

UNCLASSIFIED
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DEPARTMENT OF DEFENCE CORPORATE FILE

S. 47F



Title: S. 47F
Anti Malaria Trial (Legal Aspects)

File Number: S. 47F

CRS Number: A11502

Primary Keyword: LEGAL SERVICES:LITIGATION

Originating Workgroup: DLIT : Directorate of Litigation

Creation Date: 30 September 2004 11:47:44

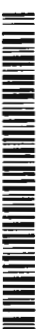
Cross Reference(Links):

Local Identifier:

UNCLASSIFIED
Legal-in-Confidence

DEPARTMENT OF DEFENCE CORPORATE FILE

2005/1002365/1



Title: Anti-Malaria Trials - Litigation Threat

File Number: 2005/1002365/1

CRS Number: A11502

Primary Keyword: LEGAL SERVICES:LITIGATION

Originating Workgroup: DLIT : Directorate of Litigation

Creation Date: 11 January 2005 08:22:25 AM

Cross Reference(Links):

Local Identifier:



Department of Defence
**The Defence Legal Service
File Note**

FOI 286/15/16
Document 2

**Australian Government
Department of Defence**

Matter <i>Anti-Malarial</i>		
Author <i>AC</i>	Date <i>28/9/04</i>	Time
Telephone attendance <input checked="" type="checkbox"/>	Meeting attendance <input type="checkbox"/>	
Further action required	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

Spoke to contact at DVA.

- No MCRS or DVA claim.

- As on operation ^{s. 47F} [redacted] at the time, any compo claim would go through DVA or no rights under MCRS.

∴ most likely not one of ours.

- No further action needed.

AC

28/9/04

s. 47F [Redacted]

→ No.

s. 47F [Redacted]

s. 47F [Redacted]

Complaint by [Redacted] legal approach made to Army Malarial Institute.

[Redacted] → CDF 29/8/04
Clinical side effects re. partic in anti malarial trial in

[Redacted]

s. 47F [Redacted]

s. 47F [Redacted]

Mifloquin

s. 47F

· volunteered to join trial. Not an order. In 4 RAR, 1/2 of 4 RAR were on trial. All by choice.

· Mifloquin approved, used around world, not a brand new drug. Used by ADF in past but hadn't undertaken trials to see how goes. Looking at it from command perspective as Doxy (normal) has to be taken every day & Mit only once a week.

- Not Guinea pigs or trialing new drug. Recog by drug authority.

- Problems if you have an alcohol problem or psychiatric condition

↓
all had medical before
on trial ~~to that point~~

s. 47F

s. 47F

- Most people go home ^{Aust.} for leave.

s. 47F



s. 47F

s. 47F

s. 47F

- Went through post trial
protocol. → 3 months after
then came off it →

s. 47F

s. 47F

- 4RAR trial ^{was} supervised

- 2RAR supervision more problematic,

- Person in charge of
now in

s. 47F

s. 47F

- ^{s. 47F} requested all data
& reports of Army trials
from ~~the~~ Malanial Unit. They
have not yet been published

s. 47F

- ^{s. 47F} might be one of a
no.

s. 47F

s. 47F





Upshot

- legal approach made to AMI →
talking of class action)

←
don't know why trial &
report haven't been
released.

- 3 ed.'s ago Army Newspaper
ran this as obituary

- s. 33(a)(iii) [redacted] has named
[redacted]

- Check if an MCRS claim.

s. 47F [redacted] on ops then
↳ on operation of [redacted] s. 47F

∴ Would go through
DVA

Miller, Richard MR 1

From: Cunliffe, Mark MR
Sent: Thursday, 2 December 2004 16:43
To: Hannan, Mike BRIG
Cc: Pezzullo, Michael MR; Adams, Brian RADM; Austin, Tony AIRCDRE; Miller, Richard MR 1
Subject: s. 47F

Mike

Can I clarify please; when you talk of 'the trial', do you mean a legal or medical 'trial', please?

Mark

Mark Cunliffe
Head, Defence Legal
Department of Defence
R G Casey Building (RGC-3)
Barton ACT 2600

Tel: 61 2 6266 8898

Fax: 61 2 6266 8899

Mob: s22

-----Original Message-----

From: Hannan, Mike BRIG
Sent: Thursday, 2 December 2004 15:50
To: Cunliffe, Mark MR; Pezzullo, Michael MR
Cc: Adams, Brian RADM; Austin, Tony AIRCDRE
Subject: RE: s47F

All, notwithstanding the fact that we don't have any information, s. is insistent that s. has had more calls on this that from any other story in recent memory. When questioned about the numbers, s. insisted that there had been more than 100. S. also gave a detailed and critical account of the conduct of the trial including the level of briefing and agreements. Regardless of what we might think here in Canberra, there is an indication that things might not be seen quite the same way up north. I would suggest that we investigate this ourselves. Regards all, Mike Hannan

-----Original Message-----

From: Cunliffe, Mark MR
Sent: Thursday, 2 December 2004 13:27
To: Pezzullo, Michael MR; Hannan, Mike BRIG
Cc: Adams, Brian RADM; Austin, Tony AIRCDRE
Subject: s. 47F

fyi

Mark

Mark Cunliffe
Head, Defence Legal
Department of Defence
R G Casey Building (RGC-3)
Barton ACT 2600

Tel: 61 2 6266 8898

Fax: 61 2 6266 8899

Mob: s22

-----Original Message-----

From: Miller, Richard MR 1
Sent: Thursday, 2 December 2004 10:47
To: Cunliffe, Mark MR
Subject: RE: McIlveen

Mark we don't have any cases at all.

This is still part of the s. 47G PR push to get in some legal work, at the moment it is all buzz and no bite.

Richard

-----Original Message-----

From: Cunliffe, Mark MR
Sent: Thursday, 2 December 2004 9:17
To: Miller, Richard MR 1
Subject: s. 47F

Richard

Not sure I recall the s. 47F case; is it one of the malaria ones? And do we know either its status or the status of the 'hundreds' please?

thanks

Mark

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Fax: 61 2 6266 8899
Mob: s22

-----Original Message-----

From: Hannan, Mike BRIG
Sent: Thursday, 2 December 2004 8:59
To: Austin, Tony AIRCDRE; Adams, Brian RADM; Pezzullo, Michael MR; Cunliffe, Mark MR
Subject: s. 47F

s. 47F

s. 47F

Mike Hannan

-----Original Message-----

From: Austin, Tony AIRCDRE
Sent: Thursday, 2 December 2004 8:58
To: Adams, Brian RADM; Pezzullo, Michael MR; Cunliffe, Mark MR; Hannan, Mike BRIG
Subject: s. 47F

Sir,
We have heard nothing this end to suggest that this case is proceeding.
Regards,
Tony

T.K. AUSTIN AM
AIRCDRE
Director-General Defence Health Service
DHSB
CP2-7-121
Tel: (02) 62663919
Mob: s22
Fax: (02) 62663933
E-mail: Tony.Austin@defence.gov.au

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-----Original Message-----

From: Adams, Brian RADM
Sent: Thursday, 2 December 2004 8:56
To: Pezzullo, Michael MR; Cunliffe, Mark MR; Hannan, Mike BRIG; Austin, Tony AIRCDRE
Subject: s. 47F

s. 47F

s. 47F as I understand it to be, is there value in us saying so?

