

[REDACTED]

From: [REDACTED]@health.gov.au>
Sent: Friday, 8 May 2020 4:08 PM
To: [REDACTED] /AU; [REDACTED] /AU
Cc: [REDACTED] /AU
Subject: RE: Sanofi - Plaquenil Dear HCP letter [SEC=OFFICIAL]

Dear [REDACTED],

The TGA published an update on hydroxychloroquine today, which refers to the Sanofi DHCP letter:
<https://www.tga.gov.au/alert/amendments-new-restrictions-prescribing-hydroxychloroquine-covid-19>

Please accept my apologies for not notifying you prior to publication – the approvals occurred very quickly.

Kind regards,
[REDACTED]

From: [REDACTED]
Sent: Thursday, 7 May 2020 10:00 AM
To: [REDACTED] /AU' [REDACTED]@sanofi.com>; [REDACTED] /AU [REDACTED]@sanofi.com>
Cc: [REDACTED]@sanofi.com>
Subject: RE: Sanofi - Plaquenil Dear HCP letter [SEC=OFFICIAL]

Dear [REDACTED]

Thank you for letting me know. I'll follow up our plans to publish an update to the current statement and let you know the outcome.

Kind regards,
[REDACTED]

From: [REDACTED]@sanofi.com>
Sent: Thursday, 7 May 2020 9:55 AM
To: [REDACTED]@health.gov.au>; [REDACTED]@sanofi.com>
Cc: [REDACTED]@sanofi.com>
Subject: RE: Sanofi - Plaquenil Dear HCP letter [SEC=OFFICIAL]

Hi [REDACTED]

I can confirm that the Dear HCP letter was faxed out on Wednesday 6th May.
Please don't hesitate to contact me if you require any further information.

Kind regards
[REDACTED]

From: [REDACTED]@health.gov.au>
Sent: Monday, 4 May 2020 1:33 PM
To: [REDACTED]@sanofi.com>; [REDACTED]@sanofi.com>
Cc: [REDACTED]@sanofi.com>
Subject: [EXTERNAL] RE: Sanofi - Plaquenil Dear HCP letter [SEC=OFFICIAL]

EXTERNAL : Real sender is [REDACTED]@health.gov.au

Dear [REDACTED]

No problem – thanks for providing the update.

Kind regards,
[REDACTED]

From: [REDACTED]@sanofi.com>
Sent: Monday, 4 May 2020 10:54 AM
To: [REDACTED]@health.gov.au>; [REDACTED]@sanofi.com>
Cc: [REDACTED]@sanofi.com>
Subject: RE: Sanofi - Plaquenil Dear HCP letter [SEC=OFFICIAL]

Hi [REDACTED]

Apologies for the delay in responding to you.

The team expect that the letter will be distributed today or tomorrow. I will confirm once I have more information.

Kind regards
[REDACTED]

From: [REDACTED]@health.gov.au>
Sent: Friday, 1 May 2020 2:55 PM
To: [REDACTED]@sanofi.com>; [REDACTED]@sanofi.com>
Cc: [REDACTED]@sanofi.com>
Subject: [EXTERNAL] RE: Sanofi - Plaquenil Dear HCP letter [SEC=OFFICIAL]

EXTERNAL : Real sender is [REDACTED]@health.gov.au

Hi [REDACTED]

Could you please advise when the letter will be sent? We're planning to provide a brief update to the web statement, which will refer to the DHCP letter being sent, but do not intend to replicate it on the website. We also intend to refer to the PBS changes.

Thanks,
[REDACTED]

From: [REDACTED]@sanofi.com>
Sent: Thursday, 30 April 2020 4:49 PM
To: [REDACTED]@sanofi.com>; [REDACTED]@health.gov.au>
Cc: [REDACTED]@sanofi.com>
Subject: RE: Sanofi - Plaquenil Dear HCP letter [SEC=OFFICIAL]

Dear [REDACTED],

Further to [REDACTED] email, could you please advise whether this letter will be made available on the TGA website.

Kind regards

From: [REDACTED]@sanofi.com>
Sent: Thursday, 30 April 2020 1:04 PM
To: [REDACTED]@health.gov.au>
Cc: [REDACTED]@sanofi.com>; [REDACTED]@sanofi.com>
Subject: RE: Sanofi - Plaquenil Dear HCP letter [SEC=OFFICIAL]

Dear [REDACTED]

Thanks for your time today on the call. Please find attached the final signed DCHP letter for Plaquenil. We are making plan to distribute to the HCP groups you have advised. Also the mini PI will be dispatched together with the letter.

Please feel free to let me know if you have any further question regarding this.

Regards,

[REDACTED]
SANOFI | Research and Development
Global Regulatory Affairs – Regulatory Affairs Manager Australia and New Zealand
[REDACTED]

From: [REDACTED]@health.gov.au>
Sent: Friday, 24 April 2020 4:13 PM
To: [REDACTED]@sanofi.com>
Cc: [REDACTED]@sanofi.com>; [REDACTED]@sanofi.com>
Subject: [EXTERNAL] RE: Sanofi - Plaquenil Dear HCP letter [SEC=OFFICIAL]

EXTERNAL : Real sender is [REDACTED]@health.gov.au

Dear [REDACTED],

Please accept my apologies for the delays in providing feedback on the DHCP letter. Attached are our comments on the letter (note: we have not reviewed the Annex). I have discussed the SRR with PMAB and they have confirmed it is being evaluated as a matter of priority. PMAB may contact you or [REDACTED] in regards to this as well – at this stage it appears likely to be completed next week. If you wish to send the letter prior to the PI amendments being evaluated, then it would be acceptable for you to foreshadow these changes, and represent them as being under evaluation in the DHCP letter.

With regards to the distribution strategy, we support it going to GPs, Pharmacists and specialists. Please confirm that you intend to include the relevant representative groups for these practitioners. In addition, please confirm you will send it to hospital pharmacists, and the specialty areas identified in the recent scheduling change (dermatology; intensive care medicine; paediatrics and child health; physician; emergency medicine). Lastly, as discussed with [REDACTED] it is important that this letter also be sent to clinical trial investigators. Please sent to ACTA, and also any groups that requested supply for clinical trials, and any other investigators that you are aware of.

Please let me know if you have any further questions.

Kind regards,

[REDACTED]

From: [REDACTED]@sanofi.com>
Sent: Tuesday, 21 April 2020 2:10 PM
To: [REDACTED]@health.gov.au>
Cc: [REDACTED]@sanofi.com>; [REDACTED]@sanofi.com>
Subject: Sanofi - Plaquenil Dear HCP letter [SEC=No Protective Marking]

Hi [REDACTED],

I hope this email finds you well.

I have attached for your review the Plaquenil Dear HCP letter.

The information included in Annex 1 with a "*" is currently under TGA evaluation however, we are hoping to be able to speed up the SRR approval so that all content in the letter is approved by the time the letter is sent out to HCPs.

We would also appreciate your feedback with regards to the target audience for this letter - we are proposing to distribute to GPs, Pharmacists and specialists.

I look forward to hearing from you.

Kind regards

[REDACTED]

[REDACTED]

Sanofi Australia & New Zealand
Talavera Corporate Centre - Building D,
12-24 Talavera Road
Macquarie Park NSW 2113

[REDACTED]@sanofi.com



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