From: [redacted]
To: [redacted]
Subject: DIR 65968 - Monash IVF Group - Final report to be submitted [SEC=OFFICIAL]
Date: Thursday, 1 July 2021 3:34:30 PM
Attachments: image001.png
image002.png
image003.png
image006.png
image007.png
image008.png

Dear [redacted]

Many thanks for your email You original report, DIR 65968 has been returned to your portal awaiting submission of your final report Once you have submitted the final report we will then review all of the information and considered if any follow-up is required

Many thanks for your assistance
Kind regards,
[redacted]

[redacted]
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

Phone [redacted]
Email [redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www tga gov au

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From: [redacted]
Sent: Wednesday, 30 June 2021 2:58 PM
To: [redacted]<IMCEAEX-_O=MONASH+20IVF_OU=EXCHANGE+20ADMINISTRATIVE+20GROUP+20+28FYDIBOHF23SPDLT+29_CN=RECIPIENTS_CN=[redacted]
IRIS <IRIS@health gov au>
Cc: [redacted]
Subject: RE: TGA Request for Information - DIR 65968 - Monash IVF Group

REMINDER: Think before you click! This email originated from outside our organisation Only click links or open attachments if you recognise the sender and know the content is safe

Dea [redacted]

I am writing to provide an update to the notification that we made in October 2020, advising that Monash IVF and Repromed had taken the decision to suspend our non-invasive or cell-free PGT-A screening programme I can now confirm that the organisation has now decided that this test screening programme will not be re-introduced This test was placed into voluntary suspension and was removed from our scope of practice on the NATA website However, we have now requested that this test to be to formally withdrawn from our NATA accreditation scope

Following the suspension, we undertook an open disclosure process with all affected patients We have since worked with those patients to offer remediation options of counselling support as well as ongoing medical care to enable those who wish to continue their treatment to do so We will continue to provide information and support to our patients who will be informed of the permanent withdrawal of the test today

You may be aware that a Group Proceeding, or class action, has been commenced against the organisation and as such we hope that you will understand that we are unable to provide further detail or comment

Kind regards,
[redacted]

[redacted]
T. [redacted] - M. [redacted] - F. [redacted]
[redacted]

Monash IVF Group Limited
Pelaco Building 1
Level 1, 21-31 Goodwood Street
Richmond, VIC, Australia, 3121

monashivfgroup.com.au

From: [redacted]
Sent: Friday, 27 November 2020 3:47 PM
To: 'IRIS@health gov au' <IRIS@health gov au>
Cc: [redacted]
Subject: RE: TGA Request for Information - DIR 65968 - Monash IVF Group

Please find attached Monash IVF Group s response with the information requested

Kind regards
[redacted]

[redacted]

T. [redacted] - M. [redacted] - F. [redacted]
[redacted]

Monash IVF Group Limited
Pelaco Building 1
Level 1, 21-31 Goodwood Street
RichmondVICAustralia3121

monashivfgroup.com

From: [redacted]
Sent: Friday, 30 October 2020 1:05 PM
To: [redacted]
Subject: TGA Request for Information - DIR 65968 - Monash IVF Group - Response due by COB 26 November 2020 [SEC=OFFICIAL]

Dear [redacted]

To assist in the evaluation and resolution of the Device Incident Report (DIR 65968) you recently submitted to the TGA, please provide the information requested in the attached letter and return it to this office **within 20 working days of the date of this letter,** and no later than COB 26/11/2020.

If you are unable to respond with all the information requested by the due date please advise, **within the 20 days**, when a full response will be provided. Extensions of a reasonable time frame will be accepted depending on the seriousness of the complaint and the time requested.

Thank you for your cooperation. If you require further information please contact me on [redacted] or email IRIS@health gov au

Yours sincerely,
[redacted]

[redacted]
Devices Post Market Monitoring Section
Medical Devices Surveillance Branch

Phone [redacted]
Email [redacted]

Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606
www tga gov au

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