Brian Adams
HDPE

Miller, Richard MR 1

From: Adams, Brian RADM
Sent: Friday, 3 December 2004 8:07
To: Pezzullo, Michael MR; Hannan, Mike BRIG; Miller, Richard MR 1; Austin, Tony AIRCDRE
Cc: Gordon, Ian MAJGEN (DCA)
Subject: s. 47F

From DGDHS's earlier inquiries we assured ourselves that the malaria drug trials were conducted in accordance with Australian Defence Health Research Ethics Committee guidelines.

s. 47F [redacted] particularly since we can find no truth in s. [redacted] assertions about hundreds of people seeking to sue. Instituting some form of trial on the grounds of s. [redacted] assertions seems to be exactly the incorrect response.

Tony, please brief Mike Hannan on the trials but, at this stage anyway, I do not see that any formal form of investigation is necessary. After Mike and Tony have talked, with DL involvement also, then we should see where we should go with this. Tony, the question that needs to be answered is, if the trials were conducted in accordance with ADFHREC guidelines, 'were any actions taken outside the medical sphere that might have been inappropriate?'

Brian Adams

-----Original Message-----

From: Pezzullo, Michael MR
Sent: Thursday, 2 December 2004 16:50
To: Hannan, Mike BRIG; Miller, Richard MR 1
Cc: Adams, Brian RADM; Austin, Tony AIRCDRE; Cunliffe, Mark MR
Subject: s. 47F

Could the two of you swap notes please.

We don't want to be Pearl Harbour'ed on this.

DGPA's report has a ring of truth about it -s. 47F [redacted]

MP

DEPARTMENT OF DEFENCE

MICHAEL PEZZULLO
Chief of Staff ADHQ
Head Coordination and Public Affairs

R1-5-Ministerial Suite
RUSSELL OFFICES
CANBERRA ACT 2600


Ph: 02 626 54652
Fax: 02 626 52753
Mobile: [redacted]
Email: michael.pezzullo@defence.gov.au

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s. 22(1)(a)(ii)

[redacted]


s. 22(1)(a)(ii)




s. 22(1)(a)(ii)




s. 22(1)(a)(ii)




s. 22(1)(a)(ii)



s. 22(1)(a)(ii)



s. 22(1)(a)(ii)



Miller, Richard MR 1

From: Cunliffe, Mark MR
Sent: Friday, 3 December 2004 9:06
To: Hannan, Mike BRIG
Cc: Pezzullo, Michael MR; Adams, Brian RADM; Austin, Tony AIRCDRE; Miller, Richard MR
Subject: 1: Brook, Josephine MS
s. 47F

Thanks Mike - that was my guess but I wanted to be certain!

regards

Mark

Mark Cunliffe
Head, Defence Legal
Department of Defence
R G Casey Building (RGC-3)
Barton ACT 2600

Tel: 61 2 6266 8898
Fax: 61 2 6266 8899
Mob: s22

-----Original Message-----

From: Hannan, Mike BRIG
Sent: Thursday, 2 December 2004 18:40
To: Cunliffe, Mark MR
Cc: Pezzullo, Michael MR; Adams, Brian RADM; Austin, Tony AIRCDRE; Miller, Richard MR 1
Subject: s. 47F

The medical trial of malaria drug. On this subject s. is very well informed and clearly has different information to that exposed to me so far in the handling of this matter. Mike

-----Original Message-----

From: Cunliffe, Mark MR
Sent: Thursday, 2 December 2004 16:43
To: Hannan, Mike BRIG
Cc: Pezzullo, Michael MR; Adams, Brian RADM; Austin, Tony AIRCDRE; Miller, Richard MR 1
Subject: s. 47F

Mike

Can I clarify please; when you talk of 'the trial', do you mean a legal or medical 'trial', please?


Mark

Mark Cunliffe
Head, Defence Legal
Department of Defence
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Barton ACT 2600


Tel: 61 2 6266 8898
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s. 22(1)(a)(ii)

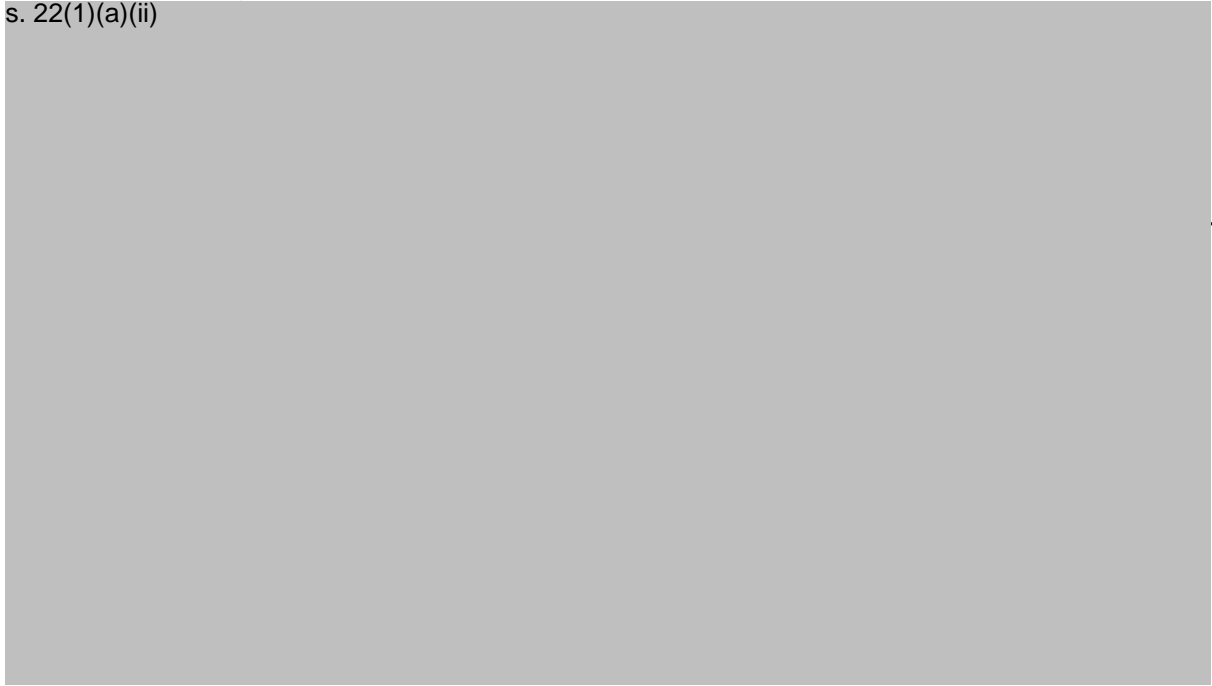
s. 22(1)(a)(ii)




s. 22(1)(a)(ii)




s. 22(1)(a)(ii)



s. 22(1)(a)(ii)



s. 22(1)(a)(ii)



s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Miller, Richard MR 1

From: Cunliffe, Mark MR
Sent: Monday, 6 December 2004 13:37
To: Miller, Richard MR 1; Brook, Josephine MS
Subject: FW: sec:unclassified FOI Anti-malarian drug

fyi

Mark

Mark Cunliffe
Head, Defence Legal
Department of Defence
R G Casey Building (RGC-3)
Barton ACT 2600

Tel: 61 2 6266 8898
Fax: 61 2 6266 8899
Mob: s22

-----Original Message-----

From: Pezzullo, Michael MR
Sent: Monday, 6 December 2004 13:14
To: Phillips, Neil MR
Cc: Cunliffe, Mark MR; Hannan, Mike BRIG; Austin, Tony AIRCDRE; Wells, Glenn COL
Subject: RE: sec:unclassified FOI Anti-malarian drug

Neil

What does the correspondence disclose about the existence or otherwise of prospective legal action?

