×	
Do you want to add a Response to this	Legislative Breach	1?		
		Dressed		
		Proceed		
3. Click Refresh .				
Legislative Breaches and Responses ()			-	
The following Legislative Breaches have been found for a post-market me	fical device review			
Evidence in relation to delacted under investigation of the registation before must review	s de atlached or a lautimary provide	ic for want model that is in the acope o	of the	
Chick on the arrow to the right of the Bleaches under investigation to select "Add	Response			
EP 1 - Devisit medical devices not to compromise health and safely	Completed	1		
Safety and porturnance of the medical device	Draft	v E		
Legislative Breaches Responses				
Click on the arrow to the right of the Response to select 'Edit' to enter the evider	toe of compliance.			
Response Name Structure a	nder investigation	Created On &		
These are increased to display.				
Other Required Responses			*	
Extension Requests			(i)	
Salutate Barly Salvach				
]	

Instructions			
4. Click Edit next to the g	enerated response area.		
Legislative Breaches and Responses ()			
The following Legislative Breaches have been found for a	a post-market medical device review		
Evidence in relation to breaches under investigation of the leg	plation below must be attached or a summary provided for each	model that is in the acope of the	
inverse.			
Cack on the arrow to the right of the threaches under investig	abon to select 'Add Response'		
Breaches under investigation	Status	Row Number +	
EP 1 - Use of medical devices not to compromise health and	d safety Completed	1 🖸	
Safety and performance of the medical device	Draft	47 🔽	
Legislative Breaches Responses Cick on the arrow to the right of the Response to select Edit Response Name	to enter the evidence of compliance Entreches under lowestigation	Created On 4-	
Response for EP 1 - Use of Imetical devices not to compromise health and safety for ARTG Number(s) 1517156,1518321,1518448,1521805	EP 1 - Use of medical devices not to compromise health and safety	23/09/2020 1:20 PM (2/10	
5. Select how you wish to	provide your response.		
a. You can choose fro	om one of the three options:		
Provide a summer	nary		

- Attach evidence of compliance
- Both

If you select "Attach evidence of compliance" or "Both", you must attach minimum one file.

HT - Die o	f shelling: shinked solt he early	12970-1398300 and		
ARTGs (I	Please note that ARTG	s can be rem	oved from th	nis response)
ARTG ID	ARTG Name	ARTG Status	Statue Reason	Created On
1513446	ITGA - TGAUAT PRODUCT- Adaptor, specify	Active	Draft	1409/0020
1518321	1TGA - TGAUAT PRODUCT- Adapto: specify	Active	Dat	14/09/2020 C
1517156	1TGA - TGAUAT PRODUCT- Adhesive, soft bissue approximation	Active	but	14/09/2020 4 08 PM
1521905	1TGA - TGAUAT PRODUCT- Adrot Quiding Catheter - Catheter, intravascular, geiding	Active	Draft	14/09/2020 # 05 PM
How do you	wish to provide your resconse?			
				×
Provide a	summary			
Attach evil	dence of compliance			

Instruc	tions	
b.	In the Summary section, provide your response. Note: the summary must be minimum 20 characters.	
lleve de ce		
Both	ou wish to provide your response?	
Dom		
С.	Refer to steps 8 and 9 for instructions on how to Add files and Upload Large Files	5.
How do y	ou wish to provide your response?	
Both	~	
Summary	*	
Attach the It is advise support up removed u d.	English version of your evidence of compliance. Med that you include the ARTG and model when entering a file name for easy identification. 'Add files' to 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be inder any circumstance. Select the check-box to acknowledge that at least one file has been uploaded and	
Name 4	click Save.	
Ditest.tx	t (1 KB) 01/10/2020 10:40 AM	
Please Save	e provide your acknowledgement that at least one file has been uploaded	

How to respond to additional information request

If a notification requires additional information on another specific matter, this is where you can provide a response.

