[redacted]

From: [redacted]
Sent: Monday, 7 May 2018 6:06 PM
To: MASRI, George
Subject: FW: ARCS Reg Affairs Interest Area Session [SEC=UNCLASSIFIED]

Categories: FOI, george to do

Hi George,

The RIS question was asked at the ARCS Reg Affairs Interest Area Session at the end of March, response highlighted in yellow below.

Regards
[redacted]

[redacted] Regulatory Pricing and Decision Review Section

Regulatory Services & Improvement Branch | Regulatory Practice & Support Division
Health Products Regulation Group
Australian Government Department of Health

[redacted]
Location: Symonston GB

PO Box 100, Canberra ACT 2601, Australia

From: [redacted]
Sent: Thursday, 29 March 2018 1:23 PM
To: [redacted]
Cc: [redacted]
Subject: RE: ARCS Reg Affairs Interest Area Session [SEC=UNCLASSIFIED]

I have included a couple of sentences for you and highlighted the text.

[redacted] Reform Coordination and Support Section

Regulatory Services and Improvement Branch | Regulatory Practice & Support Division
Health Products Regulation Group
Australian Government Department of Health

[redacted]

PO Box 100, Canberra ACT 2601, Australia

From: [redacted]
Sent: Thursday, 29 March 2018 1:13 PM
To: [redacted]

Cc: [redacted]
Subject: RE: ARCS Reg Affairs Interest Area Session [SEC=UNCLASSIFIED]

Hi [redacted]

As discussed, I am preparing draft response for questions from ARCS webinar participants. Draft responses are included below the questions in blue. Could you please suggest an appropriate response for the RIS question (question 3 under George)?

Thanks
[redacted]

From: MASRI, George
Sent: Wednesday, 28 March 2018 2:18 PM
To: [redacted]
Subject: FW: ARCS Reg Affairs Interest Area Session [SEC=UNCLASSIFIED]

I haven't looked at these yet?
G

From: [redacted]
Sent: Wednesday, 28 March 2018 11:49 AM
To: CHRISTIAN, Rochelle; NOYEN, Benjamin; MASRI, George
Cc: [redacted]
Subject: FW: ARCS Reg Affairs Interest Area Session [SEC=UNCLASSIFIED]

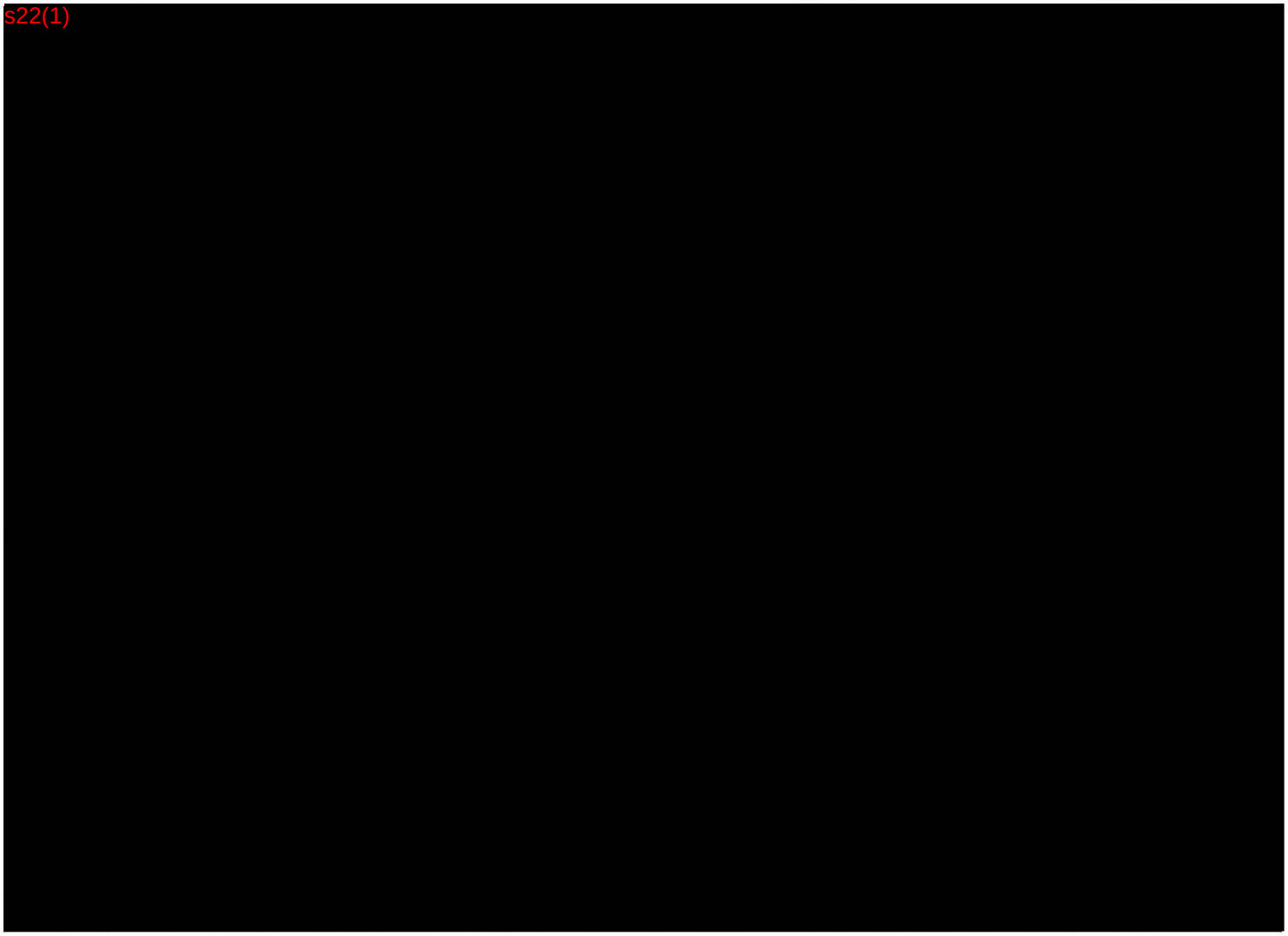
Dear Rochelle, Ben and George,

Thank you again for your time yesterday. Please find below the questions posted during the event. Please let me know if you have any questions.

Thanks again. [redacted]

s22(1) [redacted]

s22(1)



3. Has there been an impact statement prepared or industry consultation on the introduction of a fee for the Class I medical device applications?

Consultation on fees and charges for 2018-19 (including the introduction of a fee for inclusion of Class 1 medical devices has been undertaken with key therapeutic industry representative bodies in December 2017 and February/March 2018. There is no requirement to prepare a regulatory impact statement for amendments to increase fees and charges for therapeutic goods and manufacturing licences. There is a standing agreement in place between the Office of Best Practice Regulation and the Department of Health removing the need for a preliminary assessment when using the well-established formula used to calculate these amendments.

s22(1)

s22(1)

[redacted]

[redacted]

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