MP

DEPARTMENT OF DEFENCE

MICHAEL PEZZULLO
Chief of Staff ADHQ
Head Coordination and Public Affairs

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RUSSELL OFFICES
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-----Original Message-----

From: Phillips, Neil MR
Sent: Monday, 6 December 2004 13:07
To: Cunliffe, Mark MR; Pezzullo, Michael MR; Hannan, Mike BRIG; Austin, Tony AIRCDRE; Wells, Glenn COL
Subject: sec:unclassified FOI Anti-malarian drug

Good Afternoon All,

The purpose of this e-mail is to inform addressees that Defence received a request, on 3 Dec 04, from s. 47G s. 47G for access to documents associated with anti-malarian drug Lariam.

At present, s. 47G request does not come under the FOI Act. If they choose to proceed with their request under FOI they will be required to pay the FOI thirty-dollar application fee or obtain remission of the fee. The applicant may also be liable to pay associated processing charges. The FOI Directorate will write to the applicant informing them of how to make a valid request.

Regards

Neil Phillips
Director
Freedom of Information

Ph: 02 62668861

Fax: 02 62668857

Mobile: S22

Email: neil.phillips@defence.gov.au

Miller, Richard MR 1

From: Miller, Richard MR 1
Sent: Wednesday, 5 January 2005 9:25
To: Lloyd, David DR
Subject: RE: sec:unclassified FOI Drugs - Side Effects

David, I have not seen the request from S. [redacted] but assume it is related to the earlier publicity which seems to have emanated from them to the effect that a class action is to be taken regarding the malaria trials. There has been no such action.

s. 42

As to DG's request for clarification of Mr Pezzulo's query, based on earlier traffic I think he is interested in any litigation. Do you want me to respond?

R.

-----Original Message-----

From: Lloyd, David DR
Sent: Wednesday, 22 December 2004 10:20
To: Phillips, Neil MR; Miller, Richard MR 1
Cc: Harvey, Simon AIRCDRE
Subject: RE: sec:unclassified FOI Drugs - Side Effects

Neil or Richard/Michael,

Has anyone reviewed the documents the subject of the FOI request with a view to their significance for any potential litigation if S. 47G [redacted] pursue a claim, and with a view to early consideration of possible strategies for responding?

Please also confirm that, as yet, there have been no actual claims commenced.

Cheers

David

-----Original Message-----

From: Harvey, Simon AIRCDRE
Sent: Wednesday, 22 December 2004 9:21
To: Lloyd, David DR
Cc: Phillips, Neil MR
Subject: RE: sec:unclassified FOI Drugs - Side Effects

David, it is not at all clear to me what Mike P is after. Can you have someone from OGC respond or seek greater clarification if required?

Simon

-----Original Message-----

From: Phillips, Neil MR
Sent: Wednesday, 22 December 2004 8:14
To: Harvey, Simon AIRCDRE
Subject: FW: sec:unclassified FOI Drugs - Side Effects
Importance: High

Simon,

Could you please provide a response direct to Mike Pezzullo in relation to his question regarding HDL understanding of the "legal case" pertaining to drug trials.

Thanks

Neil

-----Original Message-----

From: Phillips, Neil MR
Sent: Wednesday, 22 December 2004 8:09
To: Pezzullo, Michael MR
Subject: RE: sec:unclassified FOI Drugs - Side Effects

Mike,

You are correct that the flow on effect is more a Litigation matter. I've cc DLIT staff on the original e-mail and will forward your enquiry to AIRCDRE Simon Harvey, A/HDL, for a direct response to you.

Regards

Neil Phillips
Director
Freedom of Information

Ph: 02 62668861
Fax: 02 62668857
Mobile: §22
Email: neil.phillips@defence.gov.au

-----Original Message-----

From: Pezzullo, Michael MR
Sent: Wednesday, 22 December 2004 7:11
To: Phillips, Neil MR
Cc: Smith, Ric MR (Secretary); Henderson, Alan MR (DEPSEC CS) 3; Dudfield, Rod Mr ; Austin, Tony AIRCDRE; Miller, Richard MR 1; Hannan, Mike BRIG; Cunliffe, Mark MR; Adams, Brian RADM
Subject: RE: sec:unclassified FOI Drugs - Side Effects

Neil

Acknowledging that this is more likely a matter for Litigation, what is the latest HDL understanding of the "legal case" pertaining to drug trials?

MP

DEPARTMENT OF DEFENCE

MICHAEL PEZZULLO

*Chief of Staff ADHQ
Head Coordination and Public Affairs*

R1-5-Ministerial Suite Ph: 02 626 54652
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-----Original Message-----

From: Phillips, Neil MR
Sent: Tuesday, 21 December 2004 15:54
To: Smith, Ric MR (Secretary); Henderson, Alan MR (DEPSEC CS) 3; Cunliffe, Mark MR; Pezzullo, Michael MR; Hannan, Mike BRIG; Dudfield, Rod Mr ; Austin, Tony AIRCDRE; Miller, Richard MR 1
Subject: sec:unclassified FOI Drugs - Side Effects


Good Afternoon All,

In recent times there has been a number of requests received by the FOI Directorate associated with drug trials. The purpose of this e-mail is to alert you to one current FOI request for access to documents associated with anti-malaria drug trials, s. 22(1)(a)(ii) [REDACTED]

FOI Request - Anti-malaria drug trials

2. The FOI Directorate accepted partial transfer [section 16] on 9 Dec 04 of the request from the Department of Health and Ageing, which was made by s. 47G [REDACTED] seeking access to documents relating to the East Timor trials of the anti-malaria drug, Lariam. On 15 Dec 04 s. 47G [REDACTED] were provided with a preliminary assessment of charges [\$210.00] to have the request administered.

s. 22(1)(a)(ii)



5. Should you require any additional information in relation to the above requests please do not hesitate to contact this office.