Instru	ctions
1. Cli	ck Edit to provide a response to a specific request.
Other Res	guired Responses 🕦 -
AR Asspera	Image: mail (marked) Request Created 59:4 to importance The immode minit (The importe extense of the immode minit (The importe extense of the immode minit) (The i
2. Se	lect how you wish to provide your response and complete the details
a.	Select one of the following:
	Provide a summary
	Attach evidence of compliance
	• Both
∛ Ify file	you select "Attach evidence of compliance" or "Both", you must attach minimum one e. *
	Adhoc REL Response
4	cidence for adhoc must be attached or a summary must be provided.
	Request for Exemption rengulages are managers af the spone family. The reducate solution is a myth for coloride model, aport sto, Earcon view the same mathliney. The languages and different their grammer their prestandamen and their much oppress.
	y mpone sy anny any a new communitation guardi neuroli de regulator: new respectantino tri par in nom new bandalista. In antinen 1940 il neu del ha camadalista Tanan antinina antinina in antinina del an antinina di
	few do you wish to provide your response?
	Provide a summary
	Both
b.	In the Summary section, provide your response. Note: the summary must be minimum 50 characters.

Add files and	Upload Large Files.	
How do you wish to provide your re Both Semmary * Attach the English version d. Select the cher click Save.	n of your evidence of compliance	e file has been uploaded and
	Modified	
Name 🛧		
Name 🛧	01/10/2020 10:40 AM	0

How to submit the information

Instructions
1. If you are ready to submit your response, click Validate .
$\sqrt[3]{}$ Only the Submitter will be able complete the following steps to submit the response.
PMR Notification Draft
Expand All Collapse All
Notification Details +
ARTGs and Model Details +
Legislative Breaches and Responses +
Other Required Responses +
Extension Requests +
Validate Back Refresh
 Once the response has been successfully validated, click Preview to preview your responses.
PMR RFI Draft
This SET his free is available place view on the Traves factor is placed SET Bogonices. Flex on the Texture is this to do the designment of REI. Provem Declare
🌾 You can preview the notification before you submit it.
PMR RFI Preview
- Post II
Requirement for Information under Section 41JA of the Therapeutic Goods Act 1989
The High Is instituting a point monitor serving of UNE / Excellence - Not - RRN Namine PAN 2020-01103 - Caldinar J.M 01 Review References 1948;2020-01103
Review in scope: Sportup's ARIS entries that have been added to 10.4 test environment
Review set of scope: Any ARTU entries that do not belong to Confrient on have not liver added to TUA test environment
ARTGs and Model Details
ARIG
ARTG Betry Name Eactdes: Herind - Adaptes phrindenet, resuble
ARTG Statest Active
GMDNS Code 37723
Manufacturer Name: Model: (5903)

Instructions	
3. Click Declare .	
PMR RFI Draft	
The RFT has been successfully, websited. Private cash on the Triovers' batter to convex TR1 Responses. Clock on the Toxian' history to be declaration of RFT.	
4. Select Yes if you agree to the declaration.a. Click Submit.	
RFI Declaration	×
General Inderstand that this is the final submission to a regulatory notification and this information will be used by the Therapeutic Goods Administration in evaluating compliance with the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002. I understand that the documents and information provided is required to be in English. I agree to the declaration * I No	
5. Click OK.	

How to request for an extension

If you are having difficulty providing the information in the required timeframe and need an extension, you can submit a request. Please note, that a request for extension may not be able to be provided in all cases.

Click D	raft.						
MR Cor	npliance Das	hboard					
a Repeat to take	matick -Active+				14arth	Q	
eference					Response Due Date		
siR-2020-	Review Description +	Sponsor Name	RF1 Type Section 41JA	Sent/Availing Response	+ 1106/2020 5 00 PM	171	
1103			Rection 4118	Section Destates	11052030 5 00 214		
1164			39630114104	Service of Automotion	11002000 0 30 FM		
NIIL-2020- 1234			54108 Proposal to suspend	Sent-Awating Response	06/67/2020 5:00 PM	Ψ.	
MR-3030. 1234			S41GN(Z) Proposal to Cancel	Selt-Analing Response	06/07/2020 5 00 PM		
MIL-2020- 1216			Section 41JA	Sont/Awaiting Response	13/07/2020 5:00 PM		
NFE-2020			Section 41JA	Senti-Awaiting Response	13/07/2020 5:00 PM	O View 182 h	
Click o	n the + butto	on to expan	id the Exte	ension Reque	sts section.		
Click o	n the + butto Collepse Al Information Details Breaches and Resp red Responses equests	on to expan	id the Exte	ension Reque	sts section.		
Click o	n the + butto Collepse A1 Information Details Model Details Breaches and Resp red Responses equests Back Befrech	on to expan	id the Exte	ension Reque	sts section.		
Click o	n the + butto Collecte AI Information Detail Model Details Breaches and Res red Responses equests Eack Refrech equest Exte	on to expan	id the Exte	ension Reque	sts section.		
Click o	n the + butto Collecte Al Collecte Al Coll	on to expan	Id the Exte	ension Reque	sts section.		
Click o	n the + butto Collepse Al Collepse Al Collepse Al Collepse Al Collepse Al Model Details Breaches and Resp red Responses Requests Refresh Refre	on to expan	Id the Exte	ension Reque	sts section.	ted On +	
Click o	n the + butto Collecte AI Collecte AI Coll	on to expan	New Due De 05:05:2020 8	ension Reque	sts section.	ted On ↓	

Instructions

- 4. Complete the fields.
 - a. In the **Proposed Due Date** field, enter the new date. Note: this date must be later than the current RFI date.
 - b. In the **Extension Request** field, enter the reason for requesting for an extension.
 - c. If you're ready to submit the request, select **Yes**. If not, select **No** to save the request and submit at a later date.

ion Request				~	
Proposed Due Date *					
			=		
xtension Request					
	I				
ubmit Request					
Extension Res	onse				
xtension Decision					
			~		
lesponse					
ick Save . Click OK .					
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lick Save. Click OK.	e-test.powerappsportals.com bmit the request you will not be you want to submit your request?	able to change the		*	
lick Save. Click OK. sion Requ Once you s cetals. Do	e-test.powerappsportals.com brait the request you will not be you want to submit your request?	able to change the]	я	
Lick Save. Click OK. sion Requinant Once you s cetails. Do Extens Extens	e-test.powerappsportals.com bmit the request you will not be you want to submit your request?	able to change the		*	
Lick Save. Click OK. sion Required Conce you s cetails. Do Extension D	e-test.powerappsportals.com bmit the request you will not be you want to submit your request?	able to change the		×	
Lick Save. Click OK. sion Required Once you side cetals. Do Extens Extense Response	e-test.powerappsportals.com ibmit the request you will not be you want to submit your request?	able to change the		*	
Lick Save. Click OK. sion Required Concerptions Concerption Solution Extension D	e-test.powerappsportals.com bmit the request you will not be you want to submit your request	able to change the		*	
lick Save. Click OK. sion Requine Compliant Once you si cetails. Do Extens Exemsion D	e-test.powerappsportals.com brait the request you will not be you want to submit your request?	able to change the		*	
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lick Save. Click OK. sion Requinant cetails. Do Extens Exampton D	e-test.powerappsportals.com brait the request you will not be you want to submit your request?	able to change the		*	
lick Save. Click OK.	e-test.powerappsportals.com dmit the request you will not be you want to submit your request	Says able to change the Cascel			
lick Save. Click OK.	e-test.powerappsportals.com brait the request you will not be you want to submit your request?	b says able to change the OK. Cancel			

How to respond to a "Proposal to cancel" or "Proposal to suspend"

You can view and respond to these types of notifications by following the instructions below.