Regards,

Neil Phillips
Director
Freedom of Information

Ph: 02 62668861
Fax: 02 62668857
Mobile: 
Email: neil.phillips@defence.gov.au

er, Richard MR 1

From: Dudfield, Rod Mr
Sent: Thursday, 17 March 2005 16:06
To: Landy, Rosemary LTCOL; Pezzullo, Michael MR
Cc: Ross, James GPCAPT; Hickey, Brian MR 1; 'Austin, Tony'; Miller, Richard MR 1
Subject: RE: sec:unclassified FOI Alert s. 47G [REDACTED] Lariam Trials

Thank you Rosemary.

Mike In response to your e-mail this morning, I am happy with the Sensitivity Assessment. This is one of the FOI requests that we have been tracking for some time. I also note that DDGPA(O) LtCol Elliott signed off on the TPs. The system is working.

Regards

Rod Dudfield

Deputy Director General Public Affairs
 Coordination and Public Affairs

Phone: 02 6265 2959

Mobile: s22 [REDACTED]

E-mail: rod.dudfield@defence.gov.au <<mailto:rod.dudfield@defence.gov.au>>

-----Original Message-----

From: Landy, Rosemary LTCOL
Sent: Thursday, 17 March 2005 15:54
To: Dudfield, Rod Mr
Cc: Ross, James GPCAPT; Hickey, Brian MR 1; Austin, Tony; Miller, Richard MR 1; Pezzullo, Michael MR
Subject: RE: sec:unclassified FOI Alert s. 47G [REDACTED] Lariam Trials
Importance: High

Dear Rod,

The "sensitivity" as amended by Director Litigation, is as follows:

Sensitivity: *In view of recent media coverage regarding the issue of experimental drug trials, the release of these documents may attract further media attention. There is the possibility that s. 47G [REDACTED] could use the documents in legal action for compensation.*

<< File: FOI 100_04_05 s. 47G [REDACTED] Minsub ver signed by HDPE 8 Feb 05.doc >>

The version of the Minsub as cleared by DGDHS and signed by HDPE on 8 Feb 05, including TP's, is above. The brief was initialled by MINDEF (as far as I can interpret from the copy I received back), but I have not seen the brief sent to MINASST since it was sent off.

The other relevant PA input to the mefloquine issue that I have had access to is attached.

DGDHS has been running with a lot of the associated issues, in conjunction with PA over at HDPE's office.

<< File: 050216 UpdateIII Anti-malarial drug - Mefloquine.doc >> << File: 050127 Update Anti-malarial drug - Mefloquine.doc >> << File: 9.4 ADF Anti-malarial drugs-drug studies FINAL.doc >>

There are also fact sheets prepared for a media conference in late 2004 that did not ever actually occur:

<< File: 2 Nov 04 Malaria Fact sheet.doc >> << File: 2 Nov 04 Ethical Guidelines Fact Sheet .doc >> << File: 2 Nov 04 Clinical Trials fact sheet.doc >> << File: 2 Nov 04 AMI fact sheet.doc >>

Best regards,

Rosemary Landy

17 Mar 05

Dr Rosemary A. Landy
FOI Health Policy
Exec Sec Aust Defence Human Research Ethics Committee
CP2-7-67
DEPT OF DEFENCE
CANBERRA ACT 2600
Tel: (02) 62663807
Fax: (02) 62664982

-----Original Message-----

From: Dudfield, Rod Mr
Sent: Thursday, 17 March 2005 7:26
To: Hickey, Brian; Ross, James GPCAPT
Subject: FW: sec:unclassified FOI Alert S. 47G [REDACTED] Lariam Trials
Importance: High

Ross and Brian,

We (DGPA) have not had visibility of the "For Noting Brief". Could you please advise me what the "Sensitivity assessment" may have said. That is what is the PA assessemnt of releasing the documents to the lawyers?

Thanks

Rod Dudfield

Deputy Director General Public Affairs
Coordination and Public Affairs

Phone: 02 6265 2959

Mobile: s22 [REDACTED]

E-mail: rod.dudfield@defence.gov.au <<mailto:rod.dudfield@defence.gov.au>>

-----Original Message-----

From: Pezzullo, Michael MR
Sent: Wednesday, 16 March 2005 19:10
To: Moon, Michael BRIG
Cc: Bermingham, Mary MS; Smith, Ric MR; Henderson, Alan MR (DEPSEC CS) 3; Ross, James GPCAPT; Hickey, Brian MR 1; Meldrum, Sascha Ms; Dudfield, Rod Mr; Adams, Brian RADM; Phillips, Neil MR; Cunliffe, Mark MR
Subject: RE: sec:unclassified FOI Alert S. 47G [REDACTED] Lariam Trials

DGPA

Mick

What's the one line PA impact assessment?

MP

DEPARTMENT OF DEFENCE

MICHAEL PEZZULLO

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-----Original Message-----

From: Phillips, Neil MR
Sent: Wednesday, 16 March 2005 17:07
To: Smith, Ric MR; Henderson, Alan MR (DEPSEC CS) 3; Cunliffe, Mark MR; Pezzullo, Michael MR; Adams, Brian RADM; Ross, James GPCAPT; Moon, Michael BRIG; Dudfield, Rod Mr; Hickey, Brian MR 1; Bermingham, Mary MS; Meldrum, Sascha Ms

Good Afternoon All,

The purpose of this e-mail is to alert addressees to the dispatch of the decision, under the FOI Act, to s. 47G

Request

2. By letter dated 2 December 2004, s. 47G requested the Department of Health and Ageing to provide access, under the *Freedom of Information Act 1982* (FOI Act), to:

- "1. copy Terms of Reference for the East Timor trials of Lariam; [Item 1]
2. copy Results and Recommendations arising from the trials; [Item 2]
3. copy Administrative Procedures and policies relating to the trials; [Item 3]
4. copy of the documented procedures and proformas relating to consents for those undertaking the trials; [Item 4]
5. copies of any document(s) presented, and or read, to Medical Officers, or others advising as to why the trial was being conducted; [Item 5]
6. copies of any document(s) presented to Medical Officers, or others advising as to possible side effects associated with Lariam; [Item 6]
7. copies of any reported results from the Lariam trials; [Item 7]
8. copies of any protocol, rules and/or regulations relating to the trials; [Item 8]
9. copy report prepared by Captain Leith Baird relating to the investigations carried out by Captain Baird relating to Lariam (we understand that the same was delivered to a symposium in Sydney and therefore will not be privileged [Item 9]
10. copies of any documents relating to research undertaken relating to Lariam side effects; [Item 10]
11. copies of any complaints made relating to effects of Lariam; [Item 11]
12. correspondence involving Hoffman La Roche of whatever nature relating to Lariam, whether in relation to the trials or not; [Item 12]
13. confirmation as to which relevant Hoffman La Roche Office address in the United States was the contact address for any matters relating to Lariam [Item 13]
14. any reports and/or documentation relating to the side effects of the drug, in respect of either trials of the drug and/or reports whether in formal form or not detailing any health concerns relating to the use of the drug; [Item 14]
15. copies of documents relating to research undertaken by the Administration relating to Lariam side effects; [Item 15]
16. copies of any complaints made to the administration relating to the purported side effects from taking lariam; [Item 16]
17. correspondence involving Hoffmann La Roche of whatever nature relating to Lariam." [Item 17]

Section 16 Transfer

3. Defence accepted partial transfer of Items 1 to 14 of the request from the Department of Health and Ageing, in accordance with section 16 of the FOI Act [Section 16 of the FOI Act provides for transfer of all or part of a request if the document that is sought is known to be in the possession of another Commonwealth agency or the subject matter is more closely connected with the functions of another agency].