ns	tructions						
	Click Dr a	aft.					
3	PMR Co	mpliance Da	shboard				
	■Notecation - Act	nic-				Search	٩
	Reference Number	Review Description	Sponsor Name	Notification Type	Status	Response Due Date	
	PMR-2020-01309	Devices - ARTG	1TGA	S41GB Proposal to suspend	Sent/Awaiting Response	29/10/2020 5:00 PM	
100	PMR-2020-01309	Devices - ARTG	1TGA	Section 41JA	Sent/Awaiting Response	29/10/2020 5:00 PM	Oran O View details Proview
).).	You can In the N notificat	view the notif otification Doc ion. etails ()	ication detail cuments secti	s in the Not ion, you can	ification Detai view all the do	ls section. cuments asso	ciated to this
);- No 54	You can In the No notification D 1GB Propo	view the notif otification Doc tion. etails () sal to suspend of to a post market review	ication detail cuments secti of the Therape of Devices - ARTG	s in the Not on, you can eutic Goods A	ification Detai view all the do Act 1989	ls section. cuments asso	ciated to this
No 54	You can In the No notification D 1GB Propo TGA is conduction Iffication Name	view the notif otification Doc ion. etails () sal to suspend o g a post market review	ication detail cuments secti of the Therape of Devices - ARTG	s in the Not on, you can eutic Goods A _{Reviev}	ification Detai view all the do Act 1989	ls section. cuments asso	ciated to this
C No S4 Noti	You can In the No notification D 1GB Propo TGA is conduction filication Name = 3-2020-01309 - 1	view the notif otification Doc tion. etalls () sal to suspend of ng a post market review TGA - 02	ication detail cuments secti of the Therape of Devices - ARTG	s in the Not on, you can eutic Goods A Review PMR-2	ification Detai view all the do Act 1989 v Reference Number 020-01309	ls section. cuments asso	ciated to this
No 54 Noti Met	You can In the Na notification D 1GB Propo TGA is conduction ffication Name * 8-2020-01309 - 1 filew in scope	view the notif otification Doc tion. etails () sal to suspend o og a post market review TGA - 02	ication detail cuments secti of the Therape of Devices - ARTG.	s in the Not on, you can eutic Goods A Review PMR-2	ification Detai view all the do Act 1989 v Reference Number 020-01309	ls section. cuments asso	ciated to this
No S4 Noti Noti Rev	You can In the Na notification D tification D TGA is conduction fication Name * R-2020-01309 - 1 riew in scope	view the notification Doc cion. etalls () sal to suspend of og a post market review TGA - 02	ication detail cuments secti of the Therape of Devices - ARTG.	s in the Not on, you can eutic Goods A Review PMR-2	ification Detai view all the do Act 1989 v Reference Number 020-01309	Is section. cuments asso	ciated to this
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C S4 The Noti PMF Rev All A Rev	You can In the Na notification D 1GB Propo TGA is conduction ffication Name * 8-2020-01309 - 1 filew in scope ARTG entries that filew out of scop	view the notification Doc cion. etalis () sal to suspend of ng a post market review TGA - 02 Lare required for this rev e required in this review a	ication detail cuments secti of the Therape of Devices - ARTG new are single Sponso re from all remaining S	s in the Not on, you can eutic Goods A Review PMR-2	ification Detai view all the do Act 1989 v Reference Number 020-01309	Is section. cuments asso	ciated to this
S4 The Noti Rev All A Rev	You can In the Na notification D tification D TGA is conduction (TGA is conduction) (TGA is conduction) (T	view the notif otification Doc tion. etalls () sal to suspend of ng a post market review TGA - 02 tare required for this rev p required in this review a uments	ication detail cuments secti of the Therape of Devices - ARTG new are single Sponso re from all remaining S	s in the Not on, you can eutic Goods A Review PMR-2	ification Detai view all the do Act 1989 v Reference Number 020-01309	Is section. cuments asso	ciated to this
S4 The Noti Rev NI A Rev	You can In the Na notification D tification D TGA is conduction fication Name * R=2020-01309 - 1 filew in scope ARTG entries that filew out of scope ARTG entries not ification Doct	view the notification Doc cion. etalls () sal to suspend of og a post market review TGA - 02 tare required for this rev e required in this review a uments	ication detail cuments secti of the Therape of Devices - ARTG. new are single Sponso re from all remaining S	s in the Not on, you can eutic Goods A Review PMR-2	ification Detai view all the do Act 1989 v Reference Number 020-01309	ls section. cuments asso	ciated to this
S4 The Noti Noti Noti Noti Noti	You can In the Na notification D tification D TGA is conduction fication Name * R-2020-01309 - 1 riew in scope ARTG entries that riew out of scope ARTG entries not ification Dock	view the notification Doc cion. etails () sal to suspend of og a post market review TGA - 02 t are required for this review a required in this review a uments	ication detail cuments secti of the Therape of Devices - ARTG. New are single Sponso re from all remaining S	s in the Not on, you can eutic Goods A Review PMR-2	ification Detai view all the do Act 1989 Reference Number 020-01309	ls section. cuments asso	ciated to this
	You can In the Na notification D 1GB Propo TGA is conduction ification Name [™] R-2020-01309 - 1 Hew in scope ARTG entries that hew out of scope ARTG entries not ification Doct me ♠ Emails	view the notification Doc cion. etalls () sal to suspend of ng a post market review TGA - 02 t are required for this review a inents	ication detail cuments secti of the Therape of Devices - ARTG new are single Sponso re from all remaining S	s in the Not on, you can eutic Goods A Review PMR-2	ification Detai view all the do Act 1989 v Reference Number 020-01309 Modi	Is section. cuments asso	ciated to this
S4 Noti PMF Rev All A Noti No	You can In the Na notification D IGB Propo TGA is conduction fication Name [™] R-2020-01309 - 1 filew in scope ARTG entries that filew out of scop ARTG entries not ification Doct ification Doct ification Doct arme ↑ Emails Large Files	view the notification Doc cion. etalls () sal to suspend of ng a post market review TGA - 02 t are required for this rev e required in this review a uments	ication detail cuments secti of the Therape of Devices - ARTG.	s in the Not on, you can eutic Goods A Review PMR-2	ification Detai view all the do Act 1989 v Reference Number 020-01309 Mod 28:05 28:05	Is section. cuments asso	ciated to this

Instructions In the ARTGs and Model Details section, click on Add Response to respond to the 3. selected ARTG. ARTGs and Model Details () The following ARTG entries have been selected for a post-market medical device review Click on the arrow to the right of the ARTG entry to select 'Add Response'. ARTG Entry Name ARTG ID ARTG Status Created On 4 Status Active 28/09/2020 10:04 1518446 ITGA - TGAUAT PRODUCT-Adaptor, Draft ⊡___ AM specify Add Response ----Click Proceed. 4.

Add Response	×
Do you want to add a Response to this ARTG?	
	Proceed Cancel

5. Click on **Created On** to enter the evidence of compliance for the selected ARTG.

The following ART	G entries have been selected for a p	ost-market r	nedical device review		
Click on the arrow t	o the right of the ARTG entry to select	Add Respon	ie'.		
ARTG ID	ARTG Entry Name		ARTG Status	Status	Created On 🔶
1518446	ITGA - TGAUAT PRODUCT-Ada	ptor, specify	Active	Completed	28/09/2020 10:04 AM
RTG Respons	6 5				
Click on the arrow t	o the right of the Response to select 'E	dit' to enter th	e evidence of compliance.		
Response Name	•	ARTG Entry	Name	Created On	8
				Second and second	
. Click Ed	lit. as the right of the Response to select "Ed	W to enter the	evidence of compliance.		
. Click Ed RTG Response Click on the arrow to Response Name	lit. es the right of the Response to select "Ed Al	it' to enfer the RTG Entry No	evidence of compliance.	Created On ♠	

Ins	Instructions				
7.	Select how you wish to respond.				
Edit	ARTG Response ×				
	ARTS				
	TEGA > TEGAUAT PRODUCT-Adaptor, specify				
	Legislative Breaches				
	Breaches under Inninstigation Row Number +				
	EP 1 - Use of medical devices, not to compositive health and safety T				
	How do you wish to provide your response?				
	Provide a summary				
	Attach evidence of compliance				
8.	Enter your summary.				
	w do you wish to provide your response?				
Ē	Both				
Su	immary *				
Ľ					
9.	Upload your files. You have two options ("Add files" and "Upload Large files") to upload a copy of the Instructions For Use (IFU), for both in scope and out of scope devices. Refer to instructions:				
	• 9a to use the "Add files" button to upload documents less than 50MB size.				
	• 9b to use the "Upload Large files" button to upload documents more than 50MB size.				
-Q:	Please note, folders are being created in the background to store information so it may take 1 to 2 minutes for the "Add files" and "Upload Large files" buttons to appear.				

	ŧ
• Add files Upload Large file	a j
There are no folders or files to display	

Click **Choose files** and select the file you want to upload. Once you have selected your file, click on **Add files** button.