Decision

4. GPCAPT J. Ross, Director of Clinical Policy, decided to release intact copies of documents relevant to Items 2, 3, 4, 5, 6, 7, 8, 9 and 14. The documents captured by Item 10 were deemed to already be in the public domain and therefore not considered. Items 1, 11, 12 and 13 of the request were refused under section 24A of the FOI Act on the grounds that the documents do not exist.

'For Noting' brief provided to the Minister Assisting the Minister for Defence

5. HDPE provided the Minister Assisting with a FOI 'Noting' brief advising of the decision by GPCAPT Ross. The brief was noted by the Minister Assisting on 9 Mar 05.

Dispatch of Decision

6. The decision was dispatched to s. 47G [16 Mar 05]. The documents approved for release will not be dispatched to the s. 47G until they have paid outstanding charges associated with the administration of the request.

Point of Contact Public Affairs

7. If you require any additional information in relation to the administration of the above request, please do not hesitate to contact either GPCAPT Ross Ph: (02) 62663908, Mr Brian Hickey, Public Affairs Ph: (02) 6265 5297 or myself.

Regards

Neil Phillips
Director
Freedom of Information

Ph: 02 62668861
Fax: 02 62668857
Mobile: s22
Email: neil.phillips@defence.gov.au

Miller, Richard MR 1

From: Landy, Rosemary LTCOL
Sent: Thursday, 17 March 2005 15:54
To: Dudfield, Rod Mr
Cc: Ross, James GPCAPT; Hickey, Brian MR 1; Austin, Tony; Miller, Richard MR 1; Pezzullo, Michael MR
Subject: RE: sec:unclassified FOI Alert s. 47G - Lariam Trials
Importance: High

Dear Rod,

The "sensitivity" as amended by Director Litigation, is as follows:

Sensitivity: *In view of recent media coverage regarding the issue of experimental drug trials, the release of these documents may attract further media attention. There is the possibility that s. 47G could use the documents in legal action for compensation.*



FOI 100_04_05
s. 47G

The version of the Minsub as cleared by DGDHS and signed by HDPE on 8 Feb 05, including TP's, is above. The brief was initialled by MINDEF (as far as I can interpret from the copy I received back), but I have not seen the brief sent to MINASST since it was sent off.

The other relevant PA input to the mefloquine issue that I have had access to is attached.

DGDHS has been running with a lot of the associated issues, in conjunction with PA over at HDPE's office.



050216 UpdateIII
Anti-malarial...



050127 Update
Anti-malarial dr...



9.4 ADF Anti-malarial
drugs-d...

There are also fact sheets prepared for a media conference in late 2004 that did not ever actually occur:



2 Nov 04 Malaria Fact
sheet.do...



2 Nov 04 Ethical
Guidelines Fa...



2 Nov 04 Clinical Trials
fact ...



2 Nov 04 AMI fact
sheet.doc

Best regards,


Rosemary Landy

17 Mar 05


Dr Rosemary A. Landy
SO1 Health Policy
Exec Sec Aust Defence Human Research Ethics Committee
CP2-7-67
DEPT OF DEFENCE
CANBERRA ACT 2600
Tel: (02) 62663807
Fax: (02) 62664982

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Miller, Richard MR 1

From: Cunliffe, Mark MR
Sent: Thursday, 2 December 2004 18:14
To: Pezzullo, Michael MR; Hannan, Mike BRIG; Miller, Richard MR 1
Cc: Adams, Brian RADM; Austin, Tony AIRCDRE; Brook, Josephine MS
Subject: s. 47F

Mike (P)


Until it's clear what sort of 'trial' is asserted, I'm not sure legal has any 'notes' - my guess is Mike (H) meant 'medical trials' (hence my earlier e-mail question) but I haven't seen an answer

Mark

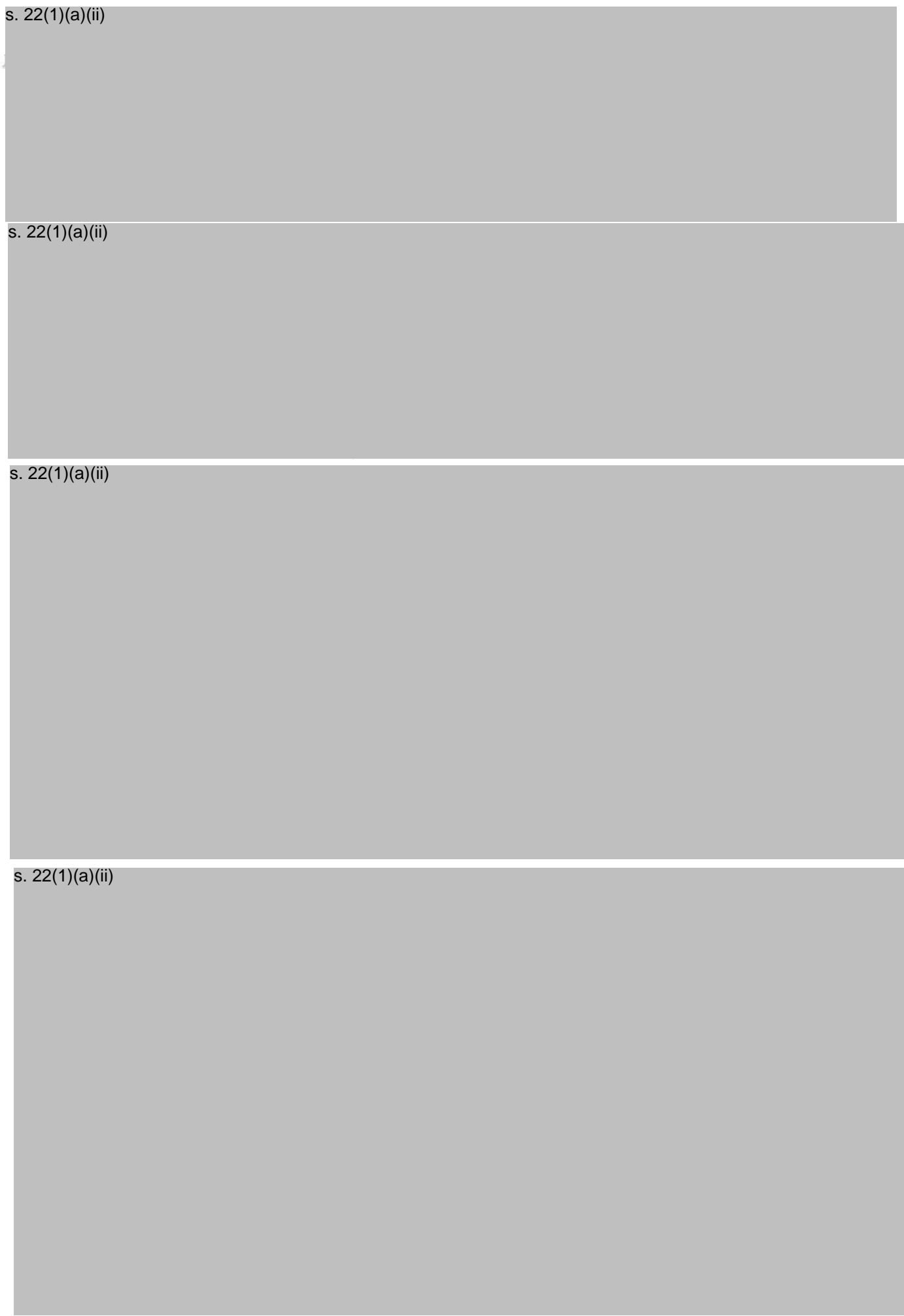
Mark Cunliffe
Head, Defence Legal
Department of Defence
R G Casey Building (RGC-3)
Barton ACT 2600

Tel: 61 2 6266 8898
Fax: 61 2 6266 8800
Mob: ^{s22}

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s. 22(1)(a)(ii)





Miller, Richard MR 1

From: Pezzullo, Michael MR
Sent: Friday, 3 December 2004 8:19
To: Adams, Brian RADM; Hannan, Mike BRIG
Cc: Gordon, Ian MAJGEN (DCA); Miller, Richard MR 1; Austin, Tony AIRCDRE
Subject: s. 47F

Brian - thanks.

Mike H - your PA lead.

MP

DEPARTMENT OF DEFENCE

MICHAEL PEZZULLO
Chief of Staff ADHQ
Head Coordination and Public Affairs

R1-5 Ministerial Suite
RUSSELL OFFICES
CANBERRA ACT 2600

Ph: 02 626 54652
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Email: michael.pezzullo@defence.gov.au

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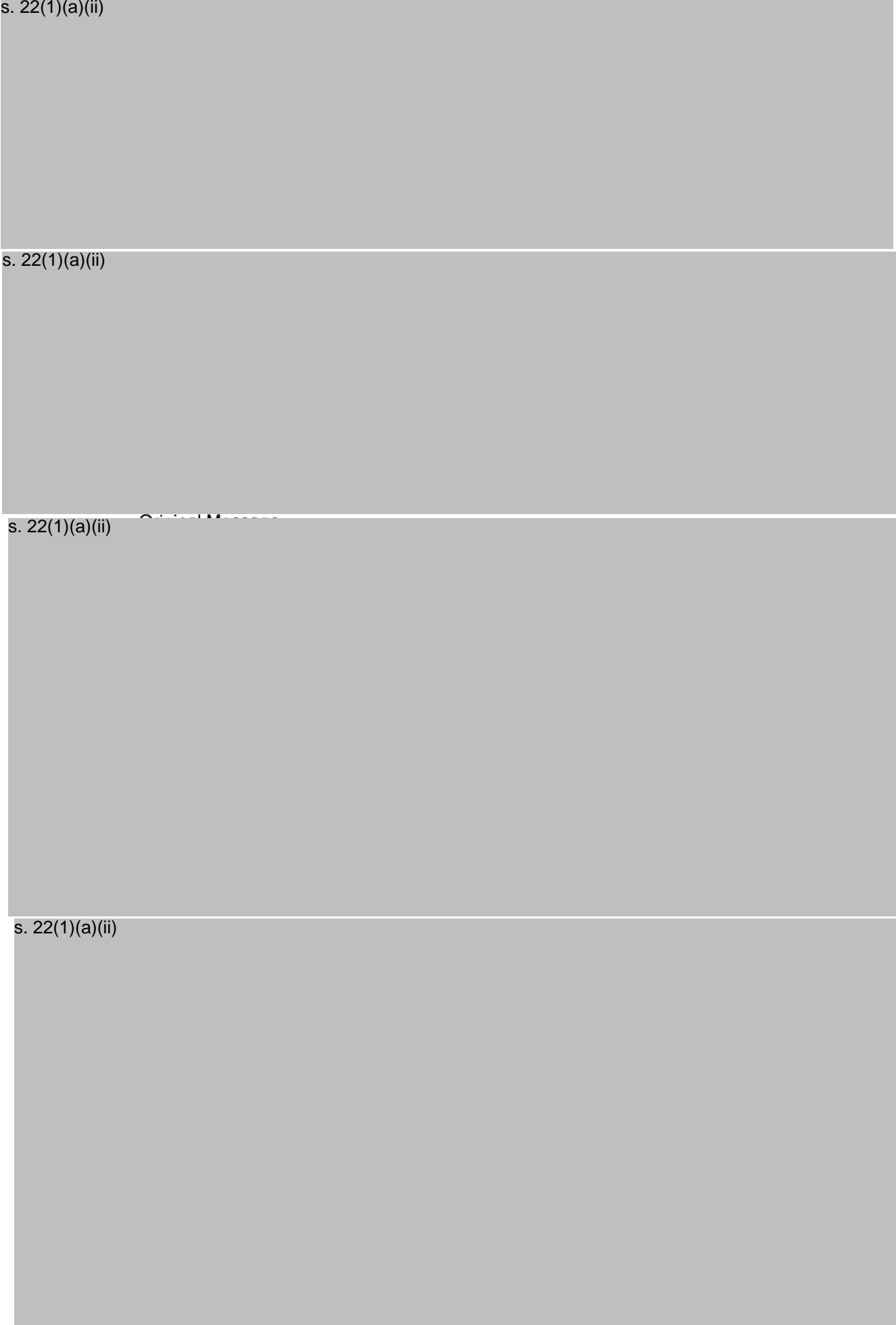
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s. 22(1)(a)(ii)



Mr, Richard MR 1

From: Austin, Tony AIRCDRE
Sent: Monday, 6 December 2004 9:58
To: Adams, Brian RADM; Pezzullo, Michael MR; Hannan, Mike BRIG; Miller, Richard MR 1; Cunliffe, Mark MR
Cc: Gordon, Ian MAJGEN (DCA); Cooper, Bob LTCOL
Subject: Antimalarials - Possible Class action.

Sirs et al,

1. I spoke with COLHLTH last week re his knowledge of anything prejudicial involving the AMI trials of antimalarials in EM. He subsequently spoke with the current RMO's at 1, 2 & 4 RAR. They are not aware of any specific problems although clearly there has been a very large staff turnover since the days of the trials.