A new window will open directing you to the SharePoint site. Click Next.

Sha	aring Link Validation	n:
You've rece	ived a secure link to:	
Lan	ge Files	
Sign in to we'8 give yo	ou access immediately.	and
	Next	

Click Upload and then Files.

lome	+ New ~ ↑ Upload ~ I	Edit in grid view
Conversations	Files	
Documents	Review > PM Folder	ton Johns
	Template	
ihared with us	v once you have uploaded the	large file(s).
ose the window	v once you have uploaded the	large file(s).
Chared with us ose the window ③ PMR Notification Draft ← → C ☆ (■	v once you have uploaded the Custom × S D365-CCF-Test-Site - Large Fi healthgovdev.sharepoint.com/sites/D365-F	large file(s).
PMR Notification Draft ← → C 介 ● SharePoint	v once you have uploaded the Custom × S D365-CCF-Test-Site - Large Fi healthgovdev.sharepoint.com/sites/D365-F	large file(s).

structions					
ect the check-box to	acknowledge that at least one file has b	een uploaded and click Save			
Attach the English version of the Instructions for Use provided with or on the device, additional information about the samples. It is advised that you include the ARTG and model when entering a file name for easy identification. 'Add files' support upto 50MB. 'Upload Large files' support upto 5GB. Large File Folder created in SharePoint should not be removed under any circumstance.					
Name 🛧	Modified				
Etest.txt (1 KB)	01/10/2020 10:40 AM	٥			
Click on Validate . Other Required Respons	es	+			
Validate Back Refr	esh				
. Click Preview to v	iew your responses.				
MR Notification	Draft				
The Notification has been successfully va					
	idated. Please click on the 'Preview' button to preview Responses. Click on the 'C	lectare' button to do the declaration of Notification			

	r
nstructions	
Print	
541GB Proposal to suspend of the Therapeutic Goods Act 1989	
The TGA is conducting a post market review of Devices - ARTG.	
Notification Name: PMR-2020-01209 - 17GA - 02 Review Reference: PMR-2020-01209	
Review in scope: All ARTQ entries that are required for this review are single Sponsor	
Review out of scope: All ARTG entries not required in this review are from all remaining Sponsors	
ARTGs and Model Details	
ARTG	
ARTG ID: 1518445	
ARTG Entry Names ITGA - TOAUAT PRODUCT-Adaptor, specify	
ARTG Status: Active	
Statuse Completed	
Response	
Name: Rescorce for EP 1 - (See of medical devices not to compromise health and caleto fee ARTS Number(s) 15182.06	
How do you with to provide your response? Both	
Responses for testing purposes	
Models	
Model	
ARTG ID: 1518445	
ARTG Entry Name: ITGA - TGAUAT PRODUCT-Adaptor, specify	
ARTG Status: Active	
GMONS Code: TG15184466	
Manufacturer Name:	
Model:	
Is this model in the scope of the review? Ves	
Cloned? No	
2. If no further changes needs to be made click Declare	
2. Il no fui thei changes needs to be made, click Deciale .	
DMD Notification Deef	
PMR Notification Draft	
The Nonfication has been successfully validated. Please click on the 'Preview' button to preview Responses. Click on the 'De	clare' botton to do the declaration of Notification
Preview Declare	
3. Select No or Yes if you agree to the declaration and click S	ubmit.
	_
Peclaration	
General	
I understand that this is the final submission to a regulatory notification and this information will be used by the	
Therapeutic Goods Administration in evaluating compliance with the Therapeutic Goods Act 1999 and the Therapeutic Goods (Medical Devices) Regulations 2002	
understand that the documents and information provided is required to be in Foreign	
r agree to the declaration	

• Yes

Instructions	
14. Click OK .	
Submit	×
Do you want to submit this Notification?	
	Ok Cancel

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Medical Devices Surveillance Branch	October 2020
V1.1	Minor additions to clarify drafting of responses process	Medical Devices Surveillance Branch	December 2020
V1.2	Minor additions to clarify drafting process and order of processes	Medical Devices Surveillance Branch	March 2021

Therapeutic Goods Administration

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Reference/Publication #