2. AMI has just received a letter from s. 47G requesting (under FOI) information about the Larium trials (there is no mention of the Tafenoquine trial). s. 47G
s. 47G

3. We have sent a copy of this letter to the FOI people to register and process in the normal manner.

regards,
Tony

T.K. AUSTIN AM
AIRCDRE
Director-General Defence Health Service
DHSB
CP2-7-121
Tel: (02) 62663919
Mob: s22
Fax: (02) 62663933
E-mail: Tony.Austin@defence.gov.au


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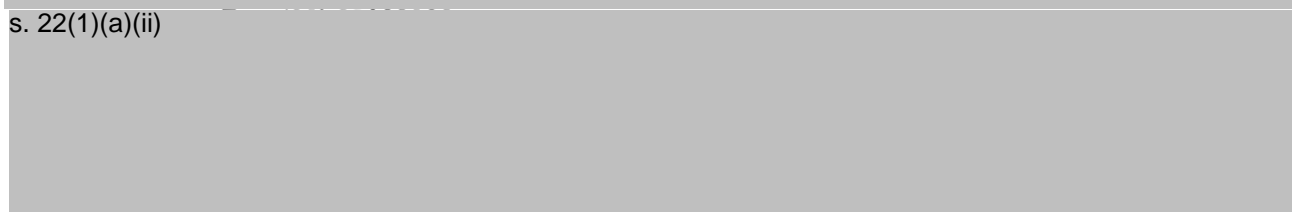
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Miller, Richard MR 1

From: Cunliffe, Mark MR
Sent: Thursday, 16 December 2004 14:32
To: Welbourne, Tony CMDR; Henderson, Ian WGCDR; Lloyd, David DR; Hemmingway, Alan GPCAPT; Miller, Richard MR 1; Woodward, Jennifer MS
Cc: Beresford, Alison MRS 1; Harvey, Simon AIRCDRE; Harvey, Nina WGCDR
Subject: RE: questions on notice for response

Thanks Tony

Mark Cunliffe
Head, Defence Legal
Department of Defence
R G Casey Building (RGC-3)
Barton ACT 2600

Tel: 61 2 6266 8898
Fax: 61 2 6266 8899
Mob: ^{s22}

-----Original Message-----

From: Welbourne, Tony CMDR
Sent: Thursday, 16 December 2004 14:30
To: Henderson, Ian WGCDR; Cunliffe, Mark MR; Lloyd, David DR; Hemmingway, Alan GPCAPT; Miller, Richard MR 1; Woodward, Jennifer MS
Cc: Beresford, Alison MRS 1; Harvey, Simon AIRCDRE; Harvey, Nina WGCDR
Subject: RE: questions on notice for response

And Nil from DAL.

-----Original Message-----

From: Henderson, Ian WGCDR
Sent: Thursday, 16 December 2004 10:12
To: Cunliffe, Mark MR; Lloyd, David DR; Welbourne, Tony CMDR; Hemmingway, Alan GPCAPT; Miller, Richard MR 1; Woodward, Jennifer MS
Cc: Beresford, Alison MRS 1; Harvey, Simon AIRCDRE; Harvey, Nina WGCDR
Subject: RE: questions on notice for response

still Nil from DMJ

Ian Henderson
Wing Commander
Acting Director Military Justice
Defence Legal
RGC-3-191

Tel: (02) 626 68950
Fax: (02) 626 68943

-----Original Message-----

From: Cunliffe, Mark MR
Sent: Wednesday, 15 December 2004 18:15
To: Henderson, Ian WGCDR; Lloyd, David DR; Welbourne, Tony CMDR; Hemmingway, Alan GPCAPT; Miller, Richard MR 1; Woodward, Jennifer MS
Cc: Beresford, Alison MRS 1; Harvey, Simon AIRCDRE; Harvey, Nina WGCDR
Subject: RE: questions on notice for response

Colleagues

First, two apologies. One, I thought the e-mail sent around on this question earlier in the week had the full text of the question (# 44) included - I now don't think it did. Second, I hadn't looked as closely at it as I should have. For the record, here is the text -

Question 44
Drug experiments and testing
Senator Bishop

Action Area: HDPE

- a) Has the DOD ever been requested by a foreign government or military to conduct tests upon Australian troops relating to any drugs or other medical supplements; if so, i) has any such request related to any anti-malarial drug or supplement, ii) when and by whom was such a request made, iii) were any such requests accepted, and iv) which requests were accepted?
- b) When, upon which personnel or groups of personnel within the ADF, and for how long were such tests operated?
- c) At any time prior to the cessation of testing, was the DOD aware of any possible side-effects that may be induced by that test; if so, i) did the DOD review the continuation of any such test in light of such knowledge, and ii) what was the outcome of any such review?
- d) If the DOD was not aware at any time prior to the cessation of testing of any possible side-effects that may be induced by that test, had the DOD made any inquiries into possible side-effects that may be induced by that test; If not, what were the findings of any such inquiry?
- e) With reference to the recent allegations that 1351 soldiers who served between 1999 and 2003 in East Timor were asked to take either of the drug Larium or the drug Tafenoquine, as stated in the *Sunday Tasmanian* on 31/10/04 in an article entitled "Diggers used as drug guinea-pigs", is this story correct; if not, in what respect(s) was it incorrect?
- f) Has the DOD requested or received any legal advice on this matter; if so, what was the nature of that request or advice?
- g) When, upon which personnel or groups of personnel within the ADF, and for how long were such tests operated?
- h) At any time *prior* to the cessation of testing, was the DOD aware of any possible side-effects that may be induced by that test; if so, i) did the DOD review the continuation of any such test in light of such knowledge, and ii) what was the outcome of any such review?
- i) If the DOD was not aware at any time prior to the cessation of testing of any possible side-effects that may be induced by that test, had the DOD made any inquiries into possible side-effects that may be induced by that test; if so, what were the findings of any such inquiry?
- j) If the DOD has become aware of any possible side-effects that may be induced by that test after the cessation of that test, what measures has it taken to ascertain the magnitude and extent of any such side-effects?
- k) Has the DOD undertaken any measures to mitigate the magnitude and extent of any such side-effects; if so, what action has been taken?
- l) Were the relevant soldiers given a choice as to whether they would participate in that test; if so, what was the nature and circumstances of that choice?
- m) Were soldiers required to either participate in the relevant test, or risk not being sent to East Timor?

I wouldn't like to suggest that the question is somewhat unclear but I am not certain that I know *exactly* what is being asked. Para (a) doesn't actually seem to be relevant to all the other parts (I think it relates to a, b, c and d only). As I read it, from para (e) onwards is a new and unrelated question (except that both parts relate to drugs) and I think para (f) relates to second part of the question, not the earlier part. If so, we are only looking at East Timor related advice (and my earlier suggestion that this might be ancient history in effect, is obviously quite wrong (sorry for the distraction)).

On that reading of the question, can I please confirm that no recipient has any knowledge of Defence requesting or receiving legal advice on the East Timor issue identified in (e). Subject to that, the legal professional privilege issue raised by Ian may or may not be important to consider. If we have provided internal legal advice, please let me know although I am not convinced it is covered by the question, as framed.

Grateful for urgent confirmation/advice please.

thanks

Mark


Mark Cunliffe
Head, Defence Legal

Department of Defence
R G Casey Building (RGC-3)
Barton ACT 2600

Tel: 61 2 6266 8898
Fax: 61 2 6266 8899
Mob: s22

PS Apologies to those -especially Simon, Richard, Jennifer and Alan - who should have been included earlier in my request.

s. 22(1)(a)(ii)



Miller, Richard MR 1

From: Cunliffe, Mark MR
Sent: Thursday, 16 December 2004 10:14
To: Henderson, Ian WGCDR; Lloyd, David DR; Welbourne, Tony CMDR; Hemmingway, Alan GPCAPT; Miller, Richard MR 1; Woodward, Jennifer MS
Cc: Beresford, Alison MRS 1; Harvey, Simon AIRCDRE; Harvey, Nina WGCDR
Subject: RE: questions on notice for response

thanks Ian

Mark

Mark Cunliffe
Head, Defence Legal
Department of Defence
R G Casey Building (RGC-3)
Barton ACT 2600

Tel: 61 2 6266 8898
Fax: 61 2 6266 8899
Mob: ^{s22} [REDACTED]

-----Original Message-----

From: Henderson, Ian WGCDR
Sent: Thursday, 16 December 2004 10:12
To: Cunliffe, Mark MR; Lloyd, David DR; Welbourne, Tony CMDR; Hemmingway, Alan GPCAPT; Miller, Richard MR 1; Woodward, Jennifer MS
Cc: Beresford, Alison MRS 1; Harvey, Simon AIRCDRE; Harvey, Nina WGCDR
Subject: RE: questions on notice for response

still Nil from DMJ

Ian Henderson
Wing Commander
Acting Director Military Justice
Defence Legal
RGC-3-191

Tel: (02) 626 68950
Fax: (02) 626 68943

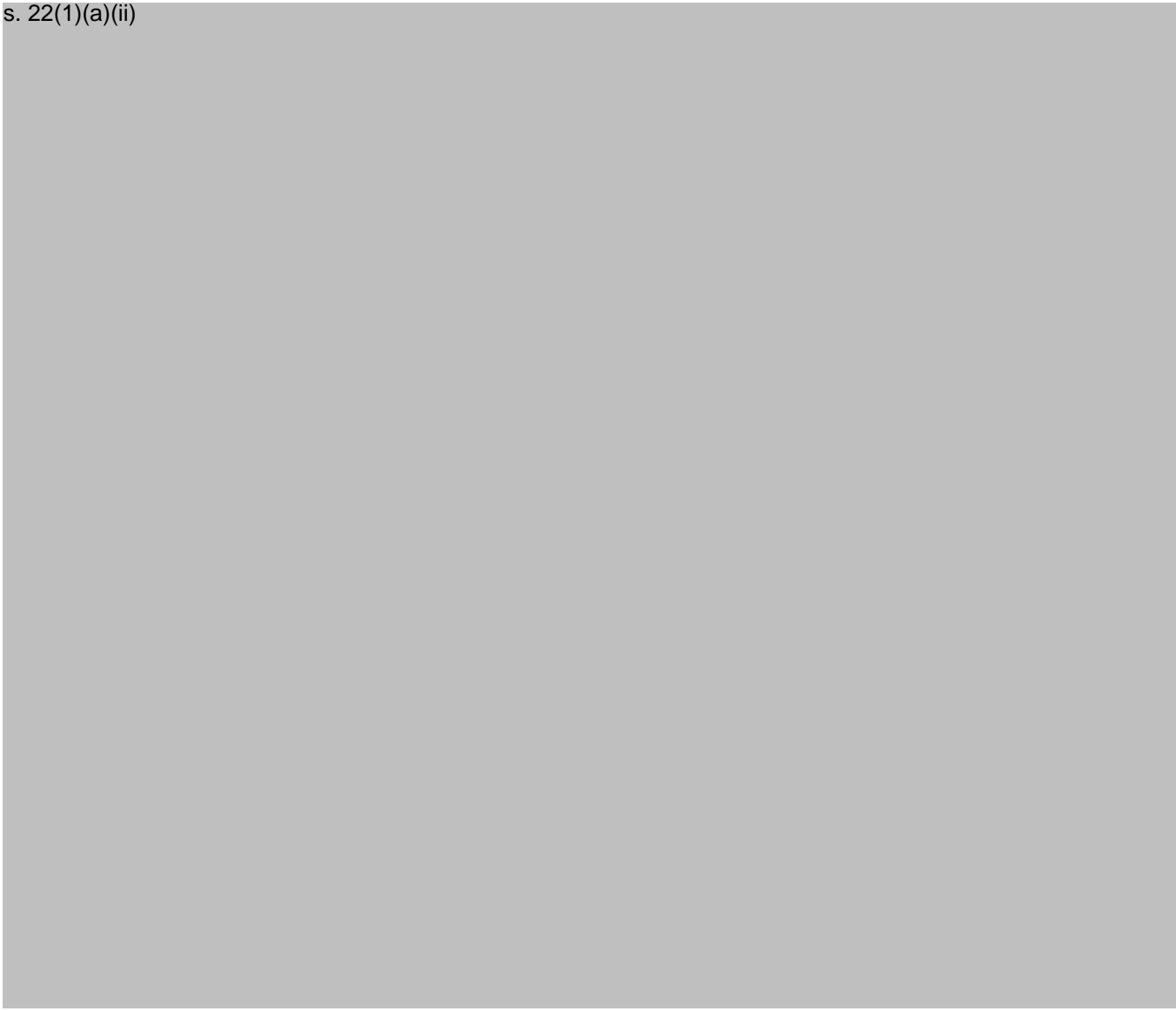
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A very large rectangular area is completely redacted with a solid grey fill.

Malvern

FOI 286/15/16
Document 14

Miller, Richard MR 1

From: Pezzullo, Michael MR
Sent: Thursday, 17 March 2005 17:00
To: Dudfield, Rod Mr
Cc: Ross, James GPCAPT; Hickey, Brian MR 1; 'Austin, Tony'; Miller, Richard MR 1; Landy, Rosemary LTCOL
Subject: RE: sec:unclassified FOI Alert s. 47G [REDACTED] - Lariam Trials

OK

MP

DEPARTMENT OF DEFENCE

MICHAEL PEZZULLO
Chief of Staff ADHQ
Head Coordination and Public Affairs

R1-5 Ministerial Suite
RUSSELL OFFICES
CANBERRA ACT 2600

Ph: 02 626 54652
Fax: 02 626 52753
Mobile: s22 [REDACTED]
Email: michael.pezzullo@defence.gov.au

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-----Original Message-----

From: Dudfield, Rod Mr
Sent: Thursday, 17 March 2005 16:06
To: Landy, Rosemary LTCOL; Pezzullo, Michael MR
Cc: Ross, James GPCAPT; Hickey, Brian MR 1; 'Austin, Tony'; Miller, Richard MR 1
Subject: RE: sec:unclassified FOI Alert s. 47G [REDACTED] - Lariam Trials

Thank you Rosemary.

Mike In response to your e-mail this morning, I am happy with the Sensitivity Assessment. This is one of the FOI requests that we have been tracking for some time. I also note that DDGPA(O) LtCol Elliott signed off on the TPs. The system is working.

Regards

Rod Dudfield

Deputy Director General Public Affairs
Coordination and Public Affairs

Phone: 02 6265 2959
Mobile: s22 [REDACTED]

E-mail: rod.dudfield@defence.gov.au <<mailto:rod.dudfield@defence.gov.au>>

s. 22(1)(a)(